1-1-2018

Advancing the Use of Ethics in Community-Based Commercial Drug Formulary Decision-Making: A Critical Analysis Focused on Pharmacy Benefits Coverage Provided by Large Employers in the U.S. Healthcare System

Roy Bentley
Royal College of Surgeons in Ireland, roybentley@rcsi.ie

Citation

This Thesis is brought to you for free and open access by the Theses and Dissertations at e-publications@RCSI. It has been accepted for inclusion in PhD theses by an authorized administrator of e-publications@RCSI. For more information, please contact epubs@rcsi.ie.
Advancing the Use of Ethics in Community-based Commercial Drug Formulary Decision-making:
A critical analysis focused on Pharmacy Benefits Coverage Provided by Large Employers in the U.S. Healthcare System

Roy Bentley

PhD 2018
Candidate Thesis Declaration

I declare that this thesis, which I submit to RCSI for examination in consideration of the award of a higher degree Doctor of Philosophy (PhD) is my own personal effort. Where any of the content presented is the result of input or data from a related collaborative research programme this is duly acknowledged in the text such that it is possible to ascertain how much of the work is my own. I have not already obtained a degree in RCSI or elsewhere on the basis of this work. Furthermore, I took reasonable care to ensure that the work is original, and, to the best of my knowledge, does not breach copyright law, and has not been taken from other sources except where such work has been cited and acknowledged within the text.

Signed:

Student Number: 11119837

Date: October 10, 2018
# Table of Content

Abbreviations ........................................................................................................... 10  
List of Figures ........................................................................................................... 14  
List of Tables ............................................................................................................ 16  
Glossary ................................................................................................................... 17  
Abstract .................................................................................................................... 23  
Acknowledgements .................................................................................................. 24  

## Chapter 1: Thesis Overview .................................................................................. 25  
1.1 Introduction .......................................................................................................... 25  
1.2 Impact of the Problem on Decision-making ....................................................... 30  
1.3 Background of the Study .................................................................................... 31  
1.4 Study Objective and Primary Research Question ............................................. 32  
1.5 Research Design .................................................................................................. 33  
1.6 PhD Researcher .................................................................................................... 34  
1.7 Scope and Delimitations ....................................................................................... 35  
1.8 Assumptions and Limitations ............................................................................. 37  
1.9 Significance of the Study .................................................................................... 38  
1.10 Summary ............................................................................................................. 39  

## Chapter 2: Review of Ethical Theories In Relation to Allocation of Healthcare Resources .............................................................................................................. 40  
2.1 Deontology .......................................................................................................... 41  
2.2 Kant’s Moral Philosophy ....................................................................................... 44  
2.3 Utilitarianism ........................................................................................................ 45  
2.4 Virtue Ethics ......................................................................................................... 48  
2.5 Biomedical Ethics ................................................................................................ 52  
2.6 Health, Healthcare and Rights ........................................................................... 58  
2.7 Trust and Fairness ............................................................................................... 61  
2.8 Allocation of Resources ....................................................................................... 66  
2.9 Managed Care Organizations and Ethics ......................................................... 71  
2.10 Discussion ............................................................................................................ 72  
2.11 Conclusion .......................................................................................................... 79
## Chapter 3: The U.S. Healthcare System

- **3.1 Access to Care in the U.S.: Facts and Figures** ......................................................... 81
- **3.2 The Affordable Care Act** ................................................................................................. 86
- **3.3 History of Managed Care in the U.S.** ............................................................................... 90
- **3.4 A Closer Look at Formularies** ....................................................................................... 94
- **3.5 Implications of New Drugs Coming to Market** .............................................................. 105
- **3.6 Flow of Funds** .............................................................................................................. 107
- **3.7 A Closer Look at the Employer Segment** .................................................................... 109
- **3.8 Physicians and their Patients** ...................................................................................... 111
- **3.9 Pharmacists** ............................................................................................................... 118
- **3.10 Employees (Insured Members)** ................................................................................ 122
- **3.11 Conclusion** ................................................................................................................ 126

## Chapter 4: Materials, Methods and Data Analysis ............................................................... 130

- **4.1 Study Objective and Research Question** ................................................................. 130
- **4.2 Research Paradigm and Methodology** ................................................................. 131
- **4.3 Data Collection** .......................................................................................................... 137
  - **4.3.1 Recruitment & Research Format** ......................................................................... 137
  - **4.3.2 EBDDM, MCOP&T, Community Practicing Physician and Community Retail Pharmacist Study Participants (Professional Group)** .......................................................................................................................... 138
  - **4.3.3 Employees (Insured Members)** ........................................................................ 138
  - **4.3.4 Data Collection Tools** ...................................................................................... 140
  - **4.3.5 Study Sample Inclusion Criteria** ..................................................................... 141
  - **4.3.6 Study Sample Exclusion Criteria** ................................................................... 142
  - **4.3.7 Purposive and Theoretical Sampling** ............................................................... 143
  - **4.3.8 Sample Size** .................................................................................................... 143
- **4.4 Data Analysis** ............................................................................................................ 144
  - **4.4.1 Transcription of recordings** ............................................................................. 144
  - **4.4.2 Reading of Transcribed Interviews / Interview Notes / Memoing** ............... 145
  - **4.4.3 Development of the Conceptual Framework: Coding of Primary Research Data and Data Analysis** .......................................................................................................................... 145
- **4.5 Literature Review** .................................................................................................... 155
4.6 Conclusion .................................................................................................................. 158

Chapter 5: Stakeholder Perspectives from the Primary Research ................................. 159

5.1 Findings from the Professional Stakeholder Group Interviews ....................... 159

5.2 Access to Rx Medicines Impacted by the Financials ........................................ 160

5.2.1 Access to Rx Medicines Impacted by the Financials: Findings associated with interviews conducted with EBDDMs ...................... 160

5.2.2 Access to Rx Medicines Impacted by the Financials: Findings associated with interviews conducted with MCOP&Ts ............... 164

5.2.3 Access to Rx Medicines Impacted by the Financials: Findings associated with interviews conducted with Community Practicing Physicians .................................................. 174

5.2.4 Access to Rx Medicines Impacted by the Financials: Findings associated with interviews conducted with Community Retail Pharmacists .................................................. 184

5.2.5 Summary for the category “Access to Rx Medicines Impacted by the Financials” ............................................................................................................................... 189

5.3 Drug Formularies are a Means to An End ......................................................... 190

5.3.1 Drug Formularies Are A Means to an End: Findings associated with interviews conducted with EBDDMs .................................................. 190

5.3.2 Drug Formularies Are A Means to an End: Findings associated with interviews conducted with MCOP&Ts .................................................. 194

5.3.3 Drug Formularies Are A Means to an End: Findings associated with interviews conducted with Community Practicing Physicians ...... 201

5.3.4 Drug Formularies Are A Means to an End: Findings associated with interviews conducted with Community Retail Pharmacists ........ 208

5.3.5 Summary for the category “Drug Formularies are a Means to An End” ............................................................................................................................... 213

5.4 Informed Decision-making Essential to Understanding Implications of Choice .................................................................................................................. 214
5.4.1 Informed Decision-making Essential to Understanding Implications of Choice: Findings associated with interviews conducted with EBDDMs .................................................. 214

5.4.2 Informed Decision-making Essential to Understanding Implications of Choice: Findings associated with interviews conducted with MCOP&Ts ........................................... 215

5.4.3 Informed Decision-making Essential to Understanding Implications of Choice: Findings associated with interviews conducted with Community Practicing Physicians ........................................... 219

5.4.4 Informed Decision-making Essential to Understanding Implications of Choice: Findings associated with interviews conducted with Community Retail Pharmacists ........................................... 225

5.4.5 Summary for the category “Informed Decision-making Essential to Understanding Implications of Choice” .......................................................... 229

5.5 Population vs Patient-level Care are not Necessarily Reconcilable ..... 230

5.5.1 Population vs Patient-level Care are not Necessarily Reconcilable: Findings associated with interviews conducted with EBDDMs ..... 230

5.5.2 Population vs Patient-level Care are not Necessarily Reconcilable: Findings associated with interviews conducted with MCOP&Ts .... 233

5.5.3 Population vs Patient-level Care are not Necessarily Reconcilable: Findings associated with interviews conducted with Community Practicing Physicians ........................................... 235

5.5.4 Population vs Patient-level Care are not Necessarily Reconcilable: Findings associated with interviews conducted with Community Retail Pharmacists ........................................... 238

5.5.5 Summary for the category “Population vs Patient-level Care are not Necessarily Reconcilable” .......................................................... 240

5.6 Findings from Focus Group Discussions with Employees (Insured Members) .................................................................................. 241

5.7 Conclusion .................................................................................. 250

Chapter 6: Analysis of Findings ................................................................ 252

6.1 Access to Rx Medicines Impacted by the Financials .......................... 254
6.1.1 Access to Rx Medicines Impacted by the Financials: Benevolence vs the economics & business goals of Employers and MCOs ........254

6.1.2 Access to Rx Medicines Impacted by the Financials: Care is determined by the contract that has been purchased .......................260

6.1.3 Access to Rx Medicines Impacted by the Financials: Care needs to be deemed reasonable; anything other than reasonable care is a privilege ..........................................................................................................................266

6.1.4 Access to Rx Medicines Impacted by the Financials: Analysis of Findings Summary ........................................................................271

6.2 Drug Formularies are a Means to An End ........................................272

6.2.1 Drug Formularies are a Means to an End: Formularies are access deterrents: struggle (hassle factor) for HCP & patients ..........273

6.2.2 Drug Formularies are a Means to an End: MCOs look to lower premiums by shifting cost to patients .............................................276

6.2.3 Drug Formularies are a Means to an End: Physicians believe they have the best interest of the patient in mind ..........................280

6.2.4 Drug Formularies are a Means to an End: Analysis of Findings Summary .....................................................................................282

6.3 Informed Decision-making Is Essential to Understanding Implications of Choices ..............................................................................283

6.3.1 Informed Decision-making Is Essential to Understanding Implications of Choices: Trusting in the recommendations of experts ..........................................................................................................................284

6.3.2 Informed Decision-making Is Essential to Understanding Implications of Choices: Understanding consequences of purchase .......................................................................................................................286

6.3.3 Informed Decision-making Is Essential to Understanding Implications of Choices: Patients ultimately accountable for their health and in making treatment choices .................................................288

6.3.4 Informed Decision-making Is Essential to Understanding Implications of Choices: Team-based approach improves healthcare outcomes ........................................................................................................292

6.3.5 Informed Decision-making Is Essential to Understanding Implications of Choices: Analysis of Findings Summary .................293

6.4 Population vs Patient-level Care are not Necessarily Reconcilable......294
6.4.1 Population vs Patient-level Care are not Necessarily Reconcilable:
Formularies not necessarily fair to the individual patient

6.4.2 Population vs Patient-level Care are not Necessarily Reconcilable:
HCP follow-up is an important element to improve patient-specific outcomes

6.4.3 Population vs Patient-level Care are not Necessarily Reconcilable:
Patient autonomy and self-worth potentially compromised due to lack of access

6.4.4 Population vs Patient-level Care are not Necessarily Reconcilable:
Analysis of Findings Summary

Chapter 7: Synthesis of Findings and Conclusion

7.1 Research Question and Insights Gained

7.2 Main Contribution of Thesis

7.3 Scope, Delimitations and Limitations

7.4 Reflections and Learnings

7.5 Future Areas of Research

APPENDIX

Appendix A: CORE-Q 32 Checklist

Appendix B: Pre-read (Brief Overview of Ethical Theories and Principles Applicable to the Research)

Appendix C: Discussion Guides

   Discussion Guide for 1:1 Phone Interviews with MCOP&T Committee Decision Makers

   Discussion Guide for 1:1 Phone Interviews with the EBDDMs

   Discussion Guide for 1:1 Phone Interviews with Practicing Physicians & Community Pharmacists

   Discussion Guide for Employee Focus Groups

Appendix D: Case Studies

   Case Study 1_Smoking Cessation

   Case Study 2_Over Active Bladder

   Case Study 3_Prostate Cancer

   Case Study 4_Quality of Life

Appendix E: Case Study Findings
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACA</td>
<td>Affordable Care Act</td>
</tr>
<tr>
<td>ACO</td>
<td>Accountable Care Organization</td>
</tr>
<tr>
<td>ACP</td>
<td>American College of Physicians</td>
</tr>
<tr>
<td>AEU</td>
<td>Affected End-Users</td>
</tr>
<tr>
<td>AHIP</td>
<td>America’s Health Insurance Plans</td>
</tr>
<tr>
<td>APA</td>
<td>American Pharmacy Association</td>
</tr>
<tr>
<td>APM</td>
<td>Alternative Payment Model</td>
</tr>
<tr>
<td>ASCO</td>
<td>American Society of Clinical Oncology</td>
</tr>
<tr>
<td>CDM</td>
<td>Core Decision Makers</td>
</tr>
<tr>
<td>CER</td>
<td>Comparative Effectiveness Research</td>
</tr>
<tr>
<td>CGT</td>
<td>Classical Grounded Theory</td>
</tr>
<tr>
<td>CHIP</td>
<td>Children’s Health Insurance Program</td>
</tr>
<tr>
<td>CMS</td>
<td>Centers for Medicare and Medicaid Services</td>
</tr>
<tr>
<td>CPP</td>
<td>Clinical Pharmacist Practitioner</td>
</tr>
<tr>
<td>CORE-Q</td>
<td>COnsolidated criteria for REporting Qualitative research</td>
</tr>
<tr>
<td>CRC</td>
<td>Clinical Review Committee</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>EBC</td>
<td>Employer Benefit Consultant</td>
</tr>
<tr>
<td>EBDDM</td>
<td>Employer Benefit Design Decision-maker</td>
</tr>
<tr>
<td>EBM</td>
<td>Evidence-based Medicine</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>ERISA</td>
<td>Employer Retirement Income Security Act of 1974</td>
</tr>
<tr>
<td>ESI</td>
<td>Express Scripts Inc.</td>
</tr>
<tr>
<td>GDR</td>
<td>Generic Dispensing Rate</td>
</tr>
<tr>
<td>GT</td>
<td>Grounded Theory</td>
</tr>
<tr>
<td>HCP</td>
<td>Health Care Provider</td>
</tr>
<tr>
<td>HEDIS</td>
<td>Health Employer Data Information Set</td>
</tr>
<tr>
<td>HMO</td>
<td>Health Maintenance Organization</td>
</tr>
<tr>
<td>HR</td>
<td>Human Resources</td>
</tr>
<tr>
<td>IPA</td>
<td>Interpretative Phenomenological Analysis</td>
</tr>
<tr>
<td>MACRA</td>
<td>Medicare Access and CHIP (Children’s Health Insurance Program) Reauthorization Act of 2015</td>
</tr>
<tr>
<td>MCO</td>
<td>Managed Care Organization</td>
</tr>
<tr>
<td>MCOP&amp;T</td>
<td>MCO Pharmacy &amp; Therapeutics Committee Member</td>
</tr>
<tr>
<td>MD</td>
<td>Medical Doctor (Physician)</td>
</tr>
<tr>
<td>MIPS</td>
<td>Merit-based Incentive Payment System</td>
</tr>
<tr>
<td>MMIT</td>
<td>Managed Markets Insights and Technology</td>
</tr>
<tr>
<td>NCQA</td>
<td>National Commission on Quality Assurance</td>
</tr>
<tr>
<td>NDC</td>
<td>National Drug Classification</td>
</tr>
<tr>
<td>NP</td>
<td>Nurse Practitioner</td>
</tr>
<tr>
<td>OAB</td>
<td>Overactive Bladder</td>
</tr>
<tr>
<td>OECD</td>
<td>Organization for Economic Co-operation and Development</td>
</tr>
<tr>
<td>Acronym</td>
<td>Full Form</td>
</tr>
<tr>
<td>---------</td>
<td>-----------</td>
</tr>
<tr>
<td>PA</td>
<td>Physician’s Assistant (Physician’s Associate)</td>
</tr>
<tr>
<td>P&amp;T</td>
<td>Pharmacy and Therapeutics</td>
</tr>
<tr>
<td>PBM</td>
<td>Pharmacy Benefit Management</td>
</tr>
<tr>
<td>PCa</td>
<td>Prostate Cancer</td>
</tr>
<tr>
<td>PCORI</td>
<td>Patient-Centered Outcomes Research Institute</td>
</tr>
<tr>
<td>PG</td>
<td>Professional Group</td>
</tr>
<tr>
<td>PhDR</td>
<td>PhD Researcher</td>
</tr>
<tr>
<td>PMPM</td>
<td>Per member per month</td>
</tr>
<tr>
<td>POS</td>
<td>Point-of-Service Plan</td>
</tr>
<tr>
<td>PPO</td>
<td>Preferred Provider Organization</td>
</tr>
<tr>
<td>Prior Auth</td>
<td>Prior Authorization</td>
</tr>
<tr>
<td>QL</td>
<td>Quantity Limit</td>
</tr>
<tr>
<td>QoL</td>
<td>Quality of Life</td>
</tr>
<tr>
<td>RPh</td>
<td>Registered Pharmacist</td>
</tr>
<tr>
<td>Rx</td>
<td>Prescription</td>
</tr>
<tr>
<td>SC</td>
<td>Smoking Cessation</td>
</tr>
<tr>
<td>SE</td>
<td>Step Edit</td>
</tr>
<tr>
<td>SGT</td>
<td>Straussian Grounded Theory</td>
</tr>
<tr>
<td>SHI</td>
<td>Statutory Health Insurance</td>
</tr>
<tr>
<td>SLR</td>
<td>Systematic Literature Review</td>
</tr>
<tr>
<td>U.S.</td>
<td>United States</td>
</tr>
<tr>
<td>VA</td>
<td>Veterans Administration</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>VAC</td>
<td>Value Assessment Committee</td>
</tr>
<tr>
<td>VISN</td>
<td>Veterans Integrated Service Networks</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
List of Figures

Figure 1.1 Visual representation of stakeholders included in the thesis: Core Decision-makers (CDMs) and Affected End-users (AEUs) ........................................ 31
Figure 1.2 Interplay of ethical theories and biomedical ethics as it relates to drug formulary decision-making .................................................................................. 32
Figure 2.1 Interplay of ethical theories and biomedical ethics as it relates to drug formulary decision-making .................................................................................. 40
Figure 2.2 Perfect vs Imperfect Duty. Highlights type of action that is morally praiseworthy or blameworthy .................................................................................. 43
Figure 2.3 Kant’s Moral Philosophy: The intersection of will, reason and universality help to define morally good behavior ............................................................................ 44
Figure 2.4 Cost-Benefit tradeoff to determine whether a person should take action to help another ............................................................................................................. 54
Figure 2.5 Macro vs Micro Allocations ..................................................................................................................................................................................... 62
Figure 2.6 A middle way for rationing healthcare resources: Technical analysis is indispensable but only at the start ...................................................................................... 78
Figure 3.1 Percentage of people by type of health insurance coverage and change from 2013 to 2015 ............................................................................................ 82
Figure 3.2 2014 per person retail prescription spending in select countries around the world ................................................................................................................... 83
Figure 3.3 More insured Americans now report difficulty affording healthcare .......... 84
Figure 3.4 Access to care as measured by number of days needed to see a doctor when sick ................................................................................................................... 85
Figure 3.5 Penalties for employers not offering coverage under the Affordable Care Act during 2017 ........................................................................................................... 87
Figure 3.6 Wellpoint’s P&T process and committee overview ........................................... 95
Figure 3.7 The power of advocacy impacting legislation ........................................................................................................................................................................... 98
Figure 3.8 Drug formulary coverage for Toviaz, commercial plans, NY State .............. 99
Figure 3.9 Drug formulary coverage for Toviaz, Medicare plans, NY State ................. 100
Figure 3.10 Number of studies that focused on assessing implications of formulary restrictions on outcomes ......................................................................................... 102
Figure 3.11 Portion of select clinical practice guideline recommendations for cardiac disease by supporting level of evidence ................................................................. 104
Figure 3.12 Implications of formularies on patient outcomes stratified by types of outcomes .................................................................................................................. 105
Figure 4.1 Visual representation of stakeholders included in the thesis: Core Decision-makers (CDMs) and Affected End-users (AEUs) ........................................ 131
Figure 4.2 Conceptual framework .................................................................................. 146
Figure 4.3 Sample coding of narrative using gerunds .................................................... 150
Figure 4.4  Ideal vs less ideal pharmacy counter scenario .................................................................152
Figure 4.5  Backward snowballing .........................................................................................................156
Figure 4.6  Concepts that emerged through constant comparison between coding and literature .........................................................................................................................157
Figure 5.1  Conceptual framework .........................................................................................................160
Figure 6.1  Substantive theory informing implications of community-based formularies: categories and concepts that emerged from the research .253
Figure 6.2  Health Care vs Health Coverage ..........................................................................................267
Figure 6.3  Number of products on PBM formulary exclusion lists, 2012-2018. Adapted from Fein (2017) ..........................................................................................................................277
Figure 7.1  Substantive theory informing implications of community-based formularies: categories and concepts that emerged from the research .307
Figure 7.2  Three-step approach to integrate ethics into the drug formulary decision-making process ...........................................................................................................................................311
List of Tables

Table 2.1  List of characteristics that could be considered as virtues. .......................51
Table 3.1  Obtaining and documenting informed consent........................................114
Table 4.1  Summary of stakeholders interviewed to complete primary research ....140
Table 4.2  Sample of coding: initial coding, focused coding and resultant categories ..................................................................................................................................................151
Glossary

Below are some of the key terms that are relevant to this thesis. These terms are provided to help acclimate the reader who might be reading this thesis and is not familiar with the U.S. healthcare system and how MCOs implement and manage formularies.

- Affordable Care Act (ACA)
  The Affordable Care Act, also known as Obamacare, was a healthcare reform bill that was signed into law by President Obama on March 23, 2010. Obamacare healthcare reform most notably mandated healthcare insurance coverage for all Americans, unless certain exemption criteria were satisfied; it prevented MCOs from denying coverage due to pre-existing conditions; it made health insurance more affordable through subsidies which were available based on income through an on-line healthcare exchange marketplace: a new marketplace where health insurance could be purchased; and it required plans to offer a minimum set of essential health benefits.

- Benefit Design
  Benefit designs can vary within a given insurance provider. For example, United Healthcare Group, the largest insurance provider in the U.S. with 70 million members and $185 billion in annual revenue, can literally have hundreds of different plan designs. Benefit designs determine what benefits will be available to the insured member, under what criteria, and the financial responsibilities of the insured member including cost-sharing.
- **Coinsurance**
  The percentage an insured member will need to pay for a specific benefit; specifically in the case of drug formularies, the percentage of the medication’s cost the insured member will need to pay to fill a prescription medication. Coinsurances can vary in range and typically there will be maximum annual out of pocket caps.

- **Copay**
  A flat amount the insured member will need to pay to acquire a given benefit within a benefit plan; in the case of a drug formulary, the copay will be determined by the tier level of the drug formulary; with lower tiers having lower out of pocket costs than higher tiers.

- **Drug Formulary**
  Drug formularies are established by MCOs based on clinical and economic value. Drug formularies are informed by the P&T Committee. Drug formularies establish placement of drugs within tiers. Tiers determine the out-of-pocket costs the patient will incur when looking to fill a given prescription medication. When a prescription medication is covered on the drug formulary, a portion of the medication’s cost will be paid for by the MCO.

- **Employer Benefit Design Decision-maker (EBDDM)**
  EBDDMs are responsible for designing and implementing the various benefits an employee receives from their employer. They help ensure benefit plans are compliant with government regulations and that the employer offerings are reflective of market trends.
Generic Substitution
Generic substitution is when a brand name drug is substituted by its generic equivalent. For example, instead of the patient taking Lipitor that was made by the original manufacturer (Pfizer), the patient will take a bioequivalent formulation of atorvastatin made by a generic manufacturer.

Generic Dispensing Rate
The Generic Dispensing Rate (GDR) is defined as (a) the number of generic prescriptions filled divided by (b) the total number of prescriptions filled; GDRs can be specific to the physician’s practice or to a larger physician practice group (which includes a number of physicians) or to the insured members covered by a benefit plan or MCO.

Health Plans
According to the Code of Federal Regulations (CFR), Title 45, Chapter A, Subchapter C, Part 160, Subpart A, Section 160.103, a health plan is an individual or group plan that provides, or pays the cost of, medical care.

Managed Care Organizations (MCOs)
MCOs are business entities that look to deliver better quality care while managing the cost of care by utilizing a variety of strategies such as leveraging economies of scale in contracting, population health management, and measuring metrics to assess performance.

Pharmacy Benefit Managers (PBMs)
A PBM is a specific type of MCO that develops and administers drug formularies only. PBMs utilize a number of strategies including Step Edits (SEs) and Prior Authorizations (Prior Auths) to help reduce the annual drug spend of their customers (such as self-insured employers).
- **Per Member Per Month (PMPM)**
  PMPM costs are equal to total costs divided by the number of members, known as covered lives, divided by 12, the number of months in a given year.

- **Premiums**
  Amount of payment due monthly, quarterly or annually, for a person to receive health insurance coverage from an MCO. These amounts can be paid for directly by the insured member if the insured member purchases coverage directly from the MCO or in part, a significant percentage will be paid for by the insured member’s employer.

- **P&T Committee**
  Pharmacy and Therapeutics (P&T) committees assess the clinical efficacy of prescription medications which in turn informs the drug formulary access level for a given medication thereby effecting its utilization. P&T Committee members typically are physicians representing varying specialties, pharmacists and in some cases other healthcare professions such as nurses. Some P&T committees may have lay person representation. P&T Committees designate prescription medications as *must add*, *may add* or *do not add*. Must add prescription medications usually represent high clinical value in a disease area of high unmet need; may add prescription medications are usually dependent on the economics of the medication; do not add products are deemed to add no value to the patient population given its clinical profile.
• Prior Authorizations (Prior Auth)
  In the application of drug formularies, Prior Auths are an administrative strategy utilized by MCOs to ensure prescription medications are utilized according to the rules set forth by the P&T Committee. Through a Prior Auths, the physician provides the necessary documentation that the criteria that has been set forth by the MCO’s P&T Committee has been satisfied before the MCO will pay, in part, for use of the prescription medication.

• Quantity Limits (QLs)
  In the application of drug formularies, QLs are utilized to ensure quantities of prescription medications dispensed per a 30-day cycle are not used more often than determined acceptable by the P&T Committee.

• Step Edits (SEs)
  A process by which MCOs mandate use of specific prescription medications, based on what is deemed acceptable by the P&T Committee, before other prescription medications will be paid for in part by the MCO. SEs enable MCOs to provide coverage for less costly medications before approving coverage for more costly medications.

• Therapeutic Substitution
  Referred to as drug switching or therapeutic interchange, therapeutic substitution is when the original prescription medication is not covered by the MCO and the physician needs to write a new prescription for a different chemical entity that should have a similar clinical impact and is covered by the MCO. Non-medical switching is a specific form of therapeutic substitution where due to changes in drug formulary coverage the MCO attempts to switch a stable patient on a given therapy to an alternative medication to lower monthly costs.
- **Total cost of coverage**
  A term that includes the annual cost of insurance premiums, deductibles and cost-sharing such as copays and coinsurance.
Abstract
This thesis answers the two-part question: (1) What are the perspectives of the core decision-makers (employer benefit design decision-makers, managed care P&T committee members) and affected end-users (community practicing physicians, community retail pharmacists, employees (insured members)) as it relates to community-based commercial drug formulary decision-making?, and (2) What are the ethical implications of these identified perspectives? The research focused on large employers in the U.S. healthcare system providing pharmacy benefits coverage to their employees. Despite the extensive use of formularies by managed care in the U.S., there is a lack of research on this topic specific to the perspectives of the stakeholders included in this thesis and the implications of their perspectives as it relates to normative ethical theories of utilitarianism, deontology, virtue ethics and principles of biomedical ethics, namely autonomy, beneficence, maleficence and justice. The PhD Researcher conducted 1:1 blinded interviews with 10 study participants from each stakeholder group included in this thesis (n=40) with the exception of the employees (insured members) who participated in one of two focus groups (n=5; n=6). Research methods associated with Grounded Theory were applied to the interview and focus group transcripts to develop initial codes, focused codes and categories. A literature review was completed on relevant ethical theories and principles as well as the U.S. healthcare system. Based on findings of the research completed, ethics is not considered in community-based commercial drug formulary decision-making and implementation. Four categories emerged from analysis of the research: (1) Access to Rx Medications is impacted by the Financials, (2) Drug Formularies are a Means to an End, (3) Informed Decision-making is Essential to Understanding Implications of Choice, and (4) Population vs Patient-level Care is not Necessarily Reconcilable. A three-step approach is proposed to integrate ethics into the commercial drug formulary decision-making process.
Acknowledgements

I would like to thank my Professor David Smith, and my advisors, Dr. Elaine Byrne and Dr. Judith Strawbridge, whose guidance enabled me to complete a thoughtful thesis.

Most importantly, I am grateful to my loving wife, Joanna, whose continual support enabled me to pursue my academic aspirations.
Chapter 1: Thesis Overview

1.1 Introduction

The following quote from John Rawl’s Theory of Justice (Rawls, 1971, p. 24) helps to encapsulate the essence of the critical discourse that is found within this thesis as it relates to advancing the use of ethics in the community-based drug formulary decision-making process in the commercial market segment of the United States (U.S.) healthcare system:

“The two main concepts of ethics are those of the right and the good; the concept of a morally worthy person is, I believe, derived from them. The structure of an ethical theory is, then, largely determined by how it defines and connects these two basic notions.”

Healthcare resource allocation is a complex decision and the type of ethical framework(s) considered in the decision-making process can affect the approach and outcome of the decision (Gardent and Reeves, 2009). In the U.S., a majority of employees at large employers receive their insurance for healthcare through 3rd parties called Managed Care Organizations (MCOs) which can include Preferred Provider Organization (PPO), Health Maintenance Organization (HMO) and Point-of-Service (POS) plans. According to the 2017 Employer Health Benefits Survey (Henry J Kaiser Family Foundation, 2017), 78% of employers offered PPO type plans, 39% offered HMO type plans, and 12% offered POS plans. These MCOs in turn contract with employers who provide medical and pharmacy benefit coverage to their employees. The MCOs work with the Employer Benefit Design Decision-maker (EBDDM) and his or her management to help determine what type of benefit coverage program to offer to the employer’s employees (insured members, who are the consumers and patients within the healthcare system). Ultimately the choice made by the EBDDM and the MCO will determine the employee’s access level to medicines which are defined by the benefit plan’s drug formulary. Different benefit options will contain different drug formularies; drug formularies are a mechanism by which MCOs control utilization of prescription medications. One of the main features of drug formularies is cost-shifting to the patient; namely the amount the patient
needs to pay when the prescription medication is dispensed by the community pharmacist. Drug formularies contain tiers which are depicted by a number sequence starting with the number one: lower tiers have lower out of pocket costs to the patient; a drug formulary can have many tiers; at times, four to six tiers. These higher end tiers typically are for high cost specialty prescription medications and can have a coinsurance that represents 30% out of pocket costs to the patient based on the retail cost of the drug; patients can incur hundreds to thousands of dollars in out of pocket costs. For the most part a drug that has lost patent protection, known as generic prescription medications, will be on the first tier of the drug formulary available with nominal or zero out of pocket costs; whereas branded drugs will be on the remaining tiers. Prescription medications on tier two or three will typically represent on average out of pocket costs of $25 to $90 for patients. There are other utilization management techniques deployed by MCOs, in addition to cost shifting, such as Therapeutic Substitution, Generic Substitution, Step Edits (SEs), Prior Authorizations (Prior Auths), and Quantity Limits (QLs) (Maio, Pizzi et al., 2005). These terms, which were defined in the glossary section of the thesis, are all ways in which MCOs can lower their financial outlay and affect patients’ access to prescription medications. Although drug formularies will be discussed in more detail in Chapter 3 of this thesis, the following example is provided to help give the reader a better sense of how drug formularies work in application.

Patient who has Overactive Bladder (OAB) sees her physician and seeks medical care for her condition. The physician, upon a diagnosis of OAB, wants to prescribe a more recently approved pharmaceutical therapy given its efficacy and safety profile and the specific needs of the patient. Several scenarios may take place relative to the physician’s choice of the prescription when the patient goes to the retail pharmacy to fill her prescription:
1. The prescription medication is covered under the patient’s drug formulary; the copay for the patient might range anywhere from $25 to $90 for a month’s supply of the prescription medication; this might be cost-prohibitive for the patient and the patient might request a less costly alternative or potentially not fill the prescription medication.

2. The prescription medication might not be covered under the patient’s drug formulary. In this case the patient would need to pay the full retail cost of a branded prescription medication which could be in excess of $300 per month (GoodRx, 2017). This might deter the patient from filling the prescription medication or the patient will ask the pharmacist to call her physician and request a lower cost prescription medication.

3. The prescription medication will not be covered by the MCO as the patient has not first tried other available, less costly medications such as generic oxybutynin. Hence if the patient wants his prescription paid for in part (covered) by the MCO, the patient will need to first try oxybutynin and if necessary the physician will then have to note the patient’s medical record that the patient tried and failed on oxybutynin (namely, the patient either could not tolerate the medication due to side effects or the medication did not help alleviate the patient’s symptoms).

4. The prescription medication will not be covered by the MCO as the physician first needs to complete a Prior Authorization (Prior Auth) form. A Prior Auth form will typically require the physician to indicate a medical diagnosis and other clinical parameters including past prescription medications that were taken by the patient for the diagnosed condition. The Prior Auth may or not be approved by the MCO based on information provided by the physician to the MCO.
Physicians and pharmacists may also be rewarded through incentives by maintaining a generic dispensing rate above a certain threshold, which is typically included in performance measures such as the Generic Dispensing Rate (GDR). The GDR is defined as (a) the number of generic prescriptions filled divided by (b) the total number of prescriptions filled and can be specific to the physician’s practice or to a larger physician practice group (which includes a number of physicians), to a retail pharmacy, or to the number of insured members covered by the MCO.

Access to prescription medicines in the U.S. is less about scarce resources and more about managing the financials as it relates to paying for prescription medicines. In the U.S. healthcare system, insurance premiums are set based on a number of factors including the total cost of care, prescription medications (claims paid) for a given covered population, the age and health status of the population, and the specific benefit design of the plan. Pharmaceutical expenditures are typically reported as a separate line item by the MCO to the employer; hence it is a line item that is managed to lower year over year increases in aggregate medication costs and in per member per month (PMPM) costs. PMPM costs, as it relates to pharmacy costs, are equal to the total pharmacy spend by the employer or MCO in aggregate divided by the number of insured members, known as covered lives, divided by 12, the number of months in a given year. Large employers, who are typically self-insured, and MCOs, make decisions on drug formularies in an attempt to lower the PMPM pharmaceutical costs in any given year. Drug formulary utilization management techniques typically promote less expensive medications which reduce the pharmacy spend but could have a negative effect on longer term clinical, humanistic and total system cost (economic) outcomes. MCOs believe that these techniques lead to the use of the most affordable and effective medication options through the application of best practices (evidence-based medicine) on a consistent basis (Prime Therapeutics, 2012). MCOs would argue that their interventions are for the benefit of the healthcare system and for those who engage the system, yet as shown by a survey (Sulmasy, 2001), physicians perceive that MCOs and their attempts at cost control have led to negative ethical implications (namely, patient trust negatively affected; physician commitment to patient loyalty questioned or
diminished; physicians taking steps to manipulate the system through deceptive coding to help patients gain access to physician-defined appropriate care). An example shown below helps to convey some of the concepts just discussed:

- An employer will meet with their MCO and discuss the various costs of their employees' medical benefits including the cost of the prescription benefit coverage.

- The top spend products by major disease category will be reviewed. The highest cost products will be identified and ways in which to lower total employer costs (for example, higher out of pocket costs being shifted to the patient to lower employer paid costs; more strict PAs; introducing SEs).

- Based on the modifications made, given the benefit design changes, the premium paid for by the employer will be reduced as the benefits paid will be less generous for patients who are taking specific medications. Patients will pay greater out of pocket costs at point of care or when filling their medication at the pharmacy.

In the opinion of the PhD Researcher, there are two important aspects of informing drug formulary decision-making within the U.S. healthcare system, namely (1) what is the appropriate medication treatment for a given patient (Pollock et al., 2007) and (2) who should pay for the identified medication treatment (Olson, 2017). In the opinion of the PhD Researcher, only when answering these two questions in sequence can one appropriately help find an ethically grounded solution to providing patients access to medications through drug formularies.
1.2 Impact of the Problem on Decision-making

Pharmaceuticals are a mainstay in treating a patient’s medical condition. Patients choose their doctors; patients choose their pharmacy; but patients rarely have the opportunity to independently choose their prescription medications; ideally physicians would prescribe what scientifically they deem best for a given patient. However, MCO formularies can affect what a physician eventually prescribes; what a patient fills at the pharmacy counter. Employers make decisions as to the type of benefits that will be provided to their employees including drug formulary coverage; this is entirely or partly informed by the MCO.

Through the application of drug formularies, the employer and the MCO impact upon the actions of the employer’s employees as well as the physicians and pharmacists, who provide services to the patient, and thereby potentially affect subsequent outcomes. For purposes of this thesis, the Core Decision-makers (CDMs) are the Employer Benefit Design Decision-maker (EBDDM) and the Managed Care Organization Pharmacy & Therapeutics Committee Member (MCOP&T) as drug formularies are set by the MCO and agreed to by the employer. Community Practicing Physicians, Community Retail Pharmacists and the Employer’s Employees (Insured Members) for this thesis are considered the Affected End-users (AEUs) of the system, given that the CDMs impact on the:

- physician’s ability to write the medication that he or she deems best for the patient may be impacted through the formulary;
- pharmacist’s actions and behavior in filling and dispensing the physician’s prescription may be affected by the formulary;
- employee’s (insured member’s / consumer’s / patient’s) ability or willingness to fill the medication may be affected by the formulary.

Hence there is a cause and effect: the decisions made by the EBDDM and the MCOP&T affect physicians, pharmacists and employees (insured members). For purposes of this thesis, the treating physicians are community-based practicing
physicians; they see patients who have different MCOs and hence different formularies; physicians are able to look up a patient’s specific drug formulary through their Electronic Medical Record system or their e-prescribing system. In contrast, a hospital physician follows the drug formulary of their hospital and hence all patients will have the same drug formulary for inpatient care; whereas the community physician may literally have dozens of different drug formularies within their patient panel.

A visual representation of this cause and effect is shown below in Figure 1.1. In addition to the CDMs and AEUs, for purposes of this thesis, the MCOP&T, EBDDM, Community Practicing Physicians, and Community Retail Pharmacists collectively comprise the Professional Group (PG).

![Figure 1.1 Visual representation of stakeholders included in the thesis: Core Decision-makers (CDMs) and Affected End-users (AEUs)](image)

### 1.3 Background of the Study

The purpose of this study is to create a formal analysis of various ethical theories and principles as it relates to ethics in the community-based commercial drug formulary decision-making process in the U.S. healthcare system. A number of theories are reviewed and discussed including theories related to the action itself (deontology), consequences of the action (utilitarianism) and the character of the person carrying
out the action (virtue ethics) as well as the principles of biomedical ethics, namely autonomy, beneficence, non-maleficence, and justice. As shown in Figure 1.2, these theories and principles have an interplay as it relates to drug formulary decision-making: the implications of drug formulary decision-making as it relates to deontology and utilitarianism; the effect of drug formulary decision-making on the four principles of biomedical ethics; the effect of virtue ethics as it relates to the character of the decision-maker.

![Figure 1.2 Interplay of ethical theories and biomedical ethics as it relates to drug formulary decision-making](image)

Other aspects that are related to ethics that are covered include health, healthcare and rights; trust and fairness; allocation of resources; and lastly MCOs and overall ethics.

### 1.4 Study Objective and Primary Research Question

The study objective of this thesis is to develop a conceptual framework and substantive theory to help advance the use of ethics in community-based commercial drug formulary decision-making. With this in mind, this research is designed to
understand the point of view of the included stakeholders, namely the PG and the employer’s employees (insured members), as it relates to community-based commercial drug formularies and access to prescription medications.

The two-part research question addressed by this thesis is the following:

1. What are the perspectives of the core decision-makers (Employer Benefit Design Decision-makers, Managed Care P&T Committee Members) and affected end-users (Community Practicing Physicians, Community Retail Pharmacists, Employees (Insured Members)) as it relates to community-based commercial drug formulary decision-making?, and

2. What are the ethical implications of these identified perspectives?

1.5 Research Design

The research design chosen for this thesis was Grounded Theory (GT). The use of GT was to uncover the various stakeholders’ perspective as it relates to access-related decision-making namely drug formularies; how the perspectives of each stakeholder included in this thesis (CDMs and AEUs) intersect with each other and the resultant implications of the application of ethical theories and principles to drug formularies (utilization controls).

GT is the most popular qualitative method within healthcare research when the researcher is looking to understand data inductively and looking to postulate how concepts interrelate for a given topic on multiple levels hence developing an emerging theory (Morse, Stern et al, 2009). GT enables the researcher to capture the perspectives of the various involved stakeholders as it relates to a topic not previously studied (Foley and Timonen, 2015). When applying GT, it is important to start with no theory and hypothesis, while maintaining flexibility in the research approach (Lawrence and Tar, 2013).
One-on-one phone interviews were conducted with 40 stakeholders that were part of the PG; namely 10 interviews within each of the 4 stakeholder types, which consisted of EBDDMs, MCOP&Ts, Community Practicing Physicians and Community Pharmacists. Two focus groups were held with employees of one large employer. More details of the research design is provided in Chapter 4. The PhD Researcher used discussion guides consisting of open-ended questions as well as case studies to gain a thorough understanding of the stakeholder’s perspective relative to the thesis research question.

1.6 PhD Researcher

The PhD Researcher has 25 years of experience working in the U.S. healthcare system. The PhD Researcher has held a number of positions as it relates to healthcare including that of (1) healthcare consultant to employers; (2) employer benefits manager; (3) sales representative and operations manager for a managed care organization; and (4) a number of different positions working in the pharmaceutical industry including positions focused on Planning & Business Development, Community Health, Local Marketing, and Market Access which entailed working with payers in the U.S. and major markets across the world. The PhD Researcher utilized his experience of the U.S. healthcare system acquired during the course of his professional career to identify the focus of the thesis, including the research question and the approach to conducting the research necessary for informing and completing the thesis. With the PhD Researcher’s knowledge of the U.S. healthcare system, and informed through readings on ethical theories and principles, the PhD Researcher developed a comprehensive discussion guide for use with study participants. The PhD Researcher remained self-aware of introducing bias throughout the research, including development of the discussion guides, interaction with the study participants, analysis of the data, and writing of the thesis. The PhD Researcher worked to reduce potential for bias through memo-writing (reflective analysis), review of findings with the PhD Researcher’s advisors, and checking consistencies / differences of findings after completion of each study participant discussion.
1.7 Scope and Delimitations

The scope of this thesis is focused on advancing the use of ethics as it relates to large self-insured employers engaging with MCOs (the CDMs) to provide access to prescription medications for its employees which is known as commercial coverage. The thesis does not apply to other forms of coverage (market segments) such as group insurance purchased by fully insured employers, Medicare or Medicaid. Medicare covers individuals who are for the most part 65 years of age or older; Medicaid provides coverage for individuals who are low income as well as pregnant women and children. Nor did this thesis include any analysis of inpatient hospital drug formulary decision-making as this is specific to the hospital that is contracted by the MCO. This thesis does not make any assessment of when branded medications lose their patent and become available as a generically bioequivalent medication. Hence for purposes of this thesis no analysis is made as it relates to generic substitution. This thesis also did not include pricing set by the pharmaceutical manufacturer and how pricing affects the use of its products in the marketplace. Given the complexity and diversity of the U.S. healthcare system, in order to be able to effectively conduct primary research and maintain focus for the thesis, only the employer-sponsored community-based commercial drug formulary decision-making process was considered.

Although this thesis focuses only on the physician as prescriber, it is important to note, that as of 2017, as stated by Herman (2017), there were 222,000 licensed Nurse Practitioners (NPs) and 115,000 practicing Physician Assistants (Physician Associates), also known as PAs. 95% of NPs prescribe medications; full time NPs on average prescribe 23 prescriptions per day. In 22 states and the District of Columbia, NPs have the same prescriptive privileges as physicians; in the remaining states, NPs need to have either physician collaborative agreements in place or require physician oversight. All PA prescribing requires physician oversight at some level (AMA, 2018). Mid-level prescribing authority is determined at the state level; all states allow for NP and PA prescribing, with the exception of Kentucky, which does not allow for PA prescribing (U.S. Department of Justice). Collectively NPs and PAs
make up 22% of the health care provider workforce. Approximately 4 billion retail prescriptions were dispensed in 2015; approximately 680 million or 17% of these prescriptions were written by NPs and PAs, up from 9% in 2010 (IMS, 2016). As reported by Jiao et al. (2018), in the commercial setting, patients with private (commercial) insurance were more likely to see a physician as compared to an NP or PA, namely, 51.3% vs 37.4% and 43.0%, respectively. Physicians were also more likely to see patients compared to NPs or PAs in the community-setting, namely 85.5% vs 36% and 45.2%, respectively. By comparison, patients in the outpatient setting are more likely to receive care from an NP; and patients in the emergency room are more likely to receive care from a PA. Nationally, NPs and PAs are found in physician group practices 56% of the time; independent providers on average utilize NPs and PAs 40% of the time (Marcum et al., 2016). Many of the challenges brought forward by this thesis as it relates to the physician most likely would apply to NPs and PAs as well but the analysis as it relates to these healthcare professionals is beyond the scope of this thesis.

In Chapter 2 there is a comprehensive overview of a number of ethical theories and principles, as described earlier in this chapter and illustrated previously by Figure 1.2, which highlights the interplay of these theories and principles as it relates to drug formulary decision-making. These include theories related to the action itself (deontology), consequences of the action (utilitarianism), the character of the person carrying out the action (virtue ethics) as well as the four principles of biomedical ethics, namely autonomy, beneficence, non-maleficence and justice. Other aspects related to ethics that are covered include health, healthcare and rights; trust and fairness; allocation of resources; and lastly MCOs and overall ethics.

A comprehensive overview of the U.S. healthcare system is provided in Chapter 3. Methods for the research are discussed in Chapter 4; summary of the primary research is provided in Chapter 5; analysis of the research is undertaken in Chapter 6; and synthesis of the findings and conclusion is found in Chapter 7.

As it relates to delimitations, this thesis does not attempt to assess whether the findings relevant to the commercial segment of the marketplace, as provided by large
employers, would have been relevant to the other market segments found in the U.S. healthcare system, such as Medicare and Medicaid. In addition, Employer Benefit Consultants (EBCs) were not included as a stakeholder group in the research. In the U.S. healthcare system, large employers might decide to utilize EBCs to further inform benefit design and coverage decisions. Given EBCs are a resource to EBDDMs, the PhD Researcher did not include EBCs in the research; EBDDMs are the ultimate decision-maker as the purchaser and the MCO has the clinical expertise and oversight of the drug formulary.

1.8 Assumptions and Limitations

The thesis was informed through primary research with stakeholders already mentioned earlier in this chapter. The stakeholder categories included in this research were selected based on the PhD Researcher’s understanding of the U.S. healthcare system.

The primary research was purposive and non-probabilistic; screening criteria was used to ensure a specific level of experience and expertise of each stakeholder included in the professional group to help the PhD Researcher understand the majority of opinions as it relates to ethics and community-based commercial drug formulary decision-making. Majority of opinions in this case was defined as 50% or more of the stakeholders included in this research having a specific perspective on the questions that were asked during the interviews. The probability of missing a particular theme as observed in the data was then expected to be 0.001 (DePaulo, 2000). In a study done on reproductive health research in two countries in Africa that interviewed 60 women, 73% of all codes and 94% of the high prevalence codes had been identified by the 6th interview. The conclusion was that a sample size of six would lead to development of meaningful themes and interpretations (Guest et al., 2006). Given the concept of data saturation is not well understood and subjective (Mason, 2010), the PhD Researcher utilized 10 participants for each stakeholder of the professional group to help ensure data saturation.

The PhD Researcher utilized standardized open-ended interviews; this allowed for the study participants to answer completely based on their perspectives and enabled
the PhD Researcher to probe study participants’ responses further based on their initial responses. This approach led to the development of a rich dataset that required the PhD Researcher to be disciplined in coding given the extensive narrative captured through the interviews (Turner III, 2010). Each study participant was asked the same question specific to a given stakeholder group.

The following limitations of this thesis were identified by the PhD Researcher:

- This thesis did not assess how adopting an ethically grounded drug formulary decision-making process would change the prescription medications that are made available by employers’ to their employees. Despite application of an ethical framework in making drug formulary decisions, the availability of medications might still vary across MCOs due to the subjectivity of the decision-makers and the challenges of understanding the specific needs of any given patient when providing population-level coverage.

- The cost implications of implementing an ethically-based drug formulary decision-making process was not evaluated. This would be an important factor to consider when deciding to implement such an ethical framework as it could have implications on the business model of MCOs in the U.S. healthcare system.

1.9 Significance of the Study

Based on the literature review completed by the PhD Researcher for this thesis, there is no study conducted to date that (1) explores and compares the different ethical theories and principles as it relates to the use of ethics in community-based commercial drug formulary decision-making in the U.S. and (2) analyzes the perspectives of the stakeholders included in this thesis namely the CDMs and AEUs.

This thesis begins to identify a possible ethical framework for CDMs and AEUs to apply in community-based commercial drug formulary decision-making as it relates to, large employer-provided, pharmacy benefits coverage.
1.10 Summary

When a prescription medication in the U.S. healthcare system is approved by the regulatory agency, the Food and Drug Administration (FDA), any patient can get a medication prescription from a physician who deems it to be medically appropriate for the patient. Two questions emerge, namely: (1) will the patient be able to afford the prescription medication and (2) will the physician and pharmacist be hassled or have undue burden ensuring the patient is able to obtain coverage through the MCO given the drug formulary the MCO has in place for that specific patient, based on what the EBDDM has agreed that the employer will provide to its employees. Based on the drug formulary the pharmacist will inform the patient of any additional requirements (such as a SE or Prior Auth for which the physician will need to be contacted) or will communicate to the patient the copay or coinsurance due which might create a barrier to access for the patient given the patient’s ability or willingness to pay. The pharmacist might make a switch to a generic-equivalent based on how the prescription was written by the physician or might recommend to the patient a lower cost alternative. With the exception of generic substitution, these are the aspects that this thesis takes a closer look in regards to patients’ access to prescription medications through drug formularies that are put in place through the MCO by the EBDDM. Based on the drug formulary that is put in place, the AEUs, namely the patient, physician and pharmacist are ultimately impacted to some degree.

The PhD Researcher has placed emphasis in this thesis on a critical analysis of community-based commercial drug formularies and the ethical implications to the CDMs and AEUs. Chapters 2 and 3 provide additional in-depth background, informed through a literature review, of ethical theories and principles as well as the dynamics of the U.S. healthcare system, respectively. Chapter 4 provides an overview of the methods utilized to complete and analyze the primary research conducted. Chapter 5 provides a summary of the findings. Chapter 6 provides an analysis and discussion of the findings and Chapter 7 provides a synthesis of the research and conclusion.
Chapter 2: Review of Ethical Theories In Relation to Allocation of Healthcare Resources

This chapter lays out background information as it relates to several of the major ethical theories and principles that will be later applied to the primary research findings of this thesis. As was shown previously in Chapter 1, Figure 1.2, (included again below for ease of reference as Figure 2.1), these theories and principles have an interplay as it relates to drug formulary decision-making: the implications of drug formulary decision-making as it relates to deontology and utilitarianism; the effect of drug formulary decision-making on the four principles of biomedical ethics; the effect of virtue ethics as it relates to the character of the decision-maker.

![Diagram: Interplay of ethical theories and biomedical ethics as it relates to drug formulary decision-making](image)

The first portion of this chapter helps to elucidate ethical theories that inform morality as it relates to the act being committed (deontology), the consequence of the act committed (utilitarianism) and the character of the agent committing the act (virtue ethics); the second portion of the chapter looks more closely at biomedical ethics and...
the four principles of autonomy, beneficence, maleficence and justice. Lastly the chapter also takes a closer look at related aspects of ethics including health, healthcare and rights; trust and fairness; allocation of resources; and lastly MCOs and overall ethics. The final two sections of the chapter is a discussion and conclusion on the concepts introduced in the chapter.

These ethical theories and principles were chosen by the PhD Researcher as they are relevant to the thesis topic. If patients need access to a particular medication that will be helpful in the treatment of their medical condition, should they not be able to receive these medications? Deontology and utilitarianism might reach similar or different conclusions with regards to the answer to the question. Similarly how does virtue affect each of the stakeholders in the professional group whether they are making drug formulary decisions (CDMs) or they are being affected by the decisions taken (AEUs)? How do biomedical ethics, including autonomy, beneficence, non-maleficence and justice factor into the ultimate decision of accessing a given medication; similarly how are rights, trust and fairness at play as it relates to allocation of resources as well as the overall application of ethics to MCOs.

2.1 Deontology

The first of the ethical theories discussed in this chapter is deontology which was most informed through the work of Immaneul Kant. Much of the foundation of deontology was established by the philosopher Kant in his work, “The Groundwork of the Metaphysics of Morals” (Kant, 1785). Kant’s deontology is based on rational thought that informs the human will which then obligates the agent to act morally based on a set of rules known as Categorical Imperatives or maxims that have universal application (Shakil, 2013). This section focuses on Kantian-based deontology which is an ethical platform that requires the principal agent to inquire to themselves what “ought I do” in a given situation (Johnson, 2016).

Good will, obligation, and duty need to be examined and understood by the agent to assess application of these concepts to inform the question on what ought to be done in a given situation and whether the approach is justified. Understanding what is the
right thing to do is essential a priori of an action and not after the fact. An after-the-fact assessment of the implications of an act is too late to guide one’s actions, because it will then be based on the analysis of the consequences rather than the principles that should have informed the action a priori. The will of the agent that informs the behavioral characteristics of the agent and its goodness (good will) are an important element to ensure the morality of decision-making. A good will needs to be absolute and not contingent on an outcome. The moral law should be the sole driver of an agent’s action thereby the action becomes the duty of the agent to fulfill. Actions of an agent should be informed by whether the act is morally warranted or to be avoided and actioned solely because it ought to be ascribed to; any other motivating factors to take a particular action are not warranted and hence without value. The act of an agent is aligned with the ought of an action if it is informed by the rational will and can be applied universally in its application; hence it becomes a categorical imperative. “I ought never to act except in such a way that I could also will that my maxim should become a universal law [of nature]” (Kant, 1785, 4:402). This is known as a Categorical Imperative I. A Categorical Imperative II complements the former Categorical Imperative I by stipulating that no action should be done that is treating another (person) as an ends to a means. Categorical Imperative II (also known as the Law of Humanity) ensures the agent does not take action that would otherwise be at the expense of another; an absolute directive that every agent most abide by, namely each person must be treated as an end to itself and not a means to an end. Every person should act in a manner that is representative of how in turn they would want to be treated by others (Papadimos, 2007). All humans have absolute worth; through the existence of reasoning that is self-determined, there needs to be equal value and respect attributed to each person (Johnson, 2016).

Duties can be further categorized as perfect and imperfect, directed at others or at the self as visually illustrated below in Figure 2.2:
Perfect duties must be followed without exception. An example of a perfect duty to self is not committing suicide; an example of perfect duty to others is repaying a loan. In order for a society to be able to function in a moral manner, perfect duties to others must apply at all times; while the law of nature requires perfect duties to self.

Imperfect duties are not focused on the morality of the action but rather on the praiseworthiness of the action and they are either permissible or not based on the relative need or ability of the agent as it relates to the situation; it can be influenced by inclination and also thought of as duties of virtue. Again these can be viewed as directed to the self or others, such as developing one’s talents or saving a drowning person, respectively (McCarty, 2015). These examples of perfect (suicide, repaying loan) vs imperfect duty (developing talents and saving a drowning person) are examples provided by Kant (Johnson, 2016).

The Kingdom of Ends, a concept introduced by Kant in “The Groundwork of the Metaphysics of Morals”, ensures that rational agents follow and legislate laws that all members of the community are able to abide by, promulgating and enforcing such laws: a “systematic union of different rational beings under common laws” (Kant, 1785). Autonomy of the principles that inform decision-making is evidenced when the moral laws that bind the individual are from the individual’s own accord rather than mandated upon the agent by another. The virtuous character of the agent is defined by the agent’s ability to carry out the will to act in a manner that conforms with the

Figure 2.2 Perfect vs Imperfect Duty. Highlights type of action that is morally praiseworthy or blameworthy. Adapted from Johnson (2016).
categorical imperative that satisfies the agent’s duties to act in a moral manner and not being redirected by temptation. Morality is a duty that needs to be consistent given that desires and interests may run contrary to what is required by moral duty. Moral righteousness needs to be the bedrock of all actions in one’s endeavors.

Good is derived from the rules that guide the agent’s actions (Heubel and Biller-Andorno, 2005). Obligation is what defines what is ethical. Heubel and Biller-Andorno recognize that the impetus for moral actions should be non-subjective (objective) and determined by necessity, driven in the human agent by practical reasoning. The authors recognize that Kant’s moral philosophy is the convergence of will, reason and universality, as depicted in the illustration below (Figure 2.3), with practical reasoning a defining trait of humans constantly applying moral laws to balance their thoughts and actions against needs and tendencies.

![Kant’s Moral Philosophy](image)

Figure 2.3 Kant’s Moral Philosophy: The intersection of will, reason and universality help to define morally good behavior. Adapted from Heubel and Biller-Andorno (2005).

### 2.2 Kant’s Moral Philosophy

The intersection of will, reason and universality help to define morally good behavior. Kaldis (2005) further reinforces Kant’s application to healthcare, that when considering the inevitable allocation of scarce resources, healthcare needs to go beyond science and economics recognizing that the individuals who affect care as well as those receiving care are the embodiment of moral law which mandate actions in accordance with duties by virtue of practical reasoning. The ethical application has to co-exist in parallel at the macro and micro levels between the institutions that facilitate the system of care and the individual practitioners providing patient-specific
care. There needs to be a minimum threshold established, due to the need to respect and maintain human dignity, below which no one will go irrespective of the economic consequences (Van Staveren, 2007). Curtailing behavior that seeks to only achieve economic gain irrespective of the negative consequences to possibly others should positively impact on society’s overall welfare. Deontology has its limits because it does not allow for prioritization of trade-offs or for exceptions when there are tensions in the system ((Crisp and Slote, 1997) as referenced by Van Staveren). With regards to allocation of (scarce) resources, physicians need to produce the best possible outcome by exercising their good will. It’s the principle of doing good, compelled by reason, that informs the physicians’ actions (Papadimos and Marco, 2004). Deontology in this regard is different from utilitarianism which at its core is about the consequence of a given action and the calculus of benefit gained through that action.

2.3 Utilitarianism

Utilitarianism is the ethical theory that looks to maximize the good, to do the most good for as many as possible, where each person’s unit of benefit is considered equal. All agents are created equal and hence the value of each agent’s happiness counts the same. Everyone has the same impetus to advocate for the good. A specific form of utilitarianism, egotistic utilitarianism, would further rationalize the motivation for everyone promoting the good, because the good would ultimately benefit the promoter. Namely, the individual being part of the system will accrue his or her share of benefit which will be greater to the agent as opposed to not being a participant in the system. By contributing to what is in the interest of the public, there will be a respective benefit to the individual (Driver, 2014).

Although utilitarianism was initially developed as an ethical theory by Jeremy Bentham (1996), several other philosophers have helped to evolve the concept of utilitarianism, such as Frances Hutcheson (Scott (1900)), John Stuart Mill (1962), Henry Sidgwick (1907) and G.E. Moore (2006). Mill addresses how utilitarianism defines right or wrong based on the degree of happiness produced or destroyed, respectively; also referred to as the Proportionality Doctrine (Brink, 2007). Brink
speaks to Bentham’s approach to assess the value of an action through felicific calculus by which the sum of benefits (pleasure) gained can be calculated. Policy-makers in today’s world continue to apply rational methods to assess utility and apply reason to plan for rational health coverage. Evaluators look to assess efficacy and cost of a specific intervention as compared to another, measuring the net treatment effect to assess the value and the unmet need satisfied by the intervention. All in an attempt to ensure that healthcare coverage is fair and just (Jonsen, 1986).

Motives are equally important to assess the morality of actions, in addition to the consequential outcome of the action (in contrast to deontology which is about one’s duty irrespective of the implication of benefit to others). Morally-based decisions should not be motivated by self-interest and rather than assessing the agent’s character, the agent is assessed on the consequences of their actions (act-evaluation). The action of the agent is morally right if it produces greater utility (net benefit which includes positive benefits offset by any potential harms) than any other alternative. Bentham evaluates the morality of action along the following dimensions: intensity, duration, certainty, proximity, fecundity, purity and radius (as measured by the number of people affected by the decision). This is in concept what is encapsulated in the quote, “rather Socrates dissatisfied than a fool satisfied” (Driver, 2014).

Rationalization of the righteousness of a moral law is contingent upon the utility of the consequences of the action taken. However, conscience and seeking justice are two guide rails for informing behavior and accepting the consequences of an agent’s actions. Virtuous behavior and traits are held in the highest esteem and enable the means to an ultimate end; sometimes the greatest benefit to the many requires individual sacrifice which is enabled by virtuous behavior. “What use is it” as proposed by Bentham (Driver, 2014), is the foundation by which policy-makers use utilitarianism as a philosophy to help inform decision-making.

A contrast to that of deontology is the example of lying; whereas this would not be acceptable under deontology (as it could not be universalized as a categorical imperative), it would be morally right under utilitarianism, if the net benefit was
positive (Sinnott-Armstrong, 2003). Different aspects of utilitarianism exist (known as various forms of consequentialism) that place constraints on the pure calculus of a net positive benefit; these constraints could be considered value constraints. For example, hedonism measures pleasure vs pain, preference measures the preference of people as it relates to a specific issue or pluralistic which quantifies various values at once.

Rawls (1971, p. 20) in his Theory of Justice, as it relates to utilitarianism (consequentialism), states that a

“society is rightly ordered, and therefore just, when its major institutions are arranged so as to achieve the greatest net balance of satisfaction summed over all the individuals belonging to it.”

Social cooperation enabled through an efficient administrative system will be most able to deliver on distributive justice across a society as it relates to limited (scarce) resources.

Classic utilitarianism can be categorized as either act-based or rule-based. Act-utilitarianism is focused purely on the consequence of the action. Act-utilitarianism in theory would not support the commitment to a promise because a promise would only be kept if it is value-maximizing. Conversely, rule-utilitarianism establishes rules that provides guidance on what actions to take that will help maximize value in the long-term because alternatively actions without rules might destroy value. Establishing the moral rule into guidelines for decision-making creates more value than not having the rule as a guide to informed decision-making (Habib, 2014).

Lastly, the concept of implications which could be considered a part of consequentialism, given it is the result of an action, can also be considered as part of deontology as discussed by Spielthenner (2005). Implications can play a role in the ethical assessment of an action. For example, a person is perceived by the public to have committed a crime even though in reality the person has not created a crime. The causal effect of the person not being punished is that there is public unrest and upheaval; the public perceives there has been a crime and demands punishment. The punishment from a causal perspective (the consequence) would be acceptable
under utilitarianism if the punishment prevents public upheaval and unrest. However, the punishment from a non-causal perspective would be unjust; which is considered an implication of the wrongness of the act of punishing an innocent person.

Savulescu (1998) identifies welfarist maximizing utilitarianism which should guide a physician’s decision-making in treating patients; however distributive justice is not considered through utilitarianism, only the maximization of the benefits of the resources utilized. Savulescu makes reference to the concept of defacto discrimination made by Harris (1996), where utilitarianism would favor use of resources towards patients who have a higher probability of survival (for example, operating on patients with appendicitis as opposed to a brain tumor, given the probability of survival in the latter group would be 50% as compared to 100% in the former group).

2.4 Virtue Ethics

Virtue is one of the oldest of ethical principles. Socrates termed the expression excellence of character which referred to the qualities of a person, moral virtues, which others admired due its goodness and where that person became a role model for others to emulate (Homiak, 2003). Plato considered four virtues, which were defined in part by Socrates, namely, wisdom, courage, moderation, and justice (Frede, 2008). Wisdom being assumed by leaders who rule a state, courage being demonstrated by soldiers, moderation which allows for harmonious coexistence in a given society, and justice which allows each member of the state to live autonomously as long as anyone’s autonomy does not interfere with the autonomy of others. The four virtues need to coexist within the moral agent in a balanced manner that ultimately leads to actions that can be defined as good; with justice being the unifying virtue that binds the four virtues together within the moral agent. The virtuous person will consistently act in a manner that produces good, and in turn happiness, which is reinforced over time and eventually becomes routine for the moral agent.

The most important aspects of virtue-based ethics for healthcare professionals is defined by Pellegrino (1995) as excellence of character traits that are oriented
towards a purpose and end, defined by reason not emotion, and based on practical judgment, mastered through repetition over time. As described by Kraut (2001) and (Homiak, 2003), Aristotle stressed the concept of the Golden Mean, which is the mid-point between two extremes, one end being defined as an action that is in excess and the other end of the spectrum being defined as an action that is deficient; either extreme being considered a vice. An example of such a mean is that of courage which exists between the vice of rashness and cowardliness. Aristotle, however, did not view the Golden Mean as an arithmetic mean that is measurable; rather an action that a good person would take given the specific individual situation where the right balance between either extreme would be acted upon, informed through reason. The moral agent would express an appropriate level of concern, would seek to make a wise decision informed by practical wisdom gained over years of experience. Practical wisdom in turn should seek out theoretical wisdom or theoretical reasoning, which is a higher state of reflection through the integration of science and intuitive understanding: these are resources that help the moral agent attain a specific goal. Aristotle believed that happiness, which is the ultimate state of being, is achieved through excellence, which is equitable to virtue, due to the soul being able to think rationally and informed by reason. Happiness is the highest attainable desire and is sought after for itself; all other good things are sought after to achieve this ultimate state, and all actions are desired to achieve this state. Hence a virtuous person will be in a state of happiness but will require use of their rationale, informed through their emotions and social skills, where the person’s soul is in harmony and hence not conflicted by their actions. The moral agent strives to be part of a community where each member is able to flourish and thrive as a result of being a member of the community. Through the actions of the community members there is greater benefit to all which leads to bonds of friendship which is transformative to the moral agent and enhances the development of the moral agent’s capacity to seek actions that will be of benefit to others. Enhancing the lives of others in turn will enhance the life of the moral agent (Homiak, 2003).

Gardiner (2003) speaks to the emotional aspect of ethical frameworks and moral behavior. Emotions sensitize the rational aspect of decision-making, and virtues,
when practiced over time, become engrained in the core of how good people think which in turn impacts on their decisions. Assessing a situation and a corresponding solution without emotion prevents the agent from understanding the specifics of a given circumstance fully. Without emotion an agent cannot completely comprehend the magnitude of a given situation and the alternatives that should be considered through rational thought.

Kant recognized the role of virtues in satisfying imperfect duties, and in addition to courage, recognized the importance of virtues such as sympathy and gratitude. However, unlike Aristotle who believed that reason and emotion spoke in one voice, Kant believed that reason kept emotion in check; otherwise emotion would control the life of the agent and create strife and discord (Homiak, 2003).

John Stuart Mill (1869) also speaks to the importance of character in making decisions based on reasoning and self-control:

“He who lets the world, or his own portion of it, choose his plan of life for him, has no need of any other faculty than the ape-like one of imitation. He who chooses his plan for himself, employs all his faculties. He must use observation to see, reasoning and judgment to foresee, activity to gather materials for decision, discrimination to decide, and when he has decided, firmness and self-control to hold to his deliberate decision.” (p. 58)

Rachels and Rachels (2003) goes on to list a broad set of characteristics that could be considered as virtues which are restated in Table 2.1 below.
Table 2.1 List of characteristics that could be considered as virtues. Adapted from Rachels and Rachels (2003).

<table>
<thead>
<tr>
<th>Benevolence</th>
<th>Fairness</th>
<th>Patience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Civility</td>
<td>Friendliness</td>
<td>Prudence</td>
</tr>
<tr>
<td>Compassion</td>
<td>Generosity</td>
<td>Reasonableness</td>
</tr>
<tr>
<td>Conscientiousness</td>
<td>Honesty</td>
<td>Self-discipline</td>
</tr>
<tr>
<td>Cooperativeness</td>
<td>Industriousness</td>
<td>Self-reliance</td>
</tr>
<tr>
<td>Courage</td>
<td>Justice</td>
<td>Tactfulness</td>
</tr>
<tr>
<td>Courteousness</td>
<td>Loyalty</td>
<td>Thoughtfulness</td>
</tr>
<tr>
<td>Dependability</td>
<td>Moderation</td>
<td>Tolerance</td>
</tr>
</tbody>
</table>

Trustworthiness, integrity and discernment have been described by Beauchamp and Childress, along with compassion and conscientiousness, as virtues a good physician practicing medicine will exhibit (Koch and Menezes, 2015). Pellegrino (1995) also identified a number of virtues that should be exhibited by the medical physician, including fidelity to trust and promise; benevolence; effacement of self-interest; compassion and caring; intellectual honesty; justice; and prudence. Walker (2010) highlights additional virtues of physicians to exhibit in their daily activities including responsibility, humility, courage, temperance, unconditional positive regard, charity, vigilance, agility, faith, hope, love, respect for patients, integrity, self-sacrifice, competence and altruism. Brody (N.D.) speaks to the 3-legged stool of virtue ethics as it relates to professionalism, namely (1) advocating for the patient, (2) advocating for the overall population (which is being a good steward when it comes to allocating scarce resources) and (3) preserving self-interests of the healthcare professional, realizing there are boundaries to what a healthcare professional can do (in this case a physician) when advocating for their patients.

Ultimately virtues define character as evidenced in behavior over time. They “are dispositions regarding actions, perceptions and emotions of the right sort, toward the right subjects, for the right end, at the right times and in the right way.” (Walker,
Walker speaks to the application of practical wisdom that based on the particular needs of a given patient, and in light of their medical situation, the physician is able to apply principles and guidelines to effectively care for the patient.

2.5 Biomedical Ethics

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was formed by Congress when the National Research Act was signed into law on July 12, 1974. The Commission produced the Belmont Report which identified the guiding ethical principles to inform how biomedical and behavioral research would be conducted that involved human subjects (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). The Commission identified 3 principles within the Report, namely respect for persons, beneficence and justice. Respect for persons is based on the autonomy of the patient, and patients whose autonomy is compromised and has a diminished ability for self-determination, needs to be protected. Beneficence ensures that a patient’s well-being is maximized in addition to not producing harm or compromising the patient’s autonomy. Justice protects populations so that no patient suffers any disproportionate burden and all patients have an equal share of the benefit.

The four principles of biomedical ethics, in turn, as defined by Beauchamp and Childress, namely, autonomy, beneficence, non-maleficence, and justice are grounded in common-sense morality, not foundationalism, and are common-sense principles that members of the medical profession can quickly agree to collectively (Holm, 1995).

Autonomy

Autonomy is the principle of respect for persons and for independence of decision-making, respecting the able-minded person to make decisions that are aligned with their own will and interest. As Gillon (2003) points out autonomy is expression of free will and is of the highest order of the four principles as it factors into how the other three principles operate; free will needs to be held in reverence and encouraged. Beauchamp and Childress
make the point that it is one thing to understand that people act autonomously but that is not the same as respecting someone’s autonomy. Kant regarded autonomy as a central construct for deontology: the moral agent determined their own actions based on their own reasoning. In Mills’ utilitarian ideals, the individual needed to be their own self; only then would the individual flourish and enable his or her own development.

**Beneficence**

Beneficence is the action taken by the moral agent that will lead to an improvement in the health and welfare of others; unlike maleficence, it is the positive intervention that results in the beneficial outcome. In addition to this point, Beauchamp and Childress (1979), further elucidate the principle into one that is a duty, namely to act in a way that leads to a benefit (positive beneficence) and also to ensure the benefits, and potential harms of the corresponding action are balanced (principle of utility). The authors also raise the point of moral obligation as a duty not only due to reciprocity (namely receiving benefits from society obligates the receiver to benefit the society) but also due to the special nature of the relationship between the physician and the patient as evidenced by the Hippocratic Oath. As the authors state, “the principle of utility should not be construed so that it allows the sacrifice of the rights of individuals to the interests of society as a whole.” If the latter would be the case, then the utility principle would outweigh all other principles which should not be the case. Rather the utility principle should be considered as one of the decision-input factors along with the other principles.

The cost of treatment (medicines) for select diseases can be greater than what is affordable by any one person hence patients will need to rely on the beneficence and justice of the community in which they live. According to Holm (1995), one is obligated to help a fellow member of the community if the cost-benefit tradeoff is warranted. Namely if the effort of intervention by Person X is less than or equal to the benefit that will be gained by Person Y
(who is in need of an intervention), then Person X should take the steps necessary to help Person Y. This formula is restated in Figure 2.4 below:

1. Y is at risk of significant loss or damage to life or health or some major interest.
2. X’s action is needed (singly or in concert with others) to prevent this loss or damage.
3. X’s action (singly or in concert with others) has a high probability of preventing it.
4. X’s action would not present significant risks, costs, or burdens to X.
5. The benefit that Y can be expected to gain outweighs any harms, costs, or burdens that X is likely to incur.

Figure 2.4 Cost-Benefit tradeoff to determine whether a person should take action to help another. Adapted from Holm (1995).

Singer (1972) stated “If it is in our power to prevent something bad from happening, without thereby sacrificing anything of comparable moral importance, we ought, morally, to do it”. Singer and others have assessed that sacrifice that is equal to 10% of one’s yearly income, including opportunity cost, is an acceptable threshold to expect in terms of foregoing personal interests to create beneficence for others. The concept of realistic expectation is introduced vs supererogatory requirements as it relates to the principle of duty, beneficence and justice. This is contrasted by Holm that if one finds themselves in an unjust society one most attempt to correct for that injustice even if the goal is not attainable. Holm also addresses the point from Walzer (1983) that the level of care provided should be based on illness-dependent need and independent of individual-specific economics. However, as stated by Walzer, Beauchamp and Childress believe that free market enterprise is the most effective way at ensuring an acceptable level of minimum healthcare is provided to patients. This brings about the possibility of a two tier system where the first tier provides a right to basic type of care and the second tier is not a right, and is considered more expensive care that is reserved to those who can afford the economics (privilege). In this model, healthcare is a
system that benefits the wealthy and creates an imbalance of care between the haves and have-nots.

**Non-maleficence**

Beauchamp and Childress (1979) define non-maleficence as not doing harm to another based on a reasonable person’s interpretation that due care was provided by the healthcare professional to the patient. There are two types of harm as described by the authors: harm that is considered intentional and harm that is categorized as risk of harm. The moral agent needs to be aware of how the actions taken by the moral agent will affect the recipient of the action; the implications of the action needs to be considered and the moral agent needs to understand the possible implications to the recipient. The Principle of Double Effect as discussed by the authors is firstly to achieve good; the action should have the intention of only achieving a good outcome; a negative outcome cannot be a means to an end of a good outcome and their needs to be disproportionate benefit to the patient as opposed to any potential risk of harm. The authors reference a point that was raised by Gerard Kelly, that therapies are to be considered as an obligation to use if they are deemed to produce a reasonable treatment effect without being excessively harmful (attributes of harm can include factors such as pain, inconvenience or costs); reasonable benefits may be reason enough to proceed with care despite these potential harmful attributes. The authors also point to an argument raised by Paul Ramsey that quality of life interpretations based on a treatment option should be avoided as they violate the principle of each life being equal (equality of life).

**Justice**

Beauchamp and Childress (1979) speak to justice as not about being fair but being based on moral properties of the individual that would warrant receipt of what is owed to that person; what a person may claim a right to, given their actions or based on need. The authors make a distinction between justice that is based on standards that are not dependent on what others may claim (non-
comparative justice) vs justice that is comparative where the claims of others need to be balanced given a limited amount of resources. The authors make reference to David Hume who stated that justice is necessary because society is comprised of individuals who have limited compassion for the needs of others when competing for scarce resources.

Gillon (1994) speaks to how justice can be categorized into three areas: distributive justice (use of scarce resources), rights-based justice (respect for people) and legal justice (respect for laws that are deemed to be moral). Justice requires that those most in need be given priority of resources, to maximize outcomes with the resources available, and to not overtax those who fund access to care. Cost of care is a moral issue and physicians should use less costly options as their first line of treatment; only after failure of initial therapy should physicians opt for more costly options. Patients should not be treated any differently because their medical condition is due to a lifestyle preference (such as smoking or drinking) vs if their medical condition is not lifestyle-related (such as a genetic polymorphism). Lastly if one feels that a specific law is unjust on moral grounds, one should take actions they believe are morally justified, recognizing that breaking the law may result in legal ramifications for the individual. However, if one is a member of a group where a decision was made that is not aligned with a given physician’s point of view (and the physician had a voice in the process but the group decision rejected the physician’s position), then morally the physician should follow the group decision continuing to advocate when forums for such advocacy is made available. There will always be individuals who are not satisfied with the outcome of the system because their specific issue was not resolved to their specifications. The system is complex and there is risk of using algorithms that try to over simplify the calculation for applying moral principles that may lead to more unrest than could be achieved by “muddling through [the system] elegantly” (Hunter, 1995). For example, as referenced by Beauchamp (2003), the Jehovah’s Witness case study speaks to how it is morally justified for the physician to override the parent’s direction of care if the child is at risk of a
significant medical outcome due to the parent’s direction. Even though the physician has an “obligation of fidelity” to the parents of the child as the initiators of the request for care, the physician has to protect the patient child because the child is not making an informed autonomous decision (the concept known as parens patriae).

The challenge with the four principles of bioethics is that the grounding of the principles are not foundational as in the case of utilitarianism (the attribute of utility) or deontology (the attribute of the categorical imperative). As stated by Gillon (1994), the four principles of bioethics are “prima facie moral commitments”. Although they are not an ethical theory, they are guiding principles to ensure commitment to a moral code and to help inform ethically-appropriate healthcare decisions in the United States. It provides a common lexicon and reference point to address moral issues as they arise in healthcare. The Hippocratic Oath commits physicians to prima facie obligations given they must provide a net benefit attributable to the provision of medical care with harm being minimized (beneficence vs non-maleficence). Only with the help of the patient, can a physician determine the most patient-appropriate (net benefit) treatment option as treatment preferences vary by patient. Another aspect for consideration of these principles is scope. Scope is an aspect that factors into the application of the moral principles. Scope is important in the assessment of the magnitude of benefits and harm, and to also identify who will be the recipient of the calculated benefits and harms. Gillon speaks to assessing the net benefit to patients and the benefit vs harm trade-off and applying scope to make such an assessment: who will benefit and to what degree; who will potentially suffer harm and to what degree. According to (Beauchamp, 2010, p. 46), scoping is important as it allows the agent to spell “out where, when, why, how, by what means, to whom, or by whom the action is to be done or avoided”. Through balancing, the principles can be navigated between global universality vs application within a specific culture recognizing the necessary flexibility as it relates to cultural diversity to help resolve competing conflicts (Gordon, 2011).
Pellegrino (2012) underscores the importance of the physician who professes to take care of the sick; “to help, to care, to ease suffering and to cure whenever possible”. Physicians should not be considered under a broader category of provider as it dilutes their commitment as part of the Hippocratic Oath which bestows upon it a moral requirement. The problem of economics is not the primary concern of care, rather having access to care and the quality of care are paramount. The patient who is unwell, decides to seek care and places trust into the hands of a physician; the physician then needs to act in a manner that morally fulfills the duty of that care. The patient is compromised and the power of the physician to heal is to be directed at the patient, not at any other 3rd party agent, to work to restore that patient to health. It is important for the physician to place themselves in the shoe of the patient and combine “objectivity with empathy”. The moral compass of the physician is not replaced by the demands of 3rd parties; the physician stands as the absolute moral compass about the care the physician decides to provide for a given patient. The moral agency of each physician becomes the collective voice of the medical community which is the guardian to ensure that medical care is just, working to correct any wrongs that jeopardize the moral responsibility of the physician taking care of the patient. Society at large depends on the formation of a physician’s character to be good and to be virtuous to ensure that patients are ultimately protected.

2.6 Health, Healthcare and Rights

Within the constitution of the WHO (World Health Organization, 2006), health is defined as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”. The WHO goes on to further state: “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition”. The above two references from the WHO constitution are the first two guiding principles listed by the WHO to help foster “happiness, harmonious relations and security”.

58
Maruthappu et al. (2013) summarizes other statements from major historical documents that address the right to medical care and health:

- The United Nation’s Universal Declaration of Human Rights (1948) states: “Everyone has the right to a standard of living adequate for the health and well-being…including…medical care”.
- In the U.S. the ‘Second Bill of Rights’ brought forward by President Roosevelt in 1943, included: “The right to adequate medical care and the opportunity to achieve and enjoy good health”.
- The International Covenant on Economic, Social, and Cultural Rights which was ascribed to by the U.S. in 1977 stipulates “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health” in addition to: “the creation of conditions which would assure to all medical service”.

Maruthappu makes the point that access to healthcare will enable one’s well-being which is a pre-requisite to access other aspects of society. Given the overwhelming need to care for members of society, distribution of resources would require definitions of acceptable minimums of care which is varied given the different needs required by different sub-populations (patients). According to Daniels (2008), justice requires that a person’s ability to achieve their potential (fair share of opportunity) be safeguarded by preventing and treating illness and equitably reducing risk of illness and consequences to all members of a given community. However, it is important to note, that to achieve this goal, one must go beyond healthcare alone and include social determinants that affect health (according to the World Health Organization (ND), the external environment that impacts on the outcome of the individual, including social and physical factors). Decision-making needs to include morality, understanding of the consequences of decisions taken, with entitlements being awarded to the extent that they are able to be met reasonably (allowing a person their fair share of realizing opportunity through a deliberative process that distributes available resources).
This then leads to the question of rights, specifically as it relates to positive rights and that healthcare needs to focus on "providing proper treatment to overcome illnesses" (Cohen-Almagor, 2002). This sparks the debate over access to these technologies given their cost implications and the careful balance that must then take place between managing the needs of society at a population level vs the individual. Barlow (1999) questions whether healthcare can be a positive right: it is difficult to define (given it can be very broad from providing access to clean water and food to organ transplants and other medical services) and the cost to fund healthcare would represent a significant burden on others.

Bradley (2010) postulates that healthcare is a right that is necessary to be able to satisfy the right to life, happiness and the pursuit of happiness. According to Daniels (2001), ensuring people have the ability to realize their potential according to their abilities is a requirement of access to healthcare; protecting equality of opportunity. It is less about the impact of health on happiness (as these are not necessarily correlated) rather the impact of health on opportunity. Opportunity equality is a more realistic measure of fairness than measures that depend on quality of life values (a potentially subjective measure) vs the ability to realize one’s potential; this deviates from maximizing utility (utilitarianism) to that of safeguarding opportunity, which perhaps can be considered as a duty under Kantian ethics. The cost of healthcare should not be disproportionately shouldered by the sick and access should not be a function of ability to pay. However, rationing is a requirement for justice as the need is potentially limitless and resources have an upper bound (budgets need to reflect prudence – “reasonableness”) due to the other demands of societies. However, one has to recognize the differences of healthcare systems (for example, in the case of the United Kingdom which allows for the wealthy to gain quicker access to care through supplemental insurance which is in contrast to Norway where this is not allowed given its implications on equality).

Rights as it pertains to deontology as opposed to utilitarianism are grounded on fundamentally different principles (Roberts and Reich, 2002). Utilitarianism justifies its actions based on the consequences of the act; whereas deontology views each
individual as an end to itself and not a means to an end; with each individual able to ascertain for himself or herself a “life plan” based on rational thought.

The definition of what is a reasonable level of access to care to achieve or protect one’s opportunity in life may be disputed by reasonable people. However there needs to be a deliberative process that society can agree to as a fair process by which such a determination can be made (Daniels, 2008). This is contrasted by Kluge (2007) who highlights the duty of the physician is to the patient, and to deliver the care that is in the best interest of the patient without taking into account any implications of the care of the patient on the rights to the broader society at large. According to Kluge, as it relates to the Hippocratic Oath,

“the physician is obligated to determine what is in the best interests of the patient, and has a fiduciary duty to acquire the resources that are necessary to meet those interests and to advance the good of the patient. The physician must do so regardless of the impact that such actions might have on other persons who might also have a need, on overall healthcare budgets, or on the ability of society to provide healthcare for its members.”

Kluge speaks to the consideration of alternative scenarios to allow the physician to consider other options besides what is solely in the best interest of the patient and that is in the practice of medicine in a Social Service Model which would allow the physician to weigh the implications of any one patient’s care in context of the broader society as well as a Business Model scenario where the physician provides a service based on the patient’s ability to pay and economics drives decision-making which is regulated by standards no different than any other business enterprise.

2.7 Trust and Fairness

There are two types of trust: status trust (trust based on professional designation) and merit trust (Buchanan, 2000). Merit trust is further distilled into primary (due to the individual) or derivative (due to association with an organization perceived as trustworthy). However, trust should not be aspired to at the highest possible level of trust, rather at the level of trust where the “greatest net benefit accrues”. Buchanan (2000) speaks to how MCOs ration in that they restrict access to certain care that “is reasonably expected to be of some net benefit for the patient” due to financial
reasons. This concept of rationing is antithetical to the physician who by design is to seek out what is best for a given patient, which is the “physician’s most fundamental obligation”. The physician’s ability to place patient first is not supportable under traditional medical ethics in the context of an MCO that controls the finances of healthcare resource utilization and is managing a set budget at the population level. This is the inherent conflict with regards to the tension between the physician acting to fulfil his duty to the patient as individual (deontology) vs the MCO treating for the benefit of the population (utilitarianism) (Panek, 1999); although 40% of physicians do factor cost into how they chose a specific treatment for a given patient (Scheunemann and White, 2011). It becomes more challenging in markets like the U.S. that are mostly for-profit driven healthcare systems, because savings associated with less costly treatment options are potentially profit benefiting to 3rd party organizations. When there are finite funds available to provide funding for an infinite need of resources, allocation decisions will impact access to resources as depicted by Figure 2.5 below.

![Figure 2.5 Macro vs Micro Allocations. Adapted from Scheunemann and White (2011).](image)

Where government-based funding is a consideration, there needs to be a decision on how much will be dedicated to healthcare as opposed to education, infrastructure, or prisons. Then as it relates to healthcare specifically, allocation decisions need to be made in terms of what is covered, how is access to coverage determined and when is coverage denied.
The patient’s lack of awareness of how an MCO impacts on the physician’s ability to treat in a manner that is consistent with their medical training impedes on the inherent trust of the patient-physician relationship. Buchanan (2000) underscores the point that in American society as a whole there has been no authoritative definition provided of what is considered adequate care; however, this is necessary as there is the recognition of the fact that maximal care cannot be provided to each and every patient in the healthcare system given limited resources.

Buchanan (2000) addresses the point that MCOs need to ensure that they do not engage in “expertise imperialism”, namely that the administrative function of the MCO does not recognize its expertise limitation and thereby makes medically-based decisions. MCOs should recognize the “physician as [the] medical expert” and consequently leverage his expertise appropriately in the appeals process. To foster trust there should be procedural fairness, with the following 5 attributes: (1) there should be no discrimination against any group of patients defined by a given set of characteristics (such as age or gender); (2) all cases that are the same should be treated as such and not swayed by relationship or other mitigating factors; (3) members of the MCO and their employees should be aware of how the plan rations (“rules of rationing”); (4) the plan should defend why they go about rationing (“the justification”); and lastly (5) the appeal process should be based on processes and protocols (“procedures”) that are “accessible, fair and timely”. These concepts are extensions of “accountability for reasonableness” based on Sabin and Daniels as referenced by Sabik and Lie (2008a), namely to ensure there are four traits to procedures that will be indicative of a “legitimate and fair” approach: (1) publicity, (2) relevance, (3) revision and appeals, and (4) regulation. However processes and procedures will not side-step the need for agreement on underlying principles but it can create a trail of decision-making to help foster a learning organization, enabling reviewers to understand consistency of assessments and how these assessments change over time with the evolution of the organization. It is important to remember that cost containment and patient interests are for the most part diametrically opposed.
An organizational entity that seeks fairness creates transparency and consistency in decision-making which helps achieve reflective equilibrium (Daniels, 2001). The benefit of having a transparent record of decision-making for a given access issue may help lead to increases in market valuations (Daniels and Sabin, 1997). Through a transparent approach there is a demonstrated commitment by the organization to fairness, to ensure that the rational that led to a given decision for a specific case can be replicated for cases that have the same underlying parameters. It demonstrates a “commitment to act on the cited reasons and principles in future similar cases” (Daniels, 2001). This approach can reveal when the rulings for new cases are decided differently from past cases due to additional evidence becoming available or reflecting a change in what factors support a given decision. This leads to a state of “institutional reflective equilibrium”, (Daniels, 2001), deploying a mechanism by which the system can understand how prior decisions were made and assessing how that decision applies to the current request for access in light of evidence and opinions changing over time. This external view places further emphasis on a process that might otherwise have “bias, self-interest, insufficient reflection, or simply excess haste, requiring decision makers to give reasons that may counter some of these tendencies” (Shauer, cited by Daniels and Sabin, 1997)).

What is important to recognize is the ability to create a system that is perfectly fair (Rescher cited by Ashcroft, 2005)). Patients should have knowledge of the decision to allocate and the supporting rationale (justification); patients should be able to “consent to allocation decisions that affect them and allocation of decisions should minimize conflicts of interest” (Trotochaud, 2006). Transparency, accountability, as well as input from experts and lay people, are requirements for allocation of healthcare resources (Ham and Coulter, 2001). Priority setting could take the approach of limiting services to help fund population level care; however decision-makers tend to favor effective use of resources for patients most likely to benefit from care rather than reducing outright the number of services provided. Oregon’s Medicaid is an exception to this mindset where 565 of 696 identified medical services were covered; the remainder being excluded from coverage (Micheal Janofsky, 1994). The inadequacy of information was highlighted in Oregon’s approach when
initial prioritization efforts led to prioritizing tooth capping over that of an appendectomy. The need for efficiency (better outcomes for less cost) as well as equity of care ultimately impacts on healthcare resource utilization which may lead to opposing conclusions (Perry and Hotze, 2011). This is seen in Sweden for example, where the number one priority is human dignity, followed by equity and then by efficiency (where beliefs in values are the over-riding determinant of resource allocation). However, the effectiveness of raising awareness in the public on the need for additional resources to fund access to effective care leads to a reallocation of funds as was seen in the case with Oregon; other examples include New Zealand and Israel (Sabik and Lie, 2008b). Fairness and reasonableness are sought-after determinants when it comes to access-related decision-making, even if the outcomes themselves are not amenable to the public.

Integrating the concept of pharmaceutical care into the delivery of healthcare is an important component of maximizing outcomes within the system. As addressed by Hepler and Strand (1990), pharmaceutical care is an essential element of pharmacy practice where pharmacists become part of a patient-centered healthcare team, applying the expertise of the pharmacist to ensure patients utilize medicines that are safe and effective, thereby reducing the negative consequences of adverse events and improving clinical outcomes. Drug-related problems, as stated by Strand et al. (1990) can result from any of the following factors: patient not being treated for a medical condition for which there is an available medicine; the incorrect medicine being prescribed for a given medical condition; the dosage being taken for the medical condition is too much or too little; the drug is contra-indicated given the patient’s medical condition or due to other medications or foods; not accessing a medicine that is indicated for a given medical condition; or taking a medicine that is not indicated for a given medical condition. All these aspects that can result in sub-optimal outcomes require pharmacists to be leveraged for their expertise, to ensure trust is maintained in the patient-pharmacist relationship and that pharmacists treat all patients equally (fairly). This is addressed by the American Pharmacists’ Association code of ethics as it relates to the distribution of health resources, namely “when
health resources are allocated, a pharmacist is fair and equitable, balancing the needs of patients and society.” (American Pharmacists Association, 2017).

### 2.8 Allocation of Resources

The finite set of healthcare resources from which one can draw to meet the needs of society is addressed by Gibson et al. (2005). Distributive justice (the concept that resources be distributed in an equitable manner) informed through procedural fairness (the concept that the process of distribution is fair) is a recognized approach by which to help inform decision-making and justify the decision (Holm, 2000; Daniels and Sabin, 2002; Klein and Williams, 2000 as cited by Gibson). Priority-setting (the concept of whose needs are prioritized) needs to take into account whether the focus is attending to the sickest or in generating the best possible outcome; then identifying which distributive principles should be at play to inform allocation of resources (Daniels, 1994 as cited by Gibson). Ultimately in the U.S., healthcare is mostly determined by the ability of the patient to be able to afford care and the reimbursement levels the payer is willing to pay for the care rendered. Ideally the most effective care would be delivered to each patient based on the available science and patient’s preference for treatment; however economics impact the type and quality of care that a patient will receive. The need of the individual needs to be weighed in the broader context of society’s focus on delivering efficient healthcare (Smith, 2001).

Evidence-based medicine (EBM), economics (efficiency) and ethics (fairness) are essential constructs to help inform decision-making. EBM utilizes, as a foundation, evidence synthesis (systematic reviews, meta-analyses) to best inform decision-making through research incorporating the practicing physician’s clinical expertise as well as the treated patient’s values (Masic et al., 2008), while efficiency ensures healthcare benefits are maximized through the use of available resources (Culyer, 1992).

The constructs addressed above were captured through the case studies utilized in the primary research of this thesis. Each of the case studies, namely, overactive bladder, smoking cessation, prostate cancer and quality of life, brings to the surface
the issues of prioritizing access to healthcare resources. Who should pay for different prescription medications based on the available evidence? Should physicians have the autonomy to prescribe what they deem best for the patient? Should patients have access to higher cost medicines through MCOs or only if they are willing to pay higher out of pocket costs: either the full cost or a portion of the cost? For example, in the case of overactive bladder (OAB), an MCO might impose a step edit (SE) which requires the use of low cost prescription medications such as oxybutynin before allowing for the patient to gain access to more costly branded medications; as seen in an example of the drug formulary policy by United Healthcare Community Plan (2017), entitled “Clinical Pharmacy Program Guidelines for Overactive Bladder Agents”. Oxybutynin may cause extensive side effects such as dry mouth but is relatively efficacious; dry mouth is a subjective experience whereas reduction in symptoms of OAB are more measurable through objective measures (such as patient bladder diaries). EBM perhaps would indicate that oxybutynin is a reasonable first choice prescription medication at a population level but how do patient-centered values factor into decision-making when a specific patient would not be considered by the treating physician as appropriate for oxybutynin as a first step pharmacologic therapy. Other case studies are discussed in more detail in Chapter 5 and Chapter 6.

Resource allocation should take into account ethical principles that address efficiency in achieving population health, fairness in reducing health disparities and utilitarianism in achieving the greatest good for the greatest number (World Health Organization, 2004). By not taking such an approach there is a risk of creating injustice, disadvantaging the vulnerable; thereby creating health disparities and not addressing the needs of those who are worse off. This furthers the need for “accountability for reasonableness” to ensure optimization of limited resources and to minimize health inequality. Accountability for reasonableness (Daniels, 2000) is accomplished by utilizing thoughtful methodologies while gaining input from diverse and relevant stakeholders. Relevant stakeholders need to be engaged, vulnerable patient populations identified; processes put in place by which members of society can understand how and why decisions are made and how those decisions stand in light of the applicable ethical theories or principles. This approach is required given
the increasing cost of healthcare and the need to ensure the sustainability of healthcare systems that are equitable and efficient (Guindo et al., 2012). The Guindo paper which was entitled “From efficacy to equity: Literature review of decision criteria for resource allocation and healthcare decision-making” identified that “equity and fairness” was the most cited criteria in healthcare decision-making. In literature, the following terms were identified in context of “equity and fairness”: “a fair chance for all”, “equality of access to healthcare resources on the basis of need”, “absence of systematic disparities in health resources on the basis of need”, “absence of systematic disparities in health between groups with different levels of underlying social advantages / disadvantages”. The Guindo paper underscores the importance of decision-makers laying out the ethical parameters that inform their decision-making to ensure that those affected by these decisions can understand how the ethical parameters ultimately informed decision-making.

There needs to be a consistent manner in which equity is achieved in access-related decision-making which includes horizontal (patients with the same conditions) and vertical (patients across different conditions) equity (Oliver and Mossialos, 2004). Oliver addresses the importance of need and the ability to pay; ability to pay affects utilization and creates differential between patients who are able to purchase services based on needs vs patients who are not able to purchase services based on needs. Stakeholder input, amplified by advocacy, impacts on policy which then impacts on the operating environment in which decisions are ultimately made (Mintrom and Vergari, 1996). What is challenging in the U.S. healthcare system is that patients of equal need will not have equal access because of the fragmented healthcare system. Patients may be paying the same or more for coverage but not have access to the same drug that another plan might be offering for their members with the same condition (Center for Medicare Advocacy, 2016). This is a concept referred to as comparative need: comparing two people with the same need and the consequences of those needs on their outcomes (Bradshaw et al., 2013).

Access to prescription medicines is an important element of healthcare in the United States. Although the U.S. has the highest per capita healthcare spend in the world, it
has worse outcomes than many other major markets including Germany, France, the United Kingdom, Canada and Australia (Davis et al., 2014). The U.S. healthcare system was ranked 37th in the world in 2010 by the WHO (Murray and Frenk 2010). The ranking was based on a weighted average of 5 performance indicators which included the following: (1) disability-adjusted life expectancy; (2) distribution of health in the populations; (3) responsiveness; (4) distribution of financing and (5) fairness (Scielo Public Health, 2000). The President’s 1983 Commission For The Study of Ethical Problems in Medicine and Biomedical Research, Securing Access to Healthcare (Jonsen, 1986) defined adequate care as “enough care to achieve sufficient welfare, opportunity, information and evidence of interpersonal concern to facilitate a reasonably full and satisfying life.” It is important to note the adjectives “sufficient” and “reasonably” are not the same as ideal and optimally. “The level of care deemed adequate should reflect a reasoned judgment not only about the impact of the condition on the welfare of the individual, but also about the efficacy and costs of care itself in relation to other conditions and the efficacy and costs of care available for them.” (President’s Commission for the Study of Ethical Problems in Medicine Biomedical Behavioral Research, 1982). This would imply that requiring lower cost treatment options to be utilized before more costly treatment options given the difference in expected treatment effect between the lower and higher cost treatment should be acceptable to society.

A key debate in the allocation of resources is one that centers around allocation of resources when those resources are attributable to poor lifestyle choices. According to a study done by the American Medical Association, approximately 25% of every healthcare dollar spent is due to medical conditions that are a result of unhealthy lifestyles. Ultimately members of society bear the economic burden of poor lifestyle choices. For example, it has been estimated that each American on average pays $221 per year to help treat Americans whose medical conditions are attributable to smoking. The argument could be made that the additional cost of healthcare should be borne by those who are victims of poor health due to poor lifestyle choices. Conversely society can adopt policies that help lead to improved lifestyle behaviors. For example, increasing the taxes on cigarette sales creates funding for care for
those afflicted by poor health due to smoking and also will help reduce the number of smokers due to the extra financial burden of purchasing cigarettes (Andre et al., 1993). Cappelen and Norheim (2005) lays out the arguments of personal accountability specific to lifestyle choices. It is difficult to separate out lifestyle choices and the consequences of outcomes; doing so can also interfere with the physician-patient relationship and the humanitarian aspect of providing care to a patient in need of medical care. Conversely, requiring consumers to pay additional fees for accessing certain products and services that negatively affect health outcomes, create mechanisms for additional funds to be available to provide for care when needed (such as taxing the sale of cigarettes or increasing the premium for smokers vs non-smokers).

The whole concept of eliminating untoward consequences of brute luck (brought about by circumstances beyond someone’s control) while maintaining personal accountability with regards to option luck (brought about by personal choices) is the basis of luck egalitarianism (Arneson, 2000). How to operationalize accountability for poor personal choices that affects health outcomes has been considered (Feiring, 2008). Backward-looking criteria would be difficult and impractical to operationalize. An example is obesity which leads to several different medical conditions including coronary artery disease and diabetes. However obesity could be from genetics or from lifestyle as well as from environment (socioeconomic determinants) that are beyond the control of any one person. There might be an opportunity to hold people accountable to achieving health targets through lifestyle changes by having contracts in place that if the patient does not follow through on personally accountable actions as defined in a contract there would be financial consequences or restricted ability to access care. This approach could place a disproportionate burden on the most disadvantaged hence exasperating the divide produced by health disparities. There is also the aspect of how allocation of healthcare resources to patients who are suffering from their medical conditions affects the treating physician in terms of beneficence and maleficence and the Hippocratic Oath (Bishop and Brodkey, 2006). The environment would have to be modified to ensure there are no confounding factors that affect patient outcomes and that patients have the competencies to
adhere to healthier lifestyles (health literacy). Lastly, programs can be introduced that reduce cost of care to individuals who take steps towards a healthier lifestyle rather than increasing cost of care to those who do not comply (Buyx, 2008).

In a study (Fortes and Zoboli, 2002) that took a closer look at how Brazilians would allocate scarce resources, most respondents focused on providing care to the vulnerable (whether patient was a toddler or an elderly person); there was greater hesitancy to treat a condition that came about due to negative lifestyle preferences (however the alcoholic was less preferred for treatment than the smoker). A mother of 3 received greater consideration for healthcare resources than a mother of 1; a married woman greater consideration than a non-married woman. A 7-year old received more consideration for healthcare services than a toddler. In some cases a deontological mindset prevailed (protecting the vulnerable) whereas in others utilitarianism dominated (mother of 3 vs mother of 1). The point of this study and similar studies done in other countries (Australia, Netherlands, Great Britain) speaks to the coexistence of various ethical theories that manifest based on preferences of society members to allocate scarce resources.

The Rule of Rescue, initially coined by Jonsen (1986), is the concept of rescuing the known (identifiable) person who is in peril, which could be considered by some as grounded in the principles of deontology (McKie and Richardson, 2003), is able to at times reverse the analysis which based on quantification would restrict access to a given medical service because it has the power to change a faceless statistic into a person with whom a connection can be drawn; based more on emotion than logic. Even as it applies to utilitarianism, although perhaps not measurable, there is intrinsic value redeemable to a society that believes there is caring and kindness, a humanity that binds a given society that acts on Rule of Rescue (Mooney as referenced by (McKie and Richardson, 2003)).

2.9 Managed Care Organizations and Ethics

Private organizations that are in the business of facilitating the provision of healthcare, such as Managed Care Organizations (MCOs), need to be held to a higher or different ethical standard than other business entities (Daniels and Sabin,
1997) given the potential for MCOs to restrict access to care which affects outcomes. These private entities provide a benefit to the population at large in the society, and hence in order to ensure there is justice, there needs to be not only public accountability but also an understanding of why and how decisions have been made that affect access to healthcare. Equally important is the perspective that the ability of a healthcare entity, such as an MCO, to effectively market its commitment to ethical principles and moral behavior, with a focus on patient-centeredness, will help increase financial viability and profitability by delivering customer satisfaction (Engelhardt and Rie, 1992). Engelhardt and Rie believe that by not focusing on healthcare as a right but rather as a commodity to be purchased, the consumer will be left to make purchase decisions based on their personal preferences that ultimately will reward those healthcare corporations that act in a manner that recognizes and meets patient specific needs.

Kaldis (2005) highlights the need for an ethical framework that takes into account the institutions of healthcare that are comprised of “collective bodies or legal persons” who are responsible for the care delivered to individuals; individuals who are more than mere citizens of a society due to their heightened state of vulnerability (brought about by illness) and the asymmetry of expertise that exists between providers and patients. Organizational entities are without emotion, without feeling, hence the challenge becomes how to ensure organizations apply ethics in their decision-making to ensure they are morally sensitive.

2.10 Discussion

The following discussion puts in context the application of the ethical theories and principles reviewed thus far in this thesis as it relates to treating a given patient with a given medical condition. Namely, the paradox of the patient vs the population needs to be reconciled given the mandate of the Hippocratic Oath: “The final challenge to the medical ethics of the 21st century is to develop a social ethic for medicine that ameliorates the hyper-individualism of the Hippocratic tradition without sacrificing the individual patient capriciously to the vicissitudes of social utility.” (Veatch, 2000). The quandary becomes how to ensure the needs of the individual patient are not forgotten.
in light of the focus on population health and the focus on treatment effect defined as point estimates that are the output of clinical studies (population level averages). Veatch goes on to describe the impossibility of the physician to make the decision that is best for the patient given patient need is greater than just the clinical assessment. As stated by Veatch (2000), the physician should empower the patient with the necessary information so that the patient can decide what is in his or her best interest given the patient’s personal preferences. This leads to better outcomes and more completely engages the patient to be an active participant in their own health and medical care (Coulter, 2007). Physicians can act as medical experts who can provide their professional expertise and remain loyal to their patients, to help advocate on the patient’s behalf, acknowledging that as the advocate (engaging the 3rd party insurer), the physician ultimately may not be successful in securing the needed treatment (unless the patient is able to afford the preferred treatment choice as a cash-paying customer).

Under Kant, there would be a reluctance to give up physician (and patient) autonomy by using 3rd party promulgated guidelines given the potential risk of causing maleficence or diminishing the ability to improve outcomes (diminished beneficence) to an individual patient; the patient would be a means to an end rather an end to himself (Panek, 1999). Especially in that the benefit of using such guidelines would not necessarily benefit the society as a whole, rather potentially the shareholders and the salaries of executives within the insurance company. In addition, under the rule of the categorical imperative, stakeholders would need to think about their willingness to participate in a given society if the specific action under consideration would be universalize-able: not being able to access a certain medication due to cost reasons; or for all members of society having to pay more for healthcare so that when a patient needs access to care, there will be no additional costs to the patient when the need arises. Contrary to the deontological point of view, in utilitarianism, the end outcome justifies the means, as standardization of cost-effective care is the goal even if on occasion the individual patient could suffer a negative or sub-optimal consequence and physicians (patients) would forego a level of autonomy and self-directed decision-making.
There needs to be a balance between the deontological considerations that a physician must consider in treating his patients (duty of care) vs the utilitarian considerations that a macro funding system needs to apply (do good for the greatest number) in order to balance a finite availability of resources in treating the population at large (Garbutt and Davies, 2011). This balance needs to be carefully maintained in order to avoid an environment that negatively impacts on the practicing physician:

“the absurdity of having high-sounding professional standards that cannot be delivered by individuals within the system in which they work… [is] a recipe for stress in the professionals and disappointment for their patients. If the strain goes too far then doctors could come to view the supporting system as a hindrance rather than as a help to the practice of their profession”.

If physicians are not able to prescribe medications they believe their patients will benefit from, if physicians are not able to assess the treatment strategy for a given patient, but instead have to follow clinical pathways presented by 3rd parties that redirect a physician’s informed treatment choice for a given patient, this will lead to stress, disappointment and frustration of practicing physicians and their patients.

Patient preferences can help inform the value of an intervention. There are two types of approaches that could be considered: subjective vs objective (Roberts and Reich, 2002). Subjective is patient specific and hence determines “willingness to pay”; conversely, objective is based on expert analysis of utility scores that are based on Quality Adjusted Life Years (QALYs). QALYs allow for various health technologies to be compared on a normative scale in a single unit of measurement; QALYs are based on the mortality of the disease and the quality of life of a person during the course of their disease on a scale of 1 to 0 with 1 equal to perfect health and 0 equal to death (Prieto and Sacristán, 2003). Utilities are fraught with potential biases that may not accurately reflect the perspectives of specific patients with a given condition due to a number of confounding factors, such as age, culture and socio-economics. Conversely, the subjective or individualistic approach could create biases that favor the patient with greater economic means. An additional challenge with QALYs is that they are based on a ‘generalisation of the truth’ (Harris, 1987). The focus is not on the patient and his or her preferences but rather the mathematical value derived from calculating QALYs. It can inform, perhaps erroneously and in an unjust manner, with
regards to use of which drug, which patient sub-population, or which disease area should be prioritized over another. Added to this challenge is the debate around QALY calculations being based off of responses to validated questionnaires by healthy members of the community vs the disabled patients who are afflicted with the condition in question; methodological challenges have also been cited by the National Institute for Health & Clinical Excellence in the United Kingdom (Neumann and Greenberg, 2009).

The conflict of using QALYs to make benefit determinations in the U.S. is highlighted by the seemingly opposing views that were adopted over a fourteen year period of time when in 1996 the U.S. Panel of Cost-Effectiveness in Health and Medicine recommended the use of QALYs but in 2010, the Affordable Care Act, prohibited the use of QALYs in comparative effectiveness research (Neumann and Weinstein, 2010). Even if a QALY is derived from someone in a wheelchair, the results might be different for patients who have been confined to a wheelchair for quite some time vs patients who have been in a wheelchair for quite some time but who have acclimated to their new lifestyle (Scheunemann and White, 2011); also the aggregate sum of QALYs, although mathematically the same, might have a different perceived value if the sum reflects improvements in a smaller vs larger number of patients (for example, 100 patients vs 10,000 patients); however in this case the worse off are not being helped to rather provide lessor health improvements to the masses.

Even though limitations are recognized of QALYs, their application perhaps may be important as one of the metrics to consider when determining how best to allocate a healthcare resource (Ashcroft, 2005). However, in the U.S. the concept of QALYs is contrary to the culture of the American society where the physician historically, despite the dominance of managed care, is expected by virtue of their “duty”, to act in the best interest of the patient based on that given patient’s need (Turner, 1997). Cost-effectiveness has the potential to make medicine a “science of numbers and robs it of the richness of clinical detail” (LaPuma cited by (Turner, 1997)); as it uses a calculation reflective of the population and community-derived preference vs the
individual patient’s preference. This reduces a unique patient-physician interaction into one that is driven by a 3rd party administered treatment algorithm.

The aspect of care is central to the physician-patient relationship; it is essential from a humanities point of view to recognize the individuality of patients and their unique needs defined in part by the socioeconomic factors that will impact on their ultimate outcomes (Garchar and Kaag, 2013). Morality requires the physician to “attend to the full range of human flourishing” and the “tragedy that threatens this flourishing” as cited by Garchar and Kaag (2013); the importance of physicians is not just to integrate ethics into their practice to better engage the patient but rather for physicians to become a better person which will result in the betterment of the individual physician.

Experience and reason are the driving forces behind achieving excellence in any particular situation (Aristotle cited by (Garchar and Kaag, 2013)). The correct outcome is achieved by cycling through various treatment options based on the physician’s personal experience grounded in science and the understanding of the patient, while at the same time recognizing the ultimate consequences to the patient of the given approach taken by the physician. Physicians must take responsibility on a personal level taking the action they believe is right given a specific situation. The lack of understanding of physicians in this regard perpetuates the absence of this ethical underpinning in the managed care environment within which physicians actively participate.

When virtues are integrated into aspects of healthcare, the importance of a cost-conscious mindset emerges as it highlights the need for some form of stewardship given that healthcare resources are not unlimited (Messer, 2005). Messer further addresses the importance of other virtues such as truthfulness (the admission of the implications of limited resources and the necessity of resultant “tragic choices” or consequences) as well as humility to prevent placing unrealistic expectations on medicine.

There is a natural tension between those who seek a technical solution vs those that are focused rather on the process of decision-making; and because there is no real
way of letting scientific calculus inform absolute decisions, there is a need to muddle through the process more than anything else, reflecting community preference, values and available knowledge (Mechanic, 1997). This is in the context that no treatments for the most part are absolutely effective or non-effective, rather the value of the treatment is contingent on the right patient being treated with the right medication at the right time. Flexibility by access decision-makers are hence central to enabling physicians to make treatment choices that are most appropriate for a particular patient.

Mechanic further highlights that medical care is less about the technical and more about negotiation and patient-specific discovery. There is a wide variance amongst patients on how they assess attributes that inform decision-making and hence the results of patient reported outcomes will not necessarily be reflective of a given patient’s treatment preference and value system. Maintaining a system that enables a physician to make patient-specific treatment decisions is important; one that allows physicians to override system rules based on individual need. Physicians who follow the guidelines and rules to the letter may be less effective than the thoughtful physician who is a knowledge seeker. However, these physicians might be frustrated by processes that attempt to curtail utilization of select services; typically by administrative staff who are not matched with the knowledge, know-how and expertise of the treating physician who then make coverage determinations which frustrates the physician and patient. The sensitivity to these issues is highlighted in a case from the United Kingdom, where one court highlighted the need to do everything humanly possible to save a life no matter how slim the likelihood of success, whereas a higher court overturned the lower court’s decision, stating that courts could not intervene in these matters, and treatment decisions should be left to those funding care. Nevertheless, difficult decisions need to be made to determine how access to care will be funded and who will have access to care based on available funding. The backdrop of assessing access to medical care is complicated by the uncertainty of evidence and the tools by which evidence is assessed, the variability of patient needs and the resultant treatment response as reflected in Figure 2.6 below:
As Klein (2005) points out, the marketplace has accepted that solutions for accessing healthcare resources are not about identifying a guiding theology but rather a blend of processes to guide decision-making and improvements in technical expertise to assess value for money. Hence the importance of having flexibility to inform decision-making. There is no certainty of outcome which fuels the controversy of the cost of a specific treatment (Scheunemann and White, 2011). There needs to be legitimacy of the approach and accountability for reasonableness (Daniels, 2000).

As highlighted by Persad and Emanuel (2016), there is a natural tension between (a) patient-centered care and providing the best care vs (b) population-level care and providing acceptable care. It is better to treat the population with a less effective level of care than not to provide treatment at all. One school of thought is not to let efficiency replace the need for equality of care but if the latter principle dominates, there will not be enough funds to provide everyone the same level of care if care is at the highest possible level vs a lower level of care which may prove to be cost-effective (less efficacy, greater side effects) but at least care is made available to all. Either everyone has less efficacious care or potentially some will receive the best care while others will receive no care. The latter compromises the principles of equality while the former satisfies the greatest good principle of utilitarianism. Under the utilitarianism principle, justice is preserved as it is better to have some level of acceptable care vs no care at all. If some patients are treated and others are not, justice is compromised. Persad and Emanuel (2016) contend that principles of utility,
equality and justice are satisfied by providing some level of care to the worse-off even if not the best level of care. There needs to be a trade-off across efficiency of care, equity of care and prioritizing care so the worse-off receive a greater percentage of available care: aspects of distributive justice (Scheunemann and White, 2011).

2.11 Conclusion

Access decision-making to healthcare resources needs to be considered carefully given access decisions can impact on the health outcomes of patients. Each member of the community has a perceived right to achieve their full potential; health is a necessary element of being able to live a full life and achieve one’s full potential. Physicians have a responsibility to provide the best possible care to patients based on their assessment of the medical condition, the patient’s needs and preferences. However access to healthcare can create a challenge as there needs to be economic considerations when making decisions to medical treatments. This creates a natural tension between the science of medicine, the protection of the vulnerable and the mechanism by which care will be funded. Utilitarianism will lean to maximizing the good for as many people as possible; deontology will encourage agents to comply with maxims that can be considered as universal categorical imperatives that also treat people as an end to themselves rather than a means to an end. Virtue ethics will rely on emotion and the character of the agent to assess the morality of the decision-making and lends itself to the four principles of biomedical ethics as it relates to autonomy, beneficence, non-maleficence and justice. MCOs are business entities that facilitate the funding of healthcare; hence the decisions taken by MCOs impact on the ability of the physician to treat the patient and the patient to get the necessary treatment. MCOs make decisions at the population level and not at the individual patient level; only the treating physician knows the patient. Hence the process of decision-making needs to find a balance between accountability for reasonableness, establishing a minimum of care, and then identifying a process by which exceptions can be made should there be available evidence on why a patient should have access to a given treatment. The ethical theories and principles reviewed in this
chapter will be revisited when the primary research completed for this thesis is analyzed and discussed in Chapter 6.
Chapter 3: The U.S. Healthcare System

The U.S. Healthcare System is highly fragmented which leads to challenges in delivering effective, efficient, and equitable care (Shih et al., 2008, Berwick et al., 2008). In the U.S., as in many parts of the world, regulatory (drug approval) pathways are not a guarantee for 3rd party payer coverage and reimbursement (Hickey, 2006). Payers need to understand the cost – benefit tradeoff relative to the standard of care to assess their willingness to pay (Gregson et al., 2005). This chapter will take a closer look at the U.S. healthcare system and help the reader to better understand the findings of the thesis as it relates to ethics and access to medicines. The chapter consists of the following sections: Access to Care in the U.S.: Facts and Figures, The Affordable Care Act, History of Managed Care in the U.S., A Closer Look at Formularies, Implications of New Drugs Coming to Market, Flow of Funds, A Closer Look at the Employer Segment, Physicians and their Patients, Community Retail Pharmacists, Insured Members, and the Conclusion.

3.1 Access to Care in the U.S.: Facts and Figures

The U.S. healthcare system, which is the largest in the world, is the only high income country that does not offer universal coverage to its citizens (Bort, 2017). Healthcare is funded from one of three sources: private insurance, government insurance, and consumers (either in the form of out of pocket costs which is what patients pay for the healthcare provided despite having insurance as well as paying a portion of the premium for having health insurance coverage) (Trivedi, N.D.). Government insurance includes Medicare (elderly & disabled), and Medicaid (those below the federal poverty limit) as well as Military (Veterans Affairs and Department of Defense). Private insurance which is referred to as commercial insurance is either employer-sponsored or self-pay or a combination. As can be seen in Figure 3.1 below, 90.9% of the population had insurance coverage in 2015; 29 million Americans did not have any insurance. 37.1% received its insurance coverage through the government, and 67.2% received its coverage privately (commercially). Government coverage consisted of 19.6% through Medicaid, 16.3% through
Medicare, and 4.7% through military coverage; private coverage included employer-based coverage at 55.7% and direct purchase at 16.3%. The numbers are not mutually exclusive as some people might have had multiple sources of coverage (Barnett, 2016).

In 2016, U.S. healthcare spending amounted to the equivalent of $10,348 per person. This represented 17.9% of the 2016 economy as compared to 17.7% in 2015 (CMS, 2016). In a recent LA Times article (Etehad, 2017), the U.S. was noted to spend more per capita on healthcare than any other OECD country; almost 300% more than the OECD average. The primary drivers for the increased spend is use of more expensive medical technologies and the higher cost per unit of care delivered.

Etehad speaks to how the U.S. in 2013 had 112 deaths per 100,000 from preventable diseases or complications that with adequate healthcare might have been averted vs other high income countries which had 90 deaths or less per 100,000 (with Australia, France and Switzerland at approximately 60 deaths per 100,000 or less). On average there are less hospital beds per capita in the U.S. then other major markets; patients have shorter durations of stay and pay more for their stay at discharge than other major markets (Squires, 2015).
In 2015, approximately 273 million Americans accessed their medical care through MCOs (MCOL, 2016). These organizations in turn contract with employers who provide medical and pharmacy benefit coverage to their employees. The purpose of MCOs is to reduce the cost of care while helping to improve the quality of care through clinical and administrative oversight; MCOs have a variety of contracts with various types of healthcare providers, hospitals, pharmacies and pharmaceutical companies to help facilitate medical care (US National Library of Medicine, N.D.).

In the U.S. in 2016, spending on prescription medicines reached $450 billion without reflecting discounts and rebates that are provided by manufacturers; reflecting discounts and rebates, the net spend was $323 billion (Berkrot, 2017). As stated by Olson (2017), the U.S. in 2015 spent the equivalent of 1.8% of its GDP on prescription medicines which represented 10% of total healthcare costs. In 2014, the average person spent $1,112 on retail prescription medicines. Figure 3.2 below compares the U.S. per person average spend to other countries around the world; by comparison, U.S. is up to 242% greater than Denmark and 44% greater than Canada.

![Figure 3.2: 2014 per person retail prescription spending in select countries around the world. Adapted from Olson (2017).](image)

83
The Kaiser Family Foundation Survey conducted in December, 2016 (DiJulio et al., 2017) showed that 67% of Americans believed the number one priority of the U.S. government should be to lower the amount Americans pay for healthcare. One-third of Americans who had health insurance claimed to have had trouble paying for their total cost of care (insurance premiums, deductibles and cost-sharing such as copays and coinsurance). As shown by Figure 3.3 below, there was an increase in the percentage of Americans who had an increased difficulty in 2017 vs 2015 in (1) affording the cost of health insurance (37% vs 27%), (2) paying their copays for doctor visits and prescription drugs (31% vs 24%), and (3) paying their deductibles (43% vs 34%).

![Figure 3.3](image.png)

*Figure 3.3 More insured Americans now report difficulty affording healthcare. Adapted from DiJulio et al. (2017).*

Of the 29% of Americans who stated they had difficulty paying their medical bills, 17% stated it had a major impact on their family; 61% used about all or most of their savings; 41% borrowed money from friends; 58% took an extra job or worked extra hours; 71% put off vacations or purchases of a major household item. Based on survey responses, 27% delayed or did not access healthcare due to cost, 23% skipped a recommended medical test or treatment and 21% did not fill a prescription.

In terms of accessing care, as shown in Figure 3.4 below, the U.S. was second to last compared to other countries in the 2013 Commonwealth Fund Report which surveyed...
11 industrialized nations. The U.S. was only 2nd to Canada in terms of the longest time in accessing healthcare, with Germany having the highest percentage of patients being able to see a physician same day or next day and the lowest percentage of patients having to wait 6 days or more (Sawyer, 2017).

Figure 3.4 Access to care as measured by number of days needed to see a doctor when sick. Adapted from Sawyer (2017).

In Germany, the largest economy in Europe, approximately 85% to 90% of the population is covered by mandatory health insurance provided through the Statutory Health Insurance (SHI); the cost to participants to purchase SHI coverage is approximately 15% of their wage or pension (wages or pension split equally between the participant and the employer or pension insurance institute). Persons who are self-employed or have income above a certain level may opt out of SHI coverage and elect to purchase private health insurance coverage. Annual out of pocket costs for patients are capped at 2% of income; with out of pocket costs representing approximately 13% of total healthcare expenditures in 2014 (Axene Health Partners, 2017, Deutsche Rentenversicherung, 2017).

The Commonwealth Fund in a 2017 report examined 11 countries including the United States, Switzerland, Sweden, France, Germany, Netherlands, Canada, United Kingdom, New Zealand, Norway, and Australia (Schneider, 2017). Of these 11 countries the U.S. performed last on a number of measures that covered 5 broad categories, namely care process, access, administrative efficiency, equity and
healthcare outcomes. Administrative efficiencies included amount of time physicians spent on resolving paperwork related to coverage restrictions and getting patients access to needed care. With the exception of care, the U.S. scored last or 2nd to last on the remaining categories. The U.S. also had greater disparity between access to care when comparing high income vs low income adults. The life expectancy from birth in the U.S. is 78.8 years compared to the OECD (Organization for Economic Cooperation and Development comprised of 34 member countries) average of 80.5 years (INDICATORS, 2015).

3.2 The Affordable Care Act

Thomas (2016) speaks to how the Affordable Care Act (ACA), which was signed into law in 2010, was passed to help ensure all Americans have access to affordable care. The accelerated growth seen in healthcare expenditures in 2014 was for the most part due to the expansion of coverage under the Affordable Care Act (ACA) most notably Medicaid and private health insurance (McRae et al., 2016).

The ACA required that employers in 2016 with 50 or more employees (known as applicable large employers) offer benefits to at least 95% of its full time employees and that the plan be affordable. Namely that the employee’s cost of the plan is not more than 9.66% of the employee’s total household income and the employer pays at least 60% of the plan’s costs. The plan must meet minimum benefit standards. If the employer does not provide these minimum benefits, and any of its employees qualify for a premium credit from the government (their income is less than 400% of the Federal Poverty Level), then there will be financial penalties levied against the employer (Sanders, 2013). This concept is known as the Play or Pay Penalty. The penalty is the greater of $2,160 x number of full time equivalents in excess of 30 employees or $3,240 x number of employees who receive a premium tax credit, based on employee income, from a health insurance exchange; both the $2,160 and the $3,240 are adjusted each year for inflation. This is further depicted in Figure 3.5 (The Henry J Kaiser Family Foundation, 2016b).
Figure 3.5 Penalties for employers not offering coverage under the Affordable Care Act during 2017. Adapted from The Henry J Kaiser Family Foundation (2016).

The above highlights the penalties for not providing a minimum level of benefit coverage. The Small Business Health Options Program (the complement of employers who are not applicable large employers) has slightly different requirements from that of larger employers. States can pass legislation that changes the application of the above to not include employers with less than 100 employees (as defined by the 2015 Protecting Affordable Coverage for Employees Act). Currently only 4 States have chosen to define the employer cutoff to be 100 or more employees, specifically California, Colorado, New York, and Vermont (National Conference of State Legislatures, 2017).

According to Thomas (2016), there is also consideration of a Cadillac (excise) Tax imposed on employers who offer benefits that are too generous as defined by the cost of the premium (premiums that are in excess of $10,200 and $27,500, for individual and family coverage respectively). At the moment the Cadillac Tax is in question and is not to take effect until 2020 due to questions on how to promulgate
the regulations; initially it was scheduled to take effect in 2013 but the implementation date has been extended several times.

The U.S. government has introduced an online platform, known as a Healthcare Exchange, to assist individuals who are looking to purchase healthcare insurance. Although Americans can purchase coverage outside the Exchange, the Exchange helps facilitate informed decision-making by enabling consumers to comparison shop for the best plan and price that meets the insured member’s needs. Americans need to purchase coverage from a Qualified Health Plan that meets minimum essential benefit standards; these are known as either Bronze, Silver, Gold or Platinum plans (collectively known as metal plans) with out of pocket costs respectively equal to 40%, 30%, 20%, and 10% respectively. Silver plans are the target benchmark plans for the Affordable Care Plan (Obamacare Facts, 2016).

As Thomas (2016) explains there are also penalties on an individual level for Americans who do not obtain healthcare insurance. The applicable penalty is calculated as the greater of either (1) 2.5% of annual household income not to exceed the premium of the national average of bronze plans or (2) $695 and $347.50, per adult and children less than 18 years old, respectively, in a family, to a maximum of $2,085.

Norris (2016), highlights that minimum essential benefits, which all metal plans must offer, include each of the following with no annual or lifetime dollar limits:
1. hospitalization
2. ambulatory services such as visits to doctors and other healthcare professionals and outpatient hospital care
3. emergency services
4. maternity and newborn care
5. services for those suffering from mental health disorders or substance abuse
6. prescription drugs
7. lab tests
8. chronic disease management, services recommended by the U.S. Preventive Services Task Force (including screenings for blood pressure, breast cancer, colorectal cancer, obesity (including counseling); tobacco counseling and interventions, and breast-feeding counseling)
9. pediatric services for children, including dental and vision care
10. rehabilitative services which include helping a person keep, learn or improve functioning for daily living

According to Schoen (2016), the effects of the ACA over the last 5 years has been overall positive to the U.S. economy and healthcare system. Medicare spending is projected to be reduced by one trillion dollars from initial estimates from 2010 through 2020. This in part is due to the focus on improving quality care and creating financial incentives for integrated care. For example, hospitalization rates for avoidable cause illnesses (illnesses that are contracted by the patient during their hospital stay, such as infection) have decreased by 25%. The formation of Accountable Care Organizations (ACOs), provider organizations that assume risk for outcomes, have helped in lowering overall healthcare spending. ACOs are a group of providers that work together to lower the cost of care by providing better quality care. CMS allows the ACO to share in that savings which results in additional revenue for the ACO (CMS, 2017). The initial ACOs, known as Pioneer ACOs, have saved $385 million in Medicare over 2012 and 2013 through a greater focus on quality and integrated care. At the same time, approximately 20 million more Americans have healthcare coverage between the 31 states that have opted into the Medicaid expansion program and with the existence of federally and state-funded health exchanges.
However, the question being asked is whether the system will be sustainable for the long-term. As stated in the Kaiser Family Foundation (Cox et al., 2016), premiums for 2017 are expected to change dramatically for Americans who are in the most common health plans, known as the Silver Plan. The top increases for unsubsidized single person monthly premiums (non-smoker, age 40) are in Arizona, Alabama, and Oklahoma (up 145% from $207 to $507; up 71% from $288 to $492; and up 67% from $295 to $493, respectively). For subsidized coverage, (subsidies exist for Americans who make below 400% of the Federal Poverty Limit which in 2017 was $48,240), single person premiums will remain for the most part unchanged, in some cases with a slight decrease in cost. For example in Indiana there was a decrease of 4% from $298 to $286. At the same time the number of MCOs participating in the healthcare exchanges has decreased from an average of 5.9 per state in 2015 to 3.9 in 2017. In 2016 85% of exchange members had a choice of 3 or more MCOs; in 2017 only 57% of exchange members had a choice of 3 or more MCOs.

Despite the ACA, there were 28.5 million non-elderly Americans who did not have healthcare insurance at the end of 2015. These individuals are without insurance either because they do not know how to access the insurance or do not qualify for subsidized and hence are not able to afford coverage. 53% of the uninsured are within a household where they are unable to pay their medical debts. Individuals without insurance receive less preventive care; care is made available through safety net providers such as public hospitals, community clinics and health centers. People without insurance typically receive less care for their chronic conditions than the insured and are more likely to be hospitalized for preventable health problems (The Henry J Kaiser Family Foundation, 2016a).

3.3 History of Managed Care in the U.S.

As Sade (2002) describes, benefits became a mainstay in the U.S. labor market during World War II when salary increases were not allowed, so instead employers began to offer various benefits such as healthcare. These became a non-taxable expense that served as a write-off from the top line for employers and eventually, with
the support of the National Labor Relations Board, became part of negotiations between the employer and the employees in terms of compensation and benefits.

The first appearance of pre-paid health coverage in the U.S. was found in 1910 at the Western Clinic in Tacoma Washington where for $0.50 per member per month employees of lumber mill companies were able to access a variety of healthcare services (Fox and Kongstvedt, 2013). One of the more recognizable names in managed care, the Kaiser Foundation Health Plan, was formed in 1937 to provide coverage for the Kaiser Construction company which at the time was building waterways in the Western part of the United States.

In 1929 one hospital offered teachers in Texas insurance coverage for hospitalization costs; this was the beginnings of the Blue Cross Plans (Niles, 2014). Eventually Blue Shield was formed to cover the costs of outpatient care. Blue Cross and Blue Shield led to the “free guild” approach of healthcare in the U.S. (Enthoven, 1993), a concept coined by Charles Weller, namely that patient choice of physicians was unimpeded as was the choice of treatment strategy by physicians for their patients. Patients could see any doctor; receive any service and the health plan paid the physicians for services rendered. Physicians determined their own income by the number of services they provided under the fee for service model and the market stayed fragmented for the most part with a preponderance of uncoordinated single specialty medical offices (for example, a pediatrician’s office or a cardiologist’s office).

Employers paid 100% of the premium costs for healthcare coverage; and except for the deductible and coinsurance, which had an annual cap after which the patient incurred no additional expenses, the patient’s financial risk was insulated; the latter being the concept known as moral hazard, where a 3rd party pays the majority cost of care; and the recipient of the care, the patient, only pays for a portion of the costs, thereby being insulated from the true cost of the service; this leads the patient to use the services less judiciously (Thoma, 2013).

As Enthoven (1993) further details, President Nixon signed into law in 1973 the HMO Act which was the beginnings of the U.S. government’s focus on helping to advance managed care as a major component of the healthcare system. The 1973 HMO Act
was informed by the work of Paul Ellwood and Alain Enthoven promoting the need for a health maintenance strategy to reign in the costs of and improve the distribution of medical care. Although the U.S. healthcare system predominately evolved from an indemnity type medical system (fee for service care that was reimbursed at a percentage of cost, for example 80%, after satisfying a deductible), into a managed care marketplace, where patients were responsible for copays; recent trends indicate that a portion of the managed care sector will utilize co-insurance to help shift a greater portion of the cost of care back to the patient, in addition to premiums paid (The Henry J Kaiser Family Foundation, 2016a).

According to Enthoven (1993), the premise of the HMO Act and the resultant market place was to foster competition among the various commercial entities that deliver care through the managed care business model. The intent of the policies that fostered managed care in the U.S. were to allow for these entities to evolve their business models, driving competition, in turn leading to better outcomes and lower costs all in an effort to better compete for available members. MCOs work with employer benefit managers and their management teams to help determine what type of benefit coverage program to offer to the employer’s employees. Ultimately the choice made by the employer benefit manager and the MCO will determine the employee’s access level to medicines. Different benefit options will contain different formularies through which access to medicines will be managed. Hence the decision-makers, the employer benefit design decision-maker and the MCO, impact upon the actions of insured members, physicians and pharmacists and affect subsequent outcomes.

Managed competition hinges on properly equipped agents making responsible purchase decisions, on behalf of their representatives: this concept of properly equipped agents applies to employers as they make available benefit options to their employees (Enthoven, 1993). A central tenet to the approach according to Enthoven is the ability to make decisions in the face of uncertainty (imperfect information) and not just administer pre-defined (fixed) rules. In the same paper, Enthoven talks about aspects of the employer that hints at the importance of being informed and being
engaged that ultimately can lead to better informed decisions; namely better quality at lower costs. For example, a diligent employer can help drive efficiency of care and lower costs to its employees by providing a list of physicians who are in multiple plans being offered by the employer and indicating which plans for a given physician are the least costly (assuming benefits are standardized). The paper stresses the concept of individual choice with the mindset that better quality will drive lower costs when applied efficiently and effectively. However there is no explicit reference to ensuring members have the necessary information as it applies to drug formularies when making decisions regarding plan enrollment.

As explained by Ruger (2004), Americans who are members of MCOs cannot sue an MCO that provides benefits coverage under an employer benefit plan (as defined by ERISA, the Employer Retirement Income Security Act of 1974) for damages incurred due to access denials except for the actual out of pocket costs incurred for medical care due to the denial. Some states do offer protection to MCO members (if not ERISA plans) for negative consequences of treatment outcomes due to the effects of plan coverage. One such state is Texas and the law protecting non-ERISA MCO members is known as the Texas Health Care Liability Act. The fact that ERISA only allows for recovery of the lost benefit and not subsequent value of the loss to the person (including damages) reduces the likelihood of a wronged member (patient) filing a suit. This tends to place the economic benefit of decision-making in favor of the MCOs. This was the situation in the Aetna vs Davalia case (United States Supreme Court, 2004) where Aetna denied coverage of an arthritis medication prescribed by the treating physician. The Aetna case was dismissed because under ERISA a member cannot sue an MCO for services provided under an employer contract to the employer’s employees who are members of the MCO’s health plan. The patient in this case needed to take a less costly medication which resulted in the patient suffering a reaction that required hospitalization. This underscores that the courts ruled not on the resultant outcome but rather who was the decision-maker (for example in this case the MCO).
3.4 A Closer Look at Formularies

Cole et al. (2008) speaks to how a

“formulary system is the ongoing process through which a health care organization establishes policies regarding the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population. Formulary systems are used in many different settings, including hospitals, acute care facilities, home care settings, and long-term-care facilities, as well as by payers such as Medicare, Medicaid, insurance companies, and managed care organizations. Many organizations have policy statements on the use of formularies.”

Formularies began in the 1940s in the military, eventually expanded into hospitals in the 1950s and became mainstream in 1965 when Medicare made reimbursement for a hospital drug contingent on it being included on formulary and the Joint Commission on the Accreditation of Hospitals made the existence of an active P&T (Pharmacy and Therapeutic) committee as part of the accreditation process. Accreditation is recognition of the hospital satisfying industry standards that have been shown to lead to improved safety, quality of care and outcomes.

MCOs have P&T committees that determine what medications are included on the formulary. P&T committees are comprised of different stakeholders who ultimately evaluate the clinical merits of a medication and decide whether the medication should be included on the drug formulary. The drug formulary in turn determines the accessibility of the medicine to the patient: whether certain criteria have to be met (Prior Authorizations or Step Edits) as well as the financial obligation of the patient when the medication is picked up at the pharmacy (cost shifting). In the U.S., patients can access any medication their doctor is willing to prescribe for them as long as the patient is willing to pay the retail cost. The question that needs to be considered by all involved stakeholders is what will be the financial implication of the prescription to the patient. What will be the time factor in accessing the needed medication through an MCO, given use of step edits and prior authorizations and will any delays impact on outcomes. Will it be full retail cost (if the pharmacy benefit considers the product off-formulary), or will it be a low copay (Tier 1), a moderate copay (Tier 2), a high copay (Tier 3 or 4) or coinsurance (Tier 5 or higher) and what
will be the impact of the out of pocket cost on the patient’s willingness, or ability, to pay for the medication.

Figure 3.6 below gives an example of one of the largest MCO’s drug formulary overview process (Sweet, N.D.). After the clinical review is completed by a group of healthcare professionals that are part of the Clinical Review Committee (CRC), members of the Value Assessment Committee (VAC) make a determination as to drug formulary placement. The VAC includes financial elements to inform the drug formulary decision whereas the CRC is solely based on the clinical elements. The ultimate drug formulary placement decision is based on the output of the VAC.

As discussed by Navarro (2009), MCOs look to control pharmacy costs by managing both the supply side and demand side of medications. Supply side management includes use of contracts with manufacturers and pharmacies to purchase medications at lower costs through the use of rebating (providing dollars back from the pharmaceutical manufacturer to the MCO) and discounting (pharmacies charging lower dispensing fees and acquisition cost of medicines). Demand side management is controlled through the use of formularies which includes a variety of techniques to impact on prescribing and filling medications such as:
• Step Therapy or Step Edit (needing to satisfy certain criteria before the medication can be dispensed through the formulary such as use of a generic before a brand medication in a different therapeutic class, or failing on one medication before using another medication).

• Prior Authorization (needing to satisfy criteria before the medication can be dispensed through the formulary which may include meeting clinical or patient specific criteria, such as severity of disease, clinical parameters above or below a certain threshold, or age requirements; medication prescribing can also be limited to select specialties).

• Quantity Limit (restricting the number of pills that can be dispensed at any one time over a specified period of time).

• NDC block (NDC is the National Drug Classification Number and is unique to each pharmaceutical product; when a formulary does not reimburse for a specific product, it is referred to as an NDC block).

• Tier levels (can range from Tier 1 through Tier 4, 5 or 6: if a plan has a three tier plan, Tier 1 products are mostly low cost generics; Tier 2 are preferred branded products and are at a lower net cost to the system than higher tiers; Tier 3 are non-preferred branded products and have a higher net cost to the system. When MCOs have 4 Tiers, the 1st Tier is for preferred generics, the 2nd Tier is for non-preferred generics, Tier 3 and Tier 4 are for preferred and non-preferred branded medications, respectively. Tier 1 through Tier 4 are typically copay tiers whereas higher tier levels such as Tier 5 and Tier 6 are reserved for higher cost medications and are available on a coinsurance basis, namely available at a percentage of the retail cost of the product).

An example of the impact of Step Therapy (Step Edits) was documented by the Alliance for Patient Access (2017): as stated by the Alliance, step therapies increased from 27% in 2005 to 67% in 2013. The Alliance found that in the case of patients with psoriasis or psoriatic arthritis, MCO step therapy requirements led to 52% of patients not receiving the original prescription that was written for their treatment. The Alliance also found that on average the physician and the physician’s office staff
spent up to 2 hours per patient trying to overcome MCO imposed administrative requirements to help their patients gain access to the necessary medications. Although MCOs believe that formularies and step therapy requirements help to reduce costs through the application of evidence-based medicine, the point of view is not necessarily shared by other stakeholders in the marketplace as can be seen in the two quotes below specific to the topic, one from a health plan association representative, the other from a patient advocacy organization:

The Senior Vice President of State Affairs at AHIP (America’s Health Insurance Plans), Leanne Gassaway, believes that “step therapy encourages physicians and patients to undertake a more evidence-based approach to treatment. When you tailor a plan to the patient, you can gauge the patient’s response to medications before graduating to the more potent and higher-risk drugs.” (McDaniel, 2016)

As stated by Patrick Stone, Director of State Government Relations at the National Psoriasis Foundation, “Step therapy protocols add to the burden of psoriasis by erecting barriers for individuals in urgent need of treatment. Failing to consider the unique needs and preferences of individual patients, and imposing a one-size-fits-all approach to care, these protocols negatively impact patients quality of life and can result in detrimental effects on health”, (McDaniel, 2016)

However the threat of step therapy is a motivating factor for pharmaceutical companies to reduce the price of a given medication (McDaniel, 2016).

The power of advocacy in the U.S. is an important aspect of creating change in policies that ultimately impact on what MCOs are able to do in a given state. This is evidenced by Figure 3.7 below which showcases the number of states that have passed legislation that requires MCOs to follow certain rules when implementing step therapies, including reviews within 3 business days and requiring “that step therapy protocols be based on sound clinical evidence, not just cost, and enumerate several instances where an exception to step therapy must be granted by the insurer.” (National Psoriasis Foundation, 2017).
The power and role of advocacy in creating new laws that impact on what MCOs are allowed to do was highlighted by Dr. Iacobellis, the President of the New York Society of Dermatology and Dermatologic Surgery. Dr. Iacobellis speaks to the power of bringing together different groups to engage with their legislators, then making the case for change based on the evidence from the perspective of clinical thought leaders enables government to pass new laws that will change MCO drug formulary practices (American Academy of Dermatology, 2017)

Different plans, even from the same MCO, may have different drug formulary placement for the same medication. A good example of the variations in formulary coverage for a given medication is provided by a company by the name of MMIT (Managed Markets Insights and Technology) at www.formularylookup.com. The first screenshot (Figure 3.8 below) shows a summary of the formulary status across 160 commercial plans in the State of New York for Toviaz (fesoterodine), an antimuscarinic used in the treatment of overactive bladder. The second screenshot (Figure 3.9 below) shows a summary for the same product except this time for Medicare plans in the same State. Toviaz (fesoterodine) is not covered in 3% of the commercial plans but this percentage increases to 17% within Medicare plans; the product is made available to a greater percentage of the commercial population than
the Medicare population (97% vs 83%). This seems to strain the construct of distributive justice. Medicare patients are more likely to suffer from the consequences of overactive bladder as this condition tends to be more prevalent in the older patient population. The efficacy, safety and tolerability of the product are based on clinical trial data that is accessible equally to decision-makers both at commercial and Medicare plans hence it seems counterintuitive that older people would have less access to the medication than the commercial population. It is the same product with the same clinical profile irrespective of whether the product is used in the Medicare or commercial population. However, the younger patient has better access, all things being equal, than the older patient; this despite the fact that Toviaz (fesoterodine) has been studied with demonstrated efficacy in the older patient population, including the vulnerable elderly (DuBeau et al., 2014). This is not to say that there are not other medications available with similar product profiles; the point being made here by the PhD Researcher is that this particular medication has better access in the commercial patient population then the Medicare patient population. When a medication is not covered on formulary, it is only accessible to the patient if they are willing to pay full retail cost, which is $199 per month, according to Consumer Reports Best Buy Drugs (Consumer Reports, 2013).

Figure 3.8 Drug formulary coverage for Toviaz, commercial plans, NY State.
(Managed Markets Insights and Technology, N.D.)
It is important to select OAB treatments that reflect a patient’s comorbidities and concomitant medication regimen with a special emphasis on cognition and cardiac function (Drutz, 2011). Physicians should personalize OAB treatment to identify the medication that delivers the best outcome for a given patient; physicians can switch to other OAB agents once a patient has failed therapy on a given OAB therapy (Ubee et al., 2010). As mentioned above, this touches upon distributive justice because two patients with the same patient and disease characteristics may have different levels of access to a particular medication even though they may have paid similar premiums. This is seen even in the Veterans Administration (VA) which provides care to U.S. veterans. There is a national drug formulary however the VA consists of 22 Veterans Integrated Service Networks (VISNs) which have autonomy to modify the drug formulary to meet the specific needs of their patient populations. The VISNs may make adjustments to the drug formularies and also grant one-off exceptions through a non-formulary waiver process. Hence from a distributive justice perspective the same two patients may have different levels of access to medications based on which VISN provides access to care and hence these patients will not be necessarily treated equally (Cassidy, 2002).

Plans use drug formulary management techniques described earlier to influence physician, pharmacist and insured member behavior when it comes to prescribing,
dispensing and filling medicines which limits access (Maio et al., 2005). These utilization management techniques typically promote less expensive medications which reduce the pharmacy spend but could have a negative effect on longer term clinical, humanistic and total system cost (economic) outcomes. In contrast, MCOs believe that these techniques lead to use of the most affordable and effective medication options through the application of best practices (evidence-based medicine) on a consistent basis (Prime Therapeutics, 2012). There are also financial incentives sometimes provided to physicians and pharmacists when insured members are prescribed and dispensed generics vs branded medications. MCOs seem to think their interventions are for the benefit of the healthcare system and those who engage the system, yet as shown by a survey (Sulmasy, 2001), physicians believe that MCOs and their attempts at cost control have led to negative ethical implications (namely, consumer trust negatively impacted; physician commitment to consumer loyalty questioned or diminished; ethically-based objections raised to the effect these utilization techniques have on behavior).

Cost-sharing is a drug formulary management tool to help offset premium costs but also to drive use of lower cost medications. However, higher out of pocket patient costs negatively impact adherence. It has been estimated that non-adherence in the U.S. healthcare system has led to expenditures of $100 to $300 billion in preventable healthcare costs, which is approximately 3% to 10% of the total healthcare costs in America (Luga and McGuire, 2014). Adherence is the term used to describe a patient following the directions of the physician in terms of how to take the medication prescribed (Osterberg and Blaschke, 2005). Medication adherence is impacted by a number of factors including but not limited to side effects, severity of the condition, the patient’s perception of health gain from treatment as well as the cost of the medication and the restrictiveness of the formulary (Zullig and Bosworth, 2017). A systematic literature review (SLR) conducted by Park et al. (2017) examined 59 studies that met the criteria of the SLR and found that the majority of outcomes were focused on drug utilization (31%), healthcare resource utilization (14%) and economic outcomes (33%), 78% in total, as opposed to medication adherence (11%), clinical
outcomes (9%) and treatment satisfaction (2%). As can be seen by Figure 3.10 below.

As stated by the authors,

“Of all of the outcome types, the majority were negatively associated with formulary restrictions (medication adherence [70.6%], clinical outcome [91.7%], patient-reported outcomes [treatment satisfaction, 100%], health care resource utilization [outpatient visits, 82.4%, and hospitalization, 64.7%], and economic outcomes [medical costs, 66.6%]). However, for pharmacy costs under economic outcomes and drug utilization, 83.3% and 91.3% of outcomes reported positive association with formulary restrictions compared with negative or neutral association, respectively”.

Reducing cost was the main reason for the formulary changes in 48 of the papers reviewed.

One of the challenges when it comes to drug formulary management is decisions, at least from a clinical or CER point of view, are based on studies that are based on inclusion / exclusion criteria that may not reflect the individual patient in real clinical practice setting. Therefore it becomes very difficult to inform patient-specific treatment decisions based on population-level analysis based on evidence that is not reflective of clinical practice (Mohr and Tunis, 2014). One of the organizations that
was newly created under the ACA was PCORI, Patient-Centered Outcomes Research Institute, which is expected to receive approximately $3.5 billion in funding through September 30, 2019 (Patient Centered Outcomes Research Institute). As stated by the PCORI website, their working definition looks to answer questions in a manner that will be patient-specific:

1. “Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?”
2. “What are my options, and what are the potential benefits and harms of those options?”
3. “What can I do to improve the outcomes that are most important to me?”
4. “How can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?”

Although this is the vision of PCORI, it addresses a future state that is not yet in operation within the U.S. healthcare system. Many decisions that are made that affects the population at large are made on evidence that might not translate to the individual patient being treated by a given physician and the evidence is potentially based on evidence that lacks appropriate rigor and applicability. This is highlighted in Figure 3.11 below which indicates the level of evidence used to inform cardiac disease guideline recommendations in the majority of cases is consensus opinion, case studies or standards of care, which in turn impacts on coverage (level of access) decision-making (Tricoci cited by Mohr and Tunis (2014)): 

103
Another example of how decision-makers are not taking into account the needs of specific sub-populations is patients with multiple sclerosis. As discussed by Gottlieb (2015), current commissioner of the Food and Drug Administration,

“Almost all of the Silver plans offered under Obamacare sport closed drug formularies, where there’s no coverage for drugs not listed on the narrow formulary lists. This means, when a drug doesn’t make a health plans list, consumers are completely uncovered… In all cases, plans provided no coverage for a substantial number of important drugs [used to treat multiple sclerosis].”

Silver plans are one level higher than the lowest level of plan coverage (which are known as the Bronze plans). Silver plans have moderate premiums and moderate out of pocket costs; but one way MCOs limit the costs of the plans is by limiting availability of certain type or level of care as evidenced by these plans not covering a number of drugs that might be considered important by physicians in the treatment of multiple sclerosis.

As discussed by Ollove (2015), given the high out of pocket costs that can be incurred by patients through the use of tiered plans that utilize coinsurance, seven states have placed limits on these costs. These states include Delaware, Louisiana, Maine, Maryland, Montana, New York and Vermont. For example, patients in Montana cannot pay more than $250 per prescription per month. In Delaware, Maryland and Louisiana the monthly cap is $150; in Vermont the upper limit is $100.
Maine sets its limit on an annualized basis in the amount of $3,500 per drug. A good example of how these measures protect patients is with regards to biologics which typically cost 22 times more than small molecule medicines with an annual average of $34,550 per year of treatment; out of pocket costs through coinsurance tiers can be anywhere between 28% to 50% of the cost of the medication. The Health Exchange in California capped coinsurance at $250 for a given monthly prescription; this change is expected to have a premium increase of 1% in year one and 3% over a three-year period. New York has prohibited the use of specialty tiers and Delaware requires at least one lower-cost alternative per class of specialty medications.

3.5 Implications of New Drugs Coming to Market

As the cost of medicines continues to rise, access to medicines through drug plans will potentially be slowed. A good example is with regard to the Hepatitis C medication that was launched by Gilead, which retails for $84,000 for a 12-week course of therapy. The standard of care is considerably less costly at about $66,000; as newer medications come to market to treat Hepatitis C, the cost of drug therapy will increase from $3B per year (as reported in 2012) to $21 B per year by 2018 (Armstrong, 2014). The Chief Financial Officer of the 4th largest PBM in the country is quoted by Armstrong as saying, “You can get to these more expensive treatments [however] you have to outweigh the costs of the first, more cost-effective treatment.” The same article goes on to cite the Chief Medical Officer of the largest PBM in the country as having said, “We will identify which drugs can be pitted against each other and make some really tough formulary decisions.” The challenge with this approach of comparing two medications at a population level to determine which product to make more readily available to plan members (perhaps at a lower copay with less access restrictions) is the issue around statistical averages vs individual patient care (National Pharmaceutical Council, N.D.). There are many patient characteristics that impact on the patient’s likelihood of responding to a given medication that is determined in part by the patient’s physiology such as age, gender, genetic make-up (existence of single nucleotide polymorphism); their health state and potentially other medications being taken concomitantly (drug-drug interactions). The healthcare
system in today’s marketplace operates on the principle of treating the average patient which tends to represent the majority of the population. The NPC publication encapsulates the core focus of this thesis:

“because most health plans design their policies to meet the needs of the majority of people, those who are different—older or younger, or with different racial or ethnic backgrounds, for example—may have a difficult time getting other treatment options covered. Some health plans require patients to try the “average” therapy first before trying another treatment, even if it is not the best option.”

The concept of differences of treatment effect based on individual patient characteristics is referred to as heterogeneity treatment effect.

Express Scripts or as it also known, ESI, a pharmacy benefit management company, in early 2014 announced it would remove from its National Preferred Formulary forty-four different products (Sliverman, 2013). Of the 100 million lives covered by Express Scripts, a Fortune 100 company and the largest PBM in the country, 30 million obtain their medications under the National Formulary and approximately 2.6% of these lives (780,000 members) currently use the medications that will no longer be available through the drug formulary. These patients, for the reasons mentioned above as it relates to heterogeneity, may suffer in their outcomes as they will have interruption of their prescriptions, and alternatives may not be as effective. Express Scripts however has noted availability of an exceptions appeal process on a medically justifiable basis, as needed. Some of these medications were for the treatment of Rheumatoid Arthritis. Express Scripts has indicated if access is approved through the appeals process, it will enable the patient to gain access at the non-preferred copay level which represents a discount from the retail cost (Arthritis Foundation, 2014). The Arthritis Foundation is advocating for patients who may be negatively affected by these access restrictions. As stated by the Foundation:

“We want to hear from people covered by the Express Scripts formulary that excludes those five drugs— Cimzia, Simponi, Simponi Aria, Stelara and Xeljanz. If you have been taking one of the drugs or if your doctor recommends that you take one, please let us know whether you have been
In a 2006 Gallup Poll regarding honesty and ethics across a number of professions, MCO managers were 3rd from the bottom; advertising practitioners and car salesmen were 2nd to last and last, respectively (Saad, 2006). 37% of those surveyed indicated honesty and ethics as low or very low vs 12% who rated this profession as high to very high. In comparison, with regards to business executives, 27% were rated low to very low and 18% were rated as high to very high.

3.6 Flow of Funds

Navarro (2009, p.20) depicts the flow of funds across the various stakeholders in the U.S. healthcare system. The system allows for discounted reimbursements on the medical and pharmacy side. These discounted reimbursement levels, as it relates to pharmaceuticals, are made possible because the pharmaceutical company provides rebates under certain conditions such as market share, drug formulary placement or outcomes-based contracts. Market share is the percent a given medication represents within a class of medicines; the higher the share, the greater the number of sales for a given medication, the more willing the pharmaceutical manufacturer is willing to pay in rebates; also known as a performance rebate contract. Formulary placement contracts pay rebates solely on the position of the medication on formulary with a Tier 2 rebate being higher than a Tier 3 rebate; outcomes-based contracts pay additional dollars to the MCO based on whether a medication delivers on a specific clinical endpoint such as Merck’s Januvia contract with Cigna and Sanofi’s Actonel contract with Health Alliance Partners (Neumann, 2011). Patients are able to acquire their medications either through retail, mail order or specialty pharmacy. Formularies, as discussed earlier in this chapter, determine the patient’s out of pocket costs in the form of copays or coinsurance. The visual in Navarro (2009, p. 20) helps to depict the various stakeholders that interact to fund and deliver care; the patient from the OAB case study can be used to further illustrate the interactions:

- The patient’s employer is the plan sponsor who purchases private (commercial) insurance for its employees. The employer contracts with an
MCO such as Aetna, for example, which is a large health plan in the U.S. The employer pays Aetna a premium per member per month (PMPM) to provide insurance coverage to its employees for the year. Aetna in turn offers to the employer’s employees’ medical coverage as well as pharmacy coverage.

- Aetna has contracts with various hospitals and physicians across the country; these hospitals and physicians will receive a contracted payment rate for services provided to Aetna members as in the case of the OAB patient.

- When the OAB patient sees her physician, she will typically pay a flat fee to the physician; this is known as the copay. The copay amount and the contracted rate from Aetna is what the physician will receive as total compensation for a given patient visit.

- When the physician prescribes a chronic medication to the patient, the patient can either fill that prescription at the local pharmacy which is in Aetna’s pharmacy network or fill the medication through Aetna’s mail order pharmacy. The first prescription from the doctor will be for a 30-day supply; the patient will pay a copay for the medication (anywhere from $0 to $90 depending on where the drug is on the formulary tier; this is not a specialty medication so there will be no coinsurance). If the patient has a good clinical response and wishes to continue to take the medication, the patient can then ask the physician to write a 90-day prescription and instead of paying the equivalent of three copays (one for each month), the patient might only have to pay the equivalent of two copays. This saving incentive is for the patient to fill her medication via mail order. The pharmacy will receive payment from Aetna at a contracted rate; the patient’s copay + the contracted rate from Aetna is what the pharmacy will receive as total compensation for filling that specific prescription. Typically the pharmacy will source the medication from a distributor who purchased the medicine from the manufacturer. Lastly, the manufacturer of the branded medication that was prescribed, if Aetna has a contract with that manufacturer, will pay Aetna a rebate based on the contract that exists between Aetna and the manufacturer.
3.7 A Closer Look at the Employer Segment

In 2012 there were approximately 314 million people in the United States. 86.3% were less than 65 years of age which translates into approximately 271 million lives (US Census, 2012). As of 2008, approximately 121 million people were considered paid employees in the U.S. (US Census, 2007): 81.7% worked for employers who employed at least 20 employees; 50.2% worked for employers who employed at least 500 employees; 32.7% worked for employers who employed at least 5,000 employees.

As of 2016, approximately 61% of employers provided health insurance to their employees, as compared to 68% in 2001 (The Henry J Kaiser Family Foundation, 2016a). 56% of the U.S. population aged 0 to 64 received their health insurance coverage through employers. 99% of workers who were covered by their employers’ health insurance were enrolled in some form of managed care (The Henry J Kaiser Family Foundation, 2013).

Based on a 2013 survey by Buck Consultants, representing 250 employers and almost 4 million employees, 99% of employers stated that they provided prescription drug coverage to their active employees (Buck Consultants, 2013); 71% stated that they spend more than 16% of healthcare spend on prescription drug coverage; 87% stated that the cost of drug coverage had to be reasonable as it is “a constant financial drain on company resources and [can] undermine the return on investment of a plan sponsor’s entire healthcare benefits program”.

Historically, employers offered benefits as a fringe benefit: to supplement wages and to gain the tax advantages associated with the benefit based on taxation rules (as discussed earlier in this chapter). These fringe benefits can be quite sizeable. On average, in 2013, annual family health insurance premium costs through employer sponsored plans equaled $16,351, of which $4,565 were paid for by the employee (The Henry J Kaiser Family Foundation, 2013). However, employers have been shifting a greater amount of the expenses to their employees as evidenced by the increase in the portion of the premium being paid for by the employee and the plan deductibles (Roy, 2013):
premium costs for Americans aged below 65 have risen as a percentage of median household income from 14.9% in 2003 to 21.5% in 2011, as well as, single and family deductibles have approximately doubled over an 8 year period (for single coverage from $518 in 2003 to $1,123 in 2011; for family coverage, from $1,079 in 2003 to $2,220 in 2011).

Larger employers are able to retain benefit consultants to help advise them on benefit designs that will help them meet business objectives. Smaller employers rely solely on the health plans / pharmacy benefit managers and the recommendations they make to help inform their decision-making. The smallest of employers typically rely on brokers to help find benefit packages that will meet the needs of their employees. Approximately 50% of employers (typically larger employers with lives in excess of 5,000) work directly with PBMs to administer their pharmacy benefits; whereas, for the most part, the remainder of employers, work through a health plan to administer their pharmacy benefits (Takeda Pharmaceuticals USA Inc, 2013). Given the above, it is important to note as stated in the Takeda study that on average 70% of employer HR professionals spend less than 25% of their time focused on drug benefits and related decision-making.

A current growing movement in the U.S. is the focus on comparative effectiveness research (CER). As mentioned earlier in this chapter, the ACA established the existence of the Patient Centered Outcomes Research Institute (PCORI) that will be the government’s main body to help inform decision-making utilizing comparative effectiveness research. Employers cite that PCORI will be one of the most reliable sources of CER to help inform their decision-making (The Benfield Group, 2011). Some employers will monitor analysis completed through PCORI directly; others will expect that the organizations they hire to help inform benefit designs and administer the available benefits will provide relevant guidance on what decisions would best lead to improved outcomes. However an important set of data variables in CER that are not currently considered in the analysis include data on productivity, absenteeism and disability. 53% of employers thought these data points would be important or very important to include in CER to help inform decision-making. Based on research
completed by the Benfield Group, on average, 60% of employers studied focused on improving employee productivity and health; the remaining 40% of employers placed emphasis on reducing healthcare spend by shifting more of the cost of care to their employees and focusing on securing the lowest price in negotiations when finalizing benefit contracts with the relevant organizations.

Specific to employers, 63% of employees were enrolled in 3 tier formularies and 14% were enrolled in 4 tier plans (The Henry J Kaiser Family Foundation, 2013). The copays by tier for employees in three or four tier plans were on average $11 for first-tier drugs, $31 for second-tier drugs, $54 for third-tier drugs and $93 for fourth-tier drugs. Typically the more tiers in a plan the higher the average copay across the tiers as higher tier levels shift a greater percentage of the medications cost to the patient (The Henry J Kaiser Family Foundation, 2015). The cost differential between tiers is one of the main mechanisms used by employers and MCOs in the U.S. healthcare system to drive generic utilization. In the United States, 80% of all prescriptions are generic accounting for approximately one quarter of all drug spend. Employers utilize several drug formulary management techniques, in varying degrees, to limit access to medicines: 76% utilize prior authorizations, 56% require failure on a lower cost therapy before approving use of a higher cost therapy, and 74% impose quantity limits. 50% of employers allow for therapeutic substitution for at least one disease area to redirect patients to fill medications that are less costly; for example, in the management of high cholesterol levels substituting atorvastatin for branded Crestor, rosvastatin. (Takeda Pharmaceuticals USA Inc, 2013). As stated by McRae et al. (2016), 50% of employees who have more than three tiers will have coinsurance for the higher cost specialty product (Tier 5 or higher); 57% of employers utilize specialty tiers.

3.8 Physicians and their Patients

Based on a study completed in Ontario, Canada (Suggs et al., 2009), the majority of physicians find formularies cumbersome and time consuming, requiring advocacy on behalf of the patient to overcome access restrictions. Formularies create inequity in access to medicines and impact on treatment strategies as defined by the physician’s
clinical assessment of the patient. Physicians indicated that they may choose a
different drug then their first choice for several reasons including (1) gaining access to
the medication quickly, (2) the possibility existing that the medication may have a
positive treatment effect and would not be expected to do harm, and (3) enabling
documentation that the patient tried a lesser expensive medication before using a
medication that had additional criteria for use. “Physicians see themselves as duty-
bound to fulfill their primary responsibility to patients, but realize that health care costs
are rising and that potential legal and financial penalties loom if they are in
contravention” of the drug formulary. Emotional implications of these formularies
included feelings of “frustration, discouragement, fatigue, and lack of appreciation”
which negatively affects the physician’s willingness to advocate for their patient. The
economic consequences can be additional visits to the physician’s office and the
emergency room.

The American Medical Association (AMA) highlights several elements that pertain to
MCOs and the use of formularies (AMA, 2002). A physician’s duty to the patient
might be negatively affected as the system tries to reign in expenditures at the macro
level. The AMA recognizes the importance for advocating access to a medicine for a
given patient and not foregoing the need of the individual patient given the focus of
population level care is driven by outcomes defined for the average patient. The
AMA assigns an ethical responsibility for physicians to advocate on behalf of their
patients who need access to a given medicine when justifiable based on the
individual patient’s unique situation; to that end the exception process put in place by
MCOs should not be designed in a manner that places the patient at risk by
restricting access to therapy options that might prove to be the most effective for that
given patient. The utilization controls used by MCOs can create undue administrative
burden to physicians and patients which reduces the likelihood of a patient gaining
access to the needed medication in a timely and medically appropriate manner. In
addition, even if the physician is able to overcome the access restriction should one
exist, the copay may still be too high for the patient to fill the medication on a regular
basis. “…the purpose of [the] health plan’s formulary is to steer [the patient] to the
least costly medications that are sufficiently effective for treating [a given] health
condition” (Bihari, 2014). According to a U.S. survey completed between August 2001 and November 2001, with 12,406 physicians surveyed, 48.7% indicated that formularies had a negative effect on quality and efficiency, 37.9% stated there was a neutral effect and 13.4% indicated a positive effect (Landon et al., 2004). The AMA also advocates for transparency of information, for the physician to have the opportunity to discuss with the patient the risk-benefit tradeoff when choosing one medication over another. Patients should also be made aware of any underlying financial incentives that may impact on the choice of medication being prescribed or filled.

The importance of following treatment guidelines as recommended by professional (medical) organizations, prescribing in a manner that is supportable by the literature in the public domain is recognized (Edersheim and Stern, 2009). However, it highlights the importance of a physician considering the risk-benefit tradeoff when prescribing one medication over another for a given patient. It underscores the importance of prescribing medications that are specific to the individual needs of the patient in order to reduce the risk of any negative consequences associated with the treatment choice. Equally important is the need for patients to make an informed choice when agreeing to their medical treatment plan (Table 3.1 below). It is essential that the patient understand treatment alternatives, to weigh their options and then initiate therapy that best suits their needs (patient preferences). It is interesting to note that the paper which focuses on “Liability Associated With Prescribing”, highlights the potential of liability extending to the managed care plan should the patient subsequently suffer an adverse event due to the medication. However we have seen earlier the limitation of liability to MCOs under ERISA plans.
The table above however does not discuss the cost implications of a given treatment. Is the physician’s choice for a given medication cost-prohibitive for a given patient in a given plan and what are the implications if the patient cannot afford to initiate or stay on a given therapy that the physician has deemed his or her first choice for that specific patient? The importance of patients understanding the consequences of the financial aspects of a given therapy option are stressed both from a moral and justice perspective (Hall, 2014). The paper highlights the importance of patient’s making informed choices; that physicians need to discuss with patients the various treatment options and the potential costs of those treatments and implications on the ability or willingness of the patient to pay which can affect outcomes. A key challenge faced by physicians is that formularies change based on contractual relationships between the MCO and the manufacturer of a given medication as well as the benefit designs that employers subscribe to for their employees. As a drug formulary contract is established, the preferential status of a given medication will change over time: not necessarily because the evidence has become better, but perhaps because there has been a greater willingness by the manufacturer to enter into a more aggressive contract.
An example of non-medical switching (not generic but therapeutic switching) which is a term that refers to a patient changing medications not because of clinical reasons but due to a change in the formulary is reflected in the quote below from (Sulmasy, 2001).

“I do have a problem with letter after letter telling me to shift from one ACE inhibitor to another, one proton-pump inhibitor to another, one SSRI to another, as they jockey their contracts around. I understand exactly what’s going on, because I am on the Pharmacy and Therapeutics committee of DakotaCare, the managed care company in South Dakota.”.

There are several studies that show that non-medical switching for patients previously well controlled on a therapy can lead to negative outcomes (Nguyen et al., 2016), (Gibofsky et al., 2017). A good example of this is Wellpoint (now part of Anthem), the 2nd largest MCO in the country, that announced in 2014 that it would pay oncologists $350 per month when the treating physician is using one of the preferred medications based on Wellpoint’s recommended treatment guidelines. The payment approach being taken by Wellpoint was considered initially as a pilot in 6 states; there were plans to roll-out nation-wide across its network in 2015. The program was slated to save annually $162M to $216M in oncologic treatment costs once fully implemented however some physicians believed the approach did not account for individual patient differences and rather addressed care on the population level (Mathews, 2014).

Axtell-Thompson (2005) speaks to the need to ensure not only that beneficence and justice are preserved in patient care but that also autonomy of decision-making is preserved. It is important that patients make informed decisions that will lead to benefit and not harm and that there are protections for patients who are already disadvantaged as it relates to health disparities, such as the poor, vulnerable and health illiterate (justice). There have been a number of recent news stories on the importance of understanding the value of a treatment derived based on the cost of treatment vs the treatment effect. Although the information at this point is not prescriptive it helps to inform physician decision-making (American College of Cardiology, 2014). 57% of the 30 largest medical societies “explicitly consider costs in developing their clinical guidance documents” (Schwartz and Pearson, 2013).
However guidance documents are vague in relation to their statements on cost considerations and that greater transparency should be adopted with regards to methodology as these guidelines impact on clinical decision-making. Similar to the American College of Cardiology, the Society of Oncologists have placed focus on developing their own scorecard to help assess cost vs value (Pollack, 2014). The article highlights the natural tension that can arise when physicians who are providing medical care to the patient and advocating for the needs of the patient also are responsible to managing the financial components of care. The Director of the Center for Liver Diseases at the University of Chicago was quoted as saying “I think ethically we are just worried about the patient in front of us and not trying to save money for the insurance industry per se, or society as a whole”. Physicians need to be more aware of the cost of drugs: writing more generics where there is a generic for a given brand (American College of Physicians, 2015) and writing for lower cost treatments where the cost difference is not warranted by the difference in efficacy vs lower cost treatment options (Damouni, 2014).

The relationship between physician and patient and role of both in assessing the available treatment choices and identifying which is best for the patient, recognizing the physician’s scientific knowledge and the patient’s preferences are at the core of deciding a given patient’s treatment strategy (Charles et al., 1997). The emergence of MCOs in the U.S. has impacted on this dynamic and has introduced a 3rd party administrative channel that has become a key determinant of treatment choice given the use of drug formulary utilization management techniques.

Based on the findings of a systematic review conducted to assess physicians’ ability to ration healthcare resources, the findings showed that in multiple countries, there was inconsistency across physicians and even specific to the same physician (Strech et al., 2008). Physicians decision-making is influenced by a number of factors such as how demanding is the patient (ability to self-advocate), is the physician in or planning to be in a long-term relationship with the given patient which is related to the degree to which the physician wants to please the patient, as well as patient preferences and socioeconomic status. The implications of these factors may lead
some physicians to manipulate the system or to not make the patient aware of certain options ("keeping my mouth shut"). The systematic review highlights the:

- conflict between physician as advocate on behalf of the patient and also the steward of rationing resources (reconciling the physician as defense lawyer as well as judge),
- reluctance of allowing a 3rd party to interfere with the professional expertise of the treating physician,
- tension between what is in the best interest of the physician vs the patient (namely the impact of finances on the physician based on use of healthcare resources), and
- challenge of having to convey administrative decisions ("explain or justify decisions") from 3rd parties that deny access to a specific type or level of care.

There is a recognition of the need to ration but how to ration fairly and efficiently (Ubel cited by (Streich et al., 2008)). Rationing can be implicit (physician-directed) or explicit (directed by the funding 3rd party). Without clear and transparent established processes there is greater likelihood of unjust distribution of healthcare resources; with transparent processes trust "in the profession and their institution can be maintained" (Goold cited by Strech et al. (2008)). This type of approach will lessen the distress of the physician in not having to make implicit rationing decisions. Once clear guidelines are in place, deviation on a patient-specific level from the criterion will need to be defended through the use of scientific arguments.

The shift from volume to value in the U.S. healthcare system will help transfer over time greater accountability of delivering value at lower cost to those who deliver care to the patients. As stated by CMS (2015), The Medicare Access and CHIP (Children’s Health Insurance Program) Reauthorization Act of 2015 (MACRA) establishes The Quality Payment Program which has two tracks from which physicians can chose namely the Advanced Alternative Payment Models (APMs) or The Merit-based Incentive Payment System (MIPS). The highest financial loss for not meeting targets can be as much as 9% of Medicare payments in the form of
penalties and the upside can be 9% or more in the form of additional payments. The program is cost neutral which means the revenue of underperforming physicians will go down and the revenue of physicians who perform above the benchmark will increase by a proportional amount. MIPS will be assessed on four parameters: quality, improvement activities, advancing care information and cost; these will be weighted respectively at 50%, 15%, 25% and 10%. APMs is an alternative pathway to MIPS for more advanced provider groups that are able to pursue innovative payment models by taking on risk, delivering the highest quality standards of care and effectively coordinating care across multi-specialty groups. Eligible providers include Physicians, Physician Assistants (Physician Associates), Nurse Practitioners, Clinical Nurses, Specialists, and Certified Registered Nurse Anesthetists.

3.9 Pharmacists

In the U.S. healthcare system, there are approximately 300,000 pharmacists with approximately 230,000 practicing pharmacies in the community (retail) setting (Bureau of Labor Statistics, 2016). As of 2010, pharmacists in the U.S. need to complete a pharmacy doctoral program in addition to licensure requirements which include the North American Pharmacist Licensing Exam (focused on pharmacotherapy, therapeutic outcomes; preparing, distributing medications; optimizing the health of patients), the Multi-State Pharmacy Jurisprudence Exam (federal and state laws specific to the practice of pharmacy), and a State-specific Written and Practical exam (Become, 2017). Although there are a few exceptions, in the U.S., pharmacists do not have prescribing authority; although supported by pharmacy associations it is not endorsed by the American Medical Association (Scott, 2016).

As stated by the American Pharmacists Association (2017), pharmacists need to abide by the following ethical code of conduct:

- respect the covenantal relationship between the patient and pharmacist
- promote the good of every patient in a caring, compassionate, and confidential manner
• respect the autonomy and dignity of each patient
• act with honesty and integrity in professional relationships
• maintain professional competence
• respect the values and abilities of colleagues and other health professionals
• serve individual, community, and societal needs
• seek justice in the distribution of health resources

Independent pharmacists contact physicians on average 9.7 times per day; pharmacists interact with physicians and their office staff to request a brand to generic change (generic switch) on the patient’s prescription or a brand to brand change (therapeutic switch). In 2015, these requests were accepted 95% and 80% of the time, respectively (Leon Michos, 2016).

As discussed by Rutter and Newby (2014), pharmacists should assemble a personal formulary conducting their own research utilizing an evidence-based medicine framework and then identifying which medication might be best for a given patient. Although the concept is focused on non-prescription medications, the concept clearly underscores the importance of having a drug formulary that meets the needs of the individual patient based on the expertise of the healthcare professional. The approach of the pharmacist should be one that is based on independent assessment and evaluation focused on defining the patient’s medical concerns, goal of treatment, cataloguing available treatment options and then selecting the treatment choice best suited to the patient based on efficacy, safety, and cost.

Latif (2001) speaks to the community pharmacist in the retail setting as having an opportunity to improve patient outcomes by working closely with the patient and the patient’s physician to help inform and monitor the medication treatment strategy of the patient. This concept referred to as pharmaceutical care is part of many pharmacist professional societies credo but requires the employer of the pharmacist to move from a conceptual model to one that is practiced in the community pharmacy setting. Community pharmacists are affected by their employers’ operating environment and community pharmacists with longer years of service seem to have
lower capacity for ethical reasoning than those with less years of service (Latif, 2001). The pressure of filling a specific number of prescriptions per day limits the time the pharmacist has to interact with patients. This introduces ethical challenges for the pharmacist; as in the case of a non-compliant patient who perhaps would have been more compliant had they better understood how to manage the adverse events associated with a given medication or had the patient better understood the negative consequences of non-compliance (Stephanie Nam, 2016). Based on a 2014 National Pharmacist Workforce Survey, 66% of pharmacists identified their work volume as either high or excessively high; 45% reported that their work volume had either a negative or very negative effect on their well-being; lastly up to 68% of pharmacists working in a retail setting felt that their work volume had a negative or very negative effect on spending time with patients (Gaither et al., 2015).

There is a tension or balance that needs to be attained: loyalty as a virtue the pharmacist needs to consider as it relates to its employer vs the trustworthiness the pharmacist needs to have to the patient (Baker, 2013). Patients trust their pharmacists however the pharmacist’s employer requires prescriptions to be filled based on drug formulary rules that apply based on a patient’s pharmacy benefit plan. All community pharmacies operate under the same requirements.

As of December, 2013, Gallup asked consumers how they would rate the honesty and ethical standards of various professions in the United States (Gallup, 2013). Highest on the list were nurses with a rating of 82% receiving a designation of high or very high (other rating choices were average, low, very low). Pharmacists were 2\textsuperscript{nd} on the list with 70% and medical doctors were 4\textsuperscript{th} on the list with 69%. According to an article, (Lowery, 2013), the CEO of the National Association of Community Pharmacists, is quoted as saying, “The combination of their goodwill with consumers, extensive training, medication expertise, and easy accessibility has pharmacists perfectly positioned to play a larger role in the U.S. healthcare system.” The role of the pharmacist from the perspective of managed care is pivotal: pharmacists are prompted by the adjudication system to make an intervention on the prescription that was written by the treating physician to switch the patient to another option based on
an MCO’s formulary. The role of ethical standards and honesty can hence be attenuated given the operating environment within which the pharmacist operates without the patient fully understanding the driving forces that may be impacting on the pharmacist’s actions. This is an important element given the complex contractual environment in which pharmacists operate. There are a number of contractual arrangements that provide incentives to pharmacists that impact their compensation (revenue) based on the number of generics they dispense, or if they redirect a patient to a lower cost product, or if they complete a therapeutic switch (Schafermeyer, 1999). The actions pharmacists take are directed by the formulary requirements for a given patient that are set by the patient’s MCO; a given medication might be preferred by one MCO and non-preferred by another MCO. Hence all other aspects being the same, the only differential factor is the drug formulary access level provided by a specific MCO for a given patient.

The community pharmacist is the most accessible healthcare professional in the United States with 90% of Americans living within 5 miles of a pharmacy (Kelling, 2015). As stated by Farley et al. (2017) the improper or unnecessary use of medications leads to $300 billion in annual healthcare costs. This creates opportunities to further leverage the community pharmacist to become an integral member of the patient’s health team and improve outcomes through pharmaceutical care management. Farley speaks to one pilot project that was undertaken in North Carolina where pharmacists received additional remuneration for delivering a select set of services to prevent drug wastage, provide patient education and address proactively potential drug therapy-related problems. Additional payments were provided to pharmacists based on other quality measures such as improved adherence, reduced use of the emergency room and hospitalization, and lowered overall healthcare spend. As discussed by Trygstad (2017), the community pharmacist can easily become the glue that binds the system: patients see multiple physicians, receive multiple medications, and there is no single healthcare professional overseeing how the various medications are interacting with each other. The community pharmacist as an integrated member of the health team can help ensure that patients are understanding which medications are being taken for which
conditions and the importance of adherence to a given medication in achieving a specific outcome.

The State of North Carolina, which is the birthplace of the concept of pharmaceutical care, has created a new designation for the pharmacist: the Clinical Pharmacist Practitioner (CPP) designation enables the pharmacist to prescribe medications to the extent there is a written protocol from a supervising physician where the prescribing authority is defined. As licensed independent practitioners, the CPP’s role is to help manage a number of chronic care conditions including anticoagulation, diabetes, hypertension, and medication management for the complex patient. The challenge for CPPs is to establish a work flow in the community pharmacy store to enable these types of interactions and securing reimbursement of services from MCOs (Bush and Daniels, 2017).

3.10 Employees (Insured Members)

The results of a survey that was conducted with employees of a self-insured employer, a large university in Pennsylvania, showed that 44% to 48% of respondents indicated that their perceived understanding of prescription drug coverage was poor to fair with three-fourths of these responses stating their perception was fair (Miller and Desselle, 2005). Although all employees received written communication about their pharmacy benefits, only 64% to 66% indicated having received such information which underscores the difference between what is done by the employer vs what is the perception of the employee: a disconnect between reality and perception. The paper talks about the potential implications of employees making a poor selection choice of benefit coverage (lower premium that provides less coverage) due to a lack of information or understanding of the potential implications of their benefit choice; this can lead to access restrictions when care is needed that may negatively affect outcomes. The paper also highlights that the wording of benefit explanations may not be discernible to employees as reference materials tend to use language that may be confusing to the employee (“industry jargon”). It is important to note, that for this study, the majority of survey respondents were females, actively employed, who considered themselves in good or very good
health. One would surmise that females who participated in this study, who are better educated and compensated than the average American, would have a better chance of understanding the specifics of pharmacy benefits and yet even among this study cohort they were not that good. Below is a list of some of the questions to which the majority of respondents did not answer the question correctly:

- Generic drugs are not available until the original brand name comes off patent and cost less due to fewer research and advertising costs (48% answered correctly)
- I pay one price for generics, a higher price for brand name drugs on the preferred list, and an even higher price for brand name drugs not on the preferred list (24% answered correctly)
- A health insurance company often refers to a list of preferred drugs as a formulary hired by my insurance company (24% answered correctly)
- The list of preferred drugs is developed and maintained to ensure standard benefits, control costs and minimize premium increases, and ensure quality drug use (28% answered correctly)
- My employer pays the largest portion of the cost for most prescription drugs obtained through my prescription drug plan. (23% answered correctly)

The above findings are placed in further context by Williams et al. (1995); in their study where they found that 42% of patients surveyed did not understand instructions related to their medications and that 43% of survey patients had low levels of health literacy.

Korobkin (2013) speaks to neoclassic economics and how it identifies rational choice as one that seeks out an efficient trade-off in order to maximize subjective expected utility. However, consumers, will likely forego care when costs are higher than expected and patients are not proficient at identifying between high and low value services. Hence patients might not be adherent with a medication to save the cost of the prescription which will eventually lead to more expensive utilization of healthcare resources (additional physician visits; ER use): “most consumers, as boundedly
rational decision-makers, would be particularly bad at making efficient trade-offs when asked to make point-of-service medical care decisions”. In addition, less than 50% of medications prescribed by physicians to their patients have evidence on their efficacy and a significant number of clinical treatment guidelines are consensus driven and not based on scientific facts. Hence, contract terms between MCOs and their members are critical as they define coverage limits; if a medication is deemed medically necessary, a patient will be able to most likely gain access to the medication through an independent external review process, unless the contract excludes coverage. Insurers in concept however have a moral hazard to limit access to care once the insurance premium is collected as it allows them to retain more of the dollars which in turn impacts the bottom line.

There have been a number of studies that have shown the impact of pharmacy benefit design on patient use of medications. One such study by Huskamp et al. (2003) showed the effect of copay design changes of employers on utilization of medications by their employees in each of three classes: statins, proton pump inhibitors and ACEs. One employer studied changed plan design from a 1-tier plan (all covered lives paid the same copay irrespective of the medication) to a 3-tier design that had different copays for each of the three tiers; each of the tiers had higher copays than the 1-tier plan design ($7 vs $8, $15, and $30, respectively). Utilization patterns of Tier 3 drugs for this employer changed remarkably with many of the members switching to a medication with a lower copay (~42% of those taking ACEs, 35% of those taking proton-pump inhibitors, and 49% of those taking statins) as compared to the control group (~4%, 2%, and 17%). In addition, twice as many employees of this employer discontinued use of Tier 3 statins and ACE drugs, discontinuing use of drugs in the class, as compared to the control group.

In another similar study by Huskamp et al. (2005), an analysis showed that implementing a 3-tier drug formulary decreased the probability of using a given medication by 17% and that there was a decrease in total medication spend of 20% with significant cost-shifting to the patients’ families vs the MCO. The implications of cost-sharing is not insignificant, even for conditions that are typically considered life
or death, such as oncology where it has been shown that patients do not pick-up their medications at the pharmacy counter once they have been filled by the pharmacist (Streeter et al., 2011). The “abandonment rate” was different by almost a factor of 4 with 6.4% of patients not filling their Rx with copays of less than $100 as compared to 24.7% of patients not filling their Rx when their copays were $500 or more. A systematic review of the literature showed the implications of formularies on four different attributes including medication adherence, clinical parameters, system costs (economics) and healthcare resource utilization (Happe et al., 2014). As shown in the illustration below (Figure 3.12), the negative impact was greatest on adherence with the impact negative or neutral the majority of the time for the remaining three attributes measured. Of the studies identified through the SLR, relative to the types of drug formulary restrictions, 60.2% were through cost sharing, 21.5% through prior authorizations, 8.6% through step therapy, 7.5% through a preferred drug list, and 2.2% through quantity limits.

![Figure 3.12 Implications of formularies on patient outcomes stratified by types of outcomes. Adapted from Happe et al (2014).](image-url)
3.11 Conclusion

The U.S. healthcare system, similar to other markets around the world, sets parameters within which a physician can operate. Even though treating physicians are the scientific experts recognized by society as best understanding the clinical needs of their patients in their offices, access to prescription medications is impacted upon by MCOs through the use of formularies. MCOs do not know the patients personally; they are statistical references, however through the use of a variety of drug formulary techniques utilized by MCOs, the patient’s ability to access prescription medications is affected: namely the patient’s ability and willingness to pay for medications through cost-sharing, especially on the higher tier levels; as well as the requirements imposed on access through step edits and prior authorizations.

Physicians need to ensure that their trust with patients is protected; therefore, physicians need to take time to explain to their patients the choice of medication being recommended for treatment and how (if) the formulary has affected the choice of the prescribed medication. A complicating factor is the true net cost of a pharmaceutical product to the health system is not known by prescribers nor the other stakeholders with the exception of the MCO who has contractual relationships with the pharmaceutical manufacturers through which the acquisition cost of a medication can be significantly reduced. Hence even though cost-effectiveness is not included at the national level (for example, PCORI assesses comparative effectiveness only), medical societies such as the American College of Physicians (ACP) and the American Society of Clinical Oncology (ASCO) encourage their physician members to take cost to the patient into account when prescribing a medication. The additional complicating factor is that the cost to the patient for the same medication will vary depending on which MCO the patient is a member of; even within the same MCO there may be a difference in access levels to a given prescription medication based on the specific benefit design of a given plan.

Employers, who provide the bulk of medical and pharmaceutical coverage to the working class of Americans, ultimately decide which benefit plan they will make available to their employees which affects a given prescription medication’s formulary
status and the ability or the willingness of the patient to be able to then take the prescribed medication.

Employers, who are not scientific experts, with input from the MCO, ultimately determine the drug formulary for their employees. Physicians, pharmacists and insured members then need to assess the best possible prescription medication choice given the patient's medical status, characteristics and ease of access within a given formulary. Ultimately drug formularies affect clinical, humanistic and economic outcomes; not all patients with the same condition and the same patient characteristics will have equal access to FDA approved medicines. This is the challenge within society where allocation of resources needs to be in context of the financials as it pertains to employers, MCOs, physicians, pharmacists and insured members. In Chapters 5 and 6, the data collected through primary research will be presented and analyzed.

Comparative effectiveness research is a focus of the system to help identify medications that are most appropriate for treating the patient that is representative of the various clinical trials conducted by manufacturers to demonstrate the efficacy of its product in context of a specific treatment strategy. However patient uniqueness cannot be overlooked and to the extent a given patient is not representative of the study population the current system does not provide the same level of access as to the patient that is representative of the study population. For patients who are able to achieve the intended treatment objectives set in concert with their physicians at the lowest cost treatment option, these patients do not experience any inequities. Patients who need to pay additional out of pocket costs, patients who need to delay their treatment option because they either cannot afford the more expensive treatment (the MCO will not cover the product or the copay is too high) or because of the additional time delays imposed by MCOs until the Prior Auth is approved or the SE is satisfied, these patients will not be able to achieve their intended treatment goal.

From an act utilitarian perspective this does not maximize the good in a technical sense because not all patients are treated equally; the patients who are same in all
regards except for their physiology and how they respond to a given medication, will be potentially at a disadvantage. From a deontological perspective, the person who does not respond could be seen as a means to an end, as premiums are kept down by instituting greater out of pocket costs for more expensive medications or because certain medication access will be curtailed or slowed. From a virtue ethics perspective, the characteristics of the access decision-makers are focused on making the overall plan affordable to the insured members and maximizing profits for shareholders; recognizing that the system cannot always allow for the best medication to be accessed. The individual patient effect as a consequence of the drug formulary is not known to the MCO and employer access decision-maker; the patient is a faceless statistic and hence the decision-maker is able to reduce emotive-driven attributes such as kindness and benevolence. With regards to biomedical ethics: autonomy of decision-making is infringed when the patient is unable to access the medication he and the treating physician would prefer and recommend, respectively; beneficence may be compromised at the patient-level as the best care is not provided but at the population level at the same time beneficence is satisfied to the extent that the average patient is able to get the necessary care without incurring additional costs to the covered population; there is a degree of maleficence when a patient suffers worse health outcomes due to the lack of formulary access to prescription medications that is best suited to his specific medical needs at a given time; and hence justice could be seen as infringed upon as well at the patient level.

Prescription medication access is driven by a focus on the use of evidence-based medicine, and recognizing that employees will have access to medicines through formularies based on the value of the insurance purchased by their employers and the employees’ willingness to incur additional out of pocket costs above and beyond the cost of the premium. The U.S. healthcare system has not explicitly defined what is the minimum level of acceptable formulary access to prescription medications and the system does not require that patients who do not benefit from the lowest cost option to be allowed access to the more expensive medications at the lower cost level. Rather the system requires focused efforts from members of the community, including the physician leadership, to bring forward information to those individuals
who are able to make legislative changes or to put enough public pressure on decision-makers so that changes are made that protect or positively impact on the individual patient. The subsequent changes then affect the population at large. Distributive justice recognizes that patients get what they pay for; autonomy allows independent decision-making but there are economic consequences to the decisions made which hence informs the decisions taken. Physicians can only prescribe what patients can afford to fill, and given there is no acceptable minimum, the physician’s duty is to ensure the patient is well-informed, that the physician does not make a treatment strategy with the intention to have personal gain at the expense of the patient, and that the physician advocates on behalf of his patient to the best of his ability to prevent any maleficence.
Chapter 4: Materials, Methods and Data Analysis

4.1 Study Objective and Research Question

This chapter reviews the materials, methods and data analysis undertaken for this thesis. The study objective of this thesis is to develop a conceptual framework and substantive theory to help advance the use of ethics in community-based commercial drug formulary decision-making. The study objective is addressed through the following two-part research question: (1) What are the perspectives of the core decision-makers (Employer Benefit Design Decision-makers, Managed Care P&T Committee Members) and affected end-users (Community Practicing Physicians, Community Retail Pharmacists, Insured Members (employees)) as it relates to community-based commercial drug formulary decision-making?, and (2) What are the ethical implications of these identified perspectives? As a reminder to the reader, as discussed in the introduction to the thesis, the access decisions made by the MCO P&T Committee Members (MCOP&Ts) and the Employer Benefit Design Decision Makers (EBDDMs), collectively referred to as the Core Decision Makers (CDMs), impact upon Community Practicing Physicians, Community Retail Pharmacists and the Insured Members (Employees), collectively referred to as the Affected End Users (AEUs). For ease of reference, the term Professional Group will be used to identify collectively EBDDMs, MCOP&Ts, Community Practicing Physicians and Community Retail Pharmacists. The schematic below, Figure 4.1, restated from Chapter 1, helps visually show the groupings described above.
For specificity, the focus of the research is limited to insured members (employees) who receive their insurance coverage from their employers; although the findings as it relates to MCOs, community practicing physicians and community retail pharmacists could have applicability beyond the immediate focus of the thesis and extend to the broad U.S. population.

The sections within this chapter include content specific to materials & methods as it relates to the underlying research design and qualitative research method, data collection, data analysis, and the literature review that informed this thesis.

### 4.2 Research Paradigm and Methodology

Lever (2013) speaks to the point that a strong research design needs to be based on a paradigm that is aligned to the researcher’s perspective with regards to the nature of reality. A paradigm can be considered a set of beliefs or worldview by which one interprets the world around them (Kivunja and Kuyini, 2017). Three aspects are highlighted as it relates to a given paradigm, namely, epistemology (how one acquires knowledge), ontology (how one defines reality), and methodology (research design and methods). For purposes of this thesis, the following paradigms were considered by the PhD Researcher: positivist/post-positivist, constructivist (interpretivist), and critical (transformative).
The positivist paradigm, as discussed by Kivunja and Kuyini (2017) and (Denzin and Lincoln, 1994, pp. 105-117), is a scientific approach to inquiry that attempts to ascertain cause and effect, based on interpretations of measurable data points and facts. This paradigm centers around hypothesis verification and arrives at conclusions through deductive logic and mathematical formulas, identifying factors that impact outcomes and have predictive power. As it relates to epistemology, positivism is based on objectivity and the methodology is that of quantitative experimental designs. In this paradigm of naïve realism, the researcher is able to undertake the study without being influenced by the object of the study or influencing the object of the study. A derivative of the positivist paradigm is the post-positivist paradigm (critical realism), where the researcher looks to understand the perspective of the study participants to gain an understanding of their actions. There is recognition that unlike the natural sciences, the social sciences are not void of values which are subjective and therefore reality can only be approximated and not fully known; however as it relates to epistemology, objectivity of the researcher is attempted to be maintained and methodology can be qualitative with a recognition that the hypothesis is not absolute but fallible.

The constructivist (interpretivist) paradigm as discussed by Kivunja and Kuyini, is designed to understand the perspectives of the study participants based on their experiences (expertise) relative to the study question. It relies on interpretation of the findings through the lens of the researcher; there is not one reality but rather multiple realities that emerge through the interaction of the researcher and the study participants; however it is important to ensure the perspectives of the study participants are well understood. As it relates to epistemology, the constructivist (interpretivist) paradigm is based on subjectivity and the methodology is naturalist (data gathered through interviews with the researcher being a participant observer). Distinctions can be made between interpretivism and
constructivism. Although both paradigms adhere to a subjectivist epistemology, ontologically, interpretivism can be considered relativist and constructivism can be considered critical realist. Constructivism acknowledges that the findings are constructs of the interaction of the researcher and the participants relative to their social situation; in comparison, interpretivism constructs emerge from the researcher interpreting the data (Levers, 2013).

- The critical (transformative) paradigm focuses on the social sciences and deals with concepts that relate to oppression and democracy, looking to create change as it relates to social justice. Critical paradigm examines the social interactions between the various stakeholders involved in a given study (Bohman, 2005). Knowledge is taken to be historical in nature and informed by human interests which are varied, exposing underlying problems of established aspects in society to aid the oppressed (Friesen, 2008). As mentioned by Kivunja, as it relates to epistemology it is transactional and the methodology is dialogic.

The constructivist paradigm most completely reflected the PhD Researcher's worldview and hence was the underpinning for the research methodology chosen.

Grounded Theory (GT) was selected as the research methodology given the study objective was to develop a conceptual framework and substantive theory to help advance the use of ethics in community-based commercial drug formulary decision-making in the U.S. healthcare system due to the lack of research in this area. The use of GT by the PhD Researcher was to uncover the various stakeholders’ perspective as it relates to access-related decision-making; how the perspectives of each stakeholder intersect with each other and the resultant implications of the application of ethical theories to drug formularies (utilization controls) and overall access to prescription medications. GT is the most popular qualitative method within healthcare research when the researcher is looking to understand data inductively.
and looking to postulate how concepts interrelate for a given topic on multiple levels hence developing an emerging theory (Morse et al., 2009). GT enables the researcher to capture the perspectives of the various involved stakeholders as it relates to a topic not previously studied (Foley and Timonen, 2015). It is important to start with no theory and hypothesis, while maintaining flexibility in the research approach (Lawrence and Tar, 2013).

GT has different meanings to different researchers and can be interpreted as a research methodology or a research method (Walsh et al., 2015). As discussed by Walsh, GT addresses not only the process by which research is undertaken, it also speaks to the output of the research which is a theory based on the data uncovered through the research itself. It is a research method that facilitates discovery through the data collection and analysis process which in turn produces patterns of data that informs the development of a conceptual framework and substantive theory. Different variations of GT, however, have different philosophical underpinnings.

As discussed by Fernandez (2012), the first variant of GT was brought forward by Glaser in 1965 and Glaser and Strauss in 1967; this initial variant, which is referred to as Classical Grounded Theory (CGT), was then modified by Strauss and Corbin (initially known as qualitative data analysis but eventually referred to as Straussian Grounded Theory, SGT). Two additional variations of GT, identified by Fernandez, was Feminist Grounded Theory and Constructivist Grounded Theory (developed by Wuest and Charmaz, respectively). Feminist Grounded Theory was developed for research in the nursing profession to elevate the voice of the female healthcare professional in a male-dominated healthcare environment (Wuest, 1995) and is outside the scope of this thesis; it is only mentioned here for completeness.

It is important to note that there are aspects across CGT, SGT and Charmaz’s Constructivist GT that converge as well as elements that diverge (Kenny and Fourie, 2015). All GT approaches ascribe to theoretical sampling, data saturation, constant comparisons, memoing and substantive theories. The point of divergence in these three approaches to GT are around coding, their perspectives on the research
paradigm (positivist, post-positivist and constructionivist, respectively) and the use of literature.

Glaser’s CGT postulates that data solely drives the emergence of categories, inductively derived from the data; whereas SGT postulates the emergence of categories during theoretical sensitivity in part informed by the researcher’s perspective and experience. (Kelle, 2007); (Gentles et al., 2014). As noted above, the objectivist (positivist /post-positivist) view stipulates that there is an absolute truth that will be discovered through the research process. It assumes there will be no bias on the part of the researcher and a theory will be discovered purely on the discovered facts (Taghipour, 2014). A post-positivist approach is aligned with the methodology of CGT. In contrast, the interpretivist view believes that the findings are subjective based on the experiences of the various stakeholders relative to their own realities, thereby, the findings are interpreted by the researcher through the construction of the stakeholder perspectives as it relates to their personal experiences. This is reflective of SGT.

The PhD Researcher used the GT methodology that is described by Charmaz which recognizes that the PhD Researcher’s interpretation of the data is part of the findings and conclusions and not separate from the interpretation (Charmaz, 2014, p. 239). This approach is considered constructivist, looking for interpretations of the data, putting the data together, in an iterative approach, to fit into an overall arching framework rather than just reporting on the data (Furniss et al., 2011). Additionally, the coding approach described by Charmaz provided enough descriptive guidance to the PhD Researcher, as opposed to CGT were there was not enough guidance. Charmaz utilizes initial and focused coding as opposed to SGT which utilizes open, axial and selective stages of coding; the latter coding approach is very prescriptive and additionally doesn’t consider that the researcher is part of the co-construction of the codes. Adopting an SGT approach would have potentially limited the creativity of the PhD Researcher to assimilate the data and identify the emergent codes and categories.
A two-step process was undertaken. Firstly, analysis of the perspectives of the CDMs and AEUAs as it relates to community-based commercial drug formulary decision-making in the context of ethical theories and principles was undertaken to inform the development of a conceptual framework. Secondly, a literature review informed by the conceptual framework led to the development of a substantive theory. As described by Charmaz (2006, p. 166) undertaking a literature review after completing analysis of the primary research strengthens the findings of the research and the credibility of the researcher. The specifics of the literature review is discussed in more detail in Section 4.6.

Other research approaches that were considered but not utilized in this thesis are the following:

- Thematic analysis is a tool to help identify patterns that are contained within the data as it relates to a specific phenomenon. Thematic analysis can then be applied in different research methods (Braun, 2006). Thematic analysis is an approach that enables the generation of a list of themes that tells a story (Braun et al., 2014, pp. 95-114). Elements of thematic analysis are encompassed within GT regarding the basic principles of coding and categorising, however, GT involves a more inductive systematic approach to coding and categorising leading to the development of a theory.

- Interpretative Phenomenological Analysis (IPA), focuses on analyzing study participants life experiences specific to the research question being studied (Callary et al., 2015). IPA is the study of phenomenology through hermeneutics (interpretation) as it relates to understanding how things appear to individuals through their personal lived experiences; the researcher tries to understand the experience from the perspective of the individual study participants through discovery and analysis of single cases in their unique context known as idiography (Pietkiewicz and Smith, 2014). IPA was not used by the PhD Researcher as the study was not focused on shared life experiences.
Critical discourse analysis is the analysis of text (written or spoken; read or heard) and how it applies in various social contexts (Miller, 1997). Given the emphasis of this type of analysis is on language and communication (Fairclough et al., 2011), it was deemed by the PhD Researcher to not be relevant to the topic of this thesis.

4.3 Data Collection

4.3.1 Recruitment & Research Format

The PhD Researcher’s employer provided access to a panel of research participants specific to the Professional Group. From this panel the PhD Researcher was able to select study participants who had interest in participating in a discussion on the topic of the research that matched the inclusion criteria specified by the PhD Researcher. The research with the Professional Group was double-blinded by design (1:1 phone-based interviews) as detailed in the approved IRB (internal review board) application. Double blinding ensured that study participants spoke more freely about their perspectives and business practices; given anonymity provided by double blinding, study participants were able to speak more freely about their daily experiences in their respective professions without concern for making compromising statements that would be traceable to a specific event, patient or company. Insured Members were not double-blinded given by definition the format of focus groups cannot be double-blinded (also for this study, the PhD Researcher was the moderator of the focus group). Also the participants of the focus groups were from the PhD Researcher’s employer and hence were part of the same industry (pharmaceutical industry). The PhD Researcher recognizes that having focus group participants from only the pharmaceutical industry potentially biases responses for this particular stakeholder group but the Insured Members stakeholder group was not the focus of the thesis rather it was included for comprehensiveness (completeness). At the same time, all employees of any employer are equally affected by their employer’s decision around drug formularies and to that extent, the focus groups included in this thesis are representative of employees in general. Additional details for the Professional Group and Insured Members are provided below.
4.3.2 EBDDM, MCOP&T, Community Practicing Physician and Community Retail Pharmacist Study Participants (Professional Group)

One-on-one phone interviews were conducted with study participants who were identified through the use of a 3rd party based on the study inclusion criteria. The 3rd party contacted, by email, study participants who met the screening criteria, and gained their consent to participate in the research. Upon receiving consent to participate, study participants received a copy of the study materials through the 3rd party which included a brief overview of ethical theories and principles applicable to the research, the discussion guide, and case studies (included in Appendix B, C, and D). Each participant was assigned a tracking code: the code identified the type of stakeholder (MCOP&T, EBBDM, Community Practicing Physician and Community Retail Pharmacist) and a sequential number starting with the number 01, which indicated their position in the interview queue within the given stakeholder type. This allowed the PhD Researcher to match a given study participant’s response with his or her professional profile (basic non-identifying descriptive profile relative to the study participant’s profession); no personal identifying information of the study participant was made available to the PhD Researcher. Once a study participant consented to the study, the 3rd party set-up a calendar invite for both the PhD Researcher and the study participant. The study participant and PhD Researcher called a toll-free conference call-in number at the scheduled time and the interview was recorded. The study participant was reminded through a pre-recorded prompt at the beginning of the call that the interview was being recorded. Study participants had the ability to terminate their participation at any point during the interview; all study participants completed the phone interviews in their entirety. Phone interviews lasted between 90 minutes to approximately 2 hours. All phone interviews were completed within 6 months of IRB approval.

4.3.3 Employees (Insured Members)

To gain a glimpse of the perspective of Insured Members, employees of a mid-sized pharmaceutical company based in Illinois were invited to participate in a focus group. The PhD researcher recognizes this might have introduced bias into the responses of
the focus group participants given the participants were employees of a pharmaceutical company however the implications of drug formulary coverage, from the perspective of the PhD Researcher, still equally affect all employees irrespective of the industry represented. Engaging with the PhD Researcher’s employer’s employees enabled the PhD Researcher from a logistics perspective to gain access to a group of Insured Members including a location to host the focus groups and allow for the discussions to be recorded. Two separate focus groups were held on August 29th and Sept 2nd, 2014. The focus groups were approximately 2 hours in duration and were recorded (participants consented to the recordings); focus groups were held at the end of the work day. Focus group attendees were invited by a colleague of the PhD Researcher who worked for the same pharmaceutical company. The PhD Researcher requested the colleague to invite a number of participants; these participants were invited by the colleague and the names of the participants were not known to the PhD Researcher until the attendees accepted the invitation to participate. This approach was taken to ensure invitees did not feel compelled or obligated to participate in the focus groups, which might have been the case if the PhD Researcher had extended the invitation directly. The colleague who extended the invitation to the focus group attendees did not participate in the focus groups.

Below, in Table 4.1, is a summary of the stakeholders interviewed to complete the primary research that informed the writing of this thesis.
Table 4.1 Summary of stakeholders interviewed to complete primary research

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Type of Interview</th>
<th>Number completed</th>
<th>Relevance to the drug formulary</th>
</tr>
</thead>
<tbody>
<tr>
<td>MCO P&amp;T Committee Member</td>
<td>1:1 Phone Interview</td>
<td>10</td>
<td>The committee member that makes the determination of what is included on a drug formulary and is considered by the employer to have the relevant expertise to make the determination.</td>
</tr>
<tr>
<td>Employer Benefit Design Decision-maker</td>
<td>1:1 Phone Interview</td>
<td>10</td>
<td>The person who works for the employer who has responsibility to make decisions on which MCO to contract and what type of benefits to offer to the employer’s employees including the specifics of the drug formulary.</td>
</tr>
<tr>
<td>Community Practicing Physician</td>
<td>1:1 Phone Interview</td>
<td>10</td>
<td>The medical professional who treats the insured member and will be affected by the patient’s drug formulary when making a decision on which medication to prescribe the patient.</td>
</tr>
<tr>
<td>Community Retail Pharmacist</td>
<td>1:1 Phone Interview</td>
<td>10</td>
<td>The healthcare professional (pharmacist) who fills the patient’s prescription at the community (retail) pharmacy.</td>
</tr>
<tr>
<td>Insured Members (Employees)</td>
<td>Focus Group</td>
<td>2 Focus Groups (N=6, N=5)</td>
<td>The employee whose drug formulary coverage will determine the patient’s out of pocket costs for filling a given prescription and whether the patient is able to get coverage for the prescription medication based on the MCO’s formulary utilization controls.</td>
</tr>
</tbody>
</table>

The research for this thesis was approved by the RCSI Research Ethics Committee (Applicant ID 000872b); a copy of which can be found in Appendix H.

4.3.4 Data Collection Tools

The discussion guide was designed to help uncover opinions and experiences of the study participants, to better understand the differences of the study participants’ perspectives of value drivers to help identify codes, categories and concepts by distilling the complexity of thoughts that surround the issues that were explored in the research. Given the complexity of ethics, qualitative interviews were used to help understand the why behind respondents answers (Langone, 2008).

In-depth interviews have been shown to be an effective method when dealing with subjective and emotive topics (Family Health International, ND). The PhD Researcher used an informal, friendly interview style to establish rapport, build trust
and create a safe environment for the study participants to offer their uncensored perspectives (Fontana and Frey, 1994). The use of 1:1 standardized open-ended interviews (phone-based) allowed for flexibility (probing further based on initial responses) to better understand interconnections of ideas and beliefs, enabling effective interpretation of facts and observations to generate insights in an effort to advance knowledge on the subject matter.

The discussion guide for use with the Professional Group consisted of a set of questions that covered a range of topics as it relates to ethics, morals and justice to help identify the perceptions of the study participants relative to ethical implications as it relates to access to prescription medications through the use of community-based commercial drug formularies by MCOs (utilization controls). There was also reference to four short case studies (vignettes) that covered off on each of the following: Smoking Cessation, Overactive Bladder, Prostate Cancer and Quality of Life. These were designed to allow the PhD Researcher to identify any additional insights as it relates to the research topic by humanizing the illustrative patient whose treatment is potentially affected through the use of drug formularies.

Most study participants commented on the thoroughness and comprehensiveness of the discussion guide and acknowledged that this was a topic that was not thought of in their everyday daily activities as it relates to drug formulary decision-making and that perhaps it should become more central to their way of thinking.

4.3.5 Study Sample Inclusion Criteria

Requirements for the Professional Group study participants to be included in the discussions were as follows: (1) EBDDMs who had responsibility within their organization in selecting the benefit plan and MCO that employees are provided that in turn determines drug formulary coverage levels to prescription medications and who have been in such roles for at least three years; (2) MCOP&Ts who had responsibility within their organization in selecting medicines on drug formularies and who have been in such roles for at least three years; (3) community practicing physicians who treated patients included in the case studies (specific to overactive bladder and prostate cancer) hence board certified internists or urologists who had active medical
practices (see at least 30 patients each week) and had practiced medicine for at least three years with at least 50% of their patients enrolled in MCOs; (4) pharmacists who were actively employed as community pharmacists for at least three years who filled and dispensed medications in a retail community setting. The insured members were employees at a major employer who had health insurance provided for them by their employer.

4.3.6 Study Sample Exclusion Criteria

Exclusion criteria by each stakeholder group were as follows:

- MCOP&Ts: who had less than three years of experience in the role to ensure participants have a significant level of experience and exposure to various prescription drug reviews to inform their perspective.
- EBDDMs: who had less than three years of experience in the role to ensure participants have a significant level of experience in selecting benefit plans and MCOs for employees.
- Physicians: who had less than three years of experience, were not board certified internists or urologists, did not have an active practice, who saw less than 30 patients per week, and who had less than 50% of their patients enrolled in managed care, to ensure physicians had a broad patient base and experience in utilization controls bestowed upon physicians, pharmacists and patients by MCOs in influencing prescription-related behaviour (writing, dispensing, filling respectively).
- Pharmacists: who had less than three years of experience as a community pharmacist in a retail setting involved in filling and dispensing medications to patients in the retail community setting to ensure pharmacists had experience in utilization controls bestowed upon pharmacists, physicians and patients by MCOs in influencing prescription behaviour.
4.3.7 Purposive and Theoretical Sampling

The sampling methodology was purposive in that the research participants included in the study either had extensive knowledge of how access to medicines is decided relative to their functional area of expertise, namely EBDDMs and MCOP&Ts (collectively referred to in this thesis as the CDMs); or how decisions affect the practice of medicine and the filling / dispensing / use of particular prescriptions (this group of stakeholders collectively referred to in this thesis as the AEUs). The study participants that comprised the Professional Group (EBDDMs, MCOP&Ts, Community Practicing Physicians and Community Retail Pharmacists) were selected based on specific experiences (also known as a critical case sample) and special expertise (also known as a key informant sample) (Marshall, 1996).

As discussed by Charmaz (2014), theoretical sampling was achieved through techniques that are consistent with GT methodology, namely constant comparison of codes and categories, memoing and moving across the various stakeholder groups included in this study to understand how patterns of data emerged from the analysis of the interviews and subsequently the literature review. These elements are more fully discussed in section 4.4.3 and Section 4.6. In addition, the diversity of stakeholders included in the Professional Group as well as the Insured Members (Employees) by which a variety of expertise were represented, and opinions and perspectives gathered, also enabled theoretical sampling (Starks and Trinidad, 2007).

4.3.8 Sample Size

The primary research (purposive in nature) conducted by the PhD Researcher is non-probabilistic (selection based on screening criteria within 5 stakeholder categories that are each, relative to themselves, homogeneous) to understand the majority of opinions on the issues of ethical constructs as it relates to the community-based commercial drug formulary decision-making process. Majority in this case is defined as 50% or more of the population having a specific perspective on the questions that were asked during the interviews. Hence, the probability of missing a particular theme as observed in the data would be 0.001 (DePaulo, 2000). In another study
done on reproductive health research in two countries in Africa that interviewed 60 women, 73% of all codes had been identified by the 6th interview and 94% of the high prevalence codes. The conclusion was that for homogenous groups a sample size of 6 would lead to development of meaningful themes and interpretations (Guest et al., 2006). Based on this statistic, an N of 10 was selected by the PhD Researcher to help ensure data saturation within any given category of stakeholders; although the concept of data saturation is not well understood and subjective (Mason, 2010).

4.4 Data Analysis

4.4.1 Transcription of recordings

Phone interviews and the focus group discussions were subsequently transcribed to ensure that insights are optimized (Charmaz, 2014, p. 136). Each wav file / transcribed word document included a unique identifier by stakeholder group which enabled the PhD Researcher to identify the stakeholder group (for example, the EBDDM) and the order in which that particular stakeholder was interviewed compared to others in the stakeholder group (01, 02, 03…). The PhD Researcher quality checked each transcription by listening to the wav file (utilizing the Express Scribe Transcription Software) and checking word for word the transcription document vs the wav file. Corrective changes were made in the transcribed word document as needed to ensure accuracy when compared to the wav file.

Once the PhD Researcher completed a quality control review of the transcripts, the transcripts were then loaded into NVivo 10 (later updated to NVivo 11) and coded (by line or by paragraph, based on the relevant content of the discussion); the emergence of higher order codes and categories were driven through the analysis of the narratives through use of memo-writing (Holton, 2007).

The PhD Researcher was self-aware that throughout the research process, the PhD Researcher was an active part of and interactive with the research data (Cutcliffe, 2000). Memoing, as explained below, helped with the reflexive aspect of the research analysis to help segment or separate the perspective of the researcher from
4.4.2 Reading of Transcribed Interviews / Interview Notes / Memoing

The PhD Researcher read each transcribed word document and corresponding notes (notes that were taken by the PhD Researcher during each interview). PhD Researcher prepared a summary memo of each interview to summarize top line the key points made by each study participant. This approach allowed for the PhD Researcher to have mastery of the research data and allow for complete immersion into the perspectives provided by the study participants that were interviewed. Memoing continued after coding was completed for a given study participant interview to enable deeper immersion into the data (Holton, 2007). Specific to data collection and analysis, theoretical sensitivity was undertaken by using gerunds and memoing as this approach takes the PhD Researcher from a static mindset to analysing actions (Charmaz, 2014, p. 245). Coding in gerunds is a process by which the researcher codes in words that are verbs ending in ‘ing’; this approach allows the researcher to think in terms of actions which allows the researcher to get closer to the data and its implications (Charmaz, 2014, p. 121). Theoretical sensitivity was also achieved by reading relevant literature which afforded the PhD Researcher the necessary background understanding of ethical theories and principles relevant to this thesis. The background literature related to ethical theories and principles as well as the professional and personal experience of the PhD Researcher, enabled the PhD Researcher to surface the prominent findings from the data, through analysis and interpretation (Straus and Corbin, 1990, p. 41).

4.4.3 Development of the Conceptual Framework: Coding of Primary Research Data and Data Analysis

NVivo (version 10, later upgraded to version 11) were used to analyse the study participant data.

As discussed in Section 4.2, the GT method utilized by the PhD Researcher was consistent with that of Charmaz’s approach to constructing GT. In the initial stage of
coding, over 500 codes were identified. During initial coding, the researcher studies data fragments which allows the researcher to move into an analytical mindset (Charmaz, 2014, Page 109). Charmaz (p.116), speaks to how the researcher is to ask questions such as:

- What is the data suggesting?
- From whose point of view?
- What categories are arising from the data?

Coding at this stage closely follows the data.

After the initial stage of coding was completed, the PHD Researcher in the second stage of coding identified higher level of codes, namely focused codes into which the initial codes were folded; reducing the total number of codes to fifteen. Focused codes brings the researcher deeper into the comparative process; categories in turn represent recurring themes and patterns. After further analysis, the codes were folded into four higher-level categories. This approach allowed the PHD Researcher to more completely assimilate the data and move from description to analysis. (Saldana, 2009, Page 11).

The conceptual framework that emerged based on the primary research with study participants described in this chapter is shown in Figure 4.2 below.

---

**Figure 4.2 Conceptual framework**
Population vs Patient-level Focus moderates Informed Decision-making which in turn mediates Drug Formularies and moderates Access to Rx Medicines. MCOs operate at the population level and not specific to any one patient. Hence drug formularies will provide a range of medications that will meet the needs of the average patient. For those patients that are not reflective of the average, their needs might not be effectively addressed through a given drug formulary. Hence informed decision-making in regards to the drug formulary is essential for not only the CDMs but also for the AEUs to ensure that there is an understanding of the implications of a given drug formulary not only as it relates to population-based outcomes but also to patient-specific outcomes. Drug formularies are a means to an end: they are designed to increase use of prescription medications that are less costly to the CDMs as well as to the patients. Drug formularies in turn ultimately impact on access to prescription medicines which is significantly impacted by the financials.

Through memoing, reflection on the initial and focused codes, and through diagramming, the PhD Researcher, constructed the conceptual framework from the data by being an interactive participant of the research, a foundational element of constructivist GT. As stated by (Charmaz, 2014, Page 239),

“a constructivist approach theorizes the interpretative work that research participants do, but also acknowledges that the resulting theory is an interpretation. The theory depends on the researcher’s view; it does not and cannot stand outside of it.”

The remainder of this section explains to the reader the steps the PhD Researcher undertook to construct the conceptual framework.

There were a number of focused codes under each of the four categories included in the conceptual framework shown in Figure 4.2. For example, under the category of “Access to Rx Medicines Impacted by the Financials”, there were a number of focused codes, namely:
• Encroaching on the physician’s judgement
• Overcoming access restrictions
• Reconciling business with need for providing care
• Taking a collaborative approach
• Working within the system

Under each focused code, there were a number of initial codes related to one another. For example, under the focused code of “Working within the system”, there were two initial codes namely,

• Dealing with reality
• Working within the constraints of the system

The two initial codes were comprised of text from the stakeholder interviews; for example, “Dealing with reality”, contains the following text from one of the stakeholders interviewed, EBDDM_02:

“I think that’s the reality side of our siloed health care system as opposed to the teamed approach. That’s the causality. That’s the Achilles heel, that’s the weakest link. That’s the downside of how our society in the U.S. treats an individual. It’s the hopefulness of being able to have the physician do what is appropriate for the patient layered then with the reality of what bounds them to not having access to that treatment plan."

“You know reality has to come into the discussion eventually. That’s the… the purest is the widest spectrum possible. And then from there you need to bring the focus more narrow which is how the health plan works. And then more narrowly the affordability of the patients with being successful to be able to pay for whatever they need to.”

A list of codes are included in Appendix F of this thesis.

For each transcript, the PhD Researcher read each line, sentence and paragraph, coding the content to best inform the analysis. As each line, sentence and paragraph was read, the PhD Researcher reviewed previously identified codes and assessed
whether the specific narrative being coded matched with any previous codes identified. The narrative was assigned to all relevant codes; in addition, new codes were created using gerunds to most effectively capture the content (description) of the narrative being coded. As text was read and coded, the PhD Researcher asked questions to help with the analysis; such as:

- What is the study participant saying?
- What assumptions are informing the study participant’s point of view?
- What is the rational the study participant is making?
- Are the points being made by the study participant surprising? Logical?

Coding was also done recognizing the four factors that play into the interactions of social life, namely who is involved (people), how they act (behaviour), where (place) and when (time) as pointed out by Lofland and Lofland (2006). An inductive approach was taken to develop conceptual categories (domains) using an interactive methodologic process (Charmaz, 2014). Charmaz views this as Grounded Theory study, namely, (1) collecting data, (2) analyzing data for actions and processes, (3) applying comparative methods, (4) drawing on narratives and descriptions to develop new concepts from the coding; and finally (5) developing inductive analytic categories through systematic data analysis. The comparison method, as mentioned above in (3), allows for the development of initial concepts which then can be tested further in follow-on research (Kolb, 2012). It moves the process from one that is descriptive to one that is analytic (Cho and Lee, 2014). Data saturation is purported to be achieved through this process as no new concepts become apparent (Jones and Alony, 2011).

Multiple codes (simultaneous nodes) were applied for a given portion of the narrative to ensure the analysis was complete and thorough. Overlapping codes (nodes) has allowed the PHD Researcher to understand the various dimensions of a given code (node). Saldana (2009), speaks of the point made by Miles and Huberman (1994), that simultaneous coding is appropriate when the text is rich in description and interpretative content.
For example, the following narrative (Figure 4.2 below) is from EBDDM_02 (Participant #2 in the EBDDM stakeholder group) when the question was asked of the ethical implications to pharmacists given formulary controls:

Based on that scenario if you can get a pharmacist who feels that they are passionate enough to work on behalf of the employee or the patient as well as take the initiative to contact the physician and be successful in actually speaking to the physician, to be able to do all of that, it’s almost like a utopian society. I think it’s absolutely wonderful. But in reality, I don’t think it ever happens. I think in reality if the pharmacist says, “oh, patient your co-pay is a 100 dollars.” And the patient says “I can’t afford that.” And the pharmacist says “well there is an equivalent at 20 dollars, would you like me to call your doctor to see if we can make that switch?” I think that’s absolutely wonderful. But it would be with a discussion first with the patient and then maybe that… or the pharmacist would say “oh well your doctor said this was the 100 dollar medication. But this medication is only 20.” You may wish to call your doctor and see if he will call me and switch your prescription” where the pharmacist won’t even make the call. The pharmacist will then enlighten the patient but then expect or encourage the patient to make the transfer.

The narrative as shown above was coded with each of the following gerunds:

- Acting responsibly (accountable)
- Acting on behalf of others
- Being informed
- Communicating information (options)

Each of the above codes in turn became part of higher order codes and categories as shown in Table 4.2 below.
<table>
<thead>
<tr>
<th>Initial Coding</th>
<th>Focused Coding</th>
<th>Categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acting responsibly (accountable)</td>
<td>Exercising fiduciary responsibility</td>
<td>Drug Formularies are a Means to an End</td>
</tr>
<tr>
<td>Acting on behalf of others</td>
<td>Overcoming access restrictions</td>
<td>Access to Rx Medicines Impacted by the Financials</td>
</tr>
<tr>
<td>Being informed</td>
<td>Enabling decision-making</td>
<td>Informed Decision-making Essential to Understanding Implications of Choice</td>
</tr>
<tr>
<td>Communicating information (options)</td>
<td>Enabling decision-making</td>
<td>Informed Decision-making Essential to Understanding Implications of Choice</td>
</tr>
</tbody>
</table>

Each of the above codes reflect a nuance to the emerging categories that informed the conceptual framework, which as shown above included “Drug formularies are a Means to an End”; “Access to Rx Medicines are Impacted by the Financials”; and “Informed Decision-making is Essential to Understanding Implications of Choice”. These codes highlight the fluidity and interactivity of the concepts that emerged from the data. This approach of identifying and comparing multiple codes allowed the PhD Researcher to let the concepts and dimensionality (inter-relatedness) emerge from the data (Bradley et al., 2007).

As described by the above-coded narrative from EBDDM_02, the two possible pathways that emerge at the pharmacy counter are “ideal” vs “less than ideal” as shown in the visual depiction below in Figure 4.3:
Upon further inspection of the initial code of *acting responsibly (accountable)*, the following aspects of the code emerged across the various stakeholders in the Professional Group:

- **Society defining a ceiling on healthcare spend (Physician_02)**
  - “So whether it’s again cost for society, cost for the patient, there’s always going to be a balancing act that has to be considered there. And to have no ceiling on how much you spend for health care, I think is... it would be irresponsible decision-making or an even unrealistic decision-making. To assume that... that health care cost will always be affordable and that everything else would have to be compromised to accommodate it.”

- **Patient having accountability for their choices (Pharmacist_05)**
  - “…because people make that choice. So you choose to not want to help yourself. This is what I mean, it’s expensive. Cigarettes are expensive. You can afford this if you really want to stop. Now who is to say down the line you know he might not have decided to do it but of course in this situation it was too late or he could be you know like my mother. Everybody smokes. The people who smoke that didn’t die. That’s the... those are the ones she identifies with. Not going to happen to me, mentality.”
• Employer taking on responsibility of benefit design (EBDDM_07)
  o “...I think that to the largest extent, the companies still self-define what that responsibility means. You know, are they going to pay for the stop-smoking drugs or are they going to pay for the lifestyle drugs? I think that sort of stuff is still well within the company’s discretion to accept responsibility for those things or to not accept that responsibility.”

• Physician’s role in impacting cost of care (MCOP&T_02)
  o “I really do believe that physicians do have a fiduciary responsibility to the cost of care. I mean, I think that in 2013, if you honestly believe that you are a free agent and don’t have any responsibility for the total cost of what you are doing, you shouldn’t be practicing medicine. I mean you are just in the wrong century. Well, I think that medical care, independent of drugs, medical care is incredibly expensive and for lots of reasons that it probably shouldn’t be. And physicians have not believed that they are responsible for the cost of care in some way, that it’s always somebody else that has that responsibility. Yet physicians actually are the ones that drive much of the cost because you know they order the tests.”

• Managed Care Organizations having many different responsibilities (MCOP&T_03):
  o “I think the best responsibility we have is to make sure they are cared for in a manner that's responsible and does no harm to them. We don't want to provide any therapy that's going to hurt them or stop them, on the path of getting better. That being said, we also have to pay the bills sort to speak and to keep the premiums down.”

By analyzing the various stakeholders around a given concept it creates a dimensionality around how a given concept is interpreted from different perspectives to understand where viewpoints converge, diverge or co-exist across a continuum; where there is alignment, divergence; where there is harmony of mindset vs tension. For the above stakeholder views, through constant comparison, the following aspects of insights surfaced as it relates to acting responsibly (accountable):
- System needs to define an upper limit on spending
- MCOs have to provide enough care to help patients improve outcomes
- Physicians have to consider cost when treating patients
- Employers need to ensure that once a certain benefit design is agreed to, that the expected level of coverage is satisfied for any given covered employee
- Patients have accountability of their outcomes based on the choices they make

In addition, for a given node, opposing perspectives were coded to the same node. For example, working as a team: lines of text would be coded to this node if there was a statement by the study participant relating to teamwork, either the absence or presence of teamwork, the pro or con of teamwork and the subsequent implications on outcomes.

- Example where there seems to be an absence of teamwork (Pharmacist_03)
  “…the doctor refused to come to the telephone. It took three hours for the nurse practitioner to come to the phone and she was upset that I was calling her and I had to wait on the phone for four minutes. The bottom line was that it was not a good conversation…”

- Example that underscores the importance of teamwork (MCOP&T_03)
  “That's a very tough mind set to try and convince patients that we are all in this together. We need to be lowering health costs together.”

- Example that addresses the potential benefits of teamwork (Pharmacist_09)
  “And it would be beneficial in my opinion to be able to work in conjunction with the physician in terms of his assessment diagnostic capabilities to be able to assist the physician in prescribing optimum therapy for that patient. That at this time does not exist.”

Given the research methodology utilized, the PhD Researcher was the central agent throughout the process; a highly interactive engagement between the data and the PhD Researcher, requiring immersion into the data, using rigor and consistency of methodology (Lofland and Lofland, 2006). As stated in Lofland et al, the PhD
Researcher maintained an open-mind approach as the data was reviewed and analyzed, thinking through various diagrams until the findings most effectively fit the analytic findings derived from the data. The concept of abduction, as described by Jo (2009) “a cerebral process, an intellectual act, a mental leap, that brings together things which one had never associated with one another: A cognitive logic of discovery”, was in play given the inevitable blend between the data findings and the working knowledge of the PhD Researcher as it relates to the two-part research question; the PHD Researcher making inferences and then rechecking the inferences against the available data from the study participants. This approach is discussed by Pidgeon, Peirce and Henwood (Timmermans and Tavory, 2012) and also addressed by Charmaz (2012).

4.5 Literature Review

The PHD Researcher accessed PubMed, Web Science, Google Scholar and a number of specific journals on ethics, such as Cambridge Quarterly of Healthcare Ethics, The American Journal of Bioethics, and the Kennedy Institute of Ethics Journal. Google Scholar was also used by the PhD Researcher as it is an effective resource to supplement traditional systematic literature reviews and is effective at finding specific references (Haddaway et al., 2015).

Relevant search terms were used to find publications that corresponded to the four categories identified through GT and the ethical theories and principles discussed in Chapter 2, namely, deontology, utilitarianism, virtue ethics and biomedical ethics (autonomy, beneficence, maleficence, justice). For ease of reference the four categories are restated below:

- Access to Rx Medicines Impacted by the Financials
- Drug Formularies are a Means to an End
- Informed Decision-making Essential to Understanding Implications of Choice
- Population vs Patient Level Care are not Necessarily Reconcilable
The PhD Researcher also applied backward snowballing; based on the findings of Jalali and Wohlin (2012), there were no material differences in the results of the findings when backward snowballing was utilized vs methods consistent with systematic literature reviews. Forward referencing was also leveraged where applicable, to identify newer, relevant papers that cite papers already identified as a relevant source (Wohlin, 2014).

An illustrative example of backward snowballing in Figure 4.5 is shown below using one of the reference papers from this thesis:

Figure 4.5  Backward snowballing

All bibliographic references were stored in EndNote X7. A complete list of search terms can be found in Appendix G.

Constant comparison between the categories, focused codes, and initial codes with the relevant literature, allowed the PhD Researcher to identify the concepts as shown in Figure 4.7 which led to the substantiated theory that is discussed in detail in Chapter 6.
Figure 4.6 Concepts that emerged through constant comparison between coding and literature
As an example, the category of “Informed Decision-making Essential to Understanding Implications of Choice” included four focused codes, namely, enabling decision-making, setting parameters to inform access decisions, understanding the trade-offs, and utilizing evidence to inform decision-making. As the literature search was then conducted relative to these codes and the ethical theories and principles discussed in Chapter 2, the PhD Researcher identified four relevant concepts, namely trusting in the recommendation of experts, understanding consequences of purchase, patients ultimately accountable for their health and in making treatment choices, and a team-based approach improves healthcare outcomes.

4.6 Conclusion

The approach of Grounded Theory utilized by the PhD researcher will allow for the development of a construct that offers CDMs (Core Decision-makers) and AEUs (Affected End-users) to more effectively discuss and understand consequences of allocating healthcare resources as it relates to access to medicines, namely prescription medications through the commercial drug formulary in the community setting. The approach provides a critical review of the findings based on primary and secondary research across all included stakeholders that are represented in this thesis. Although the focus of the research is specific to insured lives who receive their coverage from their employer, the findings may have applicability beyond this segment of the population, including their treating physicians and community pharmacists.

Different qualitative approaches could have been utilized by the PhD Researcher (for example thematic analysis) but Grounded Theory was chosen because the PhD Research wanted to develop a conceptual framework and substantive theory that could be used by other researchers to assess the potential to help bring together into a single focus how the various ethical frameworks and principles converge or diverge on the research topic. The end objective of this thesis is to ensure that ethics and principles become more visible in the overall decision-making process as it relates to prescription medications and the commercial drug formulary in the community-setting.
Chapter 5: Stakeholder Perspectives from the Primary Research

This chapter focuses on summarizing the perspectives of the stakeholders that participated in the primary research of this thesis. The critical analysis of the perspectives summarized in this chapter will be provided in Chapter 6. The summary of the perspectives are provided by stakeholder, firstly that of the Professional Group, followed by the Employees (Insured Members). The findings are presented under the four categories that formed the conceptual framework and emerged from these interviews (see section 4.4.3).

5.1 Findings from the Professional Stakeholder Group Interviews

The professional group for the reference of the reader, as stated earlier in this thesis, includes the following stakeholders:

- EBDDMs: Employer Benefit Design Decision-makers,
- MCOP&Ts: Managed Care Organization P&T Committee Members,
- Community Practicing Physicians, and
- Community Retail Pharmacists

Case Study findings (Smoking Cessation, Overactive Bladder, Prostate Cancer, Quality of Life) are summarized separately in Appendix E for each of the stakeholders included in the Professional Group (EBDDMs; MCOP&Ts; Community Practicing Physicians; Community Retail Pharmacists).

The conceptual framework that was developed by the PhD Researcher, which is restated below in Figure 5.1, will be used as an operational framework to review the perspectives provided by the Professional Group.
5.2 Access to Rx Medicines Impacted by the Financials

5.2.1 Access to Rx Medicines Impacted by the Financials: Findings associated with interviews conducted with EBDDMs

The employer’s first commitment was to the business; if the business overspent on healthcare and went out of business, no one would be employed. In some cases the rationale for coverage decisions were more obvious than in other cases, but in all cases there was a need for the EBDDM to be an advocate to help bring forward a point of view with their management and gain consensus on a decision. The ability of the EBDDM to influence and communicate with their management team was recognized as a major determinant in the benefit offerings that were ultimately approved by leadership and made available to employees. There was also a need to educate the decision-makers so they understood the consequences of their decisions.

“Education is, you know, one of those barriers and so on. When we’re designing plans, we have to keep this in mind, you know, what’s fair, what’s justice. You don’t want to put unnecessary barriers which would be easy to do obviously. There’s, you know, various thoughts about how much the co-pays and deductibles could be before employees just can’t afford to go.” (EBDDM_7)

EBDDMs recognized that their responsibility was to represent firstly the best interests of the employer and achieving corporate objectives but at the same time to be
advocates for the employees; however being an employee advocate can lead to friction between the EBDDM and senior management. The EBDDM needed to understand the strategies within the culture of the business, and then work within those boundaries but yet remaining flexible as the internal and external factors that affected decision-making changed over time.

Ultimately, for the most part, decisions came down to the finances of the employer. Ethics were trumped by economics, in that if the employer could not afford a certain level of access for its employees, there was nothing that could be done.

“...you can't give everything to everybody in the medical side. You’ve got to say, “You’re right, this is too expensive. I’m not going to do it. And too expensive, you know, that’s different for each company and each person. You know, you’re not going to take an action if you cannot afford it. What can you afford? And medical is just one part of the business. You’ve got all sorts of considerations for your company. You’ve got salaries, you’ve got expenses, you’ve got a hundred different inputs. And medical is one of your expenses. So, what are you willing to spend in that area? That thing has to drive the ethics decision. It almost doesn’t matter. If you can’t afford it and it’s the right thing to do. You can’t afford it!” (EBDDM_3)

There was mention that there should be a balance between taking care of the employee without overstepping fiduciary responsibility to the shareholders; that providing more generous benefits requires the employer to forgo a portion of the profits; this was referred to by one EBDDM as an example of virtuous behavior.

“...you want to help your employees, you want to do what’s best for them, you don’t want to go overboard to the point where you can’t run your business because you’re spending too much on salaries and benefits. The virtuous thing is to find what’s best for the employees. And I even have to temper that a little with what’s best for shareholders since most companies are public. And most, their mission is to maximize profits. And so, at the same time you want to do that with the workforce. You treat fairly, even generously. And to me the virtue is to give up some of the profits to benefit the employees. But not so much that you bankrupt the company or make the shareholders really angry at you.” (EBDDM_3)

Employers looked to lower the overall cost of coverage and despite decisions being made with the best of intentions it was recognized there may be consequences to a given individual based on the specific situation of that insured member. It was understood that coverage decisions of an employer to its employees could change
over time based on economic (market) conditions, benchmarking to the peer group or
the evolving perspective (culture) of the employer in terms of the openness or
restrictiveness of benefits to be provided. The willingness of the employee to opt for
a more or less rich benefit plan (based on willingness to pay more or less premium
dollars) could also change over time.

The culture of the employer determined to what extent coverage was marginal,
moderate or generous. The brand name of the corporation was recognized to
symbolize the culture of the organization and the degree to which the employer was
willing to do right by its employees; to go beyond the coverage policies that were
established by the employer at the beginning of the year based on (real world)
personal experiences of employees under the policies that were set. It was
recognized that different employers would react differently to employees’ experiences
under the plan that was being provided by the employer to the employee.

In addition, the employer’s sophistication on how to make coverage-related decisions
varied. Employers almost always benchmarked coverage decisions; employers
based their decisions on what other employers were doing; their decisions on
coverage were based on whether they wanted to be below, at or above the
benchmarking average. Benchmarking was done specific to industry segments and
geography. Namely employers looked to compare themselves to similar employers
(within the same industry, for example, healthcare or financial or automotive; also is
the company located in the northeast or west coast or is it national with employees
across the country).

EBDDMs believed they had a fiduciary responsibility to their employer and hence
needed to effectively make the business case for a specific benefit design and level
of coverage. Ultimately the EBDDM needed to make the business case to their
senior leadership on the benefits to be provided by the employer to the employee.
The ability of the EBDDM to understand their senior leadership’s decision-making
style, the ability of the EBDDM to effectively communicate the business rationale for a
given coverage level (benefit), determined ultimately the benefits that were put in
place for a given year.
Different employers decided to provide varying types of coverage based on their culture and financial constraints; hence two employees with the exact same condition may have different levels of coverage from two separate employers. There is for the most part awareness in society that two identical patients who are being seen by two different physicians may experience a number of different steps in diagnosis and treatment based on the perspective of the treating physician, but there is less explicit realization by society that all else being equal, two insured members may have different outcomes because of the different types of coverage provided by two different employers. The perspective of the EBDDMs were less concerned with the morality of coverage decisions and rather the outcome of decisions being cost-effective. However, there was reference to the point that decisions around cost should reflect the total cost of care including productivity and not just a portion of the healthcare cost.

“Well... first, examine your denials, your exclusions, why you’re excluding them? Do you know that there is a real cost... You can’t just compare the medical spend. What if it costs to hire a temp when somebody is out sick? That’s a real expense. But if you can just say here’s what it costs me today, and without looking at those other expenses, you’re missing the point.” (EBDDM_3)

For the most part employers voiced the opinion that they paid their employees for work rendered; there was no perceived loyalty in the employer-employee relationship; not like what was present in Corporate America in the mid and late 20th century. The point was also made that providing benefits was a contract that both the employer and employee consented to once they agreed to participate in a particular plan; hence post enrollment, decision-making was less about morality and more about satisfying the terms of the contractual agreement.

In summary, employers’ decisions are less about morality and more about cost-effectiveness; once a contract is signed for the given year, decisions become about adhering to the terms of the given contract. What level of benefit coverage is ultimately chosen by the employer will be determined by the finances of the employer but also the culture of the employer, what other similar employers are doing in terms of coverage level and the ability of the EBDDM to impact on the ultimate decision
taken by the employer’s leadership team. EBDDMs need to influence and communicate with their management team to gain endorsement of the health plan benefit design and the specific MCO that will be providing access to care and more specifically access to Rx medications. The employer will need to understand the consequences of actions taken in terms of the impact of the level of coverage on any given employee; however, the trade-offs considered are limited ultimately by what the employer can afford which may in turn negatively affect any given patient based on his or her own personal situation.

5.2.2 Access to Rx Medicines Impacted by the Financials:
Findings associated with interviews conducted with MCOP&Ts

The MCOP&T spoke of the potential for vigorous discussions that can take place within the formulary committee given there can be a difference of opinion from one committee physician to another; a P&T committee is a forum where differences of opinions could be discussed. The overarching criteria for formulary decision-making for the committee, as representatives of the network, was identified as efficacy, safety and cost as it related to the population at large and was considered an obligation of the committee:

“One of the things that I have to remind our P&T committee is as a peer committee, they are essentially making decisions about drugs and access to those drugs for the members. And they are making that for the network. So as representatives, as existential representatives of the network, they have that burden and obligation to make sure that the formulary that we put out is the most efficacious for the most people within the context of efficacy, safety and cost.” (MCOP&T_02)

One MCOP&T raised the point regarding the importance of needing to advocate for what the MCOP&T believed was important in terms of access to a specific medicine on formulary; the MCOP&T needed to be willing to fight for what they believed in, recognizing that others around the table would potentially disagree. This point surfaced relative to the Quality of Life Case Study.
“That's probably the first reason I ever began drinking scotch. Was over that question. Many days I would come home from a P&T meeting wondering why everyone couldn't see the things the same way I saw them. But I did have great respect for the gentlemen I worked with who don't share my point of view, but are great at managing cost. So I guess we kind of balance each other out and I'm proud to work with them. But I'm not always proud of the things they say. So I'm kind of like a buffer there and I try and… there are several of us who redirect back onto away from numbers, more to the patients; it is kind of a battle. And that's probably a sign of a good P&T committee. Is that you have all those points of views into play. And it's very important there's not one bully in the mix who wants always to force their way through. It is a give and take, I'm never happy about any give and take that involves compromising patient care. So again when we see this case study and talk about definite proof there's quality of life being changed, I fight very hard to make sure we are aware of that and we try and act on that.” (MCOP&T_03)

However, from a Quality of Life mindset, and the potential of how access to medicines could interfere in helping a patient recognize their full potential, another MCOP&T study participant felt that was not in scope for a P&T Committee as it related to ethics: “I think quality-of-life is too vague and if the P&T committees get into this aspect now they are practicing ethics and that isn’t the purpose of the P&T committee.” (MCOP&T_06)

One MCOP&T study participant acknowledged the importance of the EBDDM being knowledgeable and negotiating diligently to attain the most value for insured members through the plans contracted for; another MCOP&T spoke of the distrust that exists among employers as it relates to the healthcare system: “many employers see the healthcare system as a root of evil and it's a profit-driven system that often doesn’t do the right thing and there is a role for oversight”. (MCOP&T_06).

It was recognized by MCOP&Ts that the employer paid for the bulk of the premium, the MCO then administered the plan according to the terms of the policy and the physician then had to accept the terms of the plan that were in place for a specific patient. One of the MCOP&T study participants made reference to a paper by Peters and Rogers (1994) which analyzed approvals and denials of treatment coverage for patients with breast cancer. The MCOP&T highlighted from his experience the difference in approvals was not arbitrary per se but reflected the variation in expert opinion based on which outside expert was involved in the review of the case.
Insured members believed their own physicians were right in the recommended treatment plans and hence it was difficult to convince an insured member that their best interest was in mind when there was a denial or a delay in approving coverage for a particular product. “It gets very difficult to try and not play God” (MCOP&T_03).

Denying access to medicines, especially for cancer, was acknowledged as not an easy decision to have to make and not without debate, but part of the business of managed care.

“To deny someone medication that has cancer, you really have to question, is that the right thing to do ethically. And a lot of times it’s from pretty heated discussions because we’ll involve picking and choosing who gets what. And I wish it wasn’t that way but that’s where we are at right now… I know if it was my significant other, I would not want to hear that.” (MCOP&T_03)

One of the MCOP&T’s recognized that ethical behavior changed when wearing the hat of the committee member where the focus was on providing limited resources to a large population as opposed to wearing the hat of the treating physician. The MCOP&T voiced that as a committee member, decision-making was more limited when trying to treat thousands of patients.

“I may believe that patients are entitled to a much broader range of medications as an individual (physician) treating a patient. But as an individual on a committee trying to treat a thousand patients, my decision making is more limited. And I have to wear a second hat.” (MCOP&T_01)

The MCOP&T acknowledged that access restrictions turn practicing physicians to a degree into robots, where part of the ethical thinking is stripped away as the physician treats a large number of patients per day. It has the potential to instill in physicians a mindset of not caring beyond a certain point; it leads to older physicians to state they will leave the medical profession.

“I do my job, I do it like a robot, I tell the patient what I think is best for them and that’s it… I don’t personally think I could put up with managed care in practice. Unless I became the robot. And I don’t think I can do that.” (MCOP&T_01)

Under managed care, what became best for the patient from the physician’s mindset was what helped the physician get through the day with the least amount of hassle.
from the MCO. It was noted that physicians should be placing themselves in the 
shoes of their patients and thinking about what is the right thing to do. However 
community physicians were perceived as preferring not to be in the middle between 
the MCO and the patient, having to convey coverage limitations of the plan, as it 
made the physician the bad guy; however, morally, it was thought, the physician 
should be discussing the available treatment options including those not covered, 
explaining the pros and cons of the various treatment options, not just defaulting to 
the treatment option that is covered. The MCOP&T acknowledged that managed 
care affects the ability of the physician to practice medicine.

Yes, it impacts their ability to practice medicine. I'm sure if I was a physician, I 
would be extremely frustrated by the differing formularies among the different 
plans and trying to be an effective physician and trying to run that gauntlet or 
gamut of different things. I'm sure that would be extremely frustrating and 
impacting to the practice. (MCOP&T_03)

Over time, the MCOP&T believed that managed care will wear away at the ethics and 
morality of the practicing physician.

“He comes in with a basic set of ethics and morality. And he slowly changes. 
And I watched them go through med school, into practice and 5 years after 
practice and people change. They become different. Some of them do better 
medicine and some do lesser medicine. Some communicate, some don’t 
communicate, some stop caring for their patients, and just robotically do the 
job. And they can still be good docs robotically doing the job but the tendency 
is, if you are robotically doing the job, you won’t be a good doc. You’ll start to 
falter.” (MCOP&T_01)

Physicians for the most part were still seen as trying to do what is right and a good 
physician was defined as taking the time to explain the various treatment options 
available but that was seen as taking time and MCOs have led physicians to limit time 
per patient. Talking about treatment options was seen as taking away time from the 
clinical exam; physicians looked to shortcut discussions to better manage their 
schedule. Three different types of physicians were identified: (1) those that chose the 
least expensive treatment option to avoid any need for additional discussions with 
patients; (2) those that engaged in discussion with patients who they liked or patients 
who were better educated; (3) those that engaged with all patients equally, discussing 
options because of their compulsive personalities. Ideally physicians should be
“teachers, motivators and coaches” (MCOP&T_02). As stated by the MCOP&T, as it related to the smoking cessation case study, the physician who was not able toconvince the patient to pay for the more expensive and efficacious medicine, did not do "a very good job of doing what he or she is responsible for doing in terms of caring for that patient" (MCOP&T_02).

With regards to cost, MCOP&Ts felt that the physician should not make decisions about cost of medicines, rather to provide available information to the patient and let the patient make the choice. However, the intrusion of managed care was seen as making physicians question their ability to take care of their patients.

“…the physician [is left] with the creepy feeling at the end of the week, saying, ‘I don't know what difference I’m making in my patient’s life.' It is a very uneasy feeling to know that your decisions are being ruled over by people who really don’t know the patient. And I think it damages the physician’s ability to continue in practice ultimately.” (MCOP&T_01)

MCOP&Ts spoke to the importance of a physician taking time to advocate on behalf of their patients. Although the physician needed to invest administrative time in the patient’s care, at least from one MCOP&T’s point of view it made a difference, as they would approve use of the medication almost all of the time; the mindset being that if the treating physician was willing to spend the time in helping the patient gain access to the medicine there must be a true need for the medication in that particular patient’s care. Different companies however were thought to act differently in regards to coverage levels and willingness to approve access based on their culture and tone. One MCOP&T study participant stated: “I have many physician friends who are ready to punch me in the face after a conversation because they can't believe I just won't go with what they say” (MCOP&T_03). At the same time, the same MCOP&T recognized that each insured member is an individual and the case for a specific medication is patient-specific. MCOP&Ts for the most part saw the process of reviews as clear cut, requesting coverage based on the evidence and facts of the case: “…all they have to make is a clinical medical necessity argument from a clinical point of view supported by peer-reviewed evidence; it's all they have to do.” (MCOP&T_06). The same MCOP&T study participant stated that there are never any discussions directly with the treating physician; all appeals have to be done in writing.
MCOP&Ts acknowledged that the formulary is designed as a deterrent recognizing that the typical physician will not pursue access to the restricted medication. It was recognized if every physician pursued requests for access that would lead to administrative overload for the MCO. That is why it is important for physicians to bring forward appeals: appeals were seen as costly for the plan and if there were a sufficient number of appeals brought forward, the plan might realize it is not worthwhile to continue to restrict access for that given therapy. The importance of MCOs engaging with experts was noted to understand the gap in care if a particular medication is not covered. “The plan should have a rigorous and vigorous appeal process to ensure that each member is treated justly” (MCOP&T_02). The MCOP&T spoke to how the role of experts factor into decision-making and ultimately the rule of rescue will apply if there is support for the intervention from the experts who are well versed with a specific disease. However, a community-based physician who advocates on behalf of their patient was not necessarily perceived as correct in their position.

“The rule of rescue is the insurance company is going to rescue this patient. Not the doctor. I mean I think that this is where I sometimes have difficulty because one physicians’ opinion about the management of a complex disease can easily be disputed not by the insurance company but by experts in the field. I mean we would never make a decision like this without consultation with experts... (community-based) physicians make a lot of bad decisions”. (MCOP&T_02)

This was also voiced by another MCOP&T study participant who stated: “I don’t drink that Kool-Aid… I don’t agree that the physician is the wise caretaker that always practices great quality of medicine; I just don’t agree with that.” (MCOP&T_06)

At the same time, however, the importance of treating physicians being well prepared, thorough and complete in their documentation, was raised by MCOP&Ts. One specific example cited where documentation made a difference was for a patient who had Fabry’s disease who did not respond to the standard of care. The treating physician who made the appeal also had taken the time to understand where to source the medication from and the cost of the medicine as it was not available in the U.S. This led to the MCO granting an exception and providing coverage for the
medication. The MCOP&T made note that the treating physician of the patient was also known to him professionally and was considered a friend. The size of the company (MCO) was also brought up as a factor in being able to make exceptions. It was noted that the larger the corporation the more challenging perhaps to be able to bend the rules for a given patient; processes were set in place that needed to be followed. These processes introduced “constraints in the ability to do some of these things. And some of these constraints are really beyond the control of ethical individuals in a managed care company.” (MCOP&T_02). However, bringing forward complaints to management were recognized as important as it provided an opportunity for the MCO to re-examine the rationale for a decision and the implications on outcomes.

“We certainly welcome any conversations with someone who thinks we are not doing something in their best interest. Because we are never about not doing that. Have we ever changed decisions based on a consumers’ complaint? Yes. And usually it’s because they brought something to light, that maybe we weren’t quite correct on.” (MCOP&T_03)

Most physicians however did not provide the necessary documentation; they merely stated that the patient needed access to a specific therapy. Documentation was seen as essential as it laid out the case as to why a patient needed access to a specific medication. However, those physicians who always requested exceptions that were deemed unwarranted were de-prioritized over requests from physicians who seldom requested exceptions. It was recognized that there was a tension that existed between the community-based physician treating the patient and the Medical Director within the MCO overseeing the appeal.

The MCOP&T spoke of the realization that the MCO was an insurer and the first and foremost focus of the business was providing insurance without receiving any negative press coverage. The physician had the right to prescribe whatever he / she deemed most appropriate for the patient but the plan had the right to deny the request for coverage. The insurance company was thought of as having “no heart” as stated by MCOP&T_01; in contrast the employees of the MCO had a heart but the MCO as a business did not. “The bottom line rules all” as stated by the
MCOP&T_01. The MCOP&T participant spoke of a specific situation where he had requested his CEO to drop copays for chronic medications; the CEO responded that they were not a benevolent organization; later on, when there was evidence that lower copays led to better financial outcomes for the MCO, the MCO reduced the copays. “So it’s really a financial decision rather than an ethical decision.” (MCOP&T_01).

Overall MCOs were expected to make exceptions when there were no other treatment alternatives available and there was existing evidence of efficacy in a specific patient type. However, these appeals were done on a case-by-case basis. The review process almost always started with a denial; then through the appeals process there might be a decision, through discussion and review, to gain access.

“It's going to be harder for that patient to get what they need if they are the exception. But they are handled. I don't think there is anyone who is falling through the cracks from managed care sort of speak on that. We never cut off communication after a decision has been made. There's always an appeal process. But the first thing that person's probably is going to hear is no. That's honest. And then we'll dive into it and see if this is what we need. And usually the physician is quite vocal on that point honestly and immediately moves to an appeal process and if there's validation in what the physician wants, we certainly accommodate that. We find some way to do it... We even have gone as far as to cover orphan drugs that certainly we could have tried something else first, but we went into $10,000 a month therapy because we really believe that this is the patient’s only chance.” (MCOP&T_03)

One MCOP&T spoke to the point of creating potential win-wins for themselves as a business and the patient but creating a win for the MCO at the expense of the patient would be unethical.

“Is it okay for us just to change things because we can? Sometimes I think the answer is yes. If it's a blood pressure regimen and we can change them to something that is truly just as good but less expensive for them and for us. That's a win-win. But to change something solely based on what it's going to impact us, that's a little unethical.” (MCOP&T_03)

It was acknowledged that coverage was contractual based on the policy bought. The plan provided for a level of care that was commensurate with the premiums paid for by or on behalf of the insured member in accordance with the terms of the policy.
One MCOP&T spoke about how even a small extra cost on a per person basis can add millions in incremental costs; for example, an additional $0.10 increase for one person, if done for all covered lives of 30 million, becomes a large number. Hence the MCOP&T spoke of how society needed to decide on how much they were willing to pay for a certain level of care. If the marketplace wanted lower premiums than choice needed to be taken away or reasonable step edit protocols needed to be in place.

One MCOP&T participant spoke to the point of creating value through the bottom line. That care is not the absolute goal of the MCO rather it is in context of providing the best possible product at a reasonable price while improving year over year sales.

“If the goal statement and... for that organization is, we will take care of our members, yeah. But their goal statement for that organization is not that. We will produce the best product at a reasonable price and improve our sales every year. Okay, they are not into the health care business as such. They are into satisfying the owner of the company and the stockholders. So, I have not found them [that] they are making ethical decisions.” (MCOP&T_01)

The MCOP&T spoke of that physicians did not see themselves as needing to be concerned or having responsibility for the cost of care yet in reality physicians were seen as having played a significant role as their methods of diagnosis and subsequent care plans provided by the physician determined the cost of care. Was the approach taken by the physician the most efficient as it related to the necessity of approach taken and cost of approach relative to improved outcomes? One MCOP&T spoke of ultimately it was the patient’s decision with input from his or her physician to either utilize a therapy that is covered at a low(er) cost vs utilizing a therapy that was higher cost and perhaps not even covered. Patients needed to ultimately decide on what priority their care was to them vs other factors in their life.

“[They need to] come to a rational decision as an individual. We as a plan do not know all the particulars of a patient’s situation. You know, they could be a multi-millionaire or they could be scraping their last two cents together. And some of them may have different goals. They may have so much money saved away that they could either use a product that is going to... that may help extend their life a few more months or it may be the money for their grandchild to go to college or something like that. …that is a decision they should make not us.” (MCOP&T_10)
In summary, there is a recognition by the MCO that there is a need to make profit and to increase sales year over year; decisions are based on financials and not ethics. MCOs recognize that employers have a mistrust in the MCO and hence employers’ believe there needs to be oversight to ensure MCOs do the right thing but ultimately the contract that is signed between the employer and the MCO governs the requirements that the MCO must fulfill to be in compliance with the contract. Access restrictions and cost-shifting is a mechanism by which MCOs are able to control the financials and the impact on the bottom line. MCOs recognize that their decisions can be seen as heartless as business (economics) impacts on their decision-making. MCOs do not trust in the decision-making of the practicing physician, rather MCOs look to expert opinion which can vary from one expert to another; in contrast patients trust in the judgment of their treating physicians.

The consequence of the MCO business model is that the time a physician can spend with any patient is limited; but there is an increased need for physicians to spend more time with patients to help explain the various treatment options and the implications of the patient’s MCO coverage on the cost-benefit trade-off for a given medication. Ideally physicians would spend sufficient time with all their patients to explain the cost-benefit trade-off but some physicians will just write what is most likely to cause the least amount of hassle; the system turning physicians more into robots and hence becoming less caring in the process. MCOs recognize that formularies have an impact on the physician; that physicians look to get through their day with the least amount of hassle and that physicians do not want to be caught in the middle between the MCO and the patient. MCOs recognized that they intruded on the physician-patient relationship and that the MCO did not know the patient on a personal level as did the treating physician. Advocating on behalf of the patient makes a difference in patient’s being able to access a given medication (at least from a utilization management perspective) and that appeals of the local treating physician needed to be rigorous which depends on the ability of the treating physician to make the case for access to a given medication. Processes are more established at larger companies vs that of smaller companies hence in larger MCOs it is more difficult for a physician to navigate the system to be able to gain access on behalf of a patient for a
specific medication. Systems are designed to encourage inertia and processes support inertia which might be easier to overcome in smaller companies; relationships which do matter are easier to form within smaller companies. There is a natural tension between the MCO and the physician; appeals at larger companies are only through written correspondence and not through direct verbal communication between the MCO and the treating physician.

5.2.3 Access to Rx Medicines Impacted by the Financials:
Findings associated with interviews conducted with Community Practicing Physicians

Physicians have the patient-specific knowledge to make the appropriate medication choice with the patient. Pharmacists have the knowledge relevant to the medications themselves but physicians have the patient-relevant information specific to the patient’s medical condition. The physician thought that if pharmacists were attempting to make changes to the physician’s prescription for the gain of their business than there were issues with that approach. Physicians spoke of the ideal scenario which would have the pharmacist working with the physician as a team to ensure the patient received the best possible medication for their given condition; not an adversarial relationship where information was communicated by the pharmacist to the patient without the knowledge of the physician.

The physician spoke to the ethics of an MCO providing access to medicines: if there is a new medication for a given condition on the market and the medicine is better than the currently available treatment options, and the MCO has indicated they will cover treatments for that specific medical condition, then the plan should provide access to the new medication. Physicians believed to have the right to prescribe medicines that were considered reasonably appropriate for the treatment of a given condition. Patients were seen as paying a visit to the physician to determine and receive treatment based on that physician’s expertise based on his training and credentials. Physicians spoke to advocating coverage for a specific patient when the covered medicine vs the non-covered medicine would cause harm.
“…then it’s the physician’s responsibility to argue for not opting for that treatment as something to try beforehand. And that’s generally the basis of the prior approval process. That there will always be exceptions to the rule.” (Physician_02)

The physician’s duty was perceived as doing and figuring out what was best for the patient. MCOs were seen as not always having the best interest of the patient in mind. Not prescribing medicines based on the parameters of the formulary was perceived as not being efficient and practical. “Formularies can interfere with the physicians’ ability to act in a way… that he or she would want to.” (Physician_03).

Patients were known to get letters from their MCOs stating that the medication they were taking was no longer covered under the formulary, and hence the physician needed to prescribe another alternative or the patient would have to pay retail cost to stay on the medication. Formularies were seen as impacting the physician’s ability to practice medicine and making it at times difficult. Some physicians made the distinction between the fact that physicians still can prescribe what they deem best for a given patient however patients were not able to access the medicine through the MCO based on their formulary.

“…impacts our, as physicians, ability to practice medicine and prescribe medicine, yeah, it is difficult. We have someone or some force that’s telling you, you can still have some options here, but your options are what we provide to you… companies are not telling me what I can’t or can prescribe. I can prescribe whatever I want. They are basically telling the patient what the patient can or can’t get.” (Physician_03)

The existence of the formulary impedes the autonomy of the treating physician. The physician spoke to the point that as healthcare professionals they were unaware as to the motivations of decision-makers in terms of products that were placed on the formulary which created tension between those making the decisions and those affected by the decisions.

“…is the lack of autonomy by the physician because of the different restrictions that are created by other individuals that are creating the formularies and all the different economic considerations that may go into the way the formulary is created. I think there is a tremendous amount of tension there because I really don’t… I doubt very much that any physician will look at the way that a formulary is created and say: ‘Oh boy this committee was completely impartial when they came up with this”’. (Physician_05)
Some physicians felt that physicians should do what is best for that patient. So if product B was more readily tolerated that is what the physician should have prescribed irrespective of the cost.

“Now again, if the patient says, I can’t afford this, or the insurance company is saying, or the managed care plan is saying, “Well, that’s not part of our formulary”, well then again the physician’s hands are tied at that point. Then the physician is going with product A because of those other reasons. So I feel that there are conflicting interests. One is, you are trying to reduce costs by taking product A, but you are making a patient potentially suffer side effects by not choosing product B.” (Physician_03)

Fighting over access where the products were similar with regards to efficacy and where the side effect differences were manageable, was not seen as worthwhile. Overall formularies were seen as working for most patients most of the time but when a patient had needs beyond the formulary then that was not perceived as fair or just. Utilization controls either delayed certain patients from receiving effective treatment or was seen as requiring those patients to pay higher copays to improve their medical condition.

One physician spoke to the point of the United States Preventive Services Task Force finding blood tests to diagnose prostate cancer as not cost-effective; this might make sense at the population level but not at the individual patient level; outcomes may now suffer for those patients whose diagnosis would subsequently not be made in time prior to disease progression.

Some physicians spoke to the virtue of removing barriers to care to enable better outcomes including incentives provided to insured members for taking steps that are aligned with preventive health (such as screenings). Some physicians spoke to how sending correspondence to the plan to raise awareness on the need for access to a specific medication was rarely effective because if access was provided for one patient all patients would need to be granted the same level of access. At the same time physicians expressed a level of hopelessness and acceptance of how the system worked and their inability in being able to help a patient who cannot gain access to a specific medication: “…most physicians may feel bad, but won’t go over and beyond to do anything else beyond that and just say ‘These are the limitations
we have, there’s not much I can do, by myself.” (Physician_03). Physician_03 spoke to the feeling of helplessness fighting a giant and the sense of being overpowered: “I think most of us feel helpless from that perspective because we are fighting a much bigger, you know...we are fighting a giant.”

Physician_01 spoke to the point that as a physician it was easier for him to prescribe a product that would be hassle-free, which ultimately might be to a degree at the expense of the patient. Physician_01 also spoke to his point of view that perhaps the intent of the MCO was for the physician to think twice before prescribing a product.

“It is easier for me, to prescribe the generic / cheapest drug that I know is going to be most simply approved by the insurance company, or if I know I will not have to get on the phone with a Medical Director and fight with them. And tell the patient, just suck it up, deal with the side effects, etc. But am I acting as ethically... I think there certainly is room for debate on that one. I would like to believe as a clinician will always choose what is best for the patient and always put myself secondary to that. Unfortunately, it does put people in a position if you make them work too hard to prescribe something sooner or later they crumble under the pressure. Going back to where this is coming from, the insurance company, MCO, maybe that is their intent. In my bias view, I will say that it is their intent, that they want me to think twice before writing a brand drug rather than something I know is on their first tier formulary.” (Physician_01)

Physician_01 went on to say that he felt it was his ethical responsibility to fight for the patient to the extent possible and to advocate for the patient as he would for his own family member. From the physician’s perspective, if the treating physician provides a good rationale for why they want access to a specific medication, the MCO will usually agree to the request and provide authorization.

One specific physician made reference to being a puppet in the context of what MCOs dictate thereby disabling the physician from acting in a manner that the physician felt was best for the patient; at the same time the physician also accepted that there needed to be rules that one needs to comply with, otherwise it would be the Wild West.

“I think, you know, we want to practice the way we think is best. And it may in some level make us feel that we are just the puppets and being dictated to on what we can do. I mean that is one way of looking at it. Another way is that,
you can, you know, there are constraints within the system I have to work within some of those constraints. Just like laws. I mean, you know, you could go into society and not have any laws, the free wielding West if you will, the Wild West. But there are laws that exist that… certain ground rules that you have to play under… [Physicians] like certain drugs when a condition comes in, they like to prescribe a certain medication, and that becomes their medication of choice and if they can’t prescribe that then they feel that they’re… I can see how some people would feel their practices are being dictated to by insurance companies and other things. I get how that feeling can occur and I think it does occur.” (Physician_04)

One physician spoke specifically to an example and shared their viewpoint of Flomax vs Rapaflo; based on his experience Flomax might be less costly or be more readily accessible on formularies but in his opinion Rapaflo led to better results even if not based on the literature. The physician also spoke to the point that MCOs did not communicate to community physicians how a formulary decision was reached regarding a particular medication and who was involved in the decision (for example, which experts and their credentials relative to the disease area).

“Our expertise is to choose the proper medication for a given condition. There are lots of choices but I think as physicians I don’t like being told what to do. I don’t like being told I can’t prescribe this drug and the way I reason it and get around it is I say – ‘this is covered you know let’s try this. If it doesn’t work then you know I want you to come back; if it doesn’t work then I think this other drug might be better; we can try it…” (Physician_04)

The physician vocalized that to have a generalist in a disease area is not the same as speaking to the leading experts as it relates to a given sub-specialty.

Patients were seen as having to potentially forego other luxuries in their lives (such as going out to dinner) to redirect funds to pay for more expensive medications that the treating physician believed would be better for the patient given their circumstances.

“…that is the problem with population studies, they may say these things are equivalent but medicine is individualistic… how a person responds to a particular drug; it doesn’t work the same way in every patient.” (Physician_04)

Multiple physicians voiced their opinion that it was the physician’s responsibility of telling the patient of the various treatment options and the risks of choosing perhaps a
lower cost medication vs a more costly medication; explaining to the patient the consequences as it relates to efficacy and side effects of a given therapy based on the physician’s professional point of view. “The insurance company makes the decision [as it relates to coverage] but the agent of change, the person who is responsible for telling the patient, is the physician, not the insurance company.” (Physician_04). Ultimately it was perceived as not worthwhile to prescribe a medication the patient could not access or afford. The physician recognized his role to provide guidance to the patient, to help inform the patient’s decision from the available treatment options; a priori the lower cost option might work just as well for a given patient.

Many of the physicians felt that although the practice of medicine should be independent of the cost of treatment the reality was that healthcare was a business and many of the decisions were cost-specific.

“I have this more of a cynical attitude because I see where healthcare is going and you know it’s… there is no right answer. But I think that these insurance companies, these health care plans, need to stay afloat so they need to do that by cutting costs.” (Physician_03).

Physicians spoke to the point of being controlled; of not being recognized for the expertise they have, acquired through education and experience, and the processes that are put in place by the system in an effort to reduce costs.

“I have to call some insurance company and get pre-authorization and the person I am talking to has got not nearly the education I have; doesn’t even know the condition; can’t even pronounce it right. Yet I have to talk to this person to get clearance… Typically it is somebody that has much less education than I do, but what they are trying to do is look at cost and prevent things from spiraling out of control.” (Physician_04)

The frustration level of Physician_04 with managed care was well captured in the quote below; the physician felt that the physician’s obligation was to provide care that he deemed necessary; not to call MCO staff to provide his logic why a patient needed a particular medication; one physician referred to the approach as bordering on harassment the need for this level of correspondence.
“You know I got frustrated talking to these people... when I call and say this drug I really want to put the patient on this drug. It can be frustrating. There are a lots of docs out there who don’t do that. They say that’s not in my job description. My job description is to provide what I think is the best appropriate care and choice of a drug. So it’s not my responsibility you know and they will throw it back to the patient or they will just say I can’t help you...” (Physician_04)

Physicians spoke of the inconsistency of the approach from one health plan to another to get access approvals to restricted medications and the difference in decisions taken by the plans based on the information provided. The point on consistency was also raised by Physician_01, however, as it related to physicians and the concept of dealer’s choice. Two separate physicians might have a difference of opinion on how to treat a given patient but also might have a difference of opinion in their recommendation to the patient in the importance of one medication over another: “...based on the patient’s financial situation another doctor might be ok with option A but I might say no, go find a way to pay for this. This is the best drug for you and I think this is a better choice. There is some element of dealer’s choice that comes into play.”

The time spent by physicians to try to help patients gain access to medications that were restricted on the formulary was recognized as significant and onerous. It was also mentioned that physicians did not receive additional compensation for their invested time trying to get patients the best possible treatment available.

“...It's part of the ideal patient-physician relationship to be able to advocate for patients when they need the advocacy. It becomes difficult for a lot of physicians and there are a lot of physicians I think who look at this as a relatively onerous burden because of the amount of time spent doing this and the amount of clerical work that may be involved in faxing notes and sending things and making phone calls and it’s not as if there’s any change in reimbursement for the physician based upon all of this time spent.” (Physician_05)

Physician_05 addressed the point that each patient was treated the same way initially by the physician but then based on the coverage levels provided by the plan, the physician needed to make changes in his treatment approach, still trying to do the best within the plan’s operating constraints.
“So you treat everybody the same way to begin with but then if there is restrictions that the plan places, require you to do things in a different way then you have to adapt to that, and still try to maintain the highest standard that you can of doing the best that you can for them under the constraints that exist.” (Physician_05)

Although some of the physician study participants felt that their right to prescribe freely was not impeded as ultimately they had the legal right to prescribe as they deemed most appropriate, and it was the patient who had to decide whether to pay the cost of the medication, some physicians felt differently regarding autonomy and the right to prescribe, as they viewed formularies changing what a physician might have otherwise prescribed.

“I think it dramatically alters the autonomy of the physician to prescribe the way that they would want to, so it has a negative impact and it definitely restricts the ability to treat patients in an ideal way or in accordance with that right if you do believe that physicians have a right to practice in the way that they want to practice medicine.” (Physician_05)

The case studies highlighted to the physicians that they needed to practice medicine within the parameters set forth by the MCO and there was need for repeated follow-up to ensure there was a good understanding of the patient’s health status and subsequent change in his medical condition given the selected treatment strategy. Physicians saw the interactions between themselves and the MCO on some level as a game, looking to manipulate the system to achieve the best possible outcome for the patient. The specific example provided was prescribing to the patient a generic so that there would be documentation of the treatment failure but also providing the patient samples of the medication the physician most likely thought would have a positive outcome.

“You have to fail this medication before I could give you something different, I want you to try it for a couple of days, call me and tell me how you are doing on it so that I can document what happened with it. I’m going to give you these other samples to hold on to but don’t start on them until you try this other medicine. If you try this first medicine and it doesn’t work or if you have bad side effects, call me and tell me that, then you can start on these samples”. (Physician_05)
The prostate cancer case study highlighted to the physicians that ultimately their autonomy is compromised and the MCO is not following the practice of non-maleficence as the patient would have only been covered for the chemotherapy treatment, not the oral oncologic treatment which has less side-effects.

One specific physician spoke to the reality that physicians who work for MCOs are paid to make decisions that are about reducing cost and if they constantly approved access to medicines that were not covered by the MCO’s formulary; the MCO would most probably find another physician to be in that position:

“And when you have a job to be a gatekeeper which is essentially what they are functioning as when it comes to these situations. A gatekeeper has to get paid for what they are doing and if they constantly are approving that which the rules are intended to try to block in any way they can… viewing things from a different standpoint. They are being paid to specifically control it… when people are being paid, you know, there is a natural bias that goes into it. Or not even a bias, they are instructed – this is what you are being paid to do. If you do not want to do it, we will get someone else who will.” (Physician_01)

Physician_01 spoke to the importance of personalizing the communication with MCOs; how the treating physician tried to get the MCO to relate to his patients; “…if this was your father what would you like me to have done differently?” The physician voiced his point of view that he had a personal relationship with the patient, that to him, the patient was someone’s father as opposed to the MCO to whom the patient was just another person lumped into the larger insured group. The MCO was seen as making the appeal process complicated. Physician_01 felt that the insurance company forgot “there is a human being on the other side of it, which I am not allowed to forget as a physician but the insurance company somehow is allowed to do. And that is where I think it is an unfair system”.

In summary, physicians recognized that MCOs need to manage costs whereas for the most part the treating physician is to do what is best for a given patient; that the treating physician has a personal relationship with the patient whereas the MCO does not. Physicians recognized they can prescribe anything they deemed to be best for their patients but if their patients are not able to access a given medication due to a lack of formulary coverage by the MCO, then prescribing that medication by the
physician is not deemed to be good use of time. It creates tension in the system because the physician wants to prescribe something that the MCO will not cover and it is not obvious to the physician why that particular medication is not covered on a given formulary from a clinical rationale vs other possible treatment alternatives. Different MCOs will have different formularies and hence different coverage levels; one patient may have affordable access to a specific product whereas another patient will not have access only because that patient has a different MCO with a different formulary. To save costs, the physician potentially will need to choose a product that will be either less efficacious or will have more side effects. MCOs affect the autonomy of physicians but physicians still have the right to prescribe whatever they deem best for a given patient; physicians do not like being told how they should treat their patients. Physicians also recognized that in order for patients to gain access to a given medication, the physician needed on certain occasion to satisfy the rules set forth by the MCO; to play the game; namely prescribing a given medication, documenting patient failure on the treatment option and then prescribing the medication the physician intended to prescribe from the onset. Patients see their physicians to receive treatments based on their physician’s point of view; not that of the MCO who does not have any specific knowledge of a given patient. If an MCO has agreed to cover treatment of a given condition, than that MCO should cover new medications once available in the marketplace (approved by the FDA) for that given condition. Physicians recognized that they should advocate to the MCO for their patients to have access to a given medication if it will mean a difference in outcome, especially from a safety point of view, but physicians also recognized the futility of such efforts; they also recognized that the extra time investment on their part was not compensated for. Some physicians believed that their responsibility was to inform the patient on which medication was best for their patient but not to advocate on the patient’s behalf with the patient’s MCO.
5.2.4 Access to Rx Medicines Impacted by the Financials:
Findings associated with interviews conducted with Community Retail Pharmacists

Pharmacists spoke to the fact that they interact differently with patients depending on whether they knew the patient or not. If the pharmacist did not know the patient they just tended to fill the prescription as written. However, if they knew the patient and if they thought there was a product on formulary that they believed was better, either lower cost or less side effects or more efficacious, they would speak to the patient about the option and the difference in the out of pocket costs to the patient. If the out of pocket costs to the patient was high for a particular product under a given plan, pharmacists might recommend, if applicable, a lower cost over-the-counter medication as an alternative. The pharmacist might have offered to call the physician directly or asked the patient to follow-up with the treating physician. Intervening with a prescription as written was also seen as a step that delayed the patient from picking up the prescription as the steps needed to change a prescription took time.

“'[I have to tell the insured member], Guess what, it's not covered, I have no way to reach the doctor and your insurance won't pay for it anyway. So, you are going to have to wait until tomorrow.' and send worried parents home, that are going to just have to watch a sick child for another 24 hours. On top of which, one of them, if not both of them [parents], will probably miss a day of work and end up not being productive because he needs to stay home with the sick child or take them back to the doctor or deal with me the next day trying to get another medication that is covered.” (Pharmacist_07)

Pharmacists felt that physicians are not knowledgeable about the cost of a prescription to a patient; this information was seen as becoming available at the time the patient’s prescription was adjudicated. There is no benefit to patients to receive a prescription that they are not able to fill because of lack of coverage.

The pharmacist felt that they were compelled to follow the rules as set forth by the system.

“…the laws are written and the contracts are written in such a way that if you don’t do what the contract says, you are in violation. You basically have to go along with what’s done, with what is presented to you...” (Pharmacist_03)
Pharmacists felt that physicians and their office staff had at times an argumentative relationship with the pharmacist as a call from the pharmacist potentially imposed additional work on the physician and the staff, after the patient had already left the office, to explain or make a change to the prescription. The patient who picked up his prescription often did not realize the degree of effort that might had taken place between the pharmacist, the physician’s office and the insurance company to get the prescription filled.

There was awareness that physicians had the right to prescribe whatever they deemed best but formulary coverage levels affected the patients’ willingness or ability to pick-up the prescription; hence physicians were seen as being impacted by formularies. The existence of MCOs introduces a 3rd party into the physician-patient relationship that changes the way physicians treat their patients because of coverage levels. MCOs were seen as introducing a non-clinical parameter into decision-making based on the financials.

“Because they have the patients’ full history in front of them, their medical history, and they really truly believe when they write the prescription that is what they require at that time; for someone else to come and say, that has not met the patient, has no idea of what the patient is going through, or their ability to pay or not pay, having to tell the physician that that’s not what we want you to prescribe, we want you to prescribe something else. Ethically that’s an issue. That’s a big compromise for a physician.” (Pharmacist_05)

The pharmacist recognized that MCOs designed formularies to work for the majority of patients based on benefit-cost tradeoffs and that if physicians did not stay within the parameters of the formulary they would be challenged. The doctor was free to right whatever he deemed best for his patient but he needed to accept that his decision might be challenged. At the same time, it was recognized that different physicians might prescribe a different medication for the same patient based on the physician’s medical opinion.

The pharmacist spoke to the system not necessarily being fair to the patient. As stated by Pharmacist_05, “...I wish there was a better answer but that’s the reality. It’s tough. The patient is the one who has everything to lose by not getting it and it’s not fair.” The pharmacist spoke to the impact on patients when they come to the
pharmacy counter and learn that their medication is going to cost $9,000; the pharmacist spoke to how he would try to explore different resources that might be available to help the patient: such as a patient assistance program, copay cards, samples, social services or recommending another physician who might be an investigator in a clinical trial. As stated by Pharmacist_05, “…when you look at a patient, and you tell them that this cost $9,000 and it’s not covered, then it’s like deer in the headlights and you just want to go around the counter and just give him a big hug. You just know that there is no way.” Pharmacist_09 spoke of one extreme case where the patient was recommended to go to the emergency room to be able to access the medication she needed:

“have seen at least one incident in the past… where the girl ended up in the emergency room, because we couldn’t get the managed care to pay for something and we encouraged her to go to the emergency room so that she could use her major medical part of her insurance to pay for whatever she need. That’s what the pharmacist had to do.”

Pharmacists spoke to how some physicians are adamant about which prescription to fill and will not change the prescription to a lower cost option; either way, pharmacists agreed that it was necessary to spend time with patients so they understood their options, understanding the trade-offs of using one treatment vs another, so the patient could make a well-informed decision on which therapy to fill. It was seen as important that physicians document their initial prescription choice for the patient should there be a need to change the prescription due to formulary coverage. The pharmacist recognized the importance of the physician providing the necessary follow-up which is especially important if the reason the physician prescribed the specific medication only because of formulary constraints. The pharmacist felt akin to the physician in that pharmacists believed both professions were being directed or redirected by MCOs.

“Now, it's going to leave the prescriber feeling frustrated in many of the same ways because they also have the personal relationships, they also want to do their best to relieve Joe's condition or his blood pressure, his heart or whatever. Then, having to say, 'Well, Joe, drug A would be the best one for you, but we're going to have to prescribe drug B because it's what your
insurance will pay for.’ I think we share a lot of the frustration there.” (Pharmacist_07)

The pharmacist also felt that patients perceive loss of autonomy because they are not able to gain access under the plan to the medication that their physician and pharmacist thought would be best for them; in addition to autonomy, patients’ self-worth was also seen to suffer as a result. Pharmacists were frustrated with MCOs as MCO customer service representatives read off of a script and were not thought of as having compassion or caring, just being professionally polite but ultimately not deviating from how the prescription adjudicated through the system. Pharmacists were seen as needing to manage their time effectively given the volume of prescriptions they needed to fill per day, the time investment needed to call an MCO and the low probability of being able to gain coverage for the patient when calling the MCO. As stated by Pharmacist_07, “I think the system is set up to make us finally give up, but I think perseverance can turn, not every issue by the way, it may be as low as 1 out of 10, but you can turn some no’s into a yes, but the system is designed to make it extremely difficult.” The pharmacist believed that only by getting calls from the masses would there be a change in policy regarding coverage rules for the product in question.

The pharmacist spoke of the benefit of working as a team with the physician, given the physician did not have the necessary training in pharmacy, but recognized that in the current system this did not happen.

“And it would be beneficial in my opinion to be able to work in conjunction with the physician in terms of his assessment diagnostic capabilities to be able to assist the physician in prescribing optimum therapy for that patient. That at this time [this] does not exist... I have seen clear evidence that most physicians unfortunately are not able to ascertain the best clinical choice in terms of drug therapy because they are not trained to do so.” (Pharmacist_09)

Eliminating the lag in care brought about by access challenges was seen as an ethical concern; the system should be able to efficiently handle review of individual cases to ensure the necessary care is being provided to patients as needed.

Education and collaboration was seen as important drivers to improve the effectiveness of the system.
In summary, pharmacists recognize that the MCO’s coverage decisions, what the MCO will pay for and when, ultimately dictates what a patient can access through the plan and how the patient can gain that access (for example, step therapy). Pharmacists also recognized that the MCO interferes potentially with the physician-patient relationship through the formulary. Physicians had the right to prescribe whatever they deemed best for the patient but given the formulary the physician’s decision may be challenged when the patient goes to fill the prescription; for example because the patient simply could not afford the medication as prescribed. Pharmacists recognized that physicians for the most part do not know the patient’s cost for a given medication until the patient is filling the prescription at the community pharmacy. Hence the relationship between pharmacist and physician can be argumentative as a call from the pharmacy to the physician’s office is usually to request a change in prescription due to formulary coverage. Pharmacists felt that patients needed to understand their treatment options and that the pharmacist and physician working as a team would be beneficial to the patient as the knowledge of the pharmacist and physician nicely complemented each other. The pharmacist felt akin to the physician in that the MCO was interfering with what the physician and pharmacist perhaps thought would be the best possible medication for a given patient. The pharmacist and physician have a personal relationship with the patient whereas the MCO does not; the MCO was not seen as being caring or having compassion. MCOs were recognized as setting up a system where healthcare professionals ultimately give up due to their frustration with the system. Through perseverance, the physician or pharmacist might be able to help the patient gain access to a given medication but the probability of success is low and requires a significant investment of time; however the physician and pharmacist needed to manage their time effectively given the volume of patients that need to be seen. Still physicians were seen as needing to document their choice for treatment options and for following up with the patient even more so if the patient received a specific medication due solely to the formulary. Patients ultimately were thought to suffer the consequence of the access restriction as they are directly affected by not being able to fill the prescription; they lose autonomy and self-worth as a result of the process.
and not being able to secure the medication recommended by their treating physician; still physicians at times were reluctant to change the prescription to an alternative medication. Creating medication access lags for patients (time lapsing as to when patients could start their therapy) was thought to be an ethical concern.

5.2.5 Summary for the category “Access to Rx Medicines Impacted by the Financials”

At the root of all decisions is the cost factor. Affordability to the employer’s bottom line is a key determinant to whether an employer can provide access to specific products on formulary; however the culture of the employer is important as it will play a factor in whether the employer would be willing to reduce profits to broaden formulary access. The contract ultimately sets the rules of coverage and what is expected from the MCO; employers want oversight as they have diminished trust of the MCO. MCOs are focused on the economics as they look to make a profit; increasing sales year over year. They do not recognize the expertise of the local treating physician; rather they believe that they have more expertise to determine what products should be made available on formularies. All stakeholders recognized that physicians could write whatever they deemed best for a given patient but it would not be efficient to prescribe products that are not affordable to the patient. Although physicians ideally would advocate for their patients, physicians are not compensated for their extra time and the probability of success is limited from the physicians’ point of view; in contrast MCOs believed that physicians who effectively communicated the medical rationale for access were successful in their efforts. Several focused codes emerged as it relates to the category of “Access to Rx Medicines Impacted by the Financials” including: working within the system, taking a collaborative approach, reconciling business with need for providing care, overcoming access restrictions, and encroaching on the physician’s judgement.
Drug Formularies are a Means to An End

5.3.1 Drug Formularies Are A Means to an End:
Findings associated with interviews conducted with EBDDMs

EBDDMs repeatedly voiced their perspective that physicians had the right to prescribe whatever medication they deemed was best for the patient; that the physician should bring forward the recommendations that they deemed best for the given patient; however the patient needed to ultimately decide in discussion with their physician what treatment strategy they adopt. The EBDDMs also voiced their perspective that the employer has the right to decide the level of coverage that is to be provided, which as mentioned earlier was informed through benchmarking. EBDDMs believed that employers had an obligation to provide an adequate level of coverage to employees; reasonableness was informed through benchmarking. This makes the assumption that reasonableness is driven by what is done by like-minded decision-makers. However, there are no entitlements per se.

"... I think some people think they have entitlements, but they really don’t. You get what you can afford... you’re entitled to pick a job that has a certain salary and certain benefits, and you make that choice. And the company sets the benefit limits based on any number of factors. But I don’t think there’s any entitlement. And people seem to think that there is sometimes. There’s no right or wrong as far as that goes. It is what it is kind of. It’s not fair or unfair, it just is.” (EBDDM_3)

There was mention that the business has an obligation to provide varying levels of access to care (increasing levels of care at higher premiums) but the ultimate decision is between the employee (patient) and the treating physician.

“The employer has the responsibility for providing a plan that makes access to needed medical care available at an affordable cost... companies still self-determine what that responsibility means. You know, are they going to pay for the stop-smoking drugs or are they going to pay for the lifestyle drugs? I think that sort of stuff is still well within the company’s discretion to accept responsibility for those things or to not accept that responsibility.” (EBDDM_7)

The physician, in partnership with the patient, is tasked with assessing what prescription to ultimately prescribe and fill; although these decisions ideally would be based only on efficacy, the financials were recognized as a component that plays a
part in the decision-making process. There was a differentiation made between needs and wants.

“You’re not covering absolutely everything but you’re covering everything that’s needed. And so, in terms of the responsibility I’d say, that’s what you’re trying to get to is to provide for all of the needs while not necessarily getting all of the wants…” (EBDDM_7)

The concept of the treating physician knows the patient best was not sufficient logic to let the physician prescribe whatever they deemed necessary. The formulary was believed to help ensure there was some mechanism in place to curtail the physician from simply prescribing the latest product that has come to market which is typically the most expensive.

“That’s why we have them. They’re not there to help the doctor decide which is the best drug. They’re there to try and get the doctor to use the most cost-effective drug of a particular category.” (EBDDM_7)

However, the point was also raised that the true cost of a product is not known to the physician and patient due to the existence of rebates and discounts which impact on the visible price of the product. Namely the true acquisition cost for a given drug, based on the health plan’s contract with the pharmaceutical manufacturer, may be quite different from what a patient would pay if the product was being paid for at full retail cost (cash paying patient vs a patient with insurance coverage). If a physician believed that a given plan was not fair or just, in terms of the formulary coverage that was provided for the plan’s covered lives, the physician was seen as having the ability to not participate in the plan. However, it was recognized that there are so many different plans and benefit designs hence for a given physician to know in advance what is covered or not for a given patient is not feasible.

Physicians were seen as having a core set of products that they prescribed; that the formulary was recognized as an effective formulary if there was some hassle factor to the physician. EBDDMs recognized that physicians will need to adjust to the level of documentation that continues to increase in terms of gaining access to coverage. Step Edits were recognized as having value as they allowed EBDDMs to provide access to more expensive medications when less costly medicines were proven to be
ineffective for a specific patient; that without the benefit of Step Edits, there would not be coverage of the other medications in an effort to prevent unnecessary increased spending. Also mentioned was the point that a priori there is limited insight, if any, into whether an access restriction, trying a lower cost option first, will have a negative consequence on outcomes.

It was noted by the EBDDMs that the physician, who is the expert from a physiological (clinical) perspective, is not necessarily the expert in medications; rather the pharmacist is the expert. That in the U.S. healthcare system, there is no real team-based approach to selecting the best possible medication for a given patient: the physician prescribes, the patient takes the prescription to the retail pharmacy store in their neighborhood and fills the product. It is only at the pharmacy counter that the patient would learn of the out of pocket cost for a given product; however the pharmacist would be hampered because he did not have access to the clinical factors that informed the physician’s selection of the specific prescription. Society has not created a mechanism by which the pharmacist has an active role in the medication selection process; society views the physician as the expert who is deemed best informed to prescribe a given medication to the patient. The pharmacist is a facilitator conveying to the patient at the pharmacy counter whether the product is covered under the plan and the copay that is due. If the patient found the cost of the prescription too high, the pharmacist could have helped the patient gain access to a lower cost product by calling the physician or may simply have directed the patient to go back to the physician to have requested an alternative prescription. Whether it is the employer, the MCO, the physician or the pharmacist, one EBDDM highlighted that there is no consistency in the system at large and each decision-maker in the value chain went about making a decision based on their work style and approach to patient care.

At least one EBDDM voiced the opinion that there should be an expectation of the insured member to pay a total out of pocket cost for coverage and access to care in an amount equaling 10% of total annual compensation; out of pocket cost being defined as premiums, deductibles, coinsurance and copays. One challenge that was
raised is that the employer does not know the total income of an insured member and the insured member’s family beyond the employee’s compensation from the employer. Hence the employer does not know if whether the insured member is unable to pay for care, not willing to spend beyond a certain amount or believes that the premium is payment enough and all care should be provided thereafter at no additional cost. Some EBDDMs stated that insured members who used the plan should pay more for access to healthcare to help keep the overall premium as low as possible. One EBDDM spoke to the insured members’ point of view and how it contrasted with that of the business that provides coverage.

“I am afraid in the eyes of the plan member, justice is I paid my premiums I should not have to pay anything; everything should either be free, approved or I should never have a problem with a claim and not sure if we are on the same level when it comes to that. But as far as we are concerned justice is we have lived up to our promises.” (EBDDM_10)

In summary, EBDDMs felt that physicians have a right to prescribe what they deem best for the patient; the patient has a right to fill the medication the treating physician prescribes but employers have a right to determine what is covered on the formulary and that decision is informed in part based on benchmarking to other employers. Coverage for care should be adequate and higher levels of care warrant greater cost-shifting to the patient. Employers, as MCOs, did not believe that the treating physician knows what is best for the patient. Formularies were seen as a means to curtail utilization of the more expensive prescriptions. EBDDMs recognized that there was no real consistency in the system and everyone went about in their own particular style to make decisions regarding formularies and the implications of those formularies on access to care hence especially physicians had to make adjustments to their treatment strategy based on any given patient’s formulary. It was also pointed out by the EBDDMs that the pharmacist, who perhaps is the most knowledge regarding medications, had more of a facilitator role that centered around communicating to the patient the availability of a given medication given the patient’s formulary. EBDDMs recognized that insured members wanted coverage given they paid their share of the premium but the premium is the starting point and there is an additional cost of using the system which becomes the financial responsibility of the
patient in the form of cost-sharing; paying for utilization of healthcare resources for each encounter. Employers did recognize that insured members should not have to pay more than a certain percentage of their annual income, however, employers did not know what the true financial situation of an insured member was and whether they truly could not afford to pay for care or were simply not willing to pay for care. The goal of the employer is to keep overall cost of the plan as low as possible to ensure affordability for its members and the formulary is a mechanism by which to accomplish that objective.

5.3.2 Drug Formularies Are A Means to an End:
Findings associated with interviews conducted with MCOP&Ts

Employers did not want to pay more; there was no perceived loyalty among employers and their employees (insured members) with MCOs. Within the next two years, most likely, the insured member and/or employer was deemed to be using (retaining) a different MCO. If a decision is made by an MCO that is not well received by the insured member, the decision for the denial was based on the coverage levels purchased through the employer’s policy. A more expensive policy might have covered access to that particular treatment. “When you signed up, you didn’t buy the Cadillac. You only bought the transmission... We give you the best we can under that policy.” (MCOP&T_01). The consumer was perceived to be aware of the coverage decisions at the time the policy was purchased and hence was thought of as an informed purchased decision.

“The consumer, in general, has bought this product... the consumer knows what the formulary is before they buy the product or they have an opportunity to know that if they want to.” (MCOP&T_06)

The importance of the plan being viewed as a contract was raised by MCOP&Ts several times as was the importance of the purchaser having completed their due diligence to ensure that the access levels were well understood.
“Our customers have a choice. When they joined the plan, they can look through our formulary... They can look at the medications they are taking and potentially maybe taking in the future and look at how much they cost and they can make the decision whether they want to join our plan or not. And if they do not like it... the way our formulary is designed. With the cost involved that may be the deciding factor for them to go elsewhere and I think it is most ethical that we adhere to the contract that we made with the member when they signed up for the plan. I think the most ethical thing is to adhere to a deal, a contract, a promise that you made between the company and the member at the time that they joined up. And that each side of that party should live up to their promise and it does not get more ethical than that.” (MCOP&T_10)

If efficacy was a given, denials were made because costs needed to be controlled; otherwise premiums would rise. MCO mission statements need to be placed in context of business realities, namely satisfying shareholder needs.

“If the goal statement and... for that organization is, we will take care of our members, yeah. But their goal statement for that organization is not that. We will produce the best product at a reasonable price and improve our sales every year. Okay, they are not into the health care business as such. They are into satisfying the owner of the company and the stockholders.” (MCOP&T_01)

Finances were seen as a key factor in decision-making; MCOs as businesses were seen as needing to making money. It leads to tough decisions which at times results in denying access to medicines, including those that were used for the treatment of cancer. The MCOP&Ts spoke to the point that it might not be ethically fair at the individual person level but it was at the population level because it helped to keep down premiums and made coverage more affordable overall for the population.

“We've seen many things change the way we act. And unfortunately, a lot of those have been cost driven. But that's certainly a part of being a business owner. You can't be a business owner and stay there if you lose money... To deny someone medication that has cancer, you really have to question, is that the right thing to do ethically. And a lot of times it's from pretty heated discussions because we'll involve picking and choosing who gets what. And I wish it wasn't that way. But that's where we are at right now... it doesn't seem ethically fair to the one person being affected negatively, but it certainly seems ethically fair to the institution of healthcare as a whole. Because it keeps healthcare affordable.” (MCOP&T_03)

The MCOP&T study participant spoke to how MCOs have been known to make policy coverage decisions to minimize hassles to the plan based on historic experience; if
lack of coverage leads to lawyers being involved it was seen as in the best interest of the plan to provide coverage pre-emptively. When an MCO denied coverage based on the appeal made by the treating physician on behalf of a given patient the plan did not proactively seek out additional information to better inform the decision; it just reviewed the request based on the information provided even if the information was incomplete. It was seen as the responsibility of the requestor to ensure that the information package was as comprehensive and compelling as possible leveraging all relevant and available evidence. MCOP&Ts recognized utilization management controls such as copay differentials, step edits and prior authorizations as a reasonable approach to derive utility for the population at large; they also deemed restrictions that allowed only certain specialists to prescribe select medications as reasonable due to the degree of specialization needed to treat specific diseases.

“I think that the idea that limiting access to an agent for a specific reason, I think is a reasonable approach to, you know, what you described before as utility. I think that there ought to be some evidence that a person has failed standard of care before easy access to some other agent… Or it may well be that it’s perfectly appropriate that someone has access to a particular drug but only a certain specialist should be allowed to prescribe that agent because the presumption is that the specialist is going to be an expert in that field.”

(MCOP&T_02)

The MCOP&T felt that it was their obligation to review new products as they came to market for placement on formulary to ensure products met the criteria from an efficacy, safety and cost perspective in bringing value to insured members as compared to the products already on the market and seen as standard of care. The MCOP&T brought up the tension between finding the balance of what to cover:

“The dilemma we face is, what are appropriate benefits that meet the needs of the most number of people to cover what most people would say are sort of the spectrum of what ought to be covered under as actual health care related… a lot of the battle is really about who’s going to pay for something. So the battle is really about, if society says, this, whatever it is, is valuable or might have value, then the next question is who’s responsible for paying for it?”

(MCOP&T_03)

The responsibility of the MCO was viewed as making available care that was deemed medically necessary and having a therapeutic benefit. At the same time, MCOP&Ts
brought up the point that there were no true restrictions in access to medicines as all patients can technically go purchase a medication if they had a physician prescription. It was more the question of who would pay for the medication.

“…our decisions do not restrict that medication from the individual. All we are saying is as a health plan we don’t pay for it. That’s why I don’t think ethics gets necessarily into these discussions.” (MCOP&T_06)

However, it was seen as important in bringing forward evidence on outcomes (for example were patients losing their jobs due to symptoms of their condition) to better inform how access to medicines impacted on the outcome being measured and hence enabling subsequent benefit coverage adjustments. It was the cost of healthcare that has led to so many different MCOs offering a broad range of plan designs at varying premiums in an attempt to deliver affordable care. Based on what the employer was willing to pay, and their ideology on how much cost to shift to the insured member, MCOs implemented specific benefit designs. However, MCOP&Ts recognized that ethics did not factor into the discussion in regards to access coverage nor should they.

“I don’t think that health plans should get into this issue of ethical decision making unless the parameters are more clearly defined and agreed upon by many bodies, including society... ultimately this could depend on the politicians and we know where their ethics is, they don’t have any.” (MCOP&T_06)

With regards to cost and gaining access to smoking cessation medicines, the MCOP&T felt that patients who could afford to spend money on smoking should be able / willing to spend money on medicines that would help them overcome their addiction to nicotine. With regards to OAB, the MCOP&T spoke of not only focusing on the medication, but all the other factors that affected outcomes, including use of incontinence-related products (such as diapers) and dealing with side effects such as dry mouth (use of rock candy). Insured members needed to understand how their actions affected their health outcomes and should not expect the healthcare system to cover in full the costs of care attributable to poor lifestyle choices (such as not seeing a doctor regularly or smoking). If insured members wanted access to care beyond what was perceived as reasonable, it was seen as insured members needing
to pay for that extra level of care. The implications of coverage and copay differentials was made clear by the MCOP&T as it related to smoking cessation products:

“Until 5 years ago, we didn’t even cover smoking cessation. We made it non-formulary, not covered. And zero people, zero, paid for it on their own. The second we made it covered and went to a non-preferred co-pay, which was $30, utilization went through the roof. It was amazing the difference that amount coverage made and on their own they would have paid about $100 a month probably for smoking cessation therapy. It made a huge difference when we changed the wording from not covered to covered in their out of pocket expense.” (MCOP&T_03)

The MCOP&T spoke of the point that patients who were truly committed to quitting should not mind higher copays because of the dollars they would save in not spending money on cigarettes.

The MCOP&T felt that physicians had a fiduciary responsibility in terms of cost management and physicians who did not practice with cost in mind should not be practicing medicine. The use of high deductible health plans (where there is a much higher deductible before the plan participates in cost-sharing) was thought to make cost a more central part of treatment decisions going forward, with patients becoming more judicious in their use of resources, asking their physicians which services are truly essential given the cost of the diagnostic or treatment; patients asking their physicians to seek out less costly alternatives. The MCOP&T spoke to how physicians are benchmarked internally within the MCO on how their utilization of healthcare resources compared to their peers, the report being shared with the physicians: “So we try to put it in their practice among their peers where they fall as far as cost of care prescribers. And usually, that’s welcomed. We get a lot of calls from those who say, I didn't realize that's where I fell.” (MCOP&T_03). The MCOP&T spoke of the importance of physicians discussing all available treatment options with their patients and then making an informed decision with the patient. “But I think for the physician he just has an obligation to give them all the choices. And he has an obligation to give them his opinion as to what's best for them.” The MCOP&T spoke of how patients potentially needed to reprioritize their willingness to pay for
medications as patients already spend money on other items in their lives that they deemed important. The MCOP&T acknowledged that cost of a given medication to the MCO was sometimes the only reason MCOs attempted to facilitate a switch to take place; namely if the physician did not prescribe the less costly agent, the MCO would be able to drive therapeutic change through copay differentials or step therapy. Despite the focus on reigning in costs, the MCOP&T spoke to the expectation of the MCO that physicians in the community need to voice their opinion if the system was causing physicians to practice in a manner that was counter to their professional beliefs: “And he needs to speak up if he thinks he’s being treated... or forced to practice unethically.” Care that was provided needed to be deemed reasonable. Delaying access to more expensive therapy to assess effectiveness of less expensive therapies with documented evidence of effectiveness was deemed reasonable by the MCOP&T in an effort to keep premium costs down.

The MCOP&T_03 spoke of the importance of all stakeholders working together to lower cost of care: “that’s a very tough mind set to try and convince patients that we are all in this together. We need to be lowering health costs together.” Although physicians had the right to prescribe the best possible medication for a given patient the question was who will pay for it. If a product is 10% more effective but more expensive, not all patients will need the more expensive product and the additional efficacy. The lack of access to the higher cost product was seen as causing tension among all the involved stakeholders but ultimately it was up to the patients to determine their willingness to pay the higher medication acquisition cost. Ultimately, virtues that were thought to be important for an MCO to exhibit included trustworthiness, credibility, and fairness.

In summary, MCOs' recognized that formularies impacted on utilization of given medicines based on where a given medication was placed on formulary. Formularies were recognized by the MCOP&T as a mechanism by which utilization was impacted; but this was purposely done by the MCOP&T; ultimately to help minimize plan expenses. Formularies were a by-product of the coverage that was purchased by the employer for its employees. MCOs also realized that there was no loyalty to the
MCO; that employers and their insured members leave for another MCO based on need and value; hence there is no real impetus to invest in the relationship for the long-term.

The ethics from the MCO’s perspective centered around adhering to the contract; adhering to the terms of the contract that defined the coverage levels purchased and the processes for review that were stipulated in the contract. Ethics would only fit more broadly into their decision-making if society as a whole made it a requirement and defined the terms of their application. MCOs also recognized that the evidence provided by physicians to MCOs to gain access to a given medicine for a given patient often times was incomplete and that the MCO would make the decision around access based on the incomplete evidence, often times resulting in a denial or rejection. However, if the MCO felt that by not providing a certain level of access the plan would incur additional hassles or liabilities the plan would grant access as it will reduce the negative implications or consequences to the MCO.

Value was seen as a subjective term and hence ultimately the issue would come down to who would pay for the value of a medication on the formulary; who had the responsibility to absorb the cost of a medication that was deemed to have value. Formularies by design made cost a more conscious part of deciding treatment strategy and in part this was achieved by shifting additional cost to the patients receiving care. Delaying access to care as a cost-containment strategy was seen reasonable by the MCO especially because a priori it was not possible to know whether a given patient would respond as expected to a given medication. MCOs believed that physicians should practice medicine with cost in mind; that this was a requirement in order to have a license to practice medicine. Although MCOs overall recognized the importance of being thought of as trustworthy credible, and fair, MCOs felt that patients and physicians also needed to do their part to ensure that the lowest cost option was utilized before more expensive treatment options would be considered. However, MCOs always pointed out that access to a given medication was always available separate from the formulary; it was more of a question whether the patient was able or willing to pay for the medication. At the same time if the
formulary was resulting in physicians having to practice medicine in a manner that was contrary to professional standards, then physicians needed to raise awareness with the MCO otherwise the formulary would be considered acceptable.

5.3.3 Drug Formularies Are A Means to an End:
Findings associated with interviews conducted with Community Practicing Physicians

Physicians thought that the MCO’s decision to cover medications on formulary was based on a combination of acquisition cost, minimizing liability and what is considered appropriate care. Lowest cost care, deemed appropriate by the medical community, was to be covered or utilized first before covering more expensive options; also recognizing that if the customer was not given what they wanted they would go elsewhere. Physician_02 stated from an MCO perspective the logic was as follows: “where this is an appropriate treatment, it costs less so this is what we'll cover, or this is what we'll cover first before buying other treatment options.” The MCO was seen as a business and decisions were made by the MCO that would be considered necessary to sustain the business and make it profitable, not what benefited society. As stated by Physician_02, who made the analogy to soft drinks, “McDonald's will offer Coca-Cola but not Pepsi, so it is what it is.”

The employer was seen as offering healthcare coverage as a way to increase the ability to attract or keep good employees. Employers were seen as needing to satisfy employee’s needs regarding healthcare and not alienating their employees.

“I think if they have alienated all of their employees, then they haven’t really been fair or just in terms of their responsibilities... if an employer health plan is imposing various restrictions then they are probably acting less responsibly than they should be.” (Physician_03)

What coverage levels were provided by employers and MCOs was determined in part by what was seen as standard of care in the marketplace; however, not covering treatment for a disease was seen as conceivable as MCOs sold products; customers should know what was included or excluded as part of the sales transaction. Product offerings were seen as being market-driven based on what customers wanted. There
was also reference to the concept of perception vs reality; perception as what was displayed by an MCO through their behavior in the marketplace in an effort to win over customers vs the reality of the MCO's philosophy that transpired behind closed doors; ultimately society was seen as having to set the parameters within which MCOs needed to operate.

It was acknowledged that the employer’s responsibility was to provide access to reasonable care and reasonable care was based on benchmarking to the marketplace, a concept that was also spoken to by the EBDDMs (as discussed earlier under the EBDDM section). Employers than had to trust the MCO to provide adequate care.

“They have a responsibility and the responsibility is to provide services for appropriate responsible care. I mean, you know, the question is what is the benchmark; what is the basic level of care that needs to be provided; you know, and what is the basic level of expectation. There is an expectation that a certain level will be obtained.” (Physician_04)

The concept of restricting access was recognized as a cost control mechanism; rather than having all covered (insured) lives paying for broad access, there was a disproportionate out of pocket cost at the point of care to the patient who needed to use a specific product based on individual need. It was perceived that to improve access to medicines there would need to be additional costs to the member; so it was just a question of when the monies were paid for improved access: when purchasing coverage (increased premiums) or when accessing a specific product or service (increased cost-shifting at point of service in the form of a copay or coinsurance). The flexibility of tiered plans was recognized as helping to keep costs down for the overall population however it led to increased costs for those patients who chose to utilize more expensive treatment options. As long as there was access to the medicine, the use of utilization controls was less of a concern to the physicians than no coverage at all. Cost was considered a side-effect of the product; overall physicians believed it was important to have discussions with patients regarding the available treatment options and the trade-offs thereby enabling the patient to make the choice of which treatment to utilize.
“…who’s going to pay for it? So to the patient, it’s a matter of, having that discussion with the physician, to say, here’s what’s available, here are the potential side-effects, but you still have these options and the patient can still make those decisions…” (Physician_02)

Physicians spoke to the difference in coverage for the same product across plans; that one patient might have a lower copay as compared to another patient who had a different plan and level of coverage. As stated by Physician_01,

“when seeing all patients one [physician] could be used to writing this prescription for most people [patients] then this one person comes in and finds out that they have to pay ten times more than any other patient has to because that’s where their health plan is.”

There was also a recognition that outcomes were not only a factor of what services or products were covered by the plan but external factors that played into the outcome. For example, with regards to the smoking cessation case study, the patient was seen as knowing himself best and how external factors, such as peer pressure, might have affected his ability to stop smoking. Irrespective of the factors that affected outcomes, physicians recognized that patients who had an addiction needed to be treated no differently than patients with any other type of medical condition.

Physicians recognized that extremes were not reasonable; namely, neither open formularies with all medications covered at low copays without any utilization controls nor limited formularies that covered only the least costly generic medications and high side effect profiles. The point was made by physicians that insured members should be informed of what their coverage would be under the plan however most patients were not able to relate to coverage levels until they had a medical condition and needed access to specific medicines thereby potentially creating a false expectation on what was included in terms of coverage.

“…it should be upfront that if you want premium drugs, if you need premium drugs, you will need to pay X dollars for that opportunity. And that’s where it gets muddied because as I said from before, physicians do not understand the programs, patients do not understand the programs, I think unfortunately it’s just going to get worse… Most patients don’t know what they are buying into.” (Physician_04)
Physicians spoke to how even they do not understand the terms of coverage despite their expertise in healthcare; how would the average lay person then be expected to understand the details as it relates to specific coverage levels of pharmaceuticals. However, the reality of policy coverage was that the employer was providing the coverage as part of the employee’s compensation. Instead of receiving cash from the employer, employees were purchasing a level of coverage in lieu of cash and therefore employees as consumers should be informed as to what they are purchasing. It is the MCO’s responsibility to be explicit in the details of coverage; however most consumers do not read the fine print which they might not understand to begin with.

Physicians also recognized the constraints of the system and the consequences it might have on their recommendations that they might make to a given patient for a specific medical condition:

“…we go through all this training and education and so on and so forth; we think that our decisions and our judgement is reasonable and we prescribe the drug and we think that drug should be filled by the insurance companies and managed care plans. And that’s not always the case but that is the constraint of the system and we have to adopt and practice within that system.” (Physician_04)

The formulary and the need to stay within the confines of the formulary was seen as impacting on their autonomy.

“…is the lack of autonomy by the physician because of the different restrictions that are created by other individuals that are creating the formularies and all the different economic considerations that may go into the way the formulary is created.” (Physician_05)

Physicians were frustrated in that many believed their job was to recommend the treatment that in their judgement was best for the patient. Physicians recognized that some patients became emotional when they could not get the medication their physicians prescribed whereas other patients would just accept medication changes due to formulary coverage as part of the system of healthcare. However, prescribing a product just to be formulary compliant that based on the physician’s perspective was not going to work for a given patient was seen as ineffective.
“if you are going to prescribe something that the patient’s going to hate and then not come back to be seen and then not be treated for their problem, that is automatically not going to be the best way to proceed.” (Physician_05)

One physician made reference to an analogy of airline seats; irrespective of the airline seat, whether coach or business, the passenger’s expectation was arriving safely and on time; depending on the ticket purchased the seat might be more comfortable and the food might be better. Similar with access to products & services in healthcare, namely the minimum expectation by all was that outcomes would be improved through the use of safe and efficacious products or services. As stated by Physician_04,

“the expectation of these companies should be that we’re going to provide a certain level of services and if you want anything above and beyond the services that may be a premium”.

Transparency was voiced as an attribute of the system to be amplified so that insured members (patients) better understood the decision-making process even to the point of affording consumers the opportunity to listen in on decision-making discussions that were held by P&T committees.

Physicians were seen as having an ethical responsibility to help patients in a way that went beyond the focus of an MCO.

“We can talk about the virtues of being a MD, what makes a MD do what he does every day. There is a lot that goes behind it. When it comes to the insurance companies, I do not believe that is not their motivating drive to do everything they do.” (Physician_01)

MCOs were perceived as looking to provide responsible access to care, leveraging trust to the degree needed to not lose business and to make a profit; they were not seen as having compassion. Opposite to the MCO, the physician felt he was there to put up a fight, to make the care personal, to treat the patient as his own family member and be the best advocate possible to the extent reasonably possible; however physicians felt for the most part that the approach was not sustainable. Physicians spoke to the point of view that patients who were high utilizers of healthcare tended to have more of an adversarial relationship with their MCO
because of the added level of communication that was needed with the plan and the documents that needed to be provided to ensure coverage was provided.

“I really don’t think most patients would tell you that they have sort of warm fuzzy feelings about their insurer, more of a kind of adversarial relationship… the more health problems the patients develop I think the more they have a potentially adversarial relationship they develop with their covering insurer, the more pieces of paper they receive the harder it is to understand the different communications from the plan, the more phone calls there are potentially back and forth or maybe I should say the more waiting on hold there is and all those things that I think are frustrating on the patient’s end.”  (Physician_05)

Physicians saw that access to reasonable care was a right but that access to a higher level of care might be seen as a privilege. Where a challenge was identified was between deciding what was a right vs a privilege when a patient took a product based on the formulary and consequently had side effects; their right might have been compromised because they were given the product due to the formulary and not because the physician thought it was the best product for that patient. If medical care was a right than everyone should have access, whereas if it was a privilege, than the view, as stated by Physician_05, was more along the lines of “Well, you may be not able to access that particular therapy but that’s your own fault based upon your particular situation”. The challenge for physicians was also noted when a particular product was not prescribed, even though the physician perceived it was best for the patient, because of cost concerns. As stated by Physician_05, “it’s a very strong part of medical ethics that your treatment… that what you come up with is based upon what is going to be the best care for the patient irrespective of cost”. One physician spoke to the point of patients should be accessing a level of coverage that was commensurate with the insurance policy purchased by the patient; namely it is fair that patients get what they paid for.

“Did the patient pay for that insurance a price that was fair or did they buy a plan that they knew very clearly that they were buying a plan that covers generics at best. And why do you expect someone else to pay for it for you. There are no free lunches in this world and that becomes a reality… The insurance company is providing a service and you need to decide to buy or not
to buy. When I bought my insurance policy I knew I was paying X amount of money for this policy knowing that drugs will cost me this…” (Physician_01)

The physician spoke of separating needs vs wants which was not an easy task for society to undertake; an independent panel would need to make such an assessment by medical condition; for every need identified it was thought that the MCO then had an obligation to provide some form of treatment with the use of cost-sharing to offset the premiums associated with more expensive treatments. However, the physician recognized that it was not fair to a patient if the only reason a different treatment choice was selected for one patient vs another was the level of coverage provided to them through their MCO; however it was also seen as the reality of the healthcare system. Trying lesser expensive options for non-life threatening medical conditions was seen as reasonable. The insured member on some level gambled on the level of access they might need during the year; based on their health during the year determined whether the gamble paid off (low premium with less generous coverage for a healthy person paid off; the person who became ill during the course of the year and had extensive cost offsets due to less generous coverage through a low premium plan lost that gamble).

In summary, physicians recognize that MCOs for the most part provide as a first line treatment option access to those medicines that are the least costly but are nonetheless deemed by society as an appropriate treatment option; avoidance of liability also affected the MCO’s decision-making. Physicians felt there was a difference between what MCOs communicate in the marketplace to win over customers vs how they administered the plan once a consumer became a member. MCOs sold products; demand for a given product should be based on how a product is able to satisfy the needs of the customer; society however was seen as needing to establish the criteria by which certain products or practices of MCOs are deemed acceptable. Physicians felt that access to reasonable care was a right but anything above that level of reasonableness was considered a privilege; that threshold needing to be defined by society. Reasonable care requires the system to separate needs from wants. Physicians understood that it was a gamble taken by the insured member on the level of coverage they signed up for; insured members get the
coverage they pay for and if in the long-term it leads to negative consequences than that gamble did not pay off. It was not fair that two identical patients would not receive the same care just because of the differences in their treatment due solely to the level of coverage through their respective plans. Physicians believed that employers offered healthcare coverage to retain employees; and their decisions were based on what other employers were doing (the concept of benchmarking) with the aim to provide reasonable coverage. Physicians even for themselves as consumers could not decipher their own coverage provisions and hence realized that the average person would have challenges with assessing a plan’s provisions and the implications of those provisions on their outcomes. Physicians recognized that plans shifted costs to patients through the formulary to impact on utilization; physicians should explain to their patients why a particular medication is in the patient’s interest and what are the various treatment options. Physicians understood that they had a relationship with the patient and needed to advocate of behalf of their patients to the MCOs, who were mostly focused on the business of healthcare and hence not focused on what was best for the patient; however physicians also realized that this constant approach to advocacy was not sustainable. Physicians also understood that there was a correlation between the extent to which the patient utilized healthcare services and the degree to which the relationship between the plan and the patient became adversarial. Physician autonomy was impacted by the formulary; physicians adapt their prescribing behavior based on formularies but this was seen as inefficient to the extent it leads to negative outcomes and affects patient care.

5.3.4 Drug Formularies Are A Means to an End:

Findings associated with interviews conducted with Community Retail Pharmacists

MCOs force physicians to think more completely in terms of the treatment options; it forces physicians to think about the various treatment options to ensure whatever is prescribed is affordable to the patient and filled by the patient however this could compromise outcomes.
“Now what it does, it ends up causing the physician to compromise. It makes him compromise… on the optimum therapy that he wanted... he knows the managed care won't pay for it, then he has to re-think to make sure that the patient gets something that they can either afford or will even fill. So I think it makes him compromise. And thus, really, I mean and thus lowering the percentage of a good outcome. In some instances.” (Pharmacist_01)

It was recognized that insured members should have a choice; not just a one size fits all but rather a number of options from which to choose from; plans that offer more comprehensive care vs plans that offer less coverage, based on what the insured member was interested in buying. At the same pharmacists also accepted the fact that their needed to be fiduciary responsibility to the shareholders as a business; hence the solution needed to represent a balanced approach. As stated by Pharmacist_01,

“obligated to the stockholders and the board of directors and anybody else that maybe involved from a financial standpoint in creating something that is not going to break the bank.”

However, ultimately, it was the patients who needed to make the decision on what was best for them and what trade-offs they were willing to take to improve their own health and well-being. Patients were also seen as having to be more willing to go through the process laid out by the MCO, for example, step edits, and be willing to try less costly options and better managing any associated side effects, before opting to secure the more expensive, 2nd line therapy. It was recognized by pharmacists that most insured members did not understand the terms of coverage within the policy that they purchased and that plans had a responsibility to make the language understandable.

There was also a sense that less care potentially led to more profits for a health plan.

“So, it's a question of, is there a primary responsibility to their shareholders and making a profit or is to the members that signed up for their plan? And I see these days the slippery slope head more towards profit than coverage. I think that the plans obviously have a responsibility to the manufacturers, the corporations, the small business owners that contract with them to provide the best care they can, but reality is not that. Reality is we have to make a profit
and keep our shareholders happy. There's something basically wrong with this system.” (Pharmacist_07)

MCOs were seen as a business looking (needing to make money) and providing a structured environment within which to access care under the purchased policy; the approach might work well for the majority of the patients but for those that required more services due to their medical condition there should be more compassion and access to affordable care. As stated by Pharmacist_05,

“Managed care is good for 80% of the people who don’t have a lot of issues but it’s the 20% that need a little bit more compassion and understanding as to their needs and they should try to make it a little bit more affordable.”

Affordability was achieved by limiting the access available through the plan; however, under the Affordable Care Act, MCOs began to offer plans with lower premiums but much higher out of pocket expenses to patients thereby making access to care when needed less affordable. The mindset of MCOs that were not denying care just payment for care was not well received by one specific pharmacist.

“That's the third party insurer's slick little answer. If they don't like our restrictions, they can buy it [the medication] anytime they want. Well, it's crap! All you have to do is look at the price of a drug out there these days especially one that doesn't have a generic yet. People can't afford medication. I'm a pharmacist and to think that I would have to... not one of my medications, but one that my wife takes. Her co-pay is three figures, but if she had to pay cash for it, it'll still be three figures, but the first figure would not be a 1, it would be a 6. Even a pharmacist is going to take a good punch at the wall to pay for something like that. That means most of America can't afford it whatsoever. So, it's a slick answer but it's not an answer.” (Pharmacist_07)

Limiting access to the less costly medication option that was truly similar to other medications in the marketplace was seen as acceptable but not if there was a difference in metabolism; heterogeneity was recognized as a factor that affects how patients respond to various therapy options and hence the need for access to various prescription medication choices.

However, economics factors into decision-making. Managed care looks to provide reasonable care for the average member of the population; not the individual who might not match the profile of the average person. This affects individualism; for
those that need access to medicines that are low cost there is opportunity for choice; where there is a need for specific conditions that are expensive, options were seen as limited.

“The disconnect is money. They understand that we know the patient better, but the viability of managed care doesn’t depend on catering to each and every person’s need. The viability of managed care relies on a standard set for the reasonable person. And that is at odds with medicine... The viability of the managed care is looking at Joe average not Joe Smith in my pharmacy. Individualism is lost; everybody’s self-worth is redefined. Everybody’s autonomy is redefined to what the managed care company says it should be. Granted, they allow a little leeway. They’re going to cover every strength of levothyroxine for thyroid disease. Do you know why they do that? Levothyroxine is so damn cheap. When it comes to a horrible situation like cystic fibrosis, you’re going to fight tooth and nail to get TOBI covered, because cystic fibrosis is not something Joe average has.” (Pharmacist_07)

Pharmacists recognized that employers need to make a business decision on the level of care purchased for insured members. The employer was seen as having to make a trade-off between increasing the price of goods sold to generate additional revenue and laying off employees to afford more comprehensive healthcare coverage for its remaining employees or to provide less healthcare coverage while not raising prices and retaining all their employees. Hence ethics and morals were seen as needing to be weighed in context of the economics. This consequently, at least as stated by one pharmacist, had a spillover effect on the physician; as stated by Pharmacist_07,

“What are the ethical considerations from the physician's perspective in that they did not prescribe the newer medications, even though there is published evidence? You know, for me, if I was the doctor, I don't know how to live with myself...”.

Patients were seen as having limitations to what they could afford. Affordability was less of a concern when patients were spending dollars on conveniences that were negatively affecting their healthcare, for example, smoking. Patients were seen as needing to be willing to redirect their dollars from purchasing cigarettes to purchasing interventions that would reduce their need to smoke. However, at the same time, it was recognized that overall system costs were increased when the system did not enable patients who smoked to stop smoking. As stated by Pharmacist_05,
“someone that can afford $240 a month to buy the cigarettes should be able to afford $50 and I think that’s the rationale that the employer groups have. I mean it seems logical to me. If you want to stop smoking, if you really are very serious about it, you can afford the $50... So you choose to not want to help yourself.”

There was acceptance that society did not preclude coverage for patients who acquired their condition due to poor lifestyle choices; that it was considered reasonable by the majority of society to have the economic burden of additional healthcare resource utilization incurred by those who make poor lifestyle choices absorbed by the insured population; however some of the pharmacists felt that such an expectation was unreasonable but still it was the way it worked in society. One pharmacist specifically spoke to how the system should reward individuals who take care of themselves by charging them less to acquire insurance; whereas charging more for those who do not thereby rewarding good behavior focused on wellness; there was also a need seen for providing employer or government-provided programs and education to help insured members become healthier. Patients were seen as needing to have options but ultimately accountable for their own actions and needing to own the consequences of their choices. For example, the pharmacist felt it was not the MCO’s or employer’s fault the insured member was overweight.

In summary, pharmacists felt that formularies force physicians to reflect on the various available treatment options. Patients need choice but ultimately the patient’s formulary will be reflective of the level of coverage they purchased; the business (the employer and the MCO) had responsibilities to their shareholders and needed to balance the economics with the levels of access provided through the MCO. Patients needed to be more accepting of trying lower cost options first and following the utilization controls laid out through the formulary by the MCOs. Limiting access to more costly medicines that were similar to less costly medicines was considered reasonable but it was also recognized that the patient who was not the average patient would potentially have a negative experience (and outcome) under a given plan. Not writing a given medication for a patient that based on the evidence might have been perceived to be the best possible treatment option was seen to have
potential ethical consequences to physicians but that physicians did not have much choice if the patient could not afford the physician-preferred medication.

5.3.5 Summary for the category “Drug Formularies are a Means to An End”

Formularies are a means by which MCOs curtail utilization of medicines to limit the cost implications of drug spend; the formulary either shifts a portion of the cost of the product to the patient or requires the patient to fulfill certain criteria before the medication is covered by the formulary. This was seen as affecting the autonomy of the physician and it was recognized that it might be difficult for a physician to not prescribe a medication despite the available evidence just because of formulary restrictions. Ultimately patients receive the level of coverage they pay for; physicians can always write whatever medication they deem best and the patient can always acquire a prescription at retail cost; but if the patient wants coverage under the formulary, the patient and the physician have to comply with the requirements of the formulary. There is an acceptance that patients should have access to medicines that is deemed reasonable; acquiring treatment that is above and beyond reasonable is a privilege and is available to the patient based on the level of coverage purchased or at retail cost. Society needs to determine what is reasonable and if physicians believe that a formulary impacts on their ability to practice according to professional standards than physicians need to voice their opinion. MCOs will make decisions that reduce their hassle factor and limits their exposure to liability. Several focused codes were identified under the category of “Drug Formularies Means are a Means to an End”, which emerged from the data that is found in the review of this section, including: dealing with economics, defining the minimum acceptable level, exercising fiduciary responsibility and assessing the role of ethics in access decision-making.
5.4 Informed Decision-making Essential to Understanding Implications of Choice

5.4.1 Informed Decision-making Essential to Understanding Implications of Choice: Findings associated with interviews conducted with EBDDMs

EBDDMs did not believe they had the level of knowledge to question the recommendations made by MCOs; they had to trust in the expertise of the MCOs that had been retained to facilitate coverage for their employees (insured members); EBDDMs in some cases decided to retain benefit consultants to provide additional input. At the same time, employees expected the employer to complete due diligence on (1) the type of benefits provided and (2) the MCOs chosen by the employer, as employees lacked the ability to make informed decisions around coverage options and found the selection process difficult.

EBDDMs spoke to the value of collective wisdom which is gained from a panel of experts that inform the formulary and also review and decide whether coverage for a given product should be provided for a specific patient. One specific EBDDM spoke to how formularies change on a regular basis and the EBDDM mentioned that they always believed these changes to be as a result of the MCO’s assessment of a given product’s efficacy and not based on a better rebate being obtained by the MCO for a given product. This specific EBDDM realized that perhaps he was remiss by not asking the right questions to ensure the basis of changes in formulary coverage. The EBDDM realized he needed to ensure that questions were asked to help understand how coverage recommendations affected the financials (profitability) of the MCO. Instead the EBDDM assumed if employees were not complaining about unmet needs the formulary was meeting the needs of the employees.

“I feel remiss. If we have a duty I have not been performing it…we are relying on the MDs and Pharmacists [the MCO P&T Committee] who are putting this together and constantly monitoring it. And because I am not getting – the only anecdotal evidence I have that whatever we are doing must be effective is that I am getting very few complaints…” (EBDDM_10)

At the same time, selectivity of information provided in the decision-making process affects the willingness of the decision-maker to agree with a given recommendation.
One EBDDM spoke of the importance of understanding how his leadership team makes decisions and then engaging accordingly to gain alignment from the leadership team on a given recommendation.

“…how I presented it is different because the needs was, I needed to get the support for everything and not get stopped throughout the way… I guide them through some of the decisions. But yet I’m careful in how I present the information to be able to get to where I need to be at the end.” (EBDDM_02)

In summary, EBDDMs recognized that they did not have the expertise to determine what medications and types of formularies would be most appropriate for their employees; they needed to trust in the decision-making of the MCO. However, EBDDMs realized that if they did ask the right questions they will not understand the reasons for an MCO’s recommendation or rationale for their actions and decisions.

5.4.2 Informed Decision-making Essential to Understanding Implications of Choice: Findings associated with interviews conducted with MCOP&Ts

MCOP&Ts brought up the point of cost being reasonable as a product attribute that factors into adding products on formulary. Cost was determined not only on the basis of acquisition cost but also the longer term effect on overall healthcare resource utilization (such as office visits, emergency room visits). Actuaries were noted as being involved and calculating the impact of plan coverage and benefit design on a per member per month basis.

MCOP&Ts brought up the concept of certainty of evidence. There is a lack of reproducible evidence in several instances and these affect the ability of the MCOP&T to assess and defend the value of a given therapy.

“I mean we have all seen studies where once… you know, you look at 5 studies and they have much different numbers, the difference has to be… you know, significant. And something that is repeatable. You know, multiple studies show that one is more effective than the other. Not just, you know, you do not just pick and choose which study you what to be your efficacy.” (MCOP&T_10)
The P&T Committee was seen as both democratic and non-democratic in that the specialist on the committee would have greater ability to sway the decision of the committee because of their expertise in a given disease.

One MCOP&T spoke to how MCOs have taken away the autonomy of physicians. That physicians have learnt the rules of the plan and have complied with those rules as they do not want to run the risk of not being able to participate in the plan.

“…[we] tell them to use what we would like them to use. And if you don’t do it repeatedly, we might tell you to leave the plan, and you don’t want that to happen because ultimately if we tell you to leave forcibly, every plan knows about it, and it’s a black mark. So physicians have quickly learnt to accommodate to the rules, we have step edits, they know about it. They will not write prescriptions for drugs that would cause a step-edit; it’s too much work and they don’t want the hassle factor. They have learned to be obedient or else, and the ones who are not obedient or else have been removed or have learned to change their behavior... They quickly learn to accommodate the system. Sadly. Because the rebellion now is taken away from them.” (MCOP&T_01)

The MCOP&T also spoke of how physicians needed to increase the number of patients they see in a given hour and MCOs do not pay physicians for explaining the various medication options in helping patients decide which therapy option is best for them based on their preference. One specific MCOP&T spoke of how physicians should not have bonuses; as a Medical Director at the MCO, MCOP&T_01 communicated to his CEO that he did not want his bonus: “I am against bonusing in health care. I am probably the only medical director that ever sent the CEO a letter saying, I do not want a bonus while I work for your plan.”

Many factors can influence a community physician’s prescribing decision and they may not all be grounded on the scientific evidence of the given product, hence the benefit of a 3rd party formulary. Physicians were deemed not being able to assess the difference in treatment effect among agents in a particular class a priori.

“…there ought to be some evidence that a person has failed standard of care before easy access to some other agent… I think it is perfectly reasonable to require that a patient… that one documents that a patient truly has failed that generic agent before the managed care company allows access to another agent that is presumably more expensive.” (MCOP&T_02)
The MCOP&T spoke to how in a larger company it is harder to humanize the patient than a smaller company; smaller companies more readily enable the treating physician to have an in-depth and thorough conversation with decision-makers than in larger plans where talking to decision-makers might be more difficult, if at all possible. At the same time the MCOP&T spoke of how in their opinion justice is satisfied when the process of review is followed completely irrespective of the decision concluded through the process.

“Well, I think that if I believe that I have followed the rules of the benefit of what it is the person has purchased, or the employer group has purchased, and has allowed that person to go through an appeal process which is consistent with, you know, let’s say for a commercial insurance, the National Committee for Quality insurance. Obviously we are NCQA accredited. If I have allowed that and I have allowed that person to go through whatever other appeal process that might be allowed by the State for example. And the decision that we made is upheld, I believe that’s justice, I believe we’ve done everything. We’ve allowed that patient every opportunity to advocate for what it is he or she wants.” (MCOP&T_02)

At the same time the same MCOP&T spoke of how sometimes those involved in the review process do not show up to the discussion in which case the discussion needs to be rescheduled to ensure a minimum quorum are present to inform the decision. Ultimately the committee based their decisions on what was provided by the treating physician (and patient); committee members did not seek out additional information as it related to the case; hence the importance of thoroughness on the part of the treating physician’s part in the appeal submission process.

Part of the challenge in the administration of the formulary that was identified was when the treating physician communicated to the patient that the decision of the MCO was not best for the patient’s care.

“Where physicians’ leave talking negatively about the decision we made directly to the patient and they’ll call back and say my physician says that your therapy will not work. I don’t appreciate that because I don’t know how he can determine nine out of ten times things are not going to work or not unless he’s a mind reader.” (MCOP&T_03)
Incentives paid to physicians by 3rd parties should be disclosed to patients according to some of the MCOP&Ts to ensure individuals understood how their care could be affected; other MCOP&Ts felt that disclosing this type of information to patients would just lead to additional complications that would affect the ability to treat and care for the patients. Although several MCOP&Ts believed there should be no incentives that encouraged the physician to use a specific protocol, some were more receptive to such an approach.

“I think it’s put out there so the physician will think through and provide the most cost-effective product and hopefully that is the right ethical decision. So it’s there to help them make the best ethical decision because the best ethical decision is probably the most cost-effective product.” (MCOP&T_06)

Overall, it was thought that when a physician chose a specific medication the patient most likely did not know of alternatives, or how cost factored into the physician’s decision-making process.

MCOs established formularies that promoted reasonable outcomes at the lowest possible cost. For example, for patients who had anemia, the first line therapy encouraged by MCOs were generic medications for use with anemia as opposed to expensive branded drugs that have not yet lost patent protection. The difference in cost per month was calculated to be in the thousands. MCOs needed to be careful in their decision-making as they had resources to better understand the totality of the evidence. The mindset for physicians as stated by the MCOP&T needed to be “what's the least expensive most effective thing that I can prescribe... That's what's going to keep us in our own healthcare in charge of choices”. (MCOP&T_03)

The possible role of the pharmacist was eluded to by one of the MCOP&T’s, who acknowledged the benefit of having the community pharmacist involved, but also recognized that most physicians would just reinforce their original position on the therapy prescribed. The concept of a team-based approach was hinted at as well as the value of pharmacists in helping to inform treatment choices.
“There are some really smart pharmacists out there, who can immediately pick up on something that’s not the best choice for the patient. And when they pick up on that, that phone call needs to be made. This is not the best choice based on x and z. And the physician can either agree or not agree. But a lot of times they say this is what I want, just do it. Unfortunately, a lot of them [the pharmacist] go along with that. Maybe that’s not the right thing to do. Maybe we need to look at everything and not just one physicians’ point of view for the best thing for the patient.” (MCOP&T_03)

In summary, MCOP&Ts spoke of the certainty of evidence when making decisions around adding medications to formularies and the lack of reproducible evidence which undermine the ability to defend the value of a given therapy. Still MCOs felt they had the necessary expertise to assess the benefit-cost tradeoff for a given medication; an expertise that treating physicians were lacking. MCOs felt that it was important to follow the process agreed to by the MCO to inform decision-making; however the process did not necessarily translate into a thorough review. Members of review teams to make a decision regarding a specific patient gaining access to a given medicine will not show up to meetings, meetings need to be rescheduled and when the meetings do take place, decisions at times are made on incomplete information. MCOs did not show concern that access to a given medication was delayed due to the process of review; with that said, humanizing the patient is more possible in smaller companies than larger companies. Formularies are designed to impact physician decision-making; for physicians to reflect on the most cost-effective treatment option for a given patient. Leveraging input from the community pharmacist was recognized as potentially positively impacting on patient and system outcomes but was not being actively supported by the healthcare system.

5.4.3 Informed Decision-making Essential to Understanding Implications of Choice: Findings associated with interviews conducted with Community Practicing Physicians

It was mentioned that insured members chose to pay for their healthcare services and products through the use of an MCO; hence all treatment options should be discussed with a patient, whether on formulary or not; if not on formulary, insured members should still have the choice to pay for it separate from what the plan has
covered. It was viewed unethical for a physician to not offer as a treatment option a product just because it was not on formulary.

“It’s a choice between two medicines; medicine A and B are available, it doesn’t matter whether insurance is available for this patient to pay for it or not. Those two choices still need to be presented to the patient.” (Physician_02)

The pharmacist’s role was seen as ensuring the prescription was properly written and filled as well as to communicate to patients the cost of the medication based on the level of coverage through their MCO. Some physicians felt that if the pharmacist independently brought up a lower cost treatment choice, that was not appropriate for the pharmacist to do, as it was then negating the physician’s treatment decision; the pharmacist should only provide that information if prompted by the patient. There was a further distinction made; namely that did the pharmacy financially benefit from any recommendation the pharmacist made, as in that case, the information provided might not have been in the best interest of the patient. However, pharmacists should communicate the rules of the plan to the patient, namely step edits such as if a product needs to be tried first before another product is to be covered under the plan. Whatever information is ultimately provided, it should be the patient who makes the decision on whether a product should be switched. It is difficult to determine which product a patient should have as efficacy, side effects and costs need to factor into the decision-making and two physicians might have a different perspective on each of these factors and how they impact decision-making.

Cost of the product was seen as something that should be part of the initial decision-making by the physician when deciding on which therapy to prescribe. “…it is just bad judgment... to write a prescription and the patient would go to the pharmacy who's unemployed and have to pay $500 for an antibiotic... it's not going to happen. So you haven't really helped the patient....” (Physician_02). However not all physicians considered cost. Under the current system, physicians were not always mindful of costs: “I think many physicians don't look at cost when it comes to prescribing, because it's not really coming out of that physicians' pocket.” (Physician_03). However the point was also made that physicians do not know the true net cost of a medication that the MCO pays and also the cost that the patient will
need to pay in the form of cost-shifting as this only becomes apparent at the time the patient will fill their prescription at the pharmacy.

MCOs were seen as needing to cover what was deemed standard of care defined by the medical community; otherwise there could be exposure to legal liabilities. MCOs and employers were seen as needing to provide access to reasonable care but the point was made that neither physicians nor patients understood their rights nor what should be their expectations as it related to coverage of medicines.

“…an employer buys insurance for you as a worker; that there are expectations… The right to choose drug “y” may not be in that expectation list and you have to understand that the problem is most patients do not read all the fine paperwork of managed care plans… Patients aren’t savvy enough and physicians aren’t savvy enough, I mean I don’t sit and read what drugs are covered under different formularies… I think it would be very unusual for physicians or patients to read… [One specific brand name drug without a generic alternative] is covered but x drug isn’t. That’s just not on our radar screen. There are certain rights and expectations of participating in a managed care plan and so on and so forth that one has but most patients don’t know where that line is. (Physician_04)

MCOs were seen as needing to ensure consistency of decision-making; providing options and having flexibility in coverage was seen as important given the differences of opinion on treating a specific patient with a given medical condition. Formularies with step therapies were seen as an acceptable approach to care, as stated by Physician_02, because making “a priori assumptions that a treatment is not going to work, that it’s less effective, is a false argument.” In addition, it was mentioned that physicians unless they know categorically one product is better than another based on available studies, there can be a number of external factors influencing a physician to choose a product such as having samples, interacting with a pharmaceutical representative, seeing an advertisement.

There was a general point of view that there were no real denials of access by MCOs. It was just a question of whether the MCO would cover the use of the product. Patients could always source the medication if they were able to pay for it. Still there should be enough coverage to enable choice of treatment options for a given patient and condition.
“…employer or the health plan should try to be fair to its employees in terms of having medications available that are… there’s at least a wide enough range of medications that are available, to a patient such that a patient does not feel that they are limiting… that they are limited in terms of access to medications.” (Physician_03)

The challenge with formularies and cost-shifting was that prescribing a patient a medication that they will not tolerate well due to side effects or lack of efficacy was that they would stop taking the medication; similarly if the cost of the medication was too high, the patient would not stay on the medication due to the cost and would fall off treatment. This was seen as neither reasonable nor appropriate.

“…that’s the potential for what you would call ‘non-compliance’ is potential for them to not take the medication at all rises pretty significantly with either medications that are less expensive that have bad side-effects or are too expensive for the patients to take and a lot of the time the patients don’t want to bother the physician so they don’t necessarily call and say- ‘Hey, I cannot take this because it’s too expensive’ or ‘I cannot take that because it didn’t work and I don’t like the side-effects’ and then they are not being treated appropriately and then they’re not being treated in a reasonable way because they fall in between the cracks of the system.” (Physician_05)

The loss of access due to no coverage through an MCO was seen as impacting on autonomy and quality of life unless patients were able to afford purchasing the product separate from the health plan. If patients subsequently are not able to gain access to a medicine that would have benefited their health, it was seen as a level of injustice and infringement on rights.

The physician still treated the patient the same irrespective of the level of coverage they might have but based on coverage levels the physician needed to adapt their treatment approach the best they could and operate within the constraints of the system.

“So you treat everybody the same way to begin with but then if there is restrictions that the plan places, requires you to do things in a different way then you have to adapt to that and still try to maintain the highest standard that you can of doing the best that you can for them under the constraints that exist.” (Physician_05)
A specific example provided by one of the physicians was the physician still prescribed the product they deemed best, but then asked the patient to ask the pharmacist to call him directly while the patient was at the counter if the cost of the medication was too much; based on what was on formulary, if the alternative therapy was reasonable they would authorize the switch.

“And say, look this is what we are dealing with. The drug I prefer to give you may be expensive, and what I usually will do even is, I will say to the patient this is my favorite, this will cut to the chase and solve your problem most quickly. And has fewer side effects in my experience. I am going to write for it. When you get to the pharmacy, if it is in a price category that is too much for you, don’t fill it. Call me from there; have the pharmacist call me and I will change it. Especially when they tell me what is on formulary if I think it is a reasonable alternative.” (Physician_01)

Physicians felt that when they were able to speak with Medical Directors at MCOs there was a greater likelihood of the MCO approving access to a specific medication for a patient than when only written communication was allowed. This was thought of as a form of rule of rescue, not because the treating physician knew the MCO Medical Director, rather because, as stated by Physician_05, “…you are providing information that can’t necessarily be found on a piece of paper and clarifies the situation of why this particular treatment approach is appropriate for the given individual”.

The use of a 3rd party recognized as a clinically-sound organization was seen as a process by which to bring consistency to decision-making, namely that such a 3rd party would indicate where coverage of a product in treatment strategy was reasonable and hence insured members and treating physicians would know there would be coverage for that product across all plans; the only question that would remain is the level of cost-shifting to the patient. This approach would enable transparency and consistency of decision-making.

There was mixed opinion on disclosing incentives that physicians might be receiving from MCOs that impacted prescribing practices; some physicians felt outright all incentives should be disclosed, or at least those that impacted decision-making; where some felt disclosing incentives would only create unnecessary concern and
misunderstanding among patients. However, all agreed that incentives that interfere with the physician choosing what was best for the patient was not ethical.

In summary, physicians should discuss all relevant treatment options with a patient whether or not it is on formulary; all patients should be treated the same until the patient’s formulary requires a different treatment choice either to ensure affordability or coverage under the formulary (for example, a step edit requirement). Physicians should explain the various available treatment options and the associated benefits of each so that patients could ultimately decide whether to use a non-formulary product if it is in their best interest including their ability to afford the medication at full retail cost. Pharmacists should not attempt to proactively communicate information to patients to try alternative medications as this was seen as undermining the physician’s treatment recommendation, especially if the change in prescription can lead to financial gain to the pharmacist or the retail pharmacy. Rather pharmacists should focus on ensuring prescriptions are written by the treating physician completely and accurately with all the necessary information provided as well as communicating to the patient the specifics of the formulary that need to be complied with by a patient in order for the medication to be covered under the formulary (for example, step edit or prior authorization requirements).

For a physician to write a prescription that the patient could not afford was not seen as reasonable although the treating physician was seen as unaware of the true medication costs at the time of prescribing. Physicians were also not able to know a priori how a particular patient will respond to a given medication; individual physician treatment decisions were often seen as multi-factorial hence two physicians may chose a different treatment option for the same patient which underscores there is no “only one” treatment option for any given patient; variability is accepted as part of the practice of medicine. Hence step edits and prior authorizations were seen as acceptable. Reasonable care was seen as a requirement to minimize liability but it was also acknowledged that most patients and their physicians did not understand the contractual requirements of a patient’s formulary provision. Providing patients’ with choice was seen as necessary given patient heterogeneity. However, to be
efficient, writing medications where it was anticipated that the patient could not afford the medicine or would react adversely to the medication was not seen as being reasonable. Transparency and consistency of decision-making, and clinically-appropriate decision-making, was seen as important attributes that the system should aspire to and maintain.

5.4.4 Informed Decision-making Essential to Understanding Implications of Choice: Findings associated with interviews conducted with Community Retail Pharmacists

One pharmacist brought up the point of knowing the consumer will lead to more intervention by the pharmacist to help the patient; by giving additional insight to the patient around treatment options.

“…a lot of times the managed care will show those other options on the screen before I fill it but I don’t say anything because I don’t know what their current situation is. They may have tried those other medicines, I just don’t know enough about them so I usually will withhold… that kind of information and let that be up to the physician. You see what I’m saying? I hate to say it… but if I know you or I know your situation I’m more helpful than I am if I don’t know you only because I don’t like to overstep the physician’s choice.” (Pharmacist_01)

The importance of options was stressed; that one size does not fit all, and the most important aspect in the process was to ensure there were options available for the patient to choose from; as stated by Pharmacist_01, “as long as there is an option; as long as the options are there, then it is up to the patient whether or not they want to take that option.”

The pharmacist spoke of how the visible price is not the acquisition cost and hence the true acquisition cost is not known across the MCOs due to the nature of confidential price arrangements.

“We never know what a company… I guess you don’t know what the company is getting reimbursed. You don’t know what company is getting reimbursed for the prescription you are getting. If they have made a deal with the drug company that every prescription that we get of yours, we are going to reimburse you a dollar, a nickel, a percentage. You don’t know that. That’s not your business basically and you are not aware of it…” (Pharmacist_03)
The system interfering with what the physician prescribed was seen by the pharmacist as unethical because the 3\textsuperscript{rd} party was thought not to have the necessary knowledge about the patient; interference was seen as potentially leading to a different treatment option.

“…they really truly believe when they write the prescription that is what they require at that time; for someone else to come and say, that has not met the patient, has no idea of what the patient is going through or their ability to pay or not pay, having to tell the physician that that’s not what we want you to prescribe, we want you to prescribe something else. Ethically that’s an issue. That’s a big compromise for a physician. They have chosen what they think will work best for their patient and now they are being told that it’s not going to be covered. Your patient can’t get it, which means that your treatment plan is totally changed. It could be altered. You know that the outcome is not going to be what you expected nor did the patient expect that outcome. So ethically for the physician I think there is a big issue.” (Pharmacist\_05)

Rules forced physicians and patients to comply with the parameters set by the MCO; if those rules were not followed the consequences to the physician and patient were economic: potentially less income for the physician and greater out of pocket expenses for the patient. Economics ultimately determined the approach that was taken in patient care. At the same time, the point was made that physicians are not as knowledgeable perhaps as they should be on the different available treatment options; that specialists perhaps new more but that the general practitioner might not; hence formularies affected prescribing behavior. When physicians wanted to prescribe for a restricted medication, they needed to make the case for why they felt that particular medication was needed. As stated by Pharmacist\_09, “He has got to jump through a few hoops in order to allow or expect this managed care to pay for said treatment.”

The pharmacist stressed the importance of clear communication so insured members understood at the time of purchase what was to be covered vs not covered and the implications of the coverage level provided through the policy. The pharmacist felt it was the MCO’s responsibility to ensure the communication was understandable, choices were easy to make and that there were possibly more choices offered within a given cost range. The pharmacist spoke of the fact that there was a lack of understanding on the part of the pharmacist on what actually transpired in the case of
a specific denial of coverage for a given patient. Such as who was spoken to, what information was reviewed, what factors were considered; was a specialist consulted and what were their qualifications. There was also a belief that there was a lack of compassion in the decision-making in the denial by the MCO. However, it was accepted that plans treat to the average patient based on evidence assessments of products by clinicians and other relevant experts who have agreed to a set of products to be included in the list of available treatment options; based on the average patient profile, products were then identified for use in treatment strategy such as first line and second line. The insured member was seen as needing to owning the responsibility of understanding the specifics of coverage as it related to the policy that was purchased.

The concept of gambling was brought up by the pharmacist. There was a gamble being taken by the insured member and the MCO. The insured member was gambling by the level of coverage they opted for; if they elected for less coverage and became ill they would have more out of pocket costs and would hence lose the gamble. At the same time, the MCO took a gamble when they deny coverage for a product and subsequently incur additional costs due to outcomes being compromised.

With regards to physicians and spending time with patients, there was recognition on the importance of providing the necessary education to enable the patient’s decision-making. This point surfaced during the review of the smoking cessation case study. As stated by Pharmacist_05,

“I think that the doctors can spend more time with the patient and provide resources, brochures, documentation on smoking cessation options. And go through the steps that would help the patient get the option that he initially wanted to get which was C, which I think probably could have helped him.”

As surfaced during the urinary incontinence case study, providing effective patient follow-up, explaining the process of prior authorizations and the physician explaining the treatment approach given the level of formulary coverage, might have enabled a better outcome. As it related to the Prostate Cancer case study the pharmacist felt that the physician was thinking ethically when considering a product that would lead
to a better quality of life (one that would not require chemotherapy) and that it was the MCO that was compromising ethics by not providing coverage for a product that led to improved quality of life outcomes. At the same time, clinically meaningful differences in outcomes needed to be understood and agreed to by the various stakeholders and there needed to be documentation in the market of improved outcomes over time.

The pharmacist spoke of how their hands are tied because they do not have all the necessary information to effectively inform decision-making; in the clinical setting they would be able to help with treatment-related decision-making, but not in the retail setting.

“Our hands are tied at the counter and we can't make a decision unless we had access to more information about the patient. Now as a clinical pharmacist, that is something I am an expert at. However, at a retail section, in a retail sector, our hands are tied because we don't have access to this information.” (Pharmacist_09)

Employers were thought to have a responsibility to encourage wellness through program offerings but also to allow for insured members to make changes during the year should their health status change (for example, if they are diagnosed with diabetes). MCOs were seen as not necessarily accommodating those patients who have a higher degree of therapeutic need.

In summary, knowing the patient leads the pharmacist to spend more time with the patient. Being aware of treatment options was important so each patient could make the right choice based on patient preference; but the true cost of medicines was not known; only the patient out of pocket or cost-sharing at time the patient fills the prescription at the pharmacy. MCOs were seen as interfering with the physician’s expertise and their treatment recommendation; at the same time pharmacists acknowledged that physicians were not necessarily the most informed with regards to specific medications and ultimately formularies affected prescribing behavior. Formularies impacted physician prescribing behavior as not complying with the requirements set forth by the formulary would negatively affect coverage to medications on the formulary. Formularies negate the physician’s personal
knowledge of the patient and requires the physician to choose from products that are available to the patient based on the formulary. Based on the formulary rules, the physician also encounters administrative requirements or hurdles to enable the patient gaining access to a given medication. Pharmacists, as physicians, do not know how MCOs make decisions and it is the responsibility of the MCO to communicate clearly with regards to why a specific medication is denied for use by a given patient. Pharmacists recognized there was a gamble effect in that both the patient gambled that the coverage they purchased would be sufficient and the MCO gambled that the formulary would not negatively affect the total spend of the plan. The pharmacists’ hands are tied as they are not brought into the decision-making process and do not have the necessary clinical information to be a collaborative thought partner in the decision-making process. Physicians hence needed to ensure patients were fully informed to make the right treatment choice given their personal situation and preferences. Employers should provide insured members with flexibility should their health status change during the year and to encourage programs that improve the insured member’s wellness.

5.4.5 Summary for the category “Informed Decision-making Essential to Understanding Implications of Choice”

Certainty of evidence is what MCOs aspire for but this is mostly lacking in the marketplace and hence it is difficult to exactly define the value of a given medication. MCOs believe they have more expertise to assess what are the more appropriate medications to include on a formulary and the utilization controls imposed by MCOs and cost-shifting to patients help physicians chose the most cost-effective medication based on the MCO’s perspective. However, physicians and pharmacists felt there was a lack of transparency on how MCOs make their decisions and whether their decisions were consistent. MCOs ultimately were seen as interfering with the physicians’ treatment choice; this increased the importance that patients understood all the various treatment options so they could make the best choice for themselves based on their personal situation and preference. Pharmacists were also seen by physicians to overstep their boundaries when they proactively recommended different
treatment options to the patient rather than just communicating the specifics of the formulary. There is a lot of variability in how different physicians treat their patients and hence it is recognized that there is no singular treatment choice; it varies from physician to physician and based on patient characteristics. Hence formularies should provide a reasonable amount of choice. In a more collaborative system, physicians would be able to leverage the pharmacists’ knowledge on medications to inform treatment strategy. Employers who ultimately agree to the terms of coverage through the MCO do not have the necessary expertise to assess the recommendations made by the MCO and hence need to trust in the MCO’s decision-making; however, employers need to ask the right questions to ensure MCOs explain the rationale of their decisions. Several focused codes emerged as it relates to the category of “Informed Decision-making Essential to Understanding Implications of Choice” including enabling decision-making, setting parameters to inform access decisions, understanding the trade-offs, and utilizing evidence to inform decision-making.

5.5 Population vs Patient-level Care are not Necessarily Reconcilable

5.5.1 Population vs Patient-level Care are not Necessarily Reconcilable: Findings associated with interviews conducted with EBDDMs

There was an overall recognition that business decisions were cold-hearted, that the business was not there to handhold the insured members decision-making; that insured members needed to decide for themselves with their treating physicians on the level and type of care they wanted based on their health plan coverage and their willingness (ability) to pay for care. The point was highlighted that caring for the population was to provide a healthcare plan that provided access to medicines but this did not take into account the effect on the individual.

“There’s a difference between totality and individuality. To care for your employees which is plural is in totality, to be cold is individual. It’s specific to a particular situation. So to care for our employees we have a health care plan, we have access to medications. To be cold is to identify a particular individual’s treatment plan and saying that does not fit into what we have designed.” (EBDDM_2)
When it came to the consideration of fairness, the population was the focus as opposed to the individual.

“…sometimes, we get into what’s fair to the group versus what’s fair to the individual. And I’d say in general that our philosophy here is that if that’s in conflict we generally try to go with what’s fair to the group.” (EBDDM_7)

Irrespective of the reason for the formulary changes, the implications of changes were recognized as sometimes potentially positive and sometimes potentially negative for any given individual but the priority was to keep pharmaceutical costs “under control”.

“…we make formulary changes all the time, and sometimes they affect people negatively and sometimes positively and there is no guarantee that the plan design will always keep you whole whenever we make a change in benefit structure or something like that and that is where we felt we were under no compelling duty to keep people whole and keep the old plan design in effect as we pursued others to get our costs under control but having said all that – God that stinks – that is not fair.” (EBDDM_10)

Although decisions were taken at the population level, EBDDMs recognized the importance of having a process in place to assess the impact on the individual insured member (patient) and that the process be known in advance of its application. The results of the process were then used as documentation for a decision taken and the findings of the process communicated to the treating physician and patient as to why a specific decision was taken.

The engagement style of insured members was recognized by the EBDDMs as an important factor in how their request for coverage would be affected: those insured members who requested coverage changes to be made based on the need of the insured population vs one specific patient as well as the tone of the insured member making the request increased the likelihood of either a change in coverage for all insured members or coverage for the specific member in a given circumstance. How requests for exceptions are presented by the insured member / physician matter as they impact on the willingness of the decision-maker to make an exception. Although EBDDMs spoke of the importance of consistency in decision-making to ensure equity of access, EBDDMs also recognized that there was an emotional aspect of trying to
help people whose problems have surfaced to the attention of the decision-makers. EBDDMs spoke to the tension that existed between what they were compelled to do as a professional with specific responsibilities vs their innate desire to help people. One EBDDM specifically made reference to the point that if a given employee made a request for coverage there might be the possibility of somehow identifying a solution for that given employee; if other employees than came forward with the same need, to ensure consistency of decision-making, the same decision of coverage would be taken without proactively finding insured members in the same situation. In addition, the point was discussed that if insured members did not bring forward information that could impact decision-making then there was a missed opportunity and outcomes could suffer.

It was recognized that if the voice of the insured member was not engaged, especially those that utilized the plan, decision-makers might not be doing the right analysis and not gaining the necessary insights from the analysis -- only looking at the statistics might not surface important issues affecting insured members. Hence processes have to be in place to ensure exceptions could be made at the individual level when warranted.

In summary, EBDDMs recognized that decisions were taken at the population level with an awareness that on the individual patient level there could be negative or positive implications to any one individual. It was seen as important to ensure there was a process in place to better understand the implications of a decision on the individual patient level. Also that EBDDMs wanted to help individuals the best they could, especially if a specific problem was raised to the awareness level of the EBDDM; hence to positively motivate the decision-maker to identify a solution for a given patient, it was important for the insured member to engage with a specific tone and approach. Without asking the right questions and doing the right analysis it was easy to overlook the implications of decision-making at the individual patient-level.
5.5.2 Population vs Patient-level Care are not Necessarily Reconcilable: Findings associated with interviews conducted with MCOP&Ts

One specific MCOP&T spoke of the realization that dealing with large populations changed decision-making.

“When you deal with a large population and have to make the resources match what you are doing, that changes some of that ethical behavior. And I readily acknowledge that I do change my behavior when I walk into the office in a health plan… I may believe differently. I may believe that patients are entitled to a much broader range of medications as an individual treating a patient. But as an individual on a committee trying to treat a thousand patients, my decision making is more limited. And I have to wear a second hat.” (MCOP&T_01)

There was recognition to a degree that formularies changed what transpired at the physician’s office: “…decisions that are made are really related more to how does one use premium dollars in making decisions for covering a population. How does that impact the decision that a physician might have in caring for an individual patient.” (MCOP&T_02).

There was an on-going shift in the marketplace to place the patient as consumer in charge of purchasing decisions in regards to care provided. This was acknowledged by the MCOP&T:

“I think that we are going to see far more transparency in the cost of those services. So you know a patient is going to come in and say, doctor the, you know, they tell me that the MRI’s going to cost me $250. Maybe they are going to say, I have a high deductible health plan and I’m going to have to pay a thousand dollars so do I really need that…” (MCOP&T_02)

Given the MCO looked to benefit the population at large by identifying lower cost options that was to be effective for most patients, the MCO utilized step edits and prior authorizations to enable access to additional treatment options for those patients who needed such access while minimizing negative cost implications to the broader plan.
“So that's usually the things we put in the prior authorization category or in some type of step therapy to make sure that the right person is getting that and it’s not going to be a drain isn't the right word. But that's it's not going to impact the plan negatively... it just doesn't make sense to cover everything when we got something that's less expensive that's probably going to have a good outcome.” (MCOP&T_03)

However the MCO's focus on the population in the opinion of the MCOP&Ts, should not distract from the physician's ability to do what is best for the patient. “I think what we want the physician to do what is the best for the patient… I don’t think the formulary is any impediment to doing any of these things.” (MCOP&T_06).

Ultimately the plan believed that the patient needed to decide for themselves whether they were willing to pay the extra dollars for a product that was not covered by the policy of the plan. If the patient could not afford the product, the patient could always try to get patient assistance from other sources such as the manufacturer.

“We want the patient to have that discussion with their provider. Is this... what can I expect from this? So they can evaluate the product in terms of that cost. And is this going to be... You know, they can look at this product, compare it to what other things that are available that are less costly to them on the formulary, and make and come to a rational decision as an individual... I think you cannot have anything more ethical than having the patient involved in the decision-making regarding what products he takes and having them have the choice.” (MCOP&T_10)

In summary, MCOP&Ts were aware that their decisions needed to be at the population level and not on the individual patient level. That the need to be a good steward at the population level required decision-making that was different at the individual physician-patient level. Hence it was even more important that the physician treating the patient do what he or she felt was in the best interest of the patient. Subsequently, the patient needed to make the decision on what treatment option was best given his personal preferences and situation.
5.5.3 Population vs Patient-level Care are not Necessarily Reconcilable: Findings associated with interviews conducted with Community Practicing Physicians

MCOs were seen as making decisions at the population level vs physicians making decisions at the patient level. If patients wanted or needed access to more expensive medications, they always had the choice to acquire these medications by paying for it. Pharmacists at the pharmacy counter were able to provide additional information on treatment options based on coverage rules. The problem seen by one of the physicians was if the alternatives being recommended by the pharmacist provided a lessor benefit to the patient than the original medication prescribed by the physician. One challenge a physician identified with pharmacists making alternative recommendations, even if the physician decides to subsequently change the prescription, is that the physician was not able to discuss the change with the patient.

“If the physician changes the prescription based upon the rule itself, then I think that the physician may have crossed an ethical boundary that says, okay the physician is making a decision that is not... that he/she doesn't know what the patient wants. And it has to be a cooperative decision... Even if the physician may have the right intention in mind, it's ultimately the patient's decision whether they want a certain treatment or not, or change of the treatment.” (Physician_02)

Physicians were seen as needing to be proactive in the care of their patients; if a physician knew that a specific medication that was preferred by the MCO would most likely cause concerns to the patient (for example, a medication known to create gastrointestinal side effects and a patient who was gastrointestinal sensitive), than an ethical problem was seen to arise because cost was trumping what was best for that patient. The duty of the physician was seen as providing the desirable outcome to the patient in a way that the patient felt was acceptable to the patient “based on evidence-based medicine and their knowledge of their patient preferences and needs”. (Physician_02).
The concept of physicians seeing themselves as puppets and being dictated to by MCOs was raised during the interviews with physicians. The challenge with formularies was addressed in terms of the population vs the individual patient.

“…that is the problem with population studies, they may say these things are equivalent but medicine is individualistic. Everything, how a person responds to a particular drug, it doesn’t work the same way in every patient... Our expertise is to choose the proper medication for a given condition. There are lots of choices but I think as physicians I don’t like being told what to do. I don’t like being told I can’t prescribe this drug and the way I reason it and get around it is I say – ‘this is covered you know let’s try this. If it doesn’t work then you know I want you to come back; if it doesn’t work then I think this other drug might be better we can try it as’...” (Physician_04)

Physician_03 articulated the challenge of taking care of the patient; of the physician’s hands being tied when the plan does not cover a certain product or the patient cannot afford to pay for the product the physician perceived as better for a given patient. There was tension recognized between reducing the cost of care while trying to minimize side effects and improving outcomes, which the physician felt was a conflict of interest.

“They are acting based on reducing health care cost... The ethical thing to do would be, we as physicians should be treating the patient irrespective of cost. So we should be doing what’s best for that patient. So if product B is more easily tolerated, that’s what we should be looking at irrespective of the cost. Now again, if the patient says, I can’t afford this, or the insurance company is saying, or the managed care plan is saying, “Well, that’s not part of our formulary”, well then again the physician’s hands are tied at that point. Then the physician is going with product A because of those other reasons. So I feel that there are conflicting interests. One is, you are trying to reduce costs by taking product A, but you are making a patient potentially suffer side effects by not choosing product B.” (Physician_03)

Looking at trade-offs when the physician and patient feel limited by their selection was seen as frustrating. However, at a population level when using a lesser cost intervention to achieve an outcome and it succeeds 95% of the time, the system is saving money; what was good for the population might not be good at the individual patient level (the 5%). The physician tries to work within the constraints of the MCO,
explaining to the patient that they might need to identify additional financial resources to secure access to the medication that the physician thinks is more appropriate for the patient; population studies do not necessarily translate to the individual patient.

…this drug is covered under your insurance program so we can try it. If it doesn’t work you may need to put resources that you normally wouldn’t and… the resources you would use to take your wife out to dinner on a particular weekend. You may have to not take her out to dinner one time less a month, so you can buy this better drug that’s [medically the preferred] choice. …you know, that is the problem with population studies, they may say these things are equivalent but medicine is individualistic. …how a person responds to a particular drug, it doesn’t work the same way in every patient. (Physician_04)

Ultimately the patient needed to decide which treatment option they would select; in some cases the patient’s choice of a lesser cost product might have led to a good outcome; in other cases the physician’s recommendation of the more expensive medication might have been better for the patient, leading to overall savings. As stated by Physician_05, “…treat(ing) the patient fairly and with beneficence, requires treating them on an individual basis, not as just a member of a particular population.” The patient-specific need placed a disproportionate burden on the physician, uncompensated time, to engage the MCO in an attempt to secure what was best for the patient from that physician’s perspective: “relatively onerous burden because of the amount of time spent doing this and the amount of clerical work that may be involved in faxing notes and sending things and making phone calls.” (Physician_05).

The physician saw himself as the stakeholder most vested in the best outcome for the patient. As stated by Physician_01,

“The patient comes first, it is best for the patient to get the best of everything, save money, side effects and have the best treatment. But like I said I think that the physician is the least biased in this whole process to give the patient the whole package.”

In summary, physicians believe they are the medical professionals who focus purely on what they think is best for the patient irrespective of costs. Population level decision-making by the MCO which is driven by cost management makes it
challenging for patients who do not fit the average and hence formularies lead to physicians and pharmacists making alternative treatment changes that can potentially impact the patient. Patients need to make the final decision on what they deem best for themselves based on information they collect from the physician and the pharmacist but the overall system, at the population level, is geared to provide what is acceptable care for the average person. The system places additional burden on the treating physicians because it can redirect their treatment strategies for patients; this additional burden is not compensated for by the system and at the same time it creates tension between the healthcare professionals, such as the physician and pharmacist, and the patient.

5.5.4 Population vs Patient-level Care are not Necessarily Reconcilable: Findings associated with interviews conducted with Community Retail Pharmacists

Pharmacists recognized that the MCO was looking to maximize their dollars to provide care for the insured population. As stated by Pharmacist_01,

“the best ‘bang for your buck’ so to speak, they will determine which drugs are more reasonable, and cover the most patients in a population that they have within their umbrella.”

Pharmacists acknowledged that the pharmacist is the one who feels badly for the patient because the care they are receiving might be a compromise to what they need ideally based on the patient’s ability or willingness to pay. Pharmacists saw themselves as an information provider but ultimately the patient needed to decide what they did with the information that was given to them. The patient who did not meet the average profile was seen as being more prone to be singled out and to be in the minority; it was seen there was less equality for the non-average patient as they had to go through additional steps to receive therapy or pay more for therapy than the average patient; this was not seen as fair but an outcome of how the system works. Pharmacists felt that from a clinical point of view patients should have access to a medication that was deemed appropriate based on medical practice but recognized finances ultimately dictated accessibility. Namely if a patient was not able to gain
access to the medication because of financial reasons it was seen as a byproduct of income and accepting that certain levels of care were only accessible based on financial means.

The point was made that advocating on behalf of the patient was important; although time-consuming, it was seen as a worthwhile effort to help minimize negative treatment implications to patients.

“I think that, I mean it might not work all the time but it can help because ultimately it’s the patient that’s going to suffer when it doesn’t. I wish there was a better answer but that’s the reality. It's tough. The patient is the one who has everything to lose by not getting it and it’s not fair. It’s not just for them.” (Pharmacist_05)

The point of raising awareness in society on the negative consequences of worsened outcomes to help affect coverage was also highlighted. As stated by Pharmacist_05,

“unless you see the patient on the news with some rare disease needing this rare medication, you know, those patient populations that really are in unknown situations, they don’t get recognized. It’s just kind of too bad and it’s horrible. So it’s not just at all.”

This also applies overall to all patients who are not able to gain access to a needed medication due to their financial status; it will prevent them from re-entering society as productive members.

Pharmacists understood that MCOs needed to operate at the population level and treating to the average patient profile. Although physicians and pharmacists made reference to their hands being tied, one particular pharmacist mentioned the same point with regards to the MCO. As stated by Pharmacist_09,

“I believe that the decisions by managed care should be made based on the majority of the population. …I believe that we have got managed care companies with their hands tied because they are blamed for conditions that they can’t accommodate because they have to satisfy the masses... It is based on numbers.”

This particular pharmacist felt strongly around the need of insured members taking accountability for their health, including the choices they make in terms of healthcare
coverage. “In short a patient is responsible for his own health care choices. Ethics doesn’t lay with the plan. It lays with the patient’s choice of plan.”

In summary, pharmacists felt similar to the other stakeholders in the professional group that patients who were not the average patient ran the risk of being negatively affected by formularies. Advocating on behalf of the patient was important as otherwise the MCO does not have an awareness on the implications of the formulary on specific patients. However, ultimately patients needed to decide on what level of coverage they purchase and what they decide to spend on their healthcare. MCOs are trying to manage the health of the population and their decisions are designed to address patient care at the population level.

5.5.5 Summary for the category “Population vs Patient-level Care are not Necessarily Reconcilable”

In summary, across all stakeholders, the two aspects that emerged as focused codes under the category of “population vs patient-level care are not necessarily reconcilable” was balancing between managing at the population level treats to the average vs treating the individual patient. This encapsulates the natural tension that exists when MCOs are trying to manage the costs of the plan; the emphasis is on the average patient and the non-average patient is potentially placed at a disadvantage. There is an irreconcilable difference in managing the overall care at the population level vs that of the individual patient. The needs of the individual can easily be lost in the system unless there is advocacy by the physician and pharmacist and even the patient engaging with the MCO (and the employee with his or her employer) to raise awareness on the unmet need and the implications of the formulary to the individual patient. The system puts additional burden on physicians and pharmacists who need to help engage the system to access the needed care for their patients if the average level of care is not enough for a given patient. However, more often than not, physicians, pharmacists and even the patients accept the circumstances of their available care as to be the norm defined by society. Ultimately, patients need to decide for themselves what level of care they are willing to purchase and the amount of money they are willing to spend on their care to improve or maintain their health.
5.6 Findings from Focus Group Discussions with Employees (Insured Members)

Even though the participants of the focus group were employees of a pharmaceutical company, the group included a broad representation of individuals from various disciplines and experiences. Participants included individuals who were administrative assistants to individuals who worked in communications, training and marketing operations. Participants in their personal lives were at times patients and also at times caregivers to a loved one or family member. One participant recently completed her PhD in Public Health; one had a nursing background but never practiced clinically. The study participants provided their perspective as employees of a large employer that provides benefits to its employees, hence the focus group study participants were representative of the study that informed this thesis; namely access to prescription medications through employer-provided health benefits.

Based on input from the focus groups, the focus group study participants had the following overall points of view as it relates to the conceptual framework.

Access to Rx Medicines Impacted by the Financials

With respect to the concept of business and economics, the study participants voiced their opinion that when the business performance becomes the focus of healthcare, it sours the consumer to how the healthcare system operates:

“I think it leaves a bad taste in consumers mouths for better or worse when decisions about your health become a business decision but unfortunately provider offices: physicians, nurse practitioners, physician’s assistants are being driven more and more by business decisions. And let’s face it, it leaves a bad taste in the mouth of the patient.” (Focus Group 2 Participant)

Employers were not seen as having a responsibility to provide healthcare benefits to its employees although there was acknowledgement that today more employers were focusing on activities that demonstrated a commitment to corporate social responsibility. Ultimately providing healthcare benefits coverage was seen as a way for employers to be more competitive in the marketplace in part by attracting and retaining better talent. Focus group study participants felt that if an employer decided
to provide healthcare coverage they should provide benefits that were properly vetted; additionally, EBDDMs should help employees choose wisely in terms of which plan to enroll in; employees were seen as being challenged to make the right enrollment decision given the complexity of the marketplace:

“I have faith in what he [the EBDDM] does and we put the right person there; we cannot be an expert in everything and this is a complex issue to be a smart shopper on. I can barely buy a car…”. (Focus Group 2 Participant)

Employers however were seen as a decision-maker when it came to what copay levels were assigned to a given tier under a formulary and that employers should not just take at face value what an MCO says:

“I blame the employer at that point… there is no reason for them to do a lack of due diligence before they buy a health plan or buy into a health plan…”. (Focus Group 1 Participant)

One particular study participant (Focus Group 1) made reference to the phrase that is found in the United States Declaration of Independence, namely, “the right to life, justice and the pursuit of happiness”; however, this does not imply access to the best possible healthcare as this would not be economically feasible. The study participant spoke to how a plan would rather give patient’s access to the best possible care that is available but contingent on shifting the additional cost burden of product acquisition to the patient; hence in concept there is access but it is based on the patient’s financial means. The concept of having “prepared themselves” emerged, namely patients who were able to be better off financially will be more likely to receive the best care vs the patient who has limited financial means:

“We try to pretend that we do [have access] but the tiered system, there is going to be have and have nots… you know, in your [smoking cessation] case study, some people will be able to quit because they can afford the $70 medication and others will use the less successful method and will probably smoke the rest of their lives and probably die sooner but the person who was able to quit because they were able to afford the more successful medication prepared themselves in their lives to afford that…”. (Focus Group 1 Participant)

Requiring the physician to follow steps to help a patient receive coverage for a specific prescription under the plan of the MCO was seen as acceptable as long as
the approach was reasonable. One example that was cited as not acceptable was when an MCO would institute a step edit or prior authorization that required the same patient to fail on a specific therapy more than once.

“I have seen Step Edits when we were selling newer NSAIDs like Celebrex…but the plans were saying ‘no, they had to fail on ibuprofen in the last 3 months’, you know, which was not realistic. So every 3 months they have to go back and try their ibuprofen and that is their algorithm; that is not reasonable. So it depends on how it is structured.”  (Focus Group 1 Participant)

With regards to a given patient’s accountability to leading a healthy lifestyle, in the case of the smoker vs the patient with prostate cancer, it was perceived to be less fair for a person with prostate cancer to have any restrictions to prescription medications than someone who was a smoker, the latter not perceived as taking care of their health. However, it was acknowledged both patients should have access to reasonable care as defined by society as a whole; that unless issues were raised by professional societies and advocacy groups that ultimately changed policy and regulations, access to care as provided through a given formulary was deemed acceptable. It was thought that patients who had a terminal illness should not be subject to any trial and error with less costly medications; patients with a life threatening condition should not encounter access delays as the implications could result in death; however unless this was mandated by policy and regulations, these decisions would be variable based on how a formulary was administered by a given MCO.

As with the professional stakeholder group, the car analogy was used by study participants to help convey the concept of acceptable or minimum health care; if patients wanted care above a certain level, then patients should be expected to have to pay to get that extra level of care:

“The minimum level of care I personally feel that, again going back to the car analogy, I do not think everybody needs to drive a Cadillac but maybe everybody should be able to drive a Ford Focus or something like that rather than a bicycle…”  (Focus Group 1 Participant)
Drug Formularies are a Means to an End

One study participant spoke of her physician’s point of view who recently retired after more than 30 years of practicing medicine,

“as things have gone over the 30 years he said insurance is driving the bus a lot of times and he says ‘we make a recommendation but you have a budget that you have to work and unfortunately insurance companies are not always looking out for what the doctor thinks will be the best prescription for the patient and so it will not be on your formulary list so the cost has to be absorbed by the patient or go with a generic which may or may not have the efficacy’.” (Focus Group 2 Participant)

For a physician to save one life was personal to that treating physician yet for an MCO saving one life or even five lives compared to the additional costs that would be incurred if there was less cost-shifting to patients (for example, lower copays), was justifiable given the economic consequences of the decision:

“You might be able to save 1 additional life a year and they say ‘1 life is not worth it to us’…. So, they have to put… I understand they have to put, unfortunately, a dollar value on a life. So they have 50,000 lives, if they are going to lose 5 to a disease, if they lose 6 it is not significant enough for them to make a different formulary decision.” (Focus Group 1 Participant)

The focus group study participants felt that providing a tiered approach to gaining access to medicines was ethically fair as long as it was reasonable. There was mention that MCOs should undertake analysis of how a given formulary is affecting outcomes; formulary decision-making should be informed by such analyses. If ultimately cost was the deciding factor on how formulary decisions were made then that seemed to call into question the integrity of the plan and its decision-makers.

One focus group participant spoke to how patient and physician demand ultimately led to where a medication would be placed on the formulary. Plans were more likely to place a medication at a lower cost tier or without access restrictions such as step edits or prior authorization if there was high demand for the medication in order to reduce the hassle factor to the plan. Another study participant felt that copays should be adjusted if the patient tried a lower cost product and was not responsive to the medication or could not tolerate the medication; that the more costly alternative therapy should then be made available to the patient at the lower copay of the
medication previously tried. It was seen in some cases as fair for a patient to try a lower cost product as a first treatment choice because a priori the effectiveness of a given product is not known for a given patient.

Focus group study participants recognized the tension that exists between MCOs and physicians treating their patients.

“The prescriber in the hierarchy of things will chose the best efficacy and safety for the patients right off the bat and the cost to them is secondary; a physician or pharmacist on the P&T Committee makes that decision in harmony at the same time; they consider those elements equally; whereas perhaps the prescriber first thinks efficacy and safety… they consider that cost criteria earlier in the decision then a physician might. How does that fit into concept of justice in medicine? They are blinded to the patient. They do not have to face them and explain anything. They make utilitarian decisions for the greatest number of their members.” (Focus Group 2 Participant)

Hence there was a question of the degree of trust that could be extended to P&T Committee members when they decide if and how to reimburse for a given medication as their reviews were not necessarily unbiased as it related to the cost of treatment.

**Informed Decision-making Essential to Understanding Implications of Choice**

Participants of the focus group for the most part agreed that physicians should prescribe to patients what medically the physicians thought was best for patients. Then having a discussion with the patient to explain the rationale for the choice, explaining the other possible treatment options, and helping to manage patient expectations specific to efficacy, safety, tolerability, and cost. Participants of the focus group felt that physicians should not make assumptions with regards to patient preference but rather to discuss the treatment approach being taken with a specific patient. For example,

“I would want my physician to say ‘we are going to try this out because I think it is going to work for you; there is a higher risk of this but let’s try it out and see how it works and if you find that this is not working for you then let’s come back and revisit option 2’ because then I think then there is less opportunity for that person to fall through the cracks.” (Focus Group 1 Participant)
There was recognition that this approach did put additional burden on the physician and the physician’s office but that this approach came with the responsibilities associated with being a physician. It was recognized that at some point the shift of the additional burden placed on HCPs by MCOs was not considered as fair or just but reflected the realities of the marketplace. Spending more time with one patient might negatively affect the HCP’s ability to spend time with other patients as stated by one focus group participant: “if he has to do it, he is not seeing other patients or he is not able to spend more time with other patients, so someone’s care is suffering.”

MCOs establishing trust with their insured members was seen as important by the Focus Group participants; communicating openly with plan members around how formulary decisions are made and the rationale for why certain medications have access restrictions or are placed at a higher copay will build consumer trust. This type of approach allows purchasers to choose plans that best meet their needs.

“There is a lot to be said about relationship and being honest and being upfront; that is how you build trust. You have to be honest and you have to be able to admit your shortcomings and your faults.” (Focus Group 2 Participant)

The concept of trust in the physician was also discussed; there was a recognition that, in part, trust in the physician is possibly correlated with a given patient’s age; the older patients might more likely take at face value what the physician says (the older generation had more acceptance of physician paternalism) but the younger generation wants to be more involved and better understand the various available treatment options. As stated by one focus group participant,

“…trusting their doctor… that to me has totally changed. I mean especially you have your… there is so much information out there. I do not want to say I do not trust them, doctors I am referring to, but you know, when you are talking about your health or your family’s health, it is like I am going to double check everything.” (Focus Group 1 Participant)

HCPs to be influenced or affected by incentives in terms of a prescription being written or filled was seen as not ethical. That any type of financial motivation that impacts a physician’s prescribing or what the pharmacist does behind the counter should be disclosed to the patient.
Focus group study participants felt that the pharmacist had limited knowledge of the patient and the discussion the patient had with the physician in the physician’s office that led to the physician writing a particular medication. Hence the pharmacist should keep his or her focus on issues related to safety concerns such as drug-drug interactions.

“Yeah, I think… the ethical thing to do is to just bud out of the conversation. Focus on safety, drug to drug interactions; things that might affect the patient’s safety but do not try to drive it to a cheaper drug that you have no idea is the right choice.” (Focus Group 1 Participant)

Filling a generic vs the brand if the prescription was written as such by the physician was viewed as acceptable, but even then the pharmacist should communicate to the patient what was specifically filled vs what was written (as opposed to the patient discovering on their own when they arrived back home that the brand name medicine that they were expecting to find in their pill bottle was replaced by a chemical name, the international non-proprietary name, that they did not recognize). However there was a level of mistrust by the focus group study participants with regards to the intentions of the pharmacist. When pharmacists start recommending a lower cost treatment option it caused concern for the focus group study participants as to the motivation of the pharmacist to make that recommendation; whether they were receiving incentives for switching patients to lower cost treatment options. At the same time, one study participant made comparison of the pharmacist to a car salesman, in terms of the pressure that the pharmacist is placing on a given physician to make a switch; not necessarily representing the patient’s needs accurately. This particular focus group study participant’s father was a primary care physician:

“And I have seen that when they call my dad as primary care, they call him, they call his office, and they are really putting pressure on, you know, ‘can we switch to the generic’. He says no. ‘Well you know the generic is a lot cheaper for the patient; the patient really wants the generic. They would rather pay $10 than $30’; the [physician] says no and then the [pharmacist] says there is ‘equivalent efficacy’ and the [physician] says well ‘I am not familiar to what you are switching to’ and you almost have to say no three times to have it mean no.” (Focus Group 2 Participant)
At the same time the study participants did feel it was the ethical responsibility of a pharmacist to tell the patient there was a lower cost option, but it should be left to the patient whether the call is made to the physician to check whether a switch would be medically appropriate.

Patients were always seen as having the right to purchase whatever medication the physician prescribed. Patients should be informed, they should be provided with the necessary information to make a well-informed educated decision on whether to fill a particular prescription. At the same time, it was recognized that patients were taking a risk that one medication would work vs another. One positive approach to lower a patient’s copay and improving overall outcomes was offering knowledge tests to patients: if the tests are taken and the patient gets 100%, their copay is lowered to $0. This approach could possibly help improve overall outcomes. It was also recognized that physicians are doing whatever they can to minimize the hassle that comes with managed care formularies; by writing a generic they are more likely to not get any callbacks from the pharmacy.

“How do they reduce their work load; reduce the callbacks they have to do. Things that in their eyes are unnecessarily taking away time. ’I get fewer push backs from everybody if I just prescribe the generic.’ It is not the best thing for the patient but they are forced to do things that are ethically… I think this is where the problem is… the physician is being forced to not do things in the best interest of the patient because of a cost issue.” (Focus Group 2 Participant)

**Population vs Patient-level Care are not Necessarily Reconcilable**

Ethically the focus group study participants felt it would be the right thing to make available all drugs to patients based on patient need and the physician’s perspective of which treatment option would be best for the patient. However, the reality of economics necessitates certain access restrictions to help control pharmacy spend and overall costs of care. The tension of population-based care vs patient-specific care was recognized including the fact that the specific patient for the most part is faceless to the MCO as the focus is rather on the overall population, which is faceless and nameless:
“from a financial standpoint I understand their role in what they are doing… they have a responsibility of trying to keep costs down and… to balance the cost and the benefit of it… to be on the other side of it, it is difficult and challenging and complex, because at the end of the day, it is… they are looking at big picture numbers and statistics and not necessarily the face of the person… so it is a struggle.” (Focus Group 1 Participant)

It was recognized that the formulary is designed with the average patient in mind (with reference to the middle of the bell curve) and the formulary was designed as an approach to help “keep costs down for a greater number of people”.

Focus group study participants recognized that the physician wearing the hat of the MCO P&T Committee member might have a different perspective from when that same physician was treating a particular patient.

“When they are on that committee their responsibility is… a fiscal responsibility to that committee vs when they are seeing that patient their responsibility should be to that patient.” (Focus Group 2 Participant)

It was not deemed to be fair but rather accepted as that is the realities of the healthcare system where economics affected resource use.

“I guess managing the faceless numbers of statistics to that personal person right in front of you; putting a face to a number I can definitely see how those decisions are different.” (Focus Group 1 Participant)

In summary, the focus group study participants echoed many of the same concepts as those that emerged through the one on one phone interviews with stakeholders of the professional group, namely the EBDDMs, MCOP&Ts, Community Practicing Physicians and Community Retail Pharmacists. These included the following:

- There was a need to reconcile medical care with the economics of business.
- Patients ultimately needed to make decisions for themselves in terms of the level of care they were willing to purchase.
- Patients needed to prepare themselves in that they needed to ensure they saved up the necessary dollars needed to acquire the level of care they preferred or wanted.
• Patient preference is unique to each individual patient and hence there should be no pre-conceived assumptions; each patient needs to be informed so he or she can make a decision that is best suited to him or herself.
• Providing access to needed medications (or the best medication) was seen as the right thing to do but the cost of care necessitates restrictions.
• MCOs manage the cost of care at the population level which is a faceless statistic but the physician needs to provide care to the individual patient with whom the physician has a relationship.
• There was a level of mistrust in the system and the business economics of care created tension between the various stakeholders.
• Community retail pharmacists were seen as needing to maintain their focus on the safety of a given medication vs trying to provide alternative treatment options to patients; and informing patients of the specific medication dispensed.
• Reasonableness was recognized as whatever standards are established by society by which MCOs need to comply.

5.7 Conclusion

The economics of business impacts on the level of access patients have to medications which is controlled by the formulary. Society establishes the norms by which MCOs need to maintain standards. Ultimately the contract that the employer signs with the MCO dictates what is accessible by an insured member through the MCO. MCOs control access by one of two means: either through utilization controls such as step edits or prior authorizations or shifting cost to the patient for a given medication. Although physicians have the right to prescribe whatever medication they deem best for their patients, these decisions need to be reviewed with the patients because ultimately patients have to decide for themselves what is their willingness to be treated with a certain medication.

The system imposes additional burden on physicians as they need to spend additional uncompensated time helping patients gain access to a given medication under a specific formulary; however physicians need to get through their day and look
to minimize the challenges associated with overcoming these access restrictions; a concept that was referred to by physicians as reducing their “hassle factor”. If physicians advocated for all patients at all times it would not be manageable and hence physicians realized it was not efficient to not prescribe within the boundaries of the formulary as set by the MCO. These restrictions ultimately dampened the physician’s autonomy and impacted the patient’s self-worth.

The effect of the system on the stakeholders is diminished trust; there is a recognition that through collaboration there would be better outcomes as decisions would be better informed through the shared expertise of the various members of the professional group however that is not how the system is set-up to operate. MCOs believe they have greater expertise to guide treatment protocols for patients; physicians hence feel stripped of their ability to treat outside the average as set by the formulary. Pharmacists are the point of contact by the patient where the true implications of the formulary become apparent which requires the pharmacist to potentially intervene in the recommendation of the treating physician and working within the confines of the system to redirect treatment to one that is covered by the formulary and more affordable to the patient. However the pharmacist has incomplete information about the patient and is seen by the physician and potentially even by the patient as meddling. At the same time, the employer who ultimately signs the contract with the MCO acknowledges that they lack the necessary expertise to oversee the clinical decision-making aspects of the MCO. MCOs manage outcomes at the population level which is a faceless statistic; formularies in turn are designed to treat to the average, whereas physicians have personal relationships with their patients and look to provide individual care to a patient. This leads to a natural tension between population-level health management as opposed to individual-level patient care.

The categories that emerged from the analysis encapsulates the findings of this chapter, namely that access to Rx medications is mostly driven by the financials, that formularies are a means to an end, that informed decision-making is essential to
understanding implications of choice and that population level health management and patient-centric care at the individual patient level is potentially irreconcilable.

These aspects will be analyzed in relation to ethics in the next chapter of this thesis, Chapter 6.

Chapter 6: Analysis of Findings

The four categories that emerged from the primary research with study participants that was summarized and highlighted throughout Chapter 5 and formed the basis of the conceptual framework included the following:

- Access to Rx Medications is Impacted by the Financials
- Drug Formularies are a Means to An End
- Informed Decision-making Is Essential to Understanding Implications of Choices
- Population vs Patient-level Care are not Necessarily Reconcilable

Figure 6.1 below lays out the substantive theory that was constructed by the PhD Researcher based on the four categories of the conceptual framework that emerged from the research utilizing grounded theory through constant comparison of the categories, focused codes, and initial codes with the relevant literature. The aspects of gamble, hassle, burden, inertia, tension, interference and trust are at the center of the illustration below as these were concepts that emerged throughout the discussions. As mentioned earlier, the access decision-makers take a gamble that the formulary that they ultimately administer does not result in greater healthcare expenditures and does not result in an increased level of burden or hassle to the system; conversely the patient takes a gamble that the level of coverage that is purchased will cover the level of care the patient will need during the course of the year. With respect to physicians and pharmacists there is an increased need (hassle / burden) for them to manage the administrative aspects of helping patients gain
access to the needed or recommended medications otherwise the patient may have to settle for a medication that is more readily accessed through the drug formulary. This in turn leads to inertia (the system eventually wears down the physician / patient and the path of least resistance is the easiest option to take); the drug formulary creates interference between the physician-patient relationship and there is an element of mistrust across all stakeholders and a question of who has the right level of expertise to inform the most efficient treatment option.

The following sections of this chapter will detail each of the four categories that are shown in Figure 6.1 as it relates to the ethical theories and principles discussed in Chapter 2 and the subsequent concepts relative to each category that emerged from the research.
6.1 Access to Rx Medicines Impacted by the Financials

As previously discussed in Chapter 5, with regard to Access to Rx Medicines Impacted by the Financials, the following concepts emerged through the primary research with the study participants, namely:

- Benevolence vs the economics & business goals of Employers and MCOs
- Care is determined by the contract that has been purchased
- Care provided, needs to be reasonable; anything other than reasonable care is a privilege

These three concepts are examined in detail in the following three sections.

6.1.1 Access to Rx Medicines Impacted by the Financials:
Benevolence vs the economics & business goals of Employers and MCOs

A dominant mindset that emerged in the primary research is that the delivery of healthcare in the U.S. is a business. This raises the question of how does business and medicine contrast, which was summarized by Pellegrino (1999):

“Business ethics accepts health care as a commodity, its primary principle is non-maleficence, it is investor- or corporate-oriented, its attitude is pragmatic, and it legitimates self-interest, competitive edge, and unequal treatment based on unequal ability to pay. Professional ethics, on the other hand, sees health care not as a commodity but as a necessary human good, its primary principle is beneficence, and it is patient-oriented. It requires a certain degree of altruism and even effacement of self-interest.”

Pellegrino at its core highlights that business has a focus on profit-taking and self-interest, whereas, healthcare, is about foregoing that self-interest for the benefit of the ill.

Ethics in business is not a passive application; if ethics is to be effectively deployed in the work environment, it needs to be done actively, and needs to be pervasive across all aspects of the business including the most senior levels of the organization. (Stead et al., 1990). Stead speaks to how decisions that organizations consider need to take
into account ethics otherwise the consequence is moral demise. Ethics is defined in the Stead paper, based on work done by Cavanagh et al. (1981), in the context of decision-making, to be one of three ethical philosophies namely utilitarianism, individual rights or justice, with utilitarianism being the most prevalent philosophy when it comes to business management decision-making. When leadership manifests behaviors that are not grounded in ethics, it affects the rest of the culture in terms of what type of behavior is acceptable to meet corporate goals; years of building a culture and reputation of integrity can easily be destroyed literally overnight when actions perceived as non-ethical become visible to the public (Luftig and Ouellette, 2009). One of the realities that surfaced during the research, with study participants for this thesis, was the realization that ethics is not discussed at the time of P&T decisions or when decisions are made regarding coverage. MCOP&T_01 made the comment, “We are not an ethical health plan. We are an insurance policy.” Stead’s paper further speaks to a point made by the Vice President of the American Medical Association in 1998, namely that economic pressures in healthcare represent a serious threat within the healthcare industry. Stead's paper makes reference to how the combination of economic volatility, scarcity of resources and stakeholder pressures can undermine ethical behavior within organizations given the focus on maximizing profits. Yet, according to a survey conducted by Ross (1988) that gathered input from business leaders, which is referenced by Stead, indicated that 35% of leaders felt that ethics either weakened or had no effect on improving commercial value. In a survey conducted 17 years later, business leaders in most corporations still did not believe that adherence to values had a direct impact on earnings or revenue growth (Lee et al., 2005). Money and economics instead of being a means to an end has become an end to itself and people who should be an end are seen as a means to an end; economics obscure ethical clarity as discussed by Rediehs (2013).

Toenjes (2002) highlights the point that health care professionals operate according to a professional code of ethics, where the well-being of the patient is the main objective. These code of ethics are established by professional groups such as the
American Medical Association (AMA), the American College of Physicians (ACP) and the American Pharmacy Association (APA). For example, the AMA in its Code of Ethics, makes reference to how physicians should advocate for patients to be able to access the care that is considered appropriate, safeguarding the interests of patients and reducing the financial barriers that may hinder access to care (AMA, 2016).

MCOs (payers) are focused on the economics of the business which can impede on the physician-patient interaction and the resultant care. Toenjes addresses the point that business and medicine are intertwined with business in medicine and medicine in business and the concept of the three C’s that were initially identified by Robert Solomon, as a measure of social responsibility. The 3 C’s address the need for businesses to comply with regulations and the law; that through the delivery of products and services of the business there is a contribution in value to those that supply and use the products and services, and through the value generated, broader consequences to the business and the community in which the business operates are realized. Toenjes speaks to the realization that even though stakeholders will have loss of autonomy, there needs to be trust in the system; hence, this would imply that MCOs and Employers need to take into account the consequences of their decisions on relevant stakeholders. Friedman Milton speaks to this slightly differently, where Milton stresses that the main focus of a business is to make money for its shareholders; “there is one and only one social responsibility of business—to use its resources and engage in activities designed to increase its profits so long as it stays within the rules of the game, which is to say, engages in open and free competition without deception or fraud.” (Friedman, 1970).

Ejnes (2017) highlights the practice of MCOs that when formularies are changed require the physician to provide documentation on why the patient is not on a less costly medication. Even if the patient has tried previously less costly medications and have failed, the MCO may request the patient to re-try products that were not effective for the patient before approving use of the more expensive medication. This is simply attributable to a drug formulary change or a change in the patient’s MCO. Ejnes writes how MCOs
“want the patient to try drug A and/or B again before C will be approved. In other words, despite having information about the earlier failures, they want the patient to try and fail a treatment again in order to cover one that works. That is inhumane, in my view, and I’ve refused to do it. A sternly worded letter that spells out the potential consequences of what the [MCO] is demanding is often effective in getting the requested drug approved.”

This point speaks to how from a population level a drug formulary that might be seen as helping to reduce costs (as a faceless statistic) on an individual patient level can bring about potential harm. In this case the point is highlighted specific to the treating physician who deems it harmful (maleficence) to the patient to retry a medication that the patient previously did not tolerate; to retry the medication just because the formulary mandates the patient try and fail a given medication multiple times.

Champlin and Knoedler (2008) underscore the point that employers providing medical benefits for their employees and families should not just be about profit maximizing but because employers’ have a responsibility to their employees and to society in enhancing the productivity of the workforce and contributing to the social good. Champlin and Knoedler make reference to the “Veblen principle of cumulative causation” and that therefore no one person could be assigned full responsibility for an outcome and that any outcome was a confluence of factors to which all members of society have a contributing role on some degree. However, Champlin and Knoedler cite JM Clark’s perspective that government, businesses and individual’s need to work together for the betterment of the individual and hence collective good and “create a climate of positive change”. Champlin and Knoedler speak to responsible employers providing healthcare coverage and employers being irresponsible when not providing coverage.

Goodpaster (1993) speaks to the point of conducting stakeholder analysis to assess the implications of decisions on not just shareholders but among other stakeholders, namely the customer; however the analysis is spoken of in context of economic impact, “We must respect them in the way one ‘respects’ the weather, as a set of forces to be reckoned with”. Goodpaster highlights that managers are not indifferent to the situation of stakeholders overall but the focus on the shareholder trumps other stakeholders. Goodpaster highlights the mindset of market forces impacting on the
decision-making (for example, to remain competitive the business needs to do what will reward companies for their actions along with legal requirements in which companies operate). This also speaks to the point that was raised by study participants, namely, that society needs to define the parameters in which MCOs operate. Goodpaster speaks to how decision-makers need to align with the strategic interests of their employer despite their possible empathy to other stakeholders (non-shareholders) who are affected by a given company’s business decision. As stated by Edward (1984), and referenced by Goodpaster, “We must not leave out any group or individual who can affect or is affected by organizational purpose, because that group may prevent our accomplishments.” An interesting point brought forward by Goodpaster is an employee of a corporation should only act in a manner that “would apply to any human being toward other members of the community”. This however seems to be in contrast to the point that was highlighted by the MCOP&T study participants who spoke to the point that decisions they make as a P&T committee member is not the decision they would potentially make as a practicing physician caring for a particular patient.

Graff et al. (2017) did a study with participants representing payers, employers, patients, and individuals who were either in consulting or academia, where of the 17 participants surveyed, 65% were either neutral (9 of 17) or found it acceptable (2 of 17) to have differential copays which includes the situation where patients will end up paying more for a given medication even though the lower cost option which they initially tried did not work for the patient. However with the exception of one, 16 of the 17 participants surveyed, found it acceptable to charge the higher copay if the patient preferred the higher cost treatment option to avoid possible side effects. Wang et al. (2016) speaks to the external good which is focused on the profitability of a business and an internal good which is a feeling of good due to the virtuous and moral character of the agent. This point was highlighted by the Physician and Community Pharmacy study participants who spoke to the point that as a healthcare provider, the motivation of patient care, the virtues of the person who becomes a healthcare provider, are of a different level than that of the business of the MCO.
The need to be profitable can corrupt the ethical virtue of benevolence; a point raised by Roy (2010). Hence when employers experience economic hardships, they look to reduce the value of healthcare coverage to the employee and their families, which reduces the ability to access care. Beauchamp (2008) speaks to a moral obligation as defined by principles or rules in normative ethics that dictates what a moral agent should do in a given situation. With regards to beneficence this can be the passive act of not doing any harm, which can be done by a rational person impartially (a concept brought forward by Bernard Gert), or through the active act of helping others. Benevolence, the virtue which leads to beneficence is not a binary act but rather an act that is defined across a continuous spectrum from the nominal (giving more of oneself) to the supererogatory (self-sacrifice), operating at a level of moral excellence as defined by Aristotle. These acts might not be required of everyone but rather by those individuals who have special roles or responsibilities in society. Beauchamp (2008) makes reference to David Hume’s belief that benevolence is a core element of being human with justice being a process by which interests of members of society are protected thereby creating ‘public utility’ and the greatest good. Benevolence can be viewed not as an altruistic act but an act that is undertaken due to the expected benefit of the act to the person or organization undertaking the act. A concept that was supported by Milton Friedman namely that the goal of a company is to maximize profits for its shareholders (Friedman, 1970); Adam Smith similarly spoke of actions directed by self-interest rather than for the benefit of others (Glaeser, 2009). Under utilitarianism, as addressed by Beauchamp (2008), beneficence is central to the normative theory and is the act that brings about the “greatest balance of beneficial consequences”; Kant defines it as a duty but does not define the limits of such actions. Friedman addresses the point that the person as an individual, outside of his responsibility to the corporation for whom he works, may decide to act in a manner that is socially responsible, where he is his own principal. However as an employee, he is an agent of the company for whom he works, and therefore must focus his actions [making] “as much money as possible while conforming to the basic rules of the society” in which it operates hence benevolence will only be a virtue exhibited by
employees when making decisions on behalf of the corporation to the extent it can be seen as meeting the economic needs of the company.

6.1.2 Access to Rx Medicines Impacted by the Financials:
Care is determined by the contract that has been purchased

Mariner (1995) speaks to Edmund Pellegrino’s point on the conflict of interest that potentially exists within managed care. Namely, “managed care, by its nature, places the good of the patient into conflict with… (1) the good of all the other patients served by the plan; (2) the good of the plan and the organization, themselves…; and (3) the self-interest of the physician.” As discussed by Mariner, MCO economic objectives focus on the economics of medical care not the physician-patient relationship; the market dynamics in which MCOs operate may reduce equitable access to healthcare however the business community believes that competitive forces can deliver improved outcomes at lower costs. Mariner speaks to the point that managed care is a market approach to controlling costs; the point is made that cost control primarily can only be achieved by (1) reducing reimbursement levels to providers, (2) not providing access to care or (3) shifting cost to the patients. As stated by Mariner,

“[t]he organization is an economic entity, often a corporation—a legal fiction, not a person in a profession with a history of professional ethics. Thus, the ethical principles that have traditionally been thought to apply to healthcare practitioners do not easily fit MCOs.”

Physicians and pharmacists have a 1:1 relationship with the patient; they usually know the patient’s family; they understand the patient’s needs and preferences. The MCO, as a business, does not have this level of engagement nor does it have the moral codes as earlier referenced above that are established by healthcare professional associations such as the AMA.

Mariner questions whether business entities have the capacity for ethics; there seems to be a divide on adherence to standards that apply to a business as compared to standards that apply to maintain the physician’s commitment to the welfare of the patient but not a combination of the two. Mariner highlights that physicians have an obligation to provide care that is in the best interest of the patient whereas the MCO’s
obligation is to comply with the contract in place between the MCO and its various stakeholders (such as the employer who subscribed for coverage on behalf of its employees, the employees who are now members of the MCO’s health plan, and the physicians who provide care for the members enrolled in the MCO’s health plan). Mariner speaks to the point that concepts that are considered in relation to MCOs are not ethics per se rather standards (business objectives) such as efficiency, quality, information sharing and fair competition. Mariner highlights the concept that business assumes all parties to the transaction have equal levels of knowledge; however in the physician-patient relationship, the physician has a greater level of knowledge; the fiduciary responsibility of the business is to its shareholders which will take priority over the delivery of high quality care to its members. Mariner goes on to make the point that in theory a physician’s violation of ethical principles as set forth by the AMA could lead to the physician’s license being potentially revoked but there are no true consequences to MCO executives for violating the basic tenets of conducting business fairly and honestly other than being expelled from their professional organization which still does not prevent them from being employed in the industry.

The physician needs to act in the best interest of the patient whereas an MCO only needs to comply with the terms of the contract that define the policy for coverage. Violation of the contract then becomes a legal issue. Hence as discussed by Mariner an MCO is not unjust if it does not provide necessary and appropriate medical care as long as it is adhering to the provisions of medical care as stipulated by the contract. As stated by Mariner, “contract variations may violate some conceptions of justice, yet they are entirely consistent with market values and the goals of competition among health plans”; hence patients with the same medical condition may receive different treatment solely due to a difference in coverage levels. Mariner speaks to choice being made by the employer based on the plan or plans the employer decides to make available to its employees. Although study participants spoke of patients ultimately having choice of therapy, however; it might be cost-prohibitive for an employee to choose anything other than what is made available by the employer and then subsequently by the MCO.
Mariner speaks to how most insured members, if not all, do not understand completely the terms of their contracts; that benefit coverage descriptions are often only reviewed at a precursory level and reviewed in brochures in terms of general types of services covered; specific coverage details are not appreciated by insured members until they become patients and are in need of specific medical care: “much of the information necessary for a rational choice is not available when the choice must be made”. As discussed by Mariner, even when healthy insured members make a coverage decision, once afflicted with a medical condition, and in need of a given level of care not covered, the lack of access is deemed unfair and impersonal; there is also an element of interpretation of benefit coverage, so two plans with the same level of benefits may interpret the specifics of coverage for a given patient’s condition differently. Mariner highlights that medical ethics would support the best care being made available to a patient but does not address who pays for the care; business ethics relegates decision-making based on the contractual terms of the policy. As discussed by Mariner, although the physician is there to be the patient champion, all insured members should receive adequate care; complete understanding of coverage details specific for a given medical condition is what helps inform decision-making but insured members do not have much choice beyond what is made available to them in terms of options, hence the concept of contractual fairness is limited.

Trotsak (2016) highlights the Kantian perspective that there be “an opportunity of fair contracting and market competition in which the mankind can achieve perfection.” This brings into question the concept of a valid contract. Toenjes (2002) speaks to the concept of contracts that address fundamental issues that enable a harmonious effective relationship between individuals that are seen as “free, equal, rational and reasonable. The term of the agreement must be justifiable to all persons in order to preserve the ideal of treating all persons fairly.” However, as was stated by the study participants, employers do not have the necessary expertise in the specifics of a drug formulary and need to trust in the guidance provided by MCOs; employees do not have the necessary knowledge to make informed decisions about coverage; even
physicians stated they have difficulty understanding the terms of a given policy and the subsequent coverage levels.

The challenge according to Toenjes, is that there are norms as it relates to patient care, which hinges on the professional oath that puts the patient first and recognizes the importance of autonomous decision-making; these contrast with insurance industry norms that are focused on profitability. The purpose of the contract is to ensure medical decision-making is guided by the terms of the contract vs just providing any or all treatments to the patient given the insured member’s medical condition. Bowie (2002) speaks to the three aspect of the Categorical Imperative, namely Universalizability, the Formula for Humanity and the Kingdom of Ends as guideposts by which to consider the approach to contracts. As it relates to Universalizability, if contracts into which businesses or purchasers entered into were constructed in a manner that obviously limited the benefits to the purchaser over the seller than no purchaser would be willing to enter into such a contract.

The PhD researcher notes that due to the subtleties of healthcare, the acceptance of how MCOs operate, and the burden of illness that a patient experiences at the time the services of the MCO are utilized, coupled with the difficulty of engaging the system for change, it is difficult to raise awareness of the imperfections of the current system. Hence there is an acceptance by the masses that these are just the way things are done and one has to make the most of it. The evidence of the unmet need at the individual level, the voice of any one patient in need, is lost below the surface of visibility. Similarly Bowie speaks to that no person should be a means to an end in the contract, the premise of the Formula for Humanity. That namely the purchaser who enters into the contract should not be merely the mechanism by which the seller is able to sustain its business model and achieve profitability. Contracts need to support the rationality and autonomy of the purchaser. From the perspective of the PhD researcher, although there is freedom of the purchaser to not enter into a contract, the actual implications of the contract are not fully understood by patients even at the time the system is engaged; and the patient does not think of the contract rather just views how the plan operates; namely a given medication is just accepted.
to be not available under the formulary until the patient satisfies certain conditions (as in the case of Step Edits or Prior Authorizations) or even if the conditions are satisfied, the patient incurs greater out of pocket costs because they are not responsive to lower cost treatments.

The system lays out the rules for accessing given prescription medications, and for some patients the system will cost less than for others merely because of how a given patient responds to lower cost medications and hence needing access to a higher cost medication. Hence the contract is not viewed through the lens of the impact on any one patient rather the overall effect on the population and as long as the healthcare accessible through the plan is deemed appropriate or adequate, there is no real negative consequence within the system to the MCO as long as the MCO abides by the terms of the contract. Finally, Bowie speaks to Kant’s Kingdom of Ends that if the moral agent was both the participant of the community and the person who set the rules of the community, then what type of system would the agent have in place to equally meet the needs of the community. In this case, with respect to an MCO and contracts, the moral agent would recognize the need for the MCO to be economically viable, to determine what would be fair in terms of engaging with purchasers and how to ensure the purchaser received appropriate levels of service as it relates to the contract that was purchased. It is under this third aspect, that joint responsibility of the purchaser and the seller becomes evident; that the relationship needs to be balanced otherwise the risk increases that the seller is unable to maintain its business or the purchaser his ability to receive the appropriate benefit from the purchase. This is in part the approach taken by MCOs in that they look to provide coverage for the population, which represents the average patient, and then those patients who are outliers to the average profile, will incur additional costs and potentially procedural delays in accessing relevant care. However, there is a level of disagreement as to what level of care is medically appropriate for a given patient; and who is the appropriate medical expert to make that determination for that patient. This was raised by the MCO who believes they have greater expertise in this regard and the physician who acknowledged that unless he complies with the drug formulary the patient will have decreased access levels.
As it relates to utilitarianism, Habib (2008), highlights the point with regard to act-utilitarianism, that a contract would be broken if the terms of the agreement no longer favored one of the parties given the need to maximize the value of the contract; however no one would enter a contract if contracts were broken given the needs of the parties involved hence rule-utilitarianism places its emphasis on promise-keeping rather than the mere focus of utility maximization. Cimino (2009) analyzes contracts with regards to ethical normative theories. As discussed by Cimino, from a deontological point of view, contracts need to be written with regard to the means; whereas from a utilitarian point of view a contract is assessed based on the consequences: hence from a utilitarian point of view it may be more beneficial to break the terms of the contract as it will create more value to the parties of the contract (breaching the contract is more efficient as it creates greater monetary gains); whereas from a deontological point of view it is important to keep the promise of the contract to respect the persons involved in the contract and to protect the autonomy of those who entered into the contract.

According to Cimino, contracts are not just about the end result, the economics of the contract, but also the relationship that is formed between the parties who have entered into the contract. Cimino introduces virtue ethics as an ideal by which to approach contracting: by exemplifying Aristotle’s perspective on morality and prudence, the virtuous person is able to achieve a beneficial end through a morally justifiable means; hence the intersection between the dimensions of utilitarianism and deontology. Cimino speaks to Aristotle’s definition of justice, which is the quintessential virtue, as it represents the culmination of all other virtues; informed through practical wisdom, and when there is an imbalance of a gain or loss due to the terms of a contract, then corrective justice helps to restore the balance of benefits that should have been made available to the involved parties. It is less about the reproducibility of the outcome as two virtuous people may come to different conclusions but the process of the approach involving both moral and rational thought would be consistent from a process perspective.
From the PhD Researcher's perspective, given the findings of the research, having just outcomes informed by the contract that governs between MCOs and Employers, and hence the Employers' employees (insured members), as well as between MCOs and Physicians, needs to be assessed from the perspective of having the right level of information that goes into decision-making by all parties. The PhD Researcher believes that due to information asymmetry between the various stakeholders and due to the lack of recognition of the MCO of the physician’s practical wisdom as it pertains to taking care of a particular patient, leads to ethical challenges that impact on the autonomy of the patient and physician, potentially negatively affects beneficence, and hence impacts on justice of all patients having equitable access to care.

6.1.3 Access to Rx Medicines Impacted by the Financials:
Care needs to be deemed reasonable; anything other than reasonable care is a privilege

Jones and Kantarjian (2015) highlight the point that the U.S. Constitution and the Bill of Rights does not list healthcare as an entitlement. Jones and Kantarjian make mention of the 2011 Republican debate where one of the candidates made the point that if someone chooses to not have health insurance and as a result dies, than that is the makings of a society where there is freedom to make one’s own choice coupled with a Darwinian philosophy, namely, “freedom of choice and survival of the fittest”. Making a healthcare a right violates the rights of others as it would require services from those who might otherwise not willingly provide those services. A point stated by Campbell (2009), former Republican Congressman from California,

“A ‘right’ to services without charge, that forces someone else to provide for you, does not and should not ever exist. No one in a free society should have a ‘right’ to anything that requires others to toil against their will on behalf of those unwilling to provide for themselves.”

This mindset could be further extended to the adage, you get what you pay for, a point raised by the study participants. Ted Kennedy, former Senator of Massachusetts, spoke of how his family was able to get the care they needed because they could afford it; in particular he stated
“I think of my daughter, Kara, diagnosed with lung cancer in 2002. Few doctors were willing to try an operation. One did—and after that surgery and arduous rounds of chemotherapy and radiation, she’s alive and healthy today. My family has had the care it needed. Other families have not, simply because they could not afford it.”

Senator Kennedy advocated for “decent, quality health care as a fundamental right and not just a privilege” (Newsweek, Staff Writer, 2009).

The image below, Figure 6.2, helps to separate the medical aspect of healthcare vs the economics of utilizing healthcare within the U.S. healthcare system (National Economic & Social Rights Initiative, 2017). At the point of healthcare delivery, there is only the focus of what care for which patient based on the need. Then afterwards the reality of care becomes a factor when the patient receives a bill for services rendered and now has to pay for the care received.

![Figure 6.2 Health Care vs Health Coverage (National Economic & Social Rights Initiative, 2017)](image)

The challenge with the concept of basic care is a right is not only defining what is considered basic care but also how to pay for the care.

The AMA (Code of Medical Ethics) describes basic healthcare in terms that are non-specific to actual services or products, as follows:
(a) Is transparent.

(b) Strives to include input from all stakeholders, including the public, throughout the process.

(c) Protects the most vulnerable patients and populations, with special attention to historically disadvantaged groups.

(d) Considers best available scientific data about the efficacy and safety of health care services.

(e) Seeks to improve health outcomes to the greatest extent possible, in keeping with principles of wise stewardship.

(f) Monitors for variations in care that cannot be explained on medical grounds to ensure that the defined threshold of basic care does not have discriminatory impact.

(g) Provides for ongoing review and adjustment in consideration of innovation in medical science and practice to ensure continued, broad public support for the defined threshold of basic care.

As an example of state law defining basic healthcare, The State of Virginia Code of Law (, § 38.2-5800, defines basic healthcare in somewhat more specific terms but still at a higher level in terms of basic categories, namely “emergency services, inpatient hospital and physician care, outpatient medical services, laboratory and radiological services, mental health and substance use disorder benefits, and preventive health services.” Neither the AMA Code of Ethics nor the State of Virginia Code of Law make any statements about access to prescription medications.

The economics of providing access to healthcare are better understood when taking a closer look at the State of Vermont which attempted to institute a universal state run healthcare program mandating equal access to all Vermont residents based on need but was not able to implement the program in 2014 in part because of the cost. The State would not have been able to guarantee stemming the ever increasing cost of care and would have required additional taxes to be levied on Vermont residents from
the onset, charging an additional 11.5% tax on employers and 9.5% income tax on all wage earners; with tax rates increasing over time based on increases in cost of care (McCullum, 2017). To put the economic burden of the proposed level of healthcare coverage into further perspective, Vermont’s fiscal budget for 2015 was $4.9B; healthcare alone under the universal care proposal would have cost the state in 2017 $4.3B, essentially doubling the state’s budget (Fitzgerald, 2015).

A commentary made by Ron Holland, an emergency room physician and policy analyst, calls out the point that corporations are led by business leaders who do not understand the realities of being a practicing physician (Holland, 2016); MCOP&T study participants acknowledged that when they made decisions as an employee of the health plan, the decisions were not potentially the same as what they would have made as a physician treating a specific patient. Holland makes the point that smaller companies with medical leadership making healthcare decisions might lead to better care at lower cost as there might be less bureaucracy. This point was made by Dr. Kocher who was the only physician on the National Economic Council advising President Obama regarding healthcare policy, “Large health systems deliver “personalized” care in the same way that GM can sell you a car with the desired options. Yet personal relationships of the kind often found in smaller practices are the key to the practice of medicine.” (Kocher, 2016).

Mack (2004) speaks to utilitarianism being a normative ethical theory that looks to maximize social utility. Mack addresses Pareto’s principle of optimization, namely that overall society is better off when any one person’s status is improved without any other person being worse off; however there is no one right solution; there are potentially different solutions that result in the same net effect for the community as a whole but there will always be individuals who will be harmed by any given population-level policy. Mack acknowledges that by applying the Pareto principle to healthcare, utility at the societal level is decreased as the wealthy gain access to better care than those who have less financial means. Distributive justice looks to ensure there is equitable distribution of care to various groups within society however there is a consideration to minimize the burden of costs that members of society
would have to bear to cover costs for those individuals who cannot afford care at a higher level. Smith (2001) raises awareness on the point that the value of healthcare is determined by the administrator who is making value judgements on a given therapeutic intervention; that care at the individual level is challenged by the need to deliver efficient healthcare with an intent to reduce the cost of care. There is recognition that it is easier to make decisions on levels of healthcare to be provided on a statistical level rather than the identifiable patient level. From the PhD Researcher’s point of view, deontology would factor into decision-making once there is greater awareness on the implications of a given plan’s drug formulary on a specific patient, as it relates to duty of care. This point was raised by MCOs and EBDDMs that if they are not aware of the consequences of given drug formularies on specific patient care there is then no impetus to make a change to the formulary. This in turn puts greater burden on patients and their healthcare professionals who then have to advocate and raise awareness on the consequences of the system on a given patient and work against the inertia of the system that looks to deliver care that is focused on the population level vs the patient level.

From the PhD Researcher’s perspective, universalizability as defined by Kant, would dictate that a person in a given society have access to the healthcare that is needed to improve the well-being of the individual that ultimately would enable that individual to maintain or improve his or her health in a manner that is satisfactory to the individual; otherwise the individual would not want to belong to the society as it relates to being a contributing member and in turn receiving the level of coverage needed to maintain or improve his or her health. At the same time, Kant’s Kingdom of Ends would also mandate that the individual’s access not jeopardize the healthcare needs of others in the community and that affordability of care to any one person in that community not become overly burdensome from a financial standpoint. This leads one to recognize that to deliver ethically balanced healthcare is arduous, time-consuming and requires time-sensitive remediation if additional access to care is needed given the initial care provided to any one individual is insufficient. Ethically balanced healthcare also needs to stipulate that care above a certain minimum would need to be sourced in such a way as to not place additional financial burden on the
rest of society to fund that individual's access to care. At the same time, excellence of virtue would also require others to give of themselves freely to provide the additional level of funding for any one individual to have the access of care that is needed. The one additional virtue to provide a balance on limits of care is for the individual seeking care to be mindful of the implications, such as financial costs to others for that given individual to request a specific level of care. This addresses the point made by study participants that there should be a distinction between what patients need vs what patients want; needs are part of basic care vs wants are at a higher level of care that in the U.S. is only attainable through additional financial means.

6.1.4 Access to Rx Medicines Impacted by the Financials:
Analysis of Findings Summary

From the PhD Researcher’s perspective, based on the findings of the research, as one considers the three aspects that have been discussed in this section, namely, (1) benevolence vs the economics & business goals of Employers and MCOs, (2) care is determined by the contract that has been purchased and (3) care provided, needs to be reasonable; anything other than reasonable care is a privilege, the concepts that emerge is that society needs to define what is the minimum level of acceptable care for any given patient and ensuring that minimum level of care is achieved. However, society has not defined the minimum level of coverage that is deemed reasonable as it relates to commercially-funded drug formulary coverage (plans that are provided under ERISA). Contracts are difficult to obtain, comprehend and do not necessarily speak to the details of prescription medications that will be included on a given formulary.

Justice can be seen as being satisfied as long as the terms of the contract are satisfied, however, there are limitations to the degree distributive justice is satisfied if two patients get different levels of care solely due to the terms of their plan coverage as defined by the MCO. From a utilitarian standpoint, the MCOs are looking to maximize their shareholder value by offering health coverage to their members, increasing the cost of services to those patients who use the benefits available under
the plan through cost-sharing at the time benefits are used. Kantian-type deontology can cause economic duress and unsustainability; ultimately the physician has a disproportionate burden advocating for the patient, based on their code of professional ethics and moral excellence, given their unique knowledge that can impact on the life of the patients for whom they provide care. Autonomy is infringed upon as physicians are not able to effectively leverage their medical expertise in treating a specific patient as affordability and patient’s willingness to fill a given medication requires a physician to redirect their treatment strategy; one could consider the patient’s autonomy is infringed as well because economics curtails what otherwise might be the patient’s choice for treatment. When it comes to others shouldering the economic cost of providing access to medical care for others there is a reluctance in absorbing the additional finances that would be required which is in direct conflict with what could be seen as mandated by virtue ethics. Given each person is looking to maximize their own economic utility there is no socially recognized process for applying the various ethical theories and principles in concert that would be seen as value maximizing for the individual as well as the population. Society at a macro level will not interfere with the free market process and establish additional rules by which MCOs need to comply unless those negatively impacted by outcomes are able to raise awareness on the degree to which beneficence and maleficence are materially impacted in a manner that is unacceptable to society at large.

6.2 Drug Formularies are a Means to An End

As previously discussed in Chapter 5, with regard to Drug Formularies are a Means to An End, the following aspects emerged through the primary research with the study participants, namely:

- Formularies are access deterrents: struggle (hassle factor) for HCPs & patients
- MCOs look to lower premiums by shifting cost to patients
- Physicians believe they have the best interest of the patient in mind
These three concepts are examined in detail in the following three sections.

6.2.1 Drug Formularies are a Means to an End:
Formularies are access deterrents: struggle (hassle factor) for HCP & patients

The premise of a competitive marketplace in healthcare leading to more ethical care is potentially flawed; as highlighted by the study participants, normative ethical theories and principles are not typically discussed as it relates to the day to day operation of managed care. The concept of the invisible hand, introduced by John Adams (Rothschild, 1994), namely self-interest leading to greater societal value, perhaps does not work well in the application of managed care as there is a moral hazard in that the decision-makers (MCOs and EBDDMs) are not necessarily the end-users of the system or directly affected by the decisions taken in terms of specific patient care.

A majority of physicians acknowledged that formularies affected their prescribing and required significant time investment to address and potentially overcome the barriers that were associated with access restrictions (Suggs et al., 2009). Although the Suggs study was specific to physicians in Canada, the similarities of drug formulary use between Canada and the U.S. make the finding relevant to this thesis. In another study done by Landon et al. (2004), of the U.S. physicians surveyed (N=12,406), 48.7% of the physicians felt that formularies had a negative effect on the quality and efficiency of care provided to the patient as compared to 13.4% who felt formularies had a positive effect. The study’s perspective recognized that formularies created a struggle for physicians and placed an additional burden on physicians in that it created additional uncompensated, administrative work for physicians. A recent survey by the AMA highlights the physician perspective as it relates to specific utilization management techniques namely prior authorizations. As characterized by Wilson (2018),

“Prior authorization… is frequently characterized by insurance companies as an effort to deliver the best possible therapy to the patient and to avoid unnecessary care, but many physicians I’ve spoken with seem to think it is
simply a tactic to make expensive care more onerous, driving down the costs to the insurance companies."

92% of surveyed physicians felt that Prior Auths can have a negative effect on patient outcomes and can lead to care delays; 78% felt Prior Auths can lead to treatment being sometimes (57%), often (19%) or always (2%) abandoned; 48% stated they needed to wait at least two business days to get a response regarding a Prior Auth from the MCO (AMA). In the opinion of the PhD Researcher, from an ethics perspective, a utilitarianism mindset might view this as a necessary approach to maximize the good for the most patients as possible; however, as it relates to deontology, virtue ethics and biomedical ethics, formularies are in conflict with the physician-directed treatment strategy: the physician has the clinical experience and expertise treating the patient, yet the system is overriding the physician perspective and the patient preference based on a population-level decision that led to the adoption of a given drug formulary for a particular plan. Applying the concept of the categorical imperative, as a universal law, would physicians still want to practice medicine if they are not able to apply their expertise and knowledge to improve the patient’s outcomes; autonomy is challenged; justice is compromised as patients and physicians most likely did not know that by participating in a particular plan, access to given medicines might not be paid for by the plan.

As has been discussed earlier in this thesis, drug formularies in the U.S. healthcare system are designed to rationalize use of medicines; the one difference in the U.S. though vs other countries with socialized medicine, is there are literally hundreds of formularies in place as each MCO develops its own formulary and any given MCO may have a number of different drug formularies depending on the richness of the plan. Hence different patients, as previously stated by the PhD Researcher, who are alike in every detail except for their drug formulary coverage, will have varying levels of access to the same medication. One patient may have access to more expensive medicines with less out of pocket costs and less utilization management (such as PAs) vs the other patient and this may impact treatment plans and outcomes as was
already discussed (findings from the recent AMA survey of physicians and the impact of Prior Auths on treating patients).

Almarsdóttir and Traulsen (2005) highlights the definition of Rational Use of Medicines both by the WHO and the World Bank; both organizations explicitly address cost as a factor to inform use of medicines. According to Almarsdóttir and Traulsen, the WHO definition states that “The rational use of medicines requires that patients receive medications appropriate to their clinical needs, in doses that meet their own requirements, for an adequate period of time and at the lowest cost to them and their community” and the World Bank definition states that the “use of drugs [should be] according to scientific data on efficacy, safety and compliance” and there should be “cost-effective use of drugs within the constraints of a given health system”. Hence on all levels of society, local, regional, national and global, from the perspective of the PhD Researcher, there is a recognition that cost is an element that factors into decision-making related to accessing prescription medicines; hence society has deemed this approach of access to be justifiable to be able to maintain financially responsible access to care to the entirety of the community. This would be aligned with the normative theory of utilitarianism where the greatest utility is created through the use of formularies at the population level. Deontology however, from the PhD Researcher’s perspective is conflicted as there could be duty to society and duty to the physician-patient relationship.

The physician looks to provide the best possible care to the patient; however as the study participants stated, to prescribe a medication that is too costly to the patient or that has too many access restrictions, may lead to delayed treatment or no treatment. Hence the physician from a duty perspective ought to prescribe what is most likely to lead to a medically acceptable level of care; the physician ought to also advocate on behalf of the patient to the extent that the available prescription medicines through the MCO formulary are not medically acceptable. Hence there is a tension that exists at the physician level. The physician also has a duty to self and to others to balance their time effectively. There is also the element of virtue: from the PhD Researcher’s perspective, the physician who is virtuous, who exhibits among other traits, virtues
such as kindness, commitment, loyalty, fairness, perseverance, trust would need to extend himself to ensure the patient receives the best possible care available within the healthcare system. Conversely the MCO, that views the population and only has access to the statistics vs the individual patient experience, is able to align deontological and utilitarian elements to deliver formularies that at a population level are medically acceptable. What persists then from an ethical perspective, beyond just procedural justice, namely, to review drug formulary decisions according to the terms of the contract, is whether the MCO actively ensures that no patient is worse off under its formulary and how the MCO justifies that some patients will have more generous formularies that other patients based on the level of coverage purchased. This however, then reverts back to the market reality that in the U.S. healthcare system there is an element that those who are able to purchase better access to medicines are able to do so.

6.2.2 Drug Formularies are a Means to an End:
MCOs look to lower premiums by shifting cost to patients

Cost-shifting to the patient is a mechanism by which to better manage the payer’s budget by reducing expenditures for the plan but may potentially lead to negative healthcare outcomes (the effect being more pronounced the lower the income status of the patient). Adherence typically decreases with increased out of pocket costs and overall reduces the use of medications (Gemmill et al., 2008). Gemmill differentiates between allocative efficiency which refers to commodities being purchased by those who can afford or are willing to pay for the commodity vs healthcare-based efficiency which looks to maximize health gains. Lu et al. (2008) highlights the impact of introducing formularies with varying tier levels, where physicians will prescribe and patients will utilize those products at the lower copay tier levels vs higher cost copay tier levels.

As stated earlier, Gottlieb (2015) highlights in his article, Insurance Plans Are Narrowing Their Drug Coverage, health plans are not including certain drugs on their formularies to reduce their expenditures; as in the case of treating patients who have multiple sclerosis. Silver plans under the Affordable Care Act are offering closed
formularies and leaving off medications used to treat multiple sclerosis thereby shifting the entire cost of medication treatment to the patient.

An example of formularies as a means to an end is illustrated by CVS Caremark and Express Scripts, the two largest Pharmacy Benefit Management (PBM) organizations in the United States. As shown in Figure 6.3 below (Fein, 2017), the number of products that have been placed on exclusion lists have continued to grow over time.

![Figure 6.3 Number of products on PBM formulary exclusion lists, 2012-2018. Adapted from Fein (2017).](image)

Medications not covered on the drug formulary will require the patient to pay the full cost of the product at the pharmacy if the patient’s physician prescribed the product excluded from the formulary. CVS Caremark touts the positive economic implications from a pharmacy budget perspective on utilizing such formularies where there are products excluded; the Q1 2017 post-rebate PMPM cost was $121.12 for the Standard Opt-Out Formulary that did not include formulary exclusions as opposed to $85.90 for the standard control formulary that did include formulary exclusions. (Brennan, 2017). As stated by Brennan,

“Since 2012, when we introduced our industry-leading and rigorous approach to formulary management, through 2018, our formulary strategy is expected to deliver $13.4 billion in cumulative savings to pharmacy benefit management clients, through inclusion of lower-cost brands and transition to generics.”
A financial analyst who covers the industry recognizes that the decisions by the PBM is a price play, products being added or taken off formulary due to the difference in net acquisition cost between products and the respective economic implications (Sagonowsky, 2017). One particular drug that was taken off formulary in lieu of another branded agent was Jardiance which was replaced by Invokana; although the medications have similar efficacy in Type 2 diabetes, Invokana has a higher number of amputations due to treatment-emergent adverse events. CVS, specific to the treatment of metastatic prostate cancer, similarly took Xtandi off of formulary in 2017 before adding it back in 2018. The alternative treatment option left on formulary was Zytiga which requires concomitant administration of steroids and is hence a more complicated treatment option; some patients might also have medical conditions where steroids are contraindicated. Lastly, the lack of access to Xtandi limits physicians from treating patients once they have progressed on Zytiga.

Emanuel (2000) speaks to this point that MCOs need to be able to provide services on a fixed budget. The challenge for consumers (patients) to make informed decisions on coverage for healthcare is not only that the employer provides a select number of plans to choose from but that consumers (patients) have limited ability to make informed healthcare decisions. This limitation arises in part due to a lack of knowledge as well as being in a compromised health state due to the fact of having a medical condition; hence the importance of patients having a trusting relationship with their physicians given the latter’s training and medical expertise. As stated by Lown (2007),

“Key assumptions in market theory are that the consumer knows what he needs, appreciates differences in quality, is offered these at different price levels, has bargaining power and can exercise free choice to buy or not to buy. None of these is true in health care. Patients usually do not know what is wrong; they do not comprehend the diagnostic possibilities; they are not familiar with the therapeutic options, they cannot assess the quality of care needed, and they do not appreciate the numerous potential outcomes. No amount of surfing the internet, browsing the media, reading popular health books, or sharing nostrums with neighbors can provide the necessary insights. These are the very reasons that they seek out the expertise of intensely trained and experienced health professionals. They need to nurture a
relationship of trust with their doctors on whom they must rely on for their well-being and even survival.”

As discussed by Micewski and Troy (2007), utilitarianism places emphasis on actions that lead to a collective benefit not because the action itself is right; the good is independent of the right and the right is defined as the maximization of the good; in business, that is maximization of profit and business efficiency. Micewski and Troy speak to how utilitarianism becomes a problem when the sole focus of a business becomes meeting or exceeding profit targets: “When this goal is about one’s own benefit, the entitlements of others might be ignored and left out of the equation, or in the least might not be given sufficient recognition.” Micewski and Troy speak to the recognition in both deontology and utilitarianism that actions are taken to achieve an objective; in utilitarianism the end result validates the means whereas in deontology the means should be an end to itself; moral duty that is espoused through deontology redirects intended actions even if there is a negative consequence to the entity. Micewski and Troy speak to the categorical imperative of Kant, namely, that any action considered should be acceptable and applicable to all individuals in a harmonious and functioning society: “Act only according to that maxim whereby you can at the same time will that it should become a universal law” that one’s freedom should not be infringed by the actions of others and all should be treated equally; however to achieve this each agent needs to act responsibly. As discussed by Micewski and Troy, achieving an end without regard to the effect of the actions on others, strips away at the humanistic rights of people making them simply a means to an end which transgresses Kant’s *formula of the end in itself*. This speaks to the point of MCOs when they introduce formularies that act as a deterrent to prescribing; a point brought forward by the study participants. Although this is recognized as a mechanism by which to control costs within the plan, most insured members would probably not want to be insured by an MCO if they knew in advance that the care that their physician deemed best for them based on their medical condition would not be available to them except if other medicines were tried first or if the patient accepted a very high out of pocket cost (either due to cost-shifting based on the formulary tier-level or full cash cost if the product is not covered by the formulary).
As discussed by Bragues (2005), in Bernard Mandeville’s *The fable of the Bees* (Mandeville and Kaye, 1957), capitalism is fueled by self-interest while ethics is centered around self-denial, hence capitalism and ethics are diametrically opposed. Brague highlights Enron as an example of an organization that seemed to be outwardly committed to doing the right thing but still misled shareholders; Enron “publically identified with the causes of the contemporary business ethics movement, including good working conditions, environmental responsibility, human rights, and the fight against corruption.” Brague speaks to the focus of utilitarianism as to act in a manner that benefits society, yet MCOs do not assess formularies in terms of what generates greater value for society but rather, as mentioned by study participants, how can the MCO provide reasonable care for insured members while increasing year over year sales or keeping out of the headlines of the newspapers. Brague also speaks to deontology being a state of mind where people are treated as ends to themselves, yet study participants acknowledged that formularies are focused on the population and not the individual patient; that patients from whom the lowest cost options are not adequate, will be disadvantaged by needing to pay higher out of pocket costs or potentially needing to pay full cost for medicines if not covered by the drug formulary; this being done to keep premiums down for the overall population.

### 6.2.3 Drug Formularies are a Means to an End:

**Physicians believe they have the best interest of the patient in mind**

Champlin and Knoedler (2008) speaks to the point that healthcare has been turned into a marketplace in the U.S., where physicians are vendors selling services to make money for themselves and at the same time ensuring economic viability for their employers, “managing supply and constraining demand”, despite the resistance (reluctance) of the medical profession. Hirsch (2002) recognizes the dual nature of medicine; that it needs to provide fair access for all patients as it is a moral enterprise but at the same time be based on sound business principles. Hirsch speaks to the concept of moral distress, a state of mind brought about when HCPs need to act in a manner that is not in line with their professional expertise or point of view; this was
vocalized by some of the study participants. One of the Community Retail Pharmacy study participants made the following point:

“I go home feeling really good when I have done… a lot of good things for people… Then I feel I have done something substantial. So I go home at the end of the day very, very exhausted mentally as well… literally mentally more exhausted than physically, but sometimes it’s a physical feeling also… I have to do so much work in this time frame that I am in, to make the job acceptable to my employer. And I have had to not be able to give time to people that needed the time and I feel badly.”

Hirsch references to the “Power of One”, where through thoughtful action an HCP can make a difference in the care and outcome of the patient; more specifically, “one who declines to act because the anticipated response is ‘No!’ forfeits one’s own power and the ability to empower others.” Yet, in several instances, the MCOP&T committee study participants made the point that treating physicians do not necessarily provide complete information for MCOs to approve prior authorizations when the drug formulary requires detailed information from the treating physician to provide patients coverage for a given medication through the formulary based on medical need.

As was stated earlier in this chapter, the physician looks to provide the best possible care to the patient; however as the study participants stated, to prescribe a medication that is too costly to the patient or that has too many access restrictions, may lead to delayed treatment or no treatment. Hence the physician from a duty perspective ought to prescribe what is most likely to lead to a medically acceptable level of care; the physician ought to also advocate on behalf of the patient to the extent that the available prescription medicines through the MCO formulary are not medically acceptable. Hence there is a tension that exists at the physician level. The physician also has a duty to self and to others to balance their time effectively. There is also the element of virtue: from the PhD Researcher’s perspective, the physician who is virtuous, who exhibits among other traits, virtues such as kindness, commitment, loyalty, fairness, perseverance, trust would need to extend himself to
ensure the patient receives the best possible care available within the healthcare system.

6.2.4 Drug Formularies are a Means to an End:
Analysis of Findings Summary

From the PhD Researcher’s perspective, based on the findings of the research, as one considers the three aspects that have been discussed in this section, namely, (1) formularies are access deterrents creating a struggle (hassle factor) for HCPs and patients, (2) that MCOs look to lower premiums by shifting cost to patients, and (3) physicians believing that they have the best interest of the patient in mind, there appears to be a natural tension that exists between ethical theories and principles which becomes apparent. However, upon closer reflection, there is also a degree of alignment across the various theories and principles as well. MCOs need to facilitate care at the population level; by providing the lowest possible cost of coverage to the population at large, by shifting cost to patients who utilize the available services, the population is not exposed to additional financial burden for greater coverage than might be needed by the average person within the population. However, to the MCO, the individual patient is a faceless statistic vs a known person, hence there is no negative consequences from an ethical perspective to the MCO or EBDDM if there is no information on the effect of the drug formulary to the known patient. This however is not the case for the physician or the pharmacist who from a deontology and virtue perspective, ought to help the patient acquire the needed medication. From an Aristotle point of view, an illustration of moral excellence is for the HCP advocating for the patient. However from both a deontology and utilitarian perspective, at some point, there is diminishing return on the investment of time, and other patients would not be appropriately attended to and cared for. Imagine in an extreme case, where the physician and pharmacist completely focus on the named patient, the time consumed would prevent other patients receiving the necessary time, care and services. Where the system is at a point of irreconcilable differences, is the lack of trust by the MCO and EBDDM, in the clinical expertise of the treating physician in collaboration with the local community pharmacist, to allow for the physician treating
the patient, to make the decision to allow the patient to have access at the same copay as the lower cost medicines on formulary without time delays. This aspect of the healthcare system in turn requires all stakeholders involved to work harder and more diligently to raise awareness on the negative consequences of the drug formulary. This will be addressed in more detail in the next section that is focused on informed decision-making. However, as it relates to biomedical ethics, namely autonomy, beneficence, maleficence and justice, these principles at the individual patient level are compromised in terms of accessing a given medication for that known patient. These are provided in more detail below:

- **Autonomy**
  It is futile for physicians to prescribe a medication to patients if the coverage under the MCO’s drug formulary is too costly.

- **Beneficence / Maleficence**
  The alternative medications will potentially deliver a reduced treatment effect, perhaps not to a degree of harm but to a lesser degree of beneficence.

- **Justice**
  Two identical patients being treated differently solely because of difference in drug formulary coverage could be deemed unjust from a medical perspective; but could be viewed as fair if one patient subscribed to an MCO that had greater levels of coverage than another which could be purely an element of luck as one EBDDM was able to secure a better MCO than another EBDDM.

### 6.3 Informed Decision-making Is Essential to Understanding Implications of Choices

As previously discussed in Chapter 5, with regard to *Informed Decision-making Is Essential to Understanding Implications of Choices*, the following aspects emerged through the primary research with the study participants, namely:
• Trusting in the recommendations of experts
• Understanding consequences of purchase
• Patients ultimately accountable for their health and in making treatment choices
• Team-based approach improves healthcare outcomes

These four concepts are examined in detail in the following four sections.

6.3.1 Informed Decision-making Is Essential to Understanding Implications of Choices: Trusting in the recommendations of experts

Employers need to trust in the advice provided by MCOs as EBDDMs do not have the necessary expertise. However, the impact of competing interests is spoken of by Brecher (2011), “The supposition that conflict can be resolved to the satisfaction of the parties involved, whatever their own values might in fact be, is either sincere but naïve or – worse – awesomely disingenuous. Either way, the actual outcome is likely to be an imposition of the values of whoever holds effective power.”

From the PhD Researcher’s perspective, based on the findings of the research, the element of trust between the employer and MCO is only one aspect of the interconnected relationships that exist among the affected stakeholders; other trust-based relationships include the following:

• the patient places trust in the physician, pharmacist and other healthcare workers; and,
• the employee trusts in the employer to satisfy its fiduciary responsibility and select beneficial benefit designs and plans to provide medical & pharmacy coverage.

Yet the physician’s medical decision to treat the patient is not trusted by the MCO as the MCO deems to have greater levels of expertise to inform treatment strategies than the patient’s physician. At the same time the business interests of employers’ factor into the MCO’s decision-making and ultimately impacts on the benefit offerings
the employer makes available to their employees; equally the business interests of
the MCOs impact on the recommendations and plan offerings they in turn offer to
employers.

Bowman (2017) addresses that trust is misplaced in the system of interaction
because incomplete information is provided, there is always an expert opinion that is
polished and from the podium, hence there is no realness to discussing a particular
question or issue and understanding in a meaningful manner the relevant details from
the various stakeholders, first and foremost, the voice of the patient. Responses are
too polished and staged rather than creating a venue where there can be a real
discussion about the facts and the implications of actions taken, especially on the
patient. This was the experience that was conveyed by the study participants of this
thesis; the voice of the patient is far removed from the MCO; the patient as the
employer’s employee can enlist the support of the EBDDM, who may then still defer
to the expertise of the MCO. However in the day to day engagements between the
MCO and the treating physician, even the physician is not necessarily able to gain the
opportunity to have a phone call discussion with a suitable peer at the MCO, and the
voice of the patient is not included in the process. Ikerd (2013) speaks to the point of
the importance of kindness and empathy, virtues, that further strengthen relationships
that are initially formed based on trust, especially when it comes to matters of health.

From the PhD Researcher’s perspective, based on the findings of the research, the
treating physician has the greatest understanding of the patient, the treating physician
is the expert who has been recognized by society as the principle prescriber, the
physician is the only medical professional with complete medical knowledge of the
patient’s condition, and yet the physician is not able to necessarily treat as they deem
most appropriate. Khan (1999) speaks to the physician’s duty of care that due to his
acquired learnings and knowledge has an exceptional responsibility to the patient to
provide the best possible care for which he has capabilities. Hence from the PhD
Researcher’s point of view, it could be seen as the MCO infringes on the duty of care
a physician has in taking care of his patient based on availability of medications
through the formulary. This impacts on the physician’s autonomy, as the physician
can still prescribe whatever medication he deems most appropriate for the patient, but if the patient is not able to fill the prescription due to utilization controls or due to patient affordability, the patient will not receive the needed treatment. Hence the decision-making of the physician is re-directed due to the patient’s drug formulary, which can impact on the level of beneficence the physician can provide to the patient. From the perspective of the PhD Researcher, utilitarianism would support the physician not advocating for the patient gaining access as this would decrease the utility of the physician to take appropriate care of his other patients. Given the MCO does not collaboratively engage the physician to optimize patient care, but rather curtails the physician’s ability to treat the patient, it reduces the physician’s ability to exercise his expertise; the result is that the MCO’s management of health at the population level dominates the physician’s level of expertise in the individual care of the patient. Inherently one can see the tension that exists at the physician-patient level vs the MCO managing for the population.

6.3.2 Informed Decision-making Is Essential to Understanding Implications of Choices: Understanding consequences of purchase

There seems to be an implied disconnect between the realities of coverage as defined by the policy and the interpretation of coverage by the end-user (consumer). This is evidenced by the number of complaints made by consumers to state insurance departments. As stated by Champlin and Knoedler (2008), “Thousands of complaints against private insurers are lodged every year with state insurance commissioners citing cases where insurance companies refuse to cover particular procedures or drugs even when recommended by the individuals’ health care providers”.

Pellegrino (1999) speaks to the challenges that are faced by purchasers in understanding the true parameters of coverage given the wording of the policy and the inherent difficulties in understanding the specifics of the language. There is an element of gamble in meeting the health needs of the insured member that may change over the course of the coverage that is in effect given “the convoluted
obscurantist language of [what] the contract covers or the impossibility of predicting how much coverage one will, in fact, need, particularly to meet the uncertainty of an unexpected catastrophic illness."

Pellegrino makes mention of the realities of the employer-provided healthcare coverage marketplace, namely, that employers are the ones that select the plan options that will be made available to employees, and these offerings will be firstly informed by cost to the employer. Subsequently, the employee has no real option outside of the plans offered by the employer, unless they choose to find their own coverage which in that case would not be subsidized by their employer.

From the PhD Researcher’s perspective, based on the findings of the research, there are two aspects to understanding the consequences of a purchase. Firstly it is the employee’s employer who decides which MCOs will be available for the employee to choose from; usually choices will be limited to a few benefit design options and even likely limited to one or two different MCOs. Hence the employer decision-maker has a significant impact on the available coverage options for its employees. The second aspect is the employee understanding fully the consequences of enrolling in a given MCO’s plan made available to him by his employer and the levels of coverage available. The employee has to be effective in conveying to the employer any shortfalls in outcomes due to the drug formulary coverage levels made available by the employer; the physician needs to do the same with the MCO. At the same time the employer and the MCO should be actively seeking to understand any shortfalls in outcomes due to drug formulary coverage levels and looking to make adjustments as needed to address these shortfalls. As discussed by Kahane et al. (2017), classic utilitarianism as defined by Mills, is based on each individual having the same intrinsic value, and a unit of benefit counting the same no matter who that person is within the community; hence the access-related decision-maker is maximizing the sum of all benefits to the covered members who work for the employer. The MCO and the EBDDM believe that patients who use the services should be paying more for the care received than those who use less services. This is the purpose of cost-shifting and accepting that those receiving services should be paying a certain percentage of
the costs, in addition to the premium. All stakeholders involved need to hence vigilantly monitor for implications of the drug formulary on patient care. From the PhD Researcher’s perspective, Kant’s deontology would mandate that all stakeholders involved ought to do their part to ensure patient care is not compromised due to formularies. Virtues, such as kindness and empathy, would compel action to be taken to overcome any negative consequences of care. As it relates to utilitarianism, it is difficult to undertake the felicific calculus to quantify the negative consequences and relate these to the positive consequences to assess net outcomes. However, unless the contract clearly stipulates the importance of surveillance and monitoring outcomes, the aspect of the contract could dominate unless the degree of loss in beneficence and the level of maleficence created would be viewed as unacceptable by society.

6.3.3 Informed Decision-making Is Essential to Understanding Implications of Choices: Patients ultimately accountable for their health and in making treatment choices

Study participants universally spoke to the importance of informing the patient about available treatment options and enabling the patient to make the trade-off decision as to which therapy to utilize; a low-cost option vs a more costly treatment option that might require additional trade-offs in their lives (for example, the choice of buying presents for their grandchildren at Christmas or taking a specific medication). However, the choice of coverage for the employee (insured member) is limited to the offerings provided by the employer which is determined by the amount of dollars the employer deems sufficient to providing care to their employees. As mentioned by the EBDDM study participants, the information to make coverage choices by employers is informed by the MCO, the employer benchmarking to the marketplace, and getting insights from other experts (such as employer benefit consultants). Although as discussed by Emanuel (2000), there should be information provided to insured members on how the decision on coverage was made, this is not done by employers other than explaining at a high level what the different options are and the basics of coverage such as premiums, deductibles and cost-sharing (such as copays and
coinsurance). Emanuel speaks to the point that information needs to be available to the population so that decisions can be justified in the court of public opinion; a required criteria for an action to be considered moral. However, this is not done, as already stated previously, because even Physician study participants spoke to the point they do not themselves understand the benefit coverage of their own plans of which they are members as patients, despite their advanced education and training in medicine. Emanuel highlights that statements such as, medically necessary and appropriate, are too vague and does not provide the necessary clarity to the insured member to understand specifics of the coverage and the rational for the coverage decisions; specificity of information to make informed decisions is necessary if insured members are to be recognized as “autonomous moral agents”. Implicitly, all study participants realized the need for letting employees (insured members) to make their own decisions, hence the concept of autonomous moral agents, but no one spoke to how the lack of precise and complete information infringes on treating insured members as autonomous moral agents. Emanuel addresses the point that “justice requires that those who have to live with the consequences of the allocation be afforded the opportunity to affirm that the allocation reflects their values.” If the objective of the health plan is to improve the health of the insured population, the challenge becomes when conflict of interest affects the health of the insured member; however, there needs to be evidence that due to a conflict of interest there was a negative impact on the health of the insured member and there needs to be agreement by decision-makers that the affect was causal and meaningful. A natural tension exists when contrasting utilitarianism and deontology; as discussed by Emanuel, under utilitarianism one is trying to maximize the collective good but should the focus rather be to ensure all individuals have a positive benefit to their health status. Ruger (2008) raises the concept different people might need different care to achieve the same level of functioning; “It implies that people with the same health needs might require different levels of resources to ensure the same capability to achieve a given health state.” This approach is not practiced with the current use of formularies in that patients who respond to the lowest healthcare interventions gain the benefit of lower cost (more affordable care). Ruger speaks to preventing
undesirable affects within the healthcare system, namely discriminating against the sick as well as introducing financial barriers which become an impediment to seeking and utilizing care. Ruger also addresses the point that although clinical guidelines based on evidence-based medicine can (and will) reduce inefficient healthcare delivery, the decision for specific patients should be decided by the individual physician as it relates to a specific patient: “Physicians must use clinical judgment to make diagnostic and treatment recommendations in each individual case”. Although Ruger believes that appeals are a process that helps ensure individual patients receive the care needed and when not, the care denial is transparently documented. However, based on the input from the study participants, there is a lack of understanding how formularies are arrived at and how decisions are concluded in the appeals process.

Mechanic (2000) highlights the perspective physicians have expressed as it relates to MCOs; physicians want to deliver care that they deem is best for the patient and they feel that MCOs restrict their time, compromise their ethical mandate set forth under the Hippocratic Oath and subsequently experience a “loss of control over their clinical decisions.” Mechanic speaks to the point that physicians need to understand that the MCO environment requires physicians to allocate resources and to advocate on behalf of their patients ensuring application of procedural justice, most notably, through the use of evidence-based medicine and a focus on prevention as well as overall public health. Mechanic speaks to how the original construct of medicine, preceding MCOs, was designed to allow physicians to control all aspects of healthcare and extract the greatest possible remuneration; with the dominance of MCOs there has been a shift and dispute in the locus of control of decision-making. Interestingly, according to the views expressed by the study participants, MCOs hold the position that they do not deny care just payment for care; ultimately it is the decision of the patient to prioritize paying for care they deem is best given their personal preference. As discussed by Mechanic, the profit-focus of the MCO has replaced the physician’s unlimited income potential before the advent of managed care. Although Mechanic believes that MCOs have made rationing of care more obvious through their varied mechanisms of utilization controls; the concept of
formularies according to study participants is seen as a mechanism to keep down premium costs for the overall insured population, shift a disproportionate share of out of pocket costs to patients who use more (or are in need of more) healthcare-related services. The concept of rationing was not explicitly stated by study participants; rather the concept of a hassle factor: a formulary was deemed to be ineffective if it did not introduce a hassle factor in the care of the patient. Loewy (2002) speaks to the “hassle factor” as another name for rationing; namely by introducing a hassle factor there is a reduced likelihood that the patient will receive certain levels of care either due to the higher out of pocket costs or the administrative burden of receiving approval. Mechanic and Meyer (2000) speak to the point of how patients trust in the expertise of their treating physicians (especially given the vulnerability of the patient due to illness) and the compassion of their physicians to do the right thing on their behalf (namely, advocating); the less trust a patient has in his physician the more control the patient wants to assume in his own care. This point was highlighted by the Physician study participants who felt they were the “last person standing” who was focused on ensuring the patient received the best possible care vs minimizing care provisions in the interest of the MCO’s profitability. Mechanic stresses that advocacy for the patient is needed given patient heterogeneity and the necessity of procedural justice to ensure fairness is exercised for a given individual. Physician study participants voiced frustration over the need to advocate on behalf of patients, due to the uncompensated time involved, the administrative burden, the uncertainty of the MCO’s decision and the lack of respect for the training and expertise of the physician.

McClimans and Slowther (2016) addresses the initial rationale for evidence-based medicine (EBM) which was mainly to remove the guesswork from delivering medical care. The approach of EBM, as stated by the Evidence-Based Medicine Working Group (1992), was to “de-emphasize intuition, unsystematic clinical experience and pathophysiologic rationale as sufficient grounds for clinical decision making…” However, as McClimans highlights, there was pushback from physicians on this aspect; it was seen partly as an assault on the treating physician’s expertise and knowledge of the patient, including a given patient’s preference of how to be treated.
McClimans notes that the Evidence-based Medicine Work Group recognized that EBM is an integration of the scientifically recognized evidence in the marketplace and the physician’s clinical expertise rather than at the expense of the treating physician’s clinical judgement. McClimans notes that there is a degree of treatment uncertainty because of the lack of complete information and subjectivity in the interpretation of specific evidence; “expertise is epistemically diverse.” This concept of variability of a given physician’s subjectivity came across in the study participants’ responses; and what leads to the concept of Dealer’s choice; namely, the ultimate outcome experienced by the patient is dependent on the physician he has and the plan he is enrolled in. Goldenberg (2006) notes that given the number of different perspectives, EBM is a welcomed approach to align diversity of thinking among stakeholders; however there is a need “…to defend the unsystematic intuitions and expertise that arise from clinical experience as epistemically significant and indispensable to clinical decision-making.” This is the challenge that is introduced by formularies which are based on review of the scientific evidence and requires patients who are not the average profile (based on trial data) to either pay more for achieving the same outcome another patient might have been able to achieve at a lesser cost option and most likely also requires a time delay in accessing the care given the use of utilization controls such as prior authorizations.

As discussed by Emanuel (2000), individuals need to make their own informed choices as it enables “individuals to develop their own aims and interests and to make their values effective in the living of their lives”.

6.3.4 Informed Decision-making Is Essential to Understanding Implications of Choices: Team-based approach improves healthcare outcomes

Mitchell et al. (2012) highlight the need for team-based healthcare given the tremendous amount of information that needs to be processed and assimilated in the care of a patient. Mitchell highlights in his paper that there are more than 2,700 national clinical treatment guidelines and that each year 25,000 new clinical trials are published. Members of the knowledge-based care team extends beyond the scope of this thesis but for completeness is mentioned here and includes professionals that
represent a diversity of disciplines including physicians, nurses, physician assistants (physician associates), pharmacists, social workers, and dieticians to name a few. Mitchel recognizes that given the level of medical knowledge and experience across multiple disciplines it would possibly be harmful to not use a team-based approach to patient care; yet team-based medicine will be difficult for HCPs who are not trained to deliver healthcare in a team-based environment. The concept of team-based healthcare in the U.S. was given special emphasis as part of the Affordable Care Act of 2010 as a mechanism by which to improve the quality, reduce the cost of care and increase the focus on patient-centered care through a multi-disciplinary care team led by the physician. Studies have shown that such an approach can reduce cost of care by approximately 10% (Adamson, 2011).

6.3.5 Informed Decision-making Is Essential to Understanding Implications of Choices: Analysis of Findings Summary

From the PhD Researcher’s perspective, based on the findings of the research, as one considers the four aspects that have been discussed in this section, namely, (1) trusting in the recommendations of experts, (2) understanding consequences of purchase, (3) patients ultimately accountable for their health and in making treatment choices, (4) team-based approach improves healthcare outcomes, the overall U.S. system is fragmented which leads to value not being optimized. Trust is compromised as no one stakeholder fully trusts in the other; different stakeholders of the system do not have equal levels of knowledge to make fully informed decisions; yet the decisions taken have consequences to the level of care that any given patient will receive in the system. All of the ethical theories and principles recognize the implications of diminished trust; from rule-based utilitarianism, to deontology, to virtue and biomedical ethics. However, ultimately, the individual patient has the responsibility of making choices that are most appropriate for himself based on his or her own situation. Justice could be seen as compromised if that patient needed to make decisions on incomplete information. Although the decision taken by the individual satisfies the requirement of being an autonomous moral agent, autonomy could be seen as curtailed if the choices are limited. Under any available choice
taken, if there would be a more centralized, team-based approach to determining the appropriate level of care and then administering that level of care, there might be the ability to deliver better care that equally meets the needs of the individual patient and the population at large.

6.4 Population vs Patient-level Care are not Necessarily Reconcilable

As previously discussed in Chapter 5, with regard to *Population vs Patient-level Care are not Necessarily Reconcilable*, the following aspects emerged through the primary research with the study participants, namely:

- Formularies not necessarily fair to the individual patient
- HCP follow-up is an important element to improve patient-specific outcomes
- Patient autonomy and self-worth potentially compromised due to lack of access

These three concepts are examined in detail in the following three sections.

6.4.1 Population vs Patient-level Care are not Necessarily Reconcilable: Formularies not necessarily fair to the individual patient

Ollove (2017) writes about how health plans can change formularies in the middle of year; this is not fair to the patient as it can dramatically change the cost of the medicine and require the physician to prescribe an alternative product. Ollove speaks of a particular mental health patient that ended up trying to take her own life as the only medication that worked for the patient became unaffordable to the patient and despite the urging of the treating physician to make an exception for the patient in continuing coverage of the medication, the plan refused the request. Although the plan felt the change in the formulary was in the best interest of the overall patient population covered by the plan to help keep costs affordable for the population at large, the choice led to negative implications to the specific patient. In addition to the formulary change in this particular situation leading to maleficence, it also is a good example where the physician’s and patient’s autonomy were compromised. A deontology mindset would have supported the patient staying on the medicine that
well-controlled the patient’s medical condition; as a categorical imperative, no patient would sign up for a health plan if they were allowed to change their coverage decisions in the middle of a contract or if the plan dropped coverage for a patient’s medication when the medication was effective in maintaining the patient’s well-being. States are looking to pass legislation that prevents MCOs from changing formularies in the middle of the year. In a survey conducted by the Global Healthy Living Foundation (2017), 50% of Floridians could not afford their medications after the MCO changed the copays and 58% of patients who switched medications due to affordability stated their new medication was less effective than the previous medication; 94% of survey respondents supported legislation that would prevent an MCO from making changes in the formulary in the middle of the year. Lazarus (2004) also speaks to the potential harm a formulary can bring to the well-being of patients. Lazarus references a survey completed by Rand, consisting of 52 MCOs and 30 employers; benefit designs that doubled copays for patients led to a 45% decrease in the use of certain medications (anti-histamines, anti-inflammatory).

6.4.2 Population vs Patient-level Care are not Necessarily Reconcilable: HCP follow-up is an important element to improve patient-specific outcomes

Ha and Longnecker (2010) highlight the importance of effective communication between the physician and the patient; the shift from paternalism on the part of the physician to a patient-physician relationship of shared decision-making. When physicians communicate effectively patients are more willing to provide additional and relevant information to the physician. This places an extra level of time commitment on the physician to more effectively engage with the patient. Specific to the formulary, it is important for the physician to understand the implications of the formulary on patient care to ensure the patient will still receive quality care and achieve the intended health improvement objectives of the treatment. Responsibility of effective communication is not just the responsibility of the physician, but also the patient; but the physician’s approach helps enable the potential for effective communication and therefore better quality care with improved outcomes. Physician
study participants spoke of examples of their techniques in terms of follow-up when initial medication choices were switched by physicians due to the patient’s formulary:

- In the case where the MCO required failure on a specific medication before allowing use of another medication, the physician providing samples of the physician-preferred medication along with the prescription of the formulary mandated medication instructing the patient to call the physician’s office if the patient was not doing well with the prescribed medication.
- In the case where the MCO’s formulary had a lower copay for a medication that was not the physician’s first choice, the physician would explain to the patient to call the physician if the patient was not doing well on the lower copay medication prescribed at which point in time the physician would switch the patient to the more expensive medication.

Based on a study conducted by Abourjaily et al. (2005), physicians and related office staff took up to 18.9 minutes to make a medication switch and on average completed 37 switches per month.

Carlton et al. (2010) speaks to the implications of formulary step-edits on patient’s gaining access to their medications. In many instances patients are only aware of the formulary requirements when they present at the pharmacy to fill their prescribed medications. Carlton makes reference to a study completed by Arthur Andersen LLP (1999) that showed that pharmacists spent approximately 20% of their time on administrative tasks per month related to adjudicating claims for filling medications. Patient satisfaction decreased when patients did not receive the original medication prescribed by the physician, there was a delay in the patient accessing the medication and at times patients did not fill their prescription due to the formulary. As cited by Carlton, a study completed by Motheral et al. (2004) showed that only 29% of patients received the medication that was intended by the step edit of the formulary; 17% of patients did not fill their prescription given the step edit requirements of the formulary; 22% were able to receive their physician-intended prescription due to a medical exception being granted by the MCO; 16% paid out-of-
pocket to receive the prescription as written; 10% received a sample or an over-the-counter alternative given the step edit requirements. Hence it is important for the physician to understand what happens to the patient and their prescription once the patient leaves the physician’s office. This could be seen as a duty of the physician to provide quality care however it needs to be balanced with the time requirement of the physician. The physician can utilize members of their office to help with the follow-up to streamline the follow-up process but it also can be seen by physicians as an additional burden placed on them by the MCO which leads to inefficiencies and additional barriers of providing care in the physician’s office. It can be seen as an infringement on justice as the physician has to spend additional time, perhaps uncompensated time, to ensure the patient is able to acquire the medication that is best for the patient given the patient’s medical condition. From a deontology point of view, it can be seen as a duty to provide the follow-up; however from a utilitarian perspective, it will potentially reduce the amount of time the physician can then spend with other patients given the additional time that is needed to manage the patient’s ability to obtain the needed medication after the patient leaves the office. These aspects apply similarly to the pharmacist; the Pharmacist study participants recognized that the more time they spent with any one patient the less time they had to spend with another patient and sometimes their duty to the patient was compromised because of the volume of demands encountered at the pharmacy. This can then negatively affect the HCP’s virtues and produce mental distress for the provider because they are not able to provide the level of care and follow-up they had intended for their patients; given the additional time burden introduced by the MCO formularies.

6.4.3 Population vs Patient-level Care are not Necessarily Reconcilable: Patient autonomy and self-worth potentially compromised due to lack of access

La Puma (1998) speaks to the importance of patient autonomy and how physicians can help ensure patient autonomy is protected by how they engage with patients; by seeking to understand their patients and their needs and preferences. Yet managed
care does not seek to understand the patient’s perspective. MCOs do not seek to understand the specific need of a given patient; they rather look to provide care for the population at large that is being insured; this point was made by the study participants. Although study participants made the point that patients can always purchase any prescription the physician prescribes, based on the patient’s ability (or willingness to purchase) the prescription, the patient may need to forego treatment with the medication initially prescribed by the treating physician. The example provided earlier, by Ollove (2017), highlights how a formulary can affect patients from realizing their full potential and may diminish their self-worth. For example, the patient who became unstable due to the formulary change that led to a switch in the patient’s medication. The example of Ted Kennedy, mentioned earlier in this chapter, highlights that this may be less of an issue for patients who have the financial means to self-fund their care; but for those patients who are not able to do so, quality care and resultant outcomes may be adversely affected.

Formularies are designed to work for the average patient; it is the non-average patient who can be negatively affected by the formulary. The formulary works for the population at large but there will be patients who suffer consequences of the formulary implemented by the MCO. As stated by Dr. Stefanacci, associate professor of health policy at the University of the Sciences, “When you apply today’s population-based medicine at the granular level, it sometimes results in inappropriate care from a patient-centered point of view.” (Kelley, 2012). Although in concept population health should improve patient-specific healthcare, the challenge is to be able to build plans that are flexible enough to understand the individual aspects of patient care and ensuring patients who are not reflective of the population at large are not negatively impacted by managed care. Although there are cases where the entirety of population is negatively affected by managed care decisions as in the situation where an MCO makes a change in formulary in the middle of the year. As mentioned earlier, in these instances almost the entire population of covered lives (94%) might want to see a change in how MCOs are allowed to operate.
6.4.4 Population vs Patient-level Care are not Necessarily Reconcilable: Analysis of Findings Summary

From the PhD Researcher’s perspective, based on the findings of the research, as one considers the three aspects that have been discussed in this section, namely, (1) formularies not necessarily fair to the individual patient, (2) HCP follow-up is an important element to improve patient-specific outcomes, (3) patient autonomy and self-worth potentially compromised due to lack of access, it becomes evident that for patients who do not respond adequately to the formulary medications that have the least amount of access restrictions, there is potentially a disproportionate burden placed on these patients and the healthcare professionals that provide care for them. As in the previous sections of this chapter, utilitarianism would support such a formulary if it benefits the population at large and thus maximizes utility, however, it places at odds with what would be deemed necessary from a deontological perspective or as it relates to virtue ethics. Autonomy of the physician and patient is infringed upon, not only due to the additional administrative burden of dealing with the system, but also if ultimately the medication of choice is not accessible to the patient. Justice might be implicated if the patient is not able to achieve the same level of outcome as the rest of the population simply due to the uniqueness of the patient which prevents the patient from adequately responding from the least restrictive medication on the formulary and consequently beneficence might be negatively affected with resultant maleficence.
Chapter 7: Synthesis of Findings and Conclusion

This thesis was laid out by first providing an introductory chapter (Chapter 1) to the reader to help frame the thesis and to offer a roadmap of the approach being taken by the PhD Researcher to answer the defined research question. In Chapter 2, the ethical theories and principles that were relevant to the research question being addressed by the thesis were explained. In Chapter 3, an overview of the U.S. healthcare system was provided to enable the reader to put in context the primary research that was undertaken to complete the thesis. In Chapter 4, the methods of the primary research were discussed and, in Chapter 5, the views of the various stakeholders that were included in the primary research were presented. In Chapter 6, the findings of the primary research were analyzed and discussed in light of the categories that emerged through application of the qualitative research techniques associated with Grounded Theory.

7.1 Research Question and Insights Gained

The two-part research question addressed by this thesis was the following:

1. What are the perspectives of the core decision-makers (Employer Benefit Design Decision-makers, Managed Care P&T Committee Members) and affected end-users (Community Practicing Physicians, Community Retail Pharmacists, and Employees (Insured Members)) as it relates to community-based commercial drug formulary decision-making?, and

2. What are the ethical implications of these identified perspectives?

The two-part research question was answered through primary research that was conducted by the PhD Researcher through one-on-one double-blinded phone interviews with each of the stakeholders included in the Professional Group (EBDDMs, MCOP&Ts, Community Practicing Physicians and Community Retail Pharmacists) and through focus groups conducted with Employees (Insured
Grounded Theory was then utilized to develop a conceptual framework and substantive theory based on the research.

Employers have financial targets to meet to satisfy their commitments to shareholders in terms of annual profitability; hence the level of benefit provided often coincides with the budget that a given employer has allocated for the year to provide coverage of healthcare benefits to its employees. Based on a study conducted by the The Benfield Group (2011), 40% of employers placed emphasis on reducing healthcare spend by shifting more of the cost of care to their employees and focused on securing the lowest price in negotiations when finalizing benefit contracts with MCOs. At the same time 70% of HR professionals spend less than 25% of their time focused on drug benefits and related decision-making (Takeda Pharmaceuticals USA Inc, 2013). Employers have a limited set of expertise when it comes to being able to complete their due diligence of what type of plan to offer, hence, many employers use benchmarking (comparing themselves to other similar employers) to inform their decisions on the level of coverage to offer despite imperfect information (uncertainty); a concept brought forward by Enthoven (1993). Employers also rely on the expertise and input from their MCOs to help guide their decision-making; hence employers need to have a level of trust in the information that is being provided by the MCO to the employer that ultimately informs decisions that impact an employee’s ability to access a given medication. At the same time there seems to be, to some degree, a conflict of interest between the MCO and the employer; if the MCO does not help meet the budget targets of the employer, the MCO can quickly find themselves in a position of being terminated by the employer, and the employer switching to another MCO. As many employers are focused on their short-term financial goals (typically the annual budget), there is perhaps a limited awareness and understanding of the long term impact of a given drug formulary on the employer’s economics and the impact of the formulary on the employer’s employee population. In addition, drug formularies are designed for the average employee; the impact of a formulary on any given employee may be different than for the average employee or the overall experience at the population level. On average, drug formularies might work as planned; for some, the drug formulary might be even better than expected. In other
cases, the drug formulary may lead to challenges which impact on the employees care and outcomes; as was shown by Happe et al. (2014) in their systematic literature review (SLR) where formularies had a negative impact on a number of attributes, including medication adherence, clinical parameters, system costs (economic) and healthcare resource utilization. Ultimately, drug formulary design decisions made by employers affect how employees utilize medications, with employees selecting lower cost treatment options (Huskamp et al., 2003).

MCOs are businesses that are also looking to maximize their profitability; their focus is to provide a level of coverage that enables the physician to provide appropriate (adequate or acceptable) care to a given patient. When an employer accepts the contract of the MCO, when an employee becomes an insured member of an MCO, it is the responsibility of the employer and employee to understand and accept the terms of the contract that is being offered based on the costs associated with the plan. MCOs recognize that they manage healthcare at the population level and are not aware of the implications of drug formularies at the individual patient level; hence the importance of physician’s bringing issues that impact outcomes to the attention of the MCO. MCOs also recognize however that drug formularies by design are meant to influence on what a given physician prescribes to a patient. MCOs believe that they have a better understanding of the totality of evidence that exists with regards to understanding the efficacy and effectiveness of a given medicine. MCOs do not accept the premise that the physician knows best and when physicians decide to treat patients with medicines that are not preferred by the formulary of the MCO, then the additional costs of the medications need to be the responsibility of the patient based on the patient’s preference; based on what the patient wants. Buchanan (2000) spoke to the point of how MCOs should not engage in “expertise imperialism” and that MCOs need to recognize the “physician as [the] medical expert” leveraging his expertise where appropriate.

Physicians prescribe a given medication based on their professional expertise, their practice experience and the specific needs of the patient for whom the physician is providing care. Yet their ability to prescribe is affected by a given MCO’s drug
formulary. Furthermore, a given physician might prescribe for a given patient based on the physician’s experience with formularies relative to their practice, namely, physicians will prescribe in such a way as to reduce the hassles they may experience from an MCO if they write a non-generic or a non-preferred branded agent. Hence physicians may prescribe based on their experience with the dominant plan (MCO) in their practice which may be more restrictive than the drug formulary for a given patient being treated by the physician. In this case, that particular patient might receive a different medication than perhaps the physician would have prescribed if all the physician’s patients had this particular patient’s formulary.

There is a natural tension that exists between the MCO and employer trying to provide coverage for the population at large and the individual needs of the patient and the patient’s treating physician (Panek, 1999). The former can be viewed more as reflective of utilitarianism whereas the latter is more specific to deontology. Under deontology one could make the argument that patients should have access to the medications best suited for their specific medical needs, and although patients in the U.S. healthcare system can gain access to any medication prescribed by their treating physicians, it becomes a matter of willingness to pay as well as affordability. Employees pay a premium for their coverage; their ability or willingness to pay for more expensive medications that are on higher tiers with utilization management controls may deter patients from receiving these medications; this was shown by the SLR completed by Park et al. (2017), yet for the most part stakeholders included in the primary research viewed this as a consequence of how the U.S. healthcare system works.

As it relates to the focus of this thesis, the majority of stakeholders included in the primary research consistently considered that healthcare was not a right but rather a privilege: patients should receive the value of healthcare that is equitable to the type of plan (MCO) they subscribe to. If the employer selects a less generous plan (MCO) for its employees, then members of the plan (MCO) need to accept the realities that perhaps the more efficacious branded medications with less side effects will result in the employees incurring greater out of pocket costs than if the patients are prescribed
a low cost generic. Ultimately the terms of the contract that an employer enters into with the MCO and in turn the employee enters into when enrolling in the MCO’s plan are the determinants of the level of care that is to be provided to the employee when seeking medical treatment. The contract defines what type of care will be covered by the plan and the resultant cost of the care. There was repeated reference by the study participants included in this thesis to the automobile as an analogy to healthcare; namely, employees should expect to receive the level of care for which they signed up for. If the health plan purchased is equitable to a Ford (a more economical brand) they should not expect the quality of a Cadillac (a more luxurious brand). There was also an awareness by the stakeholders of patient needs as opposed to patient wants; patients should receive what is acceptable (appropriate or adequate) medical care; anything beyond acceptable, appropriate or adequate comes at a premium. If a particular patient could not afford the higher level of care that was ultimately the patient’s issue; although it was recognized as perhaps harsh, it was also accepted as the reality of life.

Although patients were seen as needing to have accountability for their health, it was also recognized that all patients, irrespective of what brought about their medical condition, needed to have access to the appropriate level of medical care. Formularies were seen as barriers or deterrents in a patient’s ability to access a specific level of care; that access would be defined in part by the patient’s willingness or ability to pay for higher out of pocket costs if the medicine prescribed was on a higher tier; and it also was contingent on a physician’s willingness to advocate on behalf of the patient given the imposed utilization management controls. An example of the time investment was highlighted by the Alliance for Patient Access (2017) that stated the average physician and physician’s office spent up to 2 hours per patient trying to overcome MCO imposed administrative requirements. Physicians felt it to be an infringement on their time: the additional paperwork, the additional administrative burden was time consuming; it took their time away from other patients; made it more difficult to get through a given day which is a goal of the physician. Physicians deemed their interactions with patients as personal whereas the MCO did not have a relationship with any given patient; the patient was faceless.
to the MCO and was just a statistic. The physician who was willing to invest in advocating for their patient would most likely gain access to a given medicine more readily than the physician who did not advocate for their patient. The physician advocating for the patient was seen as an ethical responsibility of the physician by the AMA (2002).

There was an understanding that there was somewhat of an adversarial relationship between the pharmacist in the retail community setting and the physician’s office. Physicians were seen as having context of the patient’s medical condition, whereas the pharmacist at the pharmacy counter did not have this information. Some stakeholders felt that pharmacists should ask their customers (patients) if they wanted to know if there were less expensive treatment options available; others felt that pharmacists should convey to their customers (patients) this information automatically. It was voiced by study participants that community retail pharmacists should only engage with the physician at the request of the patient (consumer) but the fact remained that community retail pharmacists did not know of the discussion that transpired between the physician and patient at the physician’s office and therefore the pharmacist intervening in the physician’s treatment decision could be seen as intrusive by the physician. These issues would be negated if there was more of a team-based approach to healthcare, with each stakeholder’s expertise appropriately being utilized to help improve the care of the patient.

Transparency was seen by the employees (insured members) as an important component in understanding the motivations of the physician, pharmacist, MCOs and employers, when decisions regarding drug formularies were made. However the inevitability of economics impacting access to medicines was recognized as a reflection of the realities of the marketplace. This was most clearly evidenced when a physician would make a different treatment decision when wearing the hat of the MCO P&T committee member as opposed to wearing the hat of the community physician treating a specific patient; a point made by one of the MCOP&T study participants.
7.2 Main Contribution of Thesis

The literature review that informed this thesis found limited information on the exact topic of the thesis. There was significant information on understanding the ethical theories and principles as it relates to deontology, utilitarianism, virtue ethics and biomedical ethics (autonomy, beneficence, maleficence, justice); there was similarly significant information on the U.S. healthcare system. However there was very limited information on the ethical theories and principles reviewed in this thesis as it relates to pharmacy benefit coverage in general and then more specifically to the cross-section of the stakeholders included in this thesis, namely the core decision-makers and the affected end-users. Hence from the PhD Researcher’s perspective, this thesis fills a gap in the available literature.

The main findings of the thesis is encapsulated in Figure 7.1 below which is restated from Chapter 6. Namely, Access to Rx Medications is impacted by the Financials; Drug Formularies are a Means to an End, to help balance clinical outcomes with the economics of care; Informed Decision-making is Essential to Understanding Implications of Choice; and Population vs Patient-level Care is not Necessarily Reconcilable which is an important realization as access-related decision-makers make decisions at the population level.
Figure 7.1 Substantive theory informing implications of community-based formularies: categories and concepts that emerged from the research

The above four categories could be deemed logical and intuitive especially given how the U.S. healthcare system functions:

- Economics prevail as employers providing coverage for their employees are for the most part profit-driven.
- A mechanism used by MCOs to manage access to medicines is the drug formulary, whether shifting additional cost to the patient, or through step edits and prior authorizations (utilization management controls).
- All stakeholders need to have access to relevant information to make an informed decision, and
- The decisions taken by employers and MCOs are on the population level, not on the individual patient level, which by definition introduces a tension (perhaps irreconcilable) in the delivery of healthcare.
To the extent that the physician oversees the overall coordinated care of the patient, the moral compass of the physician should not be replaced by the demands of 3rd parties; the physician stands as the absolute moral compass with respect to the care the patient receives. The moral agency of each physician becomes the collective voice of the medical community, the guardian that ensures that medical care is just, working to correct any wrongs that jeopardize the moral responsibility of the physician taking care of the patient. Society at large depends on the formation of a physician’s character to be good and to be virtuous to ensure that patients are ultimately protected (Pellegrino, 2012).

MCOs through their techniques to manage access to medicines increases the level of burden placed on the practicing physician. This is why virtue ethics becomes an important element that MCOs and employers need to reflect on otherwise there can be an irreconcilable impasse between the philosophy of utilitarianism, which is to do what is in the greatest good for the many, as opposed to not treating any one person as a means to an end, the underpinning of deontology. However, even under utilitarianism, an individual seeks out being part of the system in order to receive his or her share of benefit which will be greater to the agent as a participant in the system as opposed to not being a participant in the system. Therefore by contributing to what is in the interest of the system, there will be a respective benefit to the individual (Driver, 2014). It is through virtue ethics that the moral agent would express an appropriate level of concern, would seek to make a wise decision informed by practical wisdom gained over years of experience. Practical wisdom in turn should seek out theoretical wisdom (theoretical reasoning), a higher state of reflection achieved through the integration of science and intuitive understanding that helps the moral agent attain a specific goal (Homiak, 2003). It is the co-existence of wisdom, courage, moderation, and justice within the moral agent in a balanced manner that ultimately leads to actions that can be defined as good; with justice being the unifying virtue that binds the four virtues together within the moral agent. The virtuous person will consistently act in a manner that produces good, and in turn happiness, which is reinforced over time and eventually becomes routine for the moral agent (Frede, 2008). In comparison, as it relates to Kantian deontology, the will of the agent
ensures the morality of decision-making; it needs to be absolute and not contingent on the outcome. Given the moral law is the sole driver of the agent’s action, the action becomes the agent’s duty to fulfill (Kant, 1785). Formularies for patients who fall outside of the average patient profile could be negatively impacted by a drug formulary: it could be a contradiction to the principles of biomedical ethics. The physician has the autonomy to prescribe any medication approved by the FDA, however, if the patient cannot access the medicine due to access hurdles (step edits, prior authorizations or out of pocket costs), then that autonomy of practice is infringed on; the result can lead to a negative effect on health outcomes, an implication potentially as it relates to beneficence or non-maleficence. The perception of justice ultimately came down to whether the MCO complied with its contract to which the stakeholders agreed to. With that said a contract would not be deemed to be satisfying the principles of justice if those signing the contract were not adequately communicated with and the terms appropriately explained to ensure the decisions of the stakeholders were well informed; this occurrence rarely happening at the level of the drug formulary and pharmacy benefit coverage.

There is an acceptance in the marketplace that access to all medicines at an affordable price cannot be achieved; that healthcare like everything else in life is not a right at all levels. Society has to set the parameters within which access to medicines is determined; the voice of the many need to work in harmony to raise awareness around access challenges so that society as a whole can make the necessary changes in the marketplace. By introducing ethics as a prominent criteria for determining access levels there will be at least a better understanding of what leads to a given decision and the ethical implications of those decisions. Procedural fairness enables the application of fairness but this attribute alone is not sufficient to ensure decisions have satisfied ethical criteria. An appropriate framework would need to be established that all stakeholders could access to understand the application of ethical theories and principles. Such a framework would highlight the implications of the drug formulary as it relates to utilitarianism, deontology, virtue ethics and biomedical ethics. These could include each of the following:
Utilitarianism: does the drug formulary produce the greatest good for the greatest number?

Deontology: does any patient become a means to an end specific to the drug formulary and meeting budgetary requirements?

Virtue ethics: does the Employer and the MCO demonstrate characteristics such as trustworthiness, integrity, honesty, compassion, and thoughtfulness in the development and application of the drug formulary? Are physicians, pharmacists and employees (insured members) each doing their part to ensure the best possible outcome?

Biomedical ethics: is physician or patient autonomy affected; based on outcomes are there implications to beneficence or non-maleficence; is justice compromised based on the terms of the contract, how information was communicated as it relates to the specifics of the drug formulary?

Given the analysis completed through this thesis, the PhD Researcher proposes that the 3-step approach highlighted in Figure 7.2 below be applied to integrate ethics into the community-based commercial drug formulary decision-making process, namely what medications to add to the drug formulary and how the drug formulary should be implemented.
At the core of the approach in deciding what medications to add to a drug formulary and how the drug formulary should be implemented is virtue ethics. What attributes will the moral agent apply in their decision-making as it relates to the drug formulary? Will there be excellence of character as defined by Socrates or Aristotle? Will the character of the individual decision-makers be seen by others in society as worthy of serving as a role model? The character of the person separate from the organization and the character of the person in the organization should be harmonized to the extent possible to ensure the virtues of the person are not overshadowed by the culture of the organization. Based on the decision that is informed through virtue ethics, applying the decision through a utilitarian lens: does it maximize the good; does a given patient benefit more from being a part of the system than if the patient was outside of the system? What changes to the drug formulary would need to be taken to deliver as much value to the insured population as possible? Then to apply a deontological lens to the decisions taken as side constraints relative to each of the principles within biomedical ethics, namely, autonomy, beneficence, maleficence, and justice as it relates to the specific patient as compared to the population. A simple example of how this type of approach would impact on drug formularies could be as it
relates to step-therapies: if a patient tried and failed a prescription medication that was at a lower cost on the formulary, then to enable the patient to receive the more expensive medication at the lower cost therapy. Lastly, what mechanisms are in place that will allow the drug formulary decision-making and implementation process to be built on mutual trust and understanding that is comprehensive in its approach from the perspective of the stakeholders that were included in this thesis, namely the employer, the MCO, the community practicing physician, the community retail pharmacist and employee (insured member)?

Key elements of ensuring an ethical construct is maintained in terms of accessing medicines is trust, transparency, and inclusive decision-making while respecting the expertise of those who know the patient the best, the medications the best and recognizing that there will always be a need for exceptions that are quickly reviewed and processed..

7.3 Scope, Delimitations and Limitations

Given the diversity and complexity of the U.S. healthcare system, this thesis focused only on the commercial segment of the marketplace; it did not include other segments of the marketplace such as Medicare (coverage for the elderly and disabled) and Medicaid (coverage for those who have income below the federal poverty limit). The thesis only focused on the retail community setting; not the hospital setting and further refined focus on large employers who provide pharmacy benefits coverage for their employees through MCOs. Branded medications that lost patent protection and have bioequivalent generics available in the marketplace were not considered in the assessment of ethics as it relates to drug formulary coverage. This was assumed to be a given expectation of how the U.S. healthcare system should operate when having a choice between a higher cost brand medication and its lower cost bioequivalent generic version. Excluded from the stakeholders included in the Professional Group were Employer Benefit Consultants as these professionals are not always utilized by large employers when making drug formulary coverage decisions and was deemed by the PhD Researcher as a resource that an EBDDM may utilize; however the EBDDM remains the ultimate decision-maker in terms of
purchasing decisions related to drug formulary coverage. The thesis did not assess whether the findings relevant to the commercial segment of the marketplace, as provided by large employers, would have been relevant to the other market segments found in the U.S. healthcare system, such as Medicare and Medicaid. This thesis also did not assess how adopting an ethically grounded drug formulary decision-making process would change the prescription medications that are made available by employers’ to their employees. Despite application of an ethical framework in making drug formulary decisions, the availability of medications might still vary across MCOs due to the subjectivity of the decision-makers and the challenges of understanding the specific needs of any given patient when providing population-level coverage. Lastly, the cost implications of implementing an ethically-based drug formulary decision-making process was not evaluated. This would be an important factor to consider when deciding to implement such an ethical framework as it could have implications on the business model of MCOs in the U.S. healthcare system.

The PhD Researcher chose constructivist Grounded Theory as defined by Charmaz for the reasons discussed in Chapter 4, Section 4.2. The interpretation of the data collected through the primary research conducted by the PhD Researcher allowed for the development of a conceptual framework through systematic data analysis specific to an area that has not been studied in the literature. Subsequently, through a focused literature review based on the four categories (conceptual framework) as it relates to the ethical theories and principles detailed in Figure 1.2 (deontology, utilitarianism, virtue ethics and biomedical ethics) and through constant comparison of the categories, focused codes, and initial codes that emerged from the data with the relevant literature, the PhD Researcher constructed a substantive theory. It is recognized by the PhD Researcher that the conceptual framework and substantive theory developed in this thesis is subjective; that there is no single reality but rather multiple realities that are informed by the experiences of the study participants as well as the researcher. It is further recognized by the PhD Researcher that although the coding was done inductively from the research data, the PhD Researcher’s knowledge of the U.S. healthcare system allowed the PhD Researcher to better reflect on the perspectives brought forward by the study participants.
analysis of the data informed the conceptual framework and substantive theory which was based on the interpretation of those findings by the PhD Researcher. The analysis and outcome of this study might have been different in its findings if it had been done by another researcher. It is for this reason that the findings from this study should be considered as a viewpoint arrived at through the interplay between the PhD researcher and the data; other researchers may come to different findings. This in turn limits the generalizability of the study; the findings of this study should be considered as a first step to spur additional research on the topic as opposed to a formal theory that can be generally applied to drug-formulary decision-making.

7.4 Reflections and Learnings

Specific to the PhD Researcher, the journey entailed in writing this thesis, including developing a solid foundation of core ethical theories and principles and insights gained through the primary research, evolved the thinking of the PhD Researcher. The realization that ethical decision-making is not explicitly considered by stakeholders was confirmatory to the PhD Researcher’s assumption at the beginning of the research. What was a surprise to the PhD Researcher was the interest of stakeholders to discuss the topic, a desire of the stakeholders to make ethics more pronounced in the drug formulary decision-making process and also the realization that to get the best possible healthcare was thought of as a privilege; that appropriate (acceptable, adequate) healthcare was realized as an entitlement (although appropriate healthcare was not explicitly defined by the system) and that cost-shifting to patients at time of receiving care was a mechanism used by the system to keep overall costs affordable at the population level. Perhaps as confirmation of the completeness of the discussion guides used to inform the primary research, the PhD Researcher upon reflection and review of the guides subsequent to completing the thesis, would not have made changes to the guide despite the knowledge gained by the PhD Researcher over the course of the completion of the thesis.

On reflection, the PhD Researcher does believe that GT was the most appropriate research methodology to use; it had intuitive appeal to the PhD Researcher as it allowed for data immersion. Through the interplay between the study participants
and the data, the PhD Researcher was able to develop a conceptual framework, and then, through constant comparison with the literature, a substantive theory. The GT method fostered creativity given the approach to discovery as codes and categories emerged inductively from the data. The approach was systematic without it being overly prescriptive, based on the methods set forth by Kathy Charmaz. The PhD Researcher’s learning during the course of this study, including the writing of the thesis, is the realization that by listening to the study participants with an open mind, and through thoughtful analysis, following methodological steps characteristic of GT, data will come together in different ways, thereby forming patterns and providing structure, leading to the development of a conceptual framework and substantiated theory. Discipline and tenacity are required to capture the rich insights that are contained within the conducted interviews; constant reflection enables the researcher to ultimately identify the underlying patterns that can lead to a cogent framework and theory, allowing for the emergence of new concepts to help stakeholders more effectively problem-solve complex issues.

7.5 Future Areas of Research

It is beyond the scope of this thesis to develop an operational model that better leverages the use of ethics in community-based commercial drug formulary decision-making, but the PhD Researcher hopes that this study and body of work will help advance the paradigm of integrating ethics more completely and explicitly into the drug formulary decision-making process in the U.S. healthcare system. Hopefully this thesis will cause the reader to stop and reflect and assess how better to apply ethical theories and principles that can lead to a better healthcare system, one that explicitly references ethics to inform decision-making. This thesis only reviewed the ethical implications of large employers who offer commercial pharmacy benefits coverage to its employees; it did not look at other equally important market segments such as Medicare and Medicaid. Additional research is needed to understand if the ethical implications are the same in these segments of the market or are they different given that they represent perhaps a more vulnerable patient population. A roundtable of ethicists, working with representatives from various patient groups, physician and
pharmacy professional associations, as well as representation from employer and managed care associations, could begin to bring into more clear focus this important aspect of healthcare delivery in the United States.
# Appendix A: CORE-Q 32 Checklist

## Domain 1: Research team and reflexivity

### Personal Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Interviewer/facilitator</th>
<th>Which author/s conducted the interview or focus group?</th>
<th>The PhD Researcher (PhDR) conducted the 1:1 interviews and focus groups.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Interviewer/facilitator</td>
<td>Which author/s conducted the interview or focus group?</td>
<td>The PhD Researcher (PhDR) conducted the 1:1 interviews and focus groups.</td>
</tr>
<tr>
<td>2</td>
<td>Credentials</td>
<td>What were the researcher's credentials? <em>E.g.</em> <em>PhD, MD</em></td>
<td>The PhDR has an MSc in Pharmaceutical Medicine from Hibernia College and a BS from New York University in Biology and Mathematics.</td>
</tr>
<tr>
<td>3</td>
<td>Occupation</td>
<td>What was their occupation at the time of the study?</td>
<td>The PhDR is a Market Access professional within life sciences and has expertise in 3rd party payers, willingness to pay and access to medicines.</td>
</tr>
<tr>
<td>4</td>
<td>Gender</td>
<td>Was the researcher male or female?</td>
<td>Male</td>
</tr>
<tr>
<td>5</td>
<td>Experience and training</td>
<td>What experience or training did the researcher have?</td>
<td>The PhDR has conducted a number of primary and secondary research initiatives as part of his responsibilities within life sciences.</td>
</tr>
</tbody>
</table>
### Relationship with participants

<table>
<thead>
<tr>
<th></th>
<th>Relationship established</th>
<th>Was a relationship established prior to study commencement?</th>
<th>There was no relationship between the PhDR and the study participants (SP).</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Participant knowledge of the interviewer</th>
<th>What did the participants know about the researcher? e.g. personal goals, reasons for doing the research</th>
<th>The study design was double blinded; the SPs only knew the PhDR was facilitating research on the topic of ethics and access to medicines.</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Interviewer characteristics</th>
<th>What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic</th>
<th>PhDR’s background was discussed in the thesis as well as how the PhDR was self-aware about potential bias and how the findings reflect the PhDR’s interaction with the research / responses from SPs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Domain 2: study design

#### Theoretical framework

<table>
<thead>
<tr>
<th></th>
<th>Methodological orientation and Theory</th>
<th>What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology,</th>
<th>The PhDR used Charmaz’s approach to constructing GT and recognizes that the PhDR’s interpretation of the data is part of the findings and conclusions and not separate from the interpretation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant selection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>10</strong></td>
<td><strong>Sampling</strong></td>
<td>How were participants selected? <em>e.g.</em> <em>purposive, convenience, consecutive, snowball</em></td>
<td>Sampling was purposive; by design SPs were selected based on specific sampling criteria specific to 4 stakeholder groups: MCOPTs; EBDDMs; Practicing Physicians and Community-based Pharmacists. Employees at the PhDR’s employer were selected by another colleague of the PhDR.</td>
</tr>
<tr>
<td><strong>11</strong></td>
<td><strong>Method of approach</strong></td>
<td>How were participants approached? <em>e.g.</em> <em>face-to-face, telephone, mail, email</em></td>
<td>The 1:1 interviews were recruited by a 3rd party vendor that had a panel of experts relative to each of the above stakeholders in the professional group; interviews were conducted via phone call (both PhDR and SP called into a conference call-in number); focus group participants were recruited by a fellow colleague of the PhDR.</td>
</tr>
<tr>
<td>12</td>
<td>Sample size</td>
<td>How many participants were in the study?</td>
<td>There were 10 SPs interviewed for each of the following 4 stakeholder groups: MCOP&amp;T, EBDDM, Practicing Physicians and Community Pharmacists. Specific to the focus groups, there were two focus groups (N=5, N=6).</td>
</tr>
<tr>
<td>13</td>
<td>Non-participation</td>
<td>How many people refused to participate or dropped out? Reasons?</td>
<td>All SPs approached for the study based on criteria, were interested in participating in the research. There were no drop-outs.</td>
</tr>
<tr>
<td>Setting</td>
<td>Setting of data collection</td>
<td>Where was the data collected? e.g. home, clinic, workplace</td>
<td>1:1 phone Interviews were conducted in the PhDR's home office; focus groups were conducted at the PhDR's place of work.</td>
</tr>
<tr>
<td>14</td>
<td>Presence of non-participants</td>
<td>Was anyone else present besides the participants and researchers?</td>
<td>No one else was present during the interviews.</td>
</tr>
<tr>
<td>15</td>
<td>Description of sample</td>
<td>What are the important characteristics of the sample? e.g. demographic data,</td>
<td>SPs who presented in the 1:1 interviews were subject matter experts relative to each of the 4 stakeholders in the professional group;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>focus group participants were representative employees of a large employer.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Discussion guide was developed that covered the areas of interest for the discussion guide. Discussion guide was pilot tested with two interviewees; as the pilots were as expected, the pilots were included in the analysis. Discussion was provided to SPs in advance of the phone interviews along with a pre-read and research case studies.</td>
</tr>
<tr>
<td>Data collection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No repeat interviews were carried out.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>All research interviews were recorded.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>PhDR took notes during the interviews / focus groups; notes were also made following the</td>
</tr>
</tbody>
</table>
interviews to capture PhDR’s thoughts based on perspectives provided by the SPs.

| 21 | Duration | What was the duration of the interviews or focus group? | 1:1 interviews were on average 90 minutes to 2 hours in duration focus group was about 2 hours. |
| 22 | Data saturation | Was data saturation discussed? | Data saturation was referenced. |
| 23 | Transcripts returned | Were transcripts returned to participants for comment and/or correction? | Transcripts were not provided to SPs for review / comment given the research was double-blinded. |

**Domain 3: analysis and findings**

**Data analysis**

<p>| 24 | Number of data coders | How many data coders coded the data? | Only the PhDR coded the data. |
| 25 | Description of the coding tree | Did authors provide a description of the coding tree? | PhDR provided a sample of the coding tree and a code book in the Appendix. |
| 26 | Derivation of themes | Were themes identified in advance or derived from the data? | Themes (categories and concepts) were derived from data analysis and the research. |
| 27 | Software | What software, if applicable, was used to manage the data? | Nvivo version 10, 11; Express Scribe Transcription Software, EndNote X7 |</p>
<table>
<thead>
<tr>
<th></th>
<th>Reporting</th>
<th>Did participants provide feedback on the findings?</th>
<th>There was no participant checking as research was double-blinded.</th>
</tr>
</thead>
<tbody>
<tr>
<td>28</td>
<td>Participant checking</td>
<td>Did participants provide feedback on the findings?</td>
<td>There was no participant checking as research was double-blinded.</td>
</tr>
<tr>
<td>29</td>
<td>Quotations presented</td>
<td>Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number</td>
<td>Yes, sample quotes from the transcripts are presented in the appropriate sections of the thesis; quotes are identified by participant code indicative of stakeholder group (for example, EBDDM, and sequential number of the interviewee within a specific stakeholder group).</td>
</tr>
<tr>
<td>30</td>
<td>Data and findings consistent</td>
<td>Was there consistency between the data presented and the findings?</td>
<td>Yes, there is a convergence of the general findings which are identified and explained to the reader through the use of frameworks that emerged from analysis of the data.</td>
</tr>
<tr>
<td>31</td>
<td>Clarity of major themes</td>
<td>Were major themes clearly presented in the findings?</td>
<td>Yes, major themes (categories and concepts) were clearly presented in the findings which are identified and explained to the reader through the use of frameworks that</td>
</tr>
<tr>
<td></td>
<td>Clarity of minor themes</td>
<td>Is there a description of diverse cases or discussion of minor themes?</td>
<td>There is a comprehensive description and discussion of the perspectives of the SPs.</td>
</tr>
<tr>
<td>---</td>
<td>------------------------</td>
<td>-------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>32</td>
<td></td>
<td>emerged from analysis of the data.</td>
<td></td>
</tr>
</tbody>
</table>
Appendix B: Pre-read (Brief Overview of Ethical Theories and Principles Applicable to the Research)

Biomedical ethical principles consider four separate dimensions that apply to a physician when treating a patient:

1. Autonomy
   The requirement that the physician do what he or she perceives is in the best interest of the patient without any “influence” from outside agents. To act independently, in the best interest of the patient, once the physician has assessed the medical needs of a given patient.

2. Beneficence
   The requirement that the physician act in a manner that will most likely benefit the patient’s outcome. Given the unique characteristic of a given patient, recognizing the patient’s specific preferences, to work with the patient to help reach mutually defined health-related outcomes.

3. Non-maleficence
   The requirement to act in a manner that will minimize the likelihood of any negative health outcomes given the treatment choice that is decided upon for a given patient.

4. Justice
   To act in a manner that is just and fair; to not discriminate or prejudice against a patient; to be an advocate for the patient to ensure that the patient does not fall victim to the bureaucracy of the healthcare system.

Utilitarianism is the ethical theory whose central premise looks to deliver the greatest good for the greatest number of people ideally without making any one person worse off. What is good is right. Utilitarianism is considered not just as a philosophy for individual living but a “public philosophy”. The theory aims to define what is morally right by identifying those consequences that maximize happiness or utility for a person or persons. Under utilitarianism, choosing acts that lead to the greatest degree of happiness or utility; it is the key objective of any individual, and therefore of
any community, whether local, state or federal; the latter as defined by the collection of individuals that comprise these communities. If each individual chooses actions that aim to maximize the good, then the collective combination of all individuals who have maximized the good, should lead to maximization of the good in aggregate. Of course the challenge with a consequentialist mindset (the basis of utilitarianism), is that it is not always clearly known at the decision point whether an outcome of an action will be beneficial and whether an alternative action could have led to greater value generation. Therefore the rules that help guide action selection need to be re-evaluated from time to time to ensure that the intent of the rule is the net effect that is actualized.

Deontology is the ethical theory that recognizes the requirement that people need to act in a certain manner because it is there inherent duty to do so; to do the right thing is good. A given person ought to act in a manner that will enable a given person’s self-worth that will enable the members of a given community to function as a viable society leading to the betterment of the people within that society, and not at the expense of any one member of that society. An underling premise of deontology is the categorical imperative. It must be done to ensure that society is able to function and not destroy what is good. A simple illustration is not to lie. If a person lies even on occasion, it destroys trust. If there is no trust people will no longer believe what others say because it may be a lie and hence society would cease to function. An extension of this principle, is to not treat a person as a means to an end but rather as an end to itself.

Virtue ethics is the ethical theory that helps guide a person to act in a manner that will optimize the outcome of their actions. Virtues are means or midpoints of extremes. At either end of the spectrum are extremes of a given behavioral attribute that are considered vices. Courage is the mean of behavior that is cowardice at the one end of spectrum (courage is lacking) and foolhardiness at the other end of the spectrum (actions that are rash and lead to a worse outcome then if no action had been taken).

The rule of rescue is a principle that describes the willingness or obligation of a person to intervene in the outcome of another person given their relationship to that
other person. A managed care access decision-maker who sits remotely in an office potentially hundreds of miles away from where the physician is practicing medicine does not know the patient. The impact of the managed care organization’s access decision-maker is not known to him or her as there is no 1:1 relationship with the patient. The physician however has a 1:1 relationship with the patient.
Appendix C: Discussion Guides

Discussion Guide for 1:1 Phone Interviews with MCOP&T Committee Decision Makers

1. How are decisions made regarding access to medicines? What are the value drivers in the decision-making process?

2. How do you define ethics? How do you define morals? How do you define justice?

3. What type of ethics (ethical principles) or morals, from your perspective, should a P&T decision-maker apply, when determining access levels for a given medication?

4. How does the current managed care environment (not covering a product on formulary or placing a product on a higher co-pay tier or other utilization controls such as step edits / prior authorizations) impact the physician's ability to practice medicine? From an ethics / morals perspective, how do you think formulary coverage impacts the pharmacist? The consumer (patient)?

5. How should the cost of care impact the physician's decision of treatment choice when determining what is best for a given patient?

6. What responsibilities should a health plan have to its members when determining access levels to pharmaceutical products?
   a. How are these responsibilities affected when access to medicines are restricted through utilization controls, high co-pays through tier placement, or when products are not covered on formulary?

7. What trade-offs should be considered by a health plan when making formulary decisions for pharmaceutical products? What are the ethical implications of these trade-offs?
8. Ethical theories typically encourage actions that help restore a person’s self-worth, to restore or maintain one’s autonomy, to enable a member of the community to further develop one’s talents and further enable one’s happiness (quality of life).

   a. How does restricting access to a medicine violate this premise?

9. What are the most important characteristics of a health plan’s approach to its members that would demonstrate virtuousness of character when determining formulary access levels?

10. What do you believe is the right of the physician to be able to prescribe the medication he or she believes is the best possible medication for a given patient?

   a. How is this right affected when access to medicines are restricted or co-pays are too high?

11. What do you believe is the right of the patient to be able to access the medication that the doctor believes is the best possible medication for a given patient?

   a. How is this right affected when access to medicines are restricted or co-pays are too high?

12. How does access restrictions to medicines impact the physician as it pertains to the rule of rescue?

13. Often times in managed care, physicians are incented to increase the number of generics prescribed vs branded medications (prescribing an available generic vs a brand even if the generic is therapeutically different from the brand). Physicians are also incented to prescribe preferred products vs non-preferred products. How do these incentives impact the physician’s ability to act in an ethical manner?

14. How is justice compromised when a patient who has a clinical need is unable to gain access to a medicine that might improve the patient’s condition?

15. What ethical standards / morals do you think health plans apply when making formulary decisions?
16. How do you think employer benefit managers apply ethics / morals in their decision-making when selecting benefit designs or health plan choices that determine formulary coverage (access to medicines) for their employees?

17. How do you think the ethics / morals of access to medicines changes based on the severity of the illness or the degree to which patient directed lifestyle choices leads to the medical condition? For example, a patient with over active bladder vs a patient who is trying to quit smoking vs a patient who is diagnosed with prostate cancer?

18. What ethics-based / moral-based framework would you recommend be applied by health plans to determine access to medicines? How would access levels be different if this framework was applied?
Discussion Guide for 1:1 Phone Interviews with the EBDDMs

1. How are decisions made regarding access to medicines? What are the value drivers in the decision-making process?

2. How do you define ethics? How do you define morals? How do you define justice?

3. What type of ethics (ethical principles) / morals do you apply as an employee benefits decision-maker, when selecting benefit designs or health plan choices that determines formulary coverage? Is this different than what the (employer) organization encourages or mandates?

4. How does the current managed care environment (not covering a product on formulary or placing a product on a higher co-pay tier or other utilization controls such as step edits / prior authorizations) impact the physician’s ability to practice medicine? From an ethics / morals perspective, how do you think formulary coverage impacts the pharmacist? The consumer (patient)?

5. How should the cost of care impact the physician’s decision of treatment choice when determining what is best for a given patient?

6. What responsibilities does the employer have to its employees when determining access levels to pharmaceutical products?

   a. How are these responsibilities affected when access to medicines are restricted through utilization controls, high co-pays through tier placement, or when products are not covered on formulary?

7. What are the trade-offs considered by the employer when making formulary decisions for pharmaceutical products? What are the ethical / moral implications of these trade-offs?

8. Ethical theories typically encourage actions that help restore a person’s self-worth, to restore or maintain one’s autonomy, to enable a member of the community to further develop one’s talents and further enable one’s happiness (quality of life).
a. How does restricting access to a medicine violate this premise?

9. What are the most important characteristics of an employer's approach to its employees that would demonstrate virtuousness of character when providing benefit designs or health plan choices that have varying levels of formulary coverage?

10. What do you believe is the right of the physician to be able to prescribe the medication he or she believes is the best possible medication for a given patient?
   a. How is this right affected when access to medicines are restricted or copays are too high?

11. What do you believe is the right of the patient to be able to access the medication that the doctor believes is the best possible medication for a given patient?
   a. How is this right affected when access to medicines are restricted or copays are too high?

12. How does access restrictions to medicines impact the physician as it pertains to the rule of rescue?

13. Often times in managed care, physicians are incented to increase the number of generics prescribed vs branded medications (prescribing an available generic vs a brand even if the generic is therapeutically different from the brand). Physicians are also incented to prescribe preferred products vs non-preferred products. How do these incentives impact the physician's ability to act in an ethical/moral manner?

14. How is justice compromised when a patient who has a clinical need is unable to gain access to a medicine that might improve the patient’s condition?

15. What ethical/moral standards do you think other employers apply when selecting benefit design or health plan choices that determines formulary coverage?

16. What ethical standards/morals standards do you think health plans apply when making formulary decisions?
17. How do you think the ethics / morals of access to medicines changes based on the severity of the illness or the degree to which patient directed lifestyle choices leads to the medical condition. For example, a patient with over active bladder vs a patient who is trying to quit smoking vs a patient who is diagnosed with prostate cancer?

18. What ethics-based / morals-based framework would you recommend be applied by health plans to determine access to medicines? By employers when providing benefit designs or health plan choices with varying levels of formulary coverage? How would formulary coverage (access to medicines) be different if this framework was applied?
Discussion Guide for 1:1 Phone Interviews with Practicing Physicians & Community Pharmacists

1. How do you think decisions are made regarding access to medicines? What do you think are the value drivers in the decision-making process?

2. How do you define ethics? How do you define morality? How do you define justice?

3. How does the current managed care environment (not covering a product on formulary or placing a product on a higher co-pay tier or other utilization controls such as step edits / prior authorizations) impact the physician’s ability to practice medicine from an ethical perspective? From an ethics perspective, how do you think formulary coverage impacts the pharmacist? The consumer (patient)?

4. How should the cost of care impact the physician’s decision of treatment choice when determining what is best for a given patient?

5. What responsibilities does the employer have to its employees or health plans to its members when determining access levels to pharmaceutical products?
   a. How are these responsibilities affected when access to medicines are restricted through utilization controls, high co-pays through tier placement, or when products are not covered on formulary?

6. Ethical theories typically encourage actions that help restore a person’s self-worth, to restore or maintain one’s autonomy, to enable a member of the community to further develop one’s talents and further enable one’s happiness (quality of life).
   a. How does restricting access to a medicine violate this premise?

7. What trade-offs do you think are considered by the health plan or employer when making benefit design or health plan choices that determine formulary coverage for pharmaceutical products? What are the ethical / moral implications of these trade-offs?
8. What are the most important characteristics of a health plan’s or employer’s approach to formulary coverage decisions that would demonstrate virtuousness of character when providing benefit designs or health plan choices that have varying levels of formulary coverage?

9. What do you believe is the right of the physician to be able to prescribe the medication he or she believes is the best possible medication for a given patient?
   a. How is this right affected when access to medicines are restricted or co-pays are too high?

10. What do you believe is the right of the patient to be able to access the medication that the doctor believes is the best possible medication for a given patient?
   a. How is this right affected when access to medicines are restricted or co-pays are too high?

11. How does access restrictions to medicines impact the physician as it pertains to the rule of rescue?

12. Often times in managed care, physicians are incented to increase the number of generics prescribed vs branded medications (prescribing an available generic vs a brand even if the generic is therapeutically different from the brand). Physicians are also incented to prescribe preferred products vs non-preferred products. How do these incentives impact the physician’s ability to act in an ethical / moral manner?

13. How is justice compromised when a patient who has a clinical need is unable to gain access to a medicine that might improve the patient’s condition?

14. How do health plans or employers apply ethics / morals in their decision-making when offering benefit designs or health plan choices with varying levels of formulary coverage?
15. How do you think the ethics / morals of access to medicines changes based on the severity of the illness or the degree to which patient directed lifestyle choices leads to the medical condition. For example, a patient with over active bladder vs a patient who is trying to quit smoking vs a patient who is diagnosed with prostate cancer?

16. What ethics / morals-based framework would you recommend be applied by health plans to determine access to medicines? By employers when providing benefit designs or health plan choices with varying levels of formulary coverage? How would formulary coverage (access to medicines) be different if this framework was applied?
Discussion Guide for Employee Focus Groups

1. How do you think decisions are made by health plans regarding access to medicines? What are the value drivers in the decision-making process? How would your answer change specific to employers?

2. What type of ethics (ethical principles) or morals, from your perspective, should a P&T decision maker apply, when determining access levels for a given medication? How would your answer change specific to employers?

3. How does the current managed care environment (not covering a product on formulary or placing a product on a higher co-pay tier or other utilization controls such as step edits / prior authorizations) impact the physician’s ability to practice medicine? The consumer (patient)? The pharmacist?

4. How should the cost of care impact the physician’s decision of treatment choice when determining what is best for a given patient?

5. What responsibilities should a health plan have to its members when determining access levels to pharmaceutical products?
   a. How are these responsibilities affected when access to medicines are restricted through utilization controls, high co-pays through tier placement, or when products are not covered on formulary?

6. What trade-offs should be considered by a health plan when making formulary decisions for pharmaceutical products? What are the ethical implications of these trade-offs?

7. Ethical theories typically encourage actions that help restore a person’s self-worth, to restore or maintain one’s autonomy, to enable a member of the community to further develop one’s talents and further enable one’s happiness (quality of life).
   a. How does restricting access to a medicine violate this premise?

8. What are the most important characteristics of a health plan’s approach to its members that would demonstrate virtuousness of character when determining formulary access levels?
9. What do you believe is the right of the physician to be able to prescribe the medication he or she believes is the best possible medication for a given patient?
   a. How is this right affected when access to medicines are restricted or co-pays are too high?

10. What do you believe is the right of the patient to be able to access the medication that the doctor believes is the best possible medication for a given patient?
   a. How is this right affected when access to medicines are restricted or co-pays are too high?

11. How does access restrictions to medicines impact the physician as it pertains to the rule of rescue?

12. Often times in managed care, physicians are incented to increase the number of generics prescribed vs branded medications (prescribing an available generic vs a brand even if the generic is therapeutically different from the brand). Physicians are also incented to prescribe preferred products vs non-preferred products. How do these incentives impact the physician’s ability to act in an ethical manner?

13. How is justice compromised when a patient who has a clinical need is unable to gain access to a medicine that might improve the patient’s condition?

14. What ethical standards / morals do you think health plans apply when making formulary decisions?

15. How do you think employer benefit managers apply ethics / morals in their decision-making when selecting benefit designs or health plan choices that determine formulary coverage (access to medicines) for their employees?
16. How do you think the ethics / morals of access to medicines changes based on the severity of the illness or the degree to which patient directed lifestyle choices leads to the medical condition? For example, a patient with over active bladder vs a patient who is trying to quit smoking vs a patient who is diagnosed with prostate cancer?

17. What ethics-based / moral-based framework would you recommend be applied by health plans to determine access to medicines? How would access levels be different if this framework was applied?
Appendix D: Case Studies

Case Study 1 _ Smoking Cessation

A patient 54 years of age who has been smoking for over 20 years needs to quit smoking at the advice of his physician. The patient smokes a pack a day which is the equivalent of approximately $8 per day. Over the course of the patient’s lifetime, to date, the patient has spent over $29,200 on cigarettes. Due to poor circulation in his legs, the physician believes that if the patient continues to smoke he is at significant risk of major medical events including heart attack and stroke. The patient has tried to stop smoking using behavior modification techniques but without success. There are several different pharmaceutical treatment options available per the table below.

<table>
<thead>
<tr>
<th>Therapy Option</th>
<th>Co-pay</th>
<th>Retail w/o Coverage</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option A</td>
<td>$10</td>
<td>$1.00 per day</td>
<td>15% quit rate</td>
</tr>
<tr>
<td>Option B</td>
<td>$30</td>
<td>$3.00 per day</td>
<td>28% quit rate</td>
</tr>
<tr>
<td>Option C</td>
<td>$50</td>
<td>$5.00 per day</td>
<td>55% quit rate</td>
</tr>
</tbody>
</table>

The treating physician would like to recommend a course of therapy that he believes is the most appropriate for the patient which is Option C. However, the patient is co-pay sensitive and will not fill the script for Option C, the more expensive medication. Therefore the physician prescribes Option A and the patient is unable to quit smoking. The patient suffers a heart attack 6 months later and the healthcare system incurs significant expenses. Had the patient been prescribed Option C, the likelihood that the patient would have successfully quit smoking would have increased by more than 300% and would not have suffered a heart attack.
Case Study 2_Over Active Bladder
A 55 year old patient who has been in good health has developed symptoms of urinary incontinence due to overactive bladder. The patient experiences sudden urges that require an immediate trip to the toilet; if the patient cannot find a toilet nearby, the patient cannot contain her urine. The patient has reduced her social interaction with others and has become increasingly home bound for fear of embarrassment when in public. The patient is starting to have poor performance at work due to her incontinence. The patient has started to wear diapers inside and outside the house. There are several different treatment options available as shown in the table below.

<table>
<thead>
<tr>
<th>Therapy Option</th>
<th>Co-pay</th>
<th>Retail w/o Coverage</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option A</td>
<td>$10</td>
<td>$0.66 (3x/day)</td>
<td>50% (incontinence reduction)</td>
</tr>
<tr>
<td>Option B</td>
<td>$25</td>
<td>$4.50 (1x/day)</td>
<td>55% (incontinence reduction)</td>
</tr>
<tr>
<td>Option C</td>
<td>$75</td>
<td>$5.50 (1x/day)</td>
<td>64% (incontinence reduction)</td>
</tr>
</tbody>
</table>

Option A is a product that has been on the market for over 20 years and is known to cause side effects most notably dry mouth. It is the least expensive product on the market. Option C has the greatest reduction in incontinence based on clinical trial data and is the most expensive product. Most reviews completed by payers have concluded that the various treatment options are similar. However, it is well known that different patients respond differently to various pharmacotherapy options. The physician prescribes Option A to the patient due to the low cost of therapy and the step edit requirement of the plan (patient has to try option A and fail therapy before being able to receive option B or C). The patient discontinues option A due to lack of tolerability given the side effects. The patient does not improve and eventually loses her job due to under performance and missed days of work. The side effect profile of option B and C is decidedly improved over option A and the patient would have most
likely tolerated the medication better had she been prescribed these options vs that of option A.

Case Study 3_Prostate Cancer
A 45 year old male has been under the care of the physician for prostate cancer. The patient is scheduled for chemotherapy. Chemotherapy has serious side effects that negatively impact quality of life. There are a few new therapy options available that are more efficacious than chemotherapy however are off-label in the pre-chemo patient population. The plan denies coverage to the off-label medications and requires the patient to fail chemotherapy before being eligible for the newer non-chemo treatment options. The patient is married and has two children, ages 3 and 7. Quality of life is important to the patient given his two young children at home.

Case Study 4_Quality of Life
A patient does not have access through their health plan to a given medicine that has been approved by the FDA. This medicine has shown significant improvement over placebo in treating the patient’s medical condition. In addition, the product has been shown to improve quality of life including social interaction, sleep, concern and coping. The payer has not added the product to formulary for a number of reasons. The payer believes that:

- There is no clinically meaningful difference between the products already on the market and this new product
- There are enough products already on the market that are used by physicians to treat the condition
- The payer does not take into account the impact of the product on quality of life, just the change in the clinical status of the patient (for example, lowering of blood pressure, reduction in fractures, overall survival)
Appendix E: Case Study Findings

The following section details the findings as it relates to the Case Studies, namely Smoking Cessation, Overactive Bladder, Prostate Cancer and Quality of Life. For each of the case studies, the perspective of each stakeholder within the Professional Group is summarized separately.

Smoking Cessation Case Study

Community Practicing Physician Perspective (SC)

It is difficult to assess whether the patient would have still had a heart attack even if they started taking the more expensive medication. Patient had the choice to decide to stop smoking; there are a number of factors that impact on the ability of stopping to smoke; it is not just the medication; it is the totality of the factors that impact on the patient. Patient choses the plan for their insurance; the patient could have chosen a more comprehensive plan which would have had a higher premium. Either way the patient has to pay for access: either through the premium or at the time specific care is needed. It was ultimately the patient’s choice on how to spend his finances to improve his health.

Once the patient is a smoker that is addicted to smoking, the patient will need treatment to be able to stop smoking. Different stakeholders will see the logic of the copay differentials: from the patient’s perspective, it is not seen as a positive as access is restricted through a higher copay but from the MCO’s point of view it is logical: higher copays for more expensive medications. However, if there is higher total system costs incurred when using the lower cost medications vs the higher cost medications, it is in the MCO’s best interest to help the patient stop smoking. The patient did not have access to the best medication available; the system should work better in trying to prevent the patient from having a heart attack.

The physician did the best they could under the circumstance; the physician was limited by what he could do to treat the patient given the level of coverage available to the patient. Physicians should be checking in with patients and following up to assess how they are doing on the treatment plan. Physicians experienced a lack of
autonomy under the patient’s plan because the physician had to prescribe a medication that the patient would fill otherwise it will not be helpful to the patient. Given the level of efficacy of the medication, the MCO should make the product available to the patient at a reasonable copay. $50 per month was seen as not reasonable for many patients.

The concept of a step therapy was seen reasonable unless it was imminent that the patient get access to a therapy immediately. In the latter case, the physician should engage with the MCO to attempt to bypass the step therapy requirement for coverage.

The point made by one specific physician study participant was reflective of the general sentiment about the realities of access to medicines and the implications of formulary coverage.

“…the physician is not choosing Option A over Option C because they think it is better. They are choosing because they are acknowledging there is a cost problem here. Any physician that would do otherwise would be foolish. I will always prefer that you get what I think is the best drug. If I am giving you anything other than the best drug on purpose that would be silly… if I am giving it because I said to you ‘I am trying to save you some money so let’s start with Tier 1 and work our way up’. And as long as I explain that to the patient and I educate them properly I think ethically I have done nothing wrong. That is my view on this one.” (Physician_10)

Community Retail Pharmacist Perspective (SC)

Pharmacists believed that the physician should not make any assumptions about the patient’s willingness to fill a script; that the physician should discuss with the patient the options and then explain the benefits of a specific choice of medication the physician feels is best for the patient. If the physician does a good job in explaining to the patient why a specific prescription will be good for treating their medical condition, they will be more likely to fill the medication. Patients are not familiar with the medicines that are prescribed by the physician and when they face the copay at the pharmacy counter they might be reluctant to pay for a medication that turns out not to be effective. Using a less expensive medication first and then stepping through to the more expensive medication was seen as acceptable as it allows more patients
to be treated; there was no urgency seen for the patient to get access to the most effective medication as initial therapy given the patient was already smoking for 20 years.

Some of the pharmacists believed that the physician should have prescribed Option C, the most costly of the three medications, because it had the best efficacy of the available choices. That the physician should have taken time to explain why the physician felt that Option C was his preference for the patient and that the patient would be saving the patient significant dollars by not smoking; ultimately the patient would be trading a $240 per month cigarette cost for a $50 per month prescription cost. The physician should have stressed this point and it might have had an effect on the patient’s willingness to fill Option C thereby possibly preventing a heart attack.

“So yeah I think that the doctors can spend more time with the patient and provide resources, brochures, documentation on smoking cessation options. And go through the steps that would help the patient get the option that he initially wanted to get which was C, which I think probably could have helped him.” (Pharmacist_05)

At the same time, even writing a less efficacious medication, if the physician followed up with the patient regularly to assess the patient’s progress in his or her efforts to stop smoking, the outcomes might have improved.

Pharmacists recognized that medications needed to be affordable but given the significant cost of smoking the thought was also raised that the patient might not have been ready to stop smoking if they viewed a $50 copay a deterrent. The pharmacist also felt that had the physician prescribed Option C, the pharmacist might have been able to persuade the patient to fill the product given the importance to stop smoking. If the physician does not write the product he felt was best for the patient, the pharmacist will not know what was the real preference of the prescribing physician; by prescribing the preferred medication the physician is able to create a trail (documentation) that the preference of the physician was Option C but the patient was reluctant to fill the medication because of the higher copay. However the physician providing an ultimatum of only prescribing the most expensive option would not build a trusting relationship with the patient.
Some pharmacists felt it was not smart of the plan nor the employer to place a higher copay on the more efficacious medication. When it came to a medical condition such as smoking, the plan and employer should provide the necessary resources to help the patient stop smoking; otherwise there will be additional costs incurred by the system; the physician specifically will end up working harder because the patient's health will be worse off due to the smoking. The point of the physician losing their autonomy, self-worth and experiencing frustration surfaced in this case study.

MCOP&T Perspective (SC)

Providing coverage for a medication dramatically increases utilization. The MCOP&T recognized the want of insured members to have access to generic-like pricing for all medications but that is not a reality of the system.

“We are not going to cover the most expensive thing at a generic co-pay. I'm sure everybody would love that and it would be great. But it's not possible and again, if it's important to him, they'll find a way to make that happen because this isn't something that's going to go on forever. This is going to be a short term sacrifice on their part and we are already making a sacrifice by covering a more expensive drug.” (MCOP&T_03)

At the same time the MCOP&T felt the physician failed the patient and his responsibility if he was not able to get the patient to adhere to the more expensive, more efficacious medication. The MCO was seen as acting appropriately by making the more costly medication a higher copay.

“If this physician can't persuade this patient who he purports really wants to quit that paying $5 a day versus $8 a day is a bargain, I think that physician's not done a very good job of doing what he or she is responsible for doing in terms of caring for that patient.” (MCOP&T_02)

MCOP&Ts felt that patients had to decide which therapy option they were willing to pay for; the physician needed to provide a review of the possible treatment options and make his opinion known to the patient on why he was favoring a specific treatment option. The physician could have been adamant and only prescribe what they thought was best no matter whether the patient was willing to fill it or not. MCOP&T_05 stated that he “couldn't care less” if the patient could not afford the
medication; MCO_05 stated “If they stop smoking, they would actually be saving money. We would be doing him a favor.”

The MCOP&T felt the patient was competent to make his own decisions. The patient enjoyed smoking and most likely positively impacted his Quality of Life. The patient took a gamble by smoking and lost. However, because he is a smoker, his premium for coverage was higher given the increased likelihood of experiencing a negative medical event such as a heart attack. It was the physician's role to provide the available options but then ultimately the patient makes the decision. The patient knew the risks, made the choice and suffered the consequences.

**EBDDM Perspective (SC)**

The EBDDM spoke to behavior and choices; the insured member chose a specific MCO (plan) that had certain coverage levels; the insured member chose to smoke and not to pay for the more expensive treatment option. As stated by EBDDM_02, “The patient was totally in control of the situation”. The employer provided access to benefits but ultimately it was the insured member who decided the choices he made with regards to his lifestyle and how he choose to access care with the coverage he had chosen (purchased). Other EBDDMs felt that it was in the best interest of the employer to provide coverage to the most efficacious medication to help the insured member to stop smoking as it would lead to better health and lower costs. To that end, the employer was seen as needing to be educated so the right decisions were made in terms of benefit design and coverage. Conversely, the insured member was seen as sticking his head in the sand, ignoring the facts and continuing to smoke.

“He’s not collecting the information necessary to make good decisions. And so that makes him I guess unethical or immoral to a certain degree. Sticking your head in the sand is immoral to some degree. And that’s basically what he’s doing saying, ‘I don’t want to know the facts. I just don’t want to spend that money right now’”. (EBDDM_03)

Deciding to smoke was seen as making a bad (stupid) decision; the insured member was harming their health, becoming addicted and spending money; illogical according to EBDDM_03. EBDDM_03 would have wanted all employers to get every employee to stop smoking but recognizes that employers had to make that decision based on
their interpretation of the economics relating to coverage. An opinion expressed by the EBDDM was that copays ensured that patients filling a medication were vested in being compliant to their treatment. The insured member is willing to place the copay as a bet that they will get better as a result of the therapy. The system is built on the premise that better care costs more even though such a premise might not be optimal. Insured members believe that there should be no additional cost to access healthcare beyond the premium. However, reasonable copays were seen as necessary otherwise there would be the potential for uncontrolled use of resources and the plans would be unsustainable.
Overactive Bladder Case Study

Community Practicing Physician Perspective (OAB)

Physicians felt that step therapy was reasonable to a degree; the lower cost agent is expected to work in many patients; for those patients that do not respond to the initial therapy, there are options to move on to other therapies. Physicians stressed the patient has access to the medicines; it is just as it relates to having coverage through managed care; patients had to follow the protocol established by the MCO if they wanted coverage for their treatment.

“I think maybe their perspective is, several patients will try option A and they’ll be able to stick with it, despite the side effects. And they’ll have enough of an improvement; a 50% improvement in incontinence reduction. And then for the smaller percentage of patients that fail option A, they’ll move on to option B and option C. So it benefits the managed care plan from a financial perspective and it still allows patients who fail option A to have other options.” (Physician_03)

It was seen by the physicians that the formulary was restricting the physician’s ability to prescribe perhaps as he would prefer hence it does affect the right of the physician in context of the plan but only in terms of the timing of treatment; the physician’s first choice might have been to start with the 2nd line therapy but he needed to first try a lower cost agent in order to ensure the patient was able to access coverage under the plan.

The physician felt that the MCO considers the side effect of the lower cost option as manageable; the physician stated he would explain the options and the trade-offs and recommend to go with the more expensive medication. The physician spoke to the point that the patient chose her plan and the respective coverage levels commensurate with their premiums.

“She has a choice to get a better program if she wanted. It’s the same thing as buying the car you have a choice. You can buy a Mercedes, you can buy a Ford. Both cars drive, both cars get you from Point A to B. You are going to be a little more comfortable probably in a Mercedes than you will be in a Ford but it is a choice. You have that choice. When she signed up for her plan she had an opportunity to read the plan and understand the rules of the system. The problem is that none of us really do that as a patient.” (Physician_04)
The physician recognized that the coverage levels provided by the MCO and the physician’s approach to treating the patient contributed to the negative outcome which had significant implication to the patient’s life. However, the physician lost autonomy and their ability to treat the patient was affected by the imposed utilization controls of the plan. The MCO was seen as potentially being ‘obstructionist’ according to Physician_05. The physician learned to work within the system to help maximize patient outcomes.

“will give them the prescription for the generic medication that I don’t like prescribing…and I will tell them: ‘You have to fail this medication before I could give you something different, I want you to try it for a couple of days, call me and tell me how you are doing on it so that I can document what happened with it. I’m going to give you these other samples to hold on to but don’t start on them until you try this other medicine. If you try this first medicine and it doesn’t work or if you have bad side effects, call me and tell me that, then you can start on these samples’, and then usually I will see them back in the office after that so again I can document everything in my system.” (Physician_05)

The physician spoke of how copay cards will typically help the patient, when available, to make up the difference of copay differentials and lower the cost of acquisition of the medication. Although the copay program could have limitations or end at any time at which point the patient might stop taking the medicine. The physician stated that the employer has an obligation to provide a reasonable plan to their employees but the MCO will determine what medicines to cover under the plan; the employer will subsequently need to trust the MCO that is selected to provide their employees with coverage for adequate care.

The physician felt it was the patient’s responsibility to manage her situation and to ensure her medical condition does not interfere with her ability to work. There was also the perspective that these medications take time to take effect and so no matter which medication is prescribed there is a time element before outcome is effected; there was also no reason to think that the cheaper product would not be effective for a given patient. Treating this condition was also not one of life or death and to manage resources effectively in treating the condition was reasonable. As stated by Physician_10, ” There is only so much you can do for each individual and you have to
be reasonable as to what our expectations are to both the insurance company and even the physician from getting on the phone and trying to fight for it”.

**Community Retail Pharmacist Perspective (OAB)**

The pharmacist thought the patient should be more willing to endure side effects to achieve a better outcome based on efficacy. Patients were seen as to readily stating they are unable to take a given medication because of the side effects. Specific to the case study, Pharmacist_01 stated that the "patient should have been able to basically man up sort of speak and at least cover that time frame" to fail therapy and move on to the 2\(^{nd}\) line option. The pharmacist also recognized that a medical condition that affected the functioning of a younger adult who was still active in the community should be treated with the best medication available. However, due to cost of acquisition, it might be necessary for a patient to try the lower cost option first especially as this condition was considered to be chronic and care would be for the long term. The patient on poly pharmacy would have to decide which condition to treat with medication if they were not able to afford all their medications.

The pharmacist felt there should have been better education to the patient about side effect management, ensuring the patient understood the approach of step therapy and the process by which to try different therapy options. The physician should have been more effective in educating the patient; having better follow-up with the patient to assess treatment success and the patient should have been forthcoming in communicating about her condition. The pharmacist could have also called the physician if the patient communicated to the pharmacist that the therapy was not working. The pharmacist mentioned that the employer is not assessing the big picture in terms of the impact of coverage: how is it affecting additional costs to the MCO, productivity and ultimately unemployment.

There was the perspective that the patient waited too long to seek out care as the symptoms of the condition builds up over time. They should have been more proactive about their care and health. As stated by Pharmacist_07, “…again, a little bit less sympathy here because she did not immediately go in and address the problem.”
Step therapy was seen as reasonable; using treatments that work for the majority of patients, that was a standard of care was seen as acceptable to limit costs to the plan. As stated by Pharmacist_09, “Managed care should not be expected to meet the needs of a 100% of the population and I fully support the use of step care therapy.” However, it was seen as MCOs lacking the training to assess the needs of a patient and working with the physician to help improve outcomes and the probability of treatment success.

MCOP&T Perspective (OAB)

The MCOP&T felt that the option to try the less expensive medicine first was reasonable. The MCOP&T spoke of how this condition is only managed by these medicines; incontinence does not get cured with these medicines. Hence it was seen as important to understand how the patient manages her condition including side effects; also to discuss with the patient the total cost she spends on managing her condition. The difference in efficacy between the agents, comparing one agent with another, was not seen as necessarily having statistical validity or clinically meaningful difference.

The MCOP&T recognized that a patient, especially one that is working, would want the medication with less side effects; however, higher copay amounts deter patients from opting for the more expensive medicine. At least one MCOP&T spoke to how their actions should not be the root cause of employees losing their jobs. However, it was not necessarily about providing better access to medicines but rather educating patients on how to manage their conditions effectively.

“Shame on us all. I mean we definitely should not be having people losing their job because of a money choice for treating overactive bladder. What we should be doing is educating them on how to tolerate the side effects. There are many different ways, in and around, the side effects that exist and they don't cost anything. But again if the patient is going to… keeping them in the work force by paying for something that's more expensive and making it affordable for them, then we should be about trying to make that happen.”

(MCOP&T_03)

MCOP&T_03 spoke to the balance of providing care to insured members but at the same time managing the business of an MCO; that there is
“a duty to do no harm for sure, but there’s also a duty to be liquid at the end of the month. Have everything in place so we can continue to provide health care for the large amount of people that have paid for that health care.”

However the mindset was repeatedly stated that patients always have access to a medicine if their physician prescribes, they just have to pay for it. As stated by MCOP&T_06, “They can always pay for it. We are not restricting access to that medicine, they can always pay for it.”

MCOP&T_10 made the point that the “Plan has [a] duty to encourage patients to first try and fail" the lesser expensive product; by allocating resources based on clinical value relative to costs there is greater opportunity to provide more benefits to insured members. The totality of care the patient is expending financially should be considered by the patient to weigh whether the extra costs for a different medicine is worth the trade-off to purchase. MCOP&T highlighted the point that patients are ultimately responsible for themselves and the consequences that come from their decisions. Access decisions and cost shifting to patients need to be informed by the cost of providing coverage for a product; not effectively managing costs can lead to increased premiums, employers needing to drop healthcare coverage for their employees or possibly hiring less employees which would lead to a higher rate of unemployment, increased use of Medicaid, and subsequently taxes.

EBDDM Perspective (OAB)

Some EBDDMs felt the efficacy difference between the options was significant whereas others did not. The EBDDM felt that the patient should have been more forthcoming in their communication with the physician; speaking to her physician about her condition and the impact it was having on her life. Similarly the physician should have taken the time to better understand the impact of the condition was having on the patient’s life and not just treating the condition. Patients were seen as needing to find ways to manage through side effects, such as rock candy for dry mouth. EBDDM_03 brought up the point of funding access to medicines through a special reserve set aside for patients who could not afford the out of pocket costs for
their medicines; using an income requirement to assess level of support would ensure all employees are treated the same.

The point of reasonableness surfaced in relation to the case study. Have a step therapy for the condition to gain access to more expensive medications was seen as reasonable. The physician and patient was seen as needing to follow the protocols and if they did not the consequence was worsened outcomes. Cost savings needed to be weighed against the hassle factor of patients being able to access needed therapy. However if the benefit design was not working the decision-makers would need to be made aware so the appropriate modifications could be made to improve outcomes.

“Well, I think that step therapy is a reasonable tool. And while we do know that it can potentially result in deferred effective treatment, in general, I think that it is reasonable for the designers of this program to expect that the doctor would explain the concept of the step therapy and expect to follow up regarding the efficacy of A with the patient and so that the failure here is not necessarily the system design but in the... somewhere between the physician for failing to schedule a follow up and the patient for effectively, not following the protocols. Now, we also understand that that’s the theoretical way that it’s supposed to work and that patients don’t always do this so as we design these things, we have to design them in such a way that the relative cost is considered along with the, I don’t know want I want to call it... the hassle factor, but we know that patients don’t always take their medications, we know that patients don’t always go back for follow up and that sort of thing. When we design barriers to service in there, we have to be sure that the barriers of service are justified by the cost savings and so on. In this case, it doesn’t sound unreasonable to me but we have to be aware that if this is happening a lot that the program needs to be looked at and potentially revised.” (EBDDM_07)

The EBDDM spoke to various barriers to care that exist such as availability of the provider in a given area, availability of appointments, narrow networks, copay differences between various treatment options. Some access barriers occur naturally (lack of available provider in a geography) vs other access barriers are deliberate through the benefit design. Ultimately insured members (patients) need to overcome barriers to improve their own health status; however, insured members (patients) will not seek out care when insured members start to perceive care to be expensive; if you have patients in your plan for 20 to 30 years you want them to make optimal decisions about their healthcare.
The EBDDM acknowledged that he did not have the level of expertise needed to ensure the right questions were being asked and that outcomes were not being comprised. The EBDDM trusted in the expertise of the MCO and that changes in formularies were being done because the products covered were more efficacious, not just a lower cost option.

“I have never seen any benefit manager, question the people who develop the formularies with the issues you just brought up. Except that we have an implied trust that that is the type of question they are asking otherwise it is just a complete sham and it is just for money and I hope that is not the case… I do think we have to rely on the people who set these step therapies up that they are doing it for the right reason for the right outcomes and in general under the right research. Are they actually doing it? Do not have proof and do not know what is an adequate level of proof…” (EBDDM_10)

The EBDDM however still felt it was the employee's (patient's) responsibility to raise awareness of her condition with the employer if it was affecting her performance at work so the employer could bring additional resources to bear to improve her outcomes. The physician should have also been thinking of the entirety of the patient and thinking of her condition might be affecting her performance at work; and the consequences of her condition potentially jeopardizing her work and leading to not only loss of employment but also loss of healthcare coverage.

The EBDDM spoke of a different case where a patient needed a C-section to prevent 6 months of urinary incontinence but the patient did not meet the criteria for a C-section; however the decision-maker placed themselves in the shoes of the patient and their loved ones. As stated by EBDDM_10,

“the Medical Director, he said, I know this is against all the rules of the plan and how claims are being paid and the people who approve these C-sections; there are protocols and everything else but let me tell you I would not want my wife to go through this again. If all it takes is a C-section to make sure it does not happen again that is what she is going to get and that was the feeling of the committee.”

The EBDDM spoke to there was support for this patient gaining coverage for the procedure because of her positive way to engage the decision-makers. As stated by EBDDM_10,
“So a lot of the issues come down to how a person knows how to deal with a problem in a constructive manner. I got people who are angry as hell and they would not listen to reason and like I said before some people just like to fight and those I just listen to and say boy that is a shame and do not lift a hand to help them.”
Prostate Cancer Case Study

Community Practicing Physician  Perspective (PCa)

The physician verbalized the point of view that access is not denied by the MCO to the medication; the patient can always pay for the product just the plan will not pay for it under the patient’s policy. Therefore it is important for the physician to review treatment options with the patient so the patient can make an informed choice. Cost was considered a risk factor the patient needed to assess in their decision-making. For some of the physicians there was a strong response to ensuring the patient had access to the medication needed to improve his medical condition; given the disease was a matter of life and death. For some of the physicians this was a case where the plan could make a difference in the life of the patient and hence providing coverage was important. When only quality of life was considered vs overall survival, there was a less strong reaction to the importance of coverage but coverage was still perceived as important to ensure ethics and justice were not violated. The plan needed to focus less on making money and a profit and more on providing coverage for the treatment. As stated by Physician_03, “All plans have the ability to, it’s just them making more money and them spending more money.”

The physician spoke to the need of making an appeal to the MCO to have the medication covered with supporting documentation of evidence. If the MCO does not agree to coverage, the patient should have considered to change (leave) their MCO.

The physician raised the point of losing autonomy and not being able to practice beneficently in treating the patient ideally but also that the MCO was creating maleficence because the MCO was only willing to cover the chemotherapy which was known to have significant side effects.

“I think in this scenario the ethical consequences is if the MCO is not following the concept of kind of non-maleficence in this particular case because they are… limiting the patient to a particular option that has significant potential to cause harm and then for the physician’s perspective, again the physician is losing their autonomy in this particular scenario and they cannot act purely based upon the rules of beneficence and I think so it really does impact the kind of ethics of the prescribing physician because ethically you want to
prescribe what is the most ideal therapy that has a lowest side-effect profile.”
(Physician_05)

The majority of physicians felt that there should either be an attempt of the physician to convince the plan to provide coverage (rule of rescue) or to find a clinical trial where the patient can gain access to the therapy.

Physician_05 spoke of the implications of the treatment on the patient’s family, “this outcome is actually tied to kind of the social good as well because this has a significant impact on his family, so this has impact on more than just one individual.”

The biggest challenge for the physician was that the product was off-label; in the physician’s opinion, MCOs do not pay for experiments; for clinical trials. The physician needed to be familiar with the data, be able to make the case to the plan why treatment should be covered; informing the patient what in the physician’s opinion was the best treatment option for the patient. At that point, the physician did everything that was possible.

Community Retail Pharmacist Perspective (PCa)

The pharmacist had a strong opinion on the importance of accessing medicines for treating cancer; unlike with OAB where it was not seen as a life or death condition. As stated by Pharmacist_01,

“…without full access to try the best treatment available, you risk being too late for those types of patients. By the time the chemo is done, which is usually over months, it may be too late to do the alternate, which would have been better for the patient. So that’s where I am at with that one. And if I sound like I am little bit biased or favored to that one is because I worked hospice for a long time.”

However, the fact that the medication was off-label brought up legal concerns from a coverage perspective. Some pharmacists believed that the reason for lack of coverage was due to concerns of liability should the product not work for the patient. It is the responsibility of the manufacturer to follow the rules of the FDA and get approval for the indication. However, it was recognized that the physician can still prescribe the medication based on his medical discretion and available evidence in the marketplace.
The range of responses included strong emotion, as was stated by Pharmacist_05,

“This is one of those situations where you know you want to come across the counter and he needs a hug… This is not a compassionate insurance company that looks at this patient as a person. He is strictly a number, a cost to the bottom line… this is a tough case because they don’t put a price tag on his quality of life but they do on the therapy that he needs…”

Pharmacist_07 spoke to doing what was needed to get the patient back to health as quickly as possible. “He's only 45, and second he's got family to take care of. Let’s get this guy back out healthy into the workplace, back into the arms of his family, where he belongs.” To that end the plan should cover whatever therapy the physician deemed best for the patient. The benefits would be widespread not only to the patient but his family, the employer and to society.

The alternative viewpoint of the pharmacist was that the MCO needed to cover standard of care; the MCO did not deny treatment; the MCO just did not cover the cost of the treatment. The patient needed to make the decision as to the choice of therapy. There should be a team-based approach to helping the patient and exploring alternatives of accessing the preferred therapy choice: such as support from the drug manufacturer or enrolling in a clinical trial. There needed to be a degree of creative problem-solving to identify how the patient could access the medication but there was nothing more that could be done.

MCOP&T_Perspective (PCa)

The MCOP&T spoke to that decisions for coverage were not random or based on bureaucracy; the differences of coverage decisions across the various MCOs were based on the opinion of the expert opinion that was used to inform the coverage decision. The point was made that practicing physicians typically will look to stretch the prior authorization criteria trying to push beyond the clinical parameters for which the medication is covered. The challenge in treating patients with serious disease is that the treating physician's opinion might be challenged by experts in the field. As stated by MCOP&T_02,
“where I sometimes have difficulty because one physicians’ opinion about the management of a complex disease can easily be disputed not by the insurance company but by experts in the field… I’m not convinced… that physicians routinely make correct decisions. Just because they advocate doesn’t mean it’s correct… physicians make a lot of bad decisions.”

Legal implications were mentioned; the MCO’s lawyer is restrictive to coverage to prevent against liability. There is a safety concern; even after a medication becomes available in the marketplace for a specific indication, specific MCOs might not provide access for a period of time, for up to a year, to assess the safety in real world use; also to better understand the true size of the indicated patient population. However, when there is peer-reviewed evidence for use of the product off-label, it could be considered. It is up to the manufacturer to gain FDA approval for a specific indication but even then the MCO may want to wait to assure there is safety in its use post approval. MCOP&T_03 spoke of the exception process in specific situations such as a small child with bowel cancer where there were no available alternative:

“We make exceptions to people that have to have something. In other words this is the only thing that might possibly change their outcome like a small bowel disorder we had with an infant child and we chose to cover an off-label use for small bowel. Because there was no other choice and the child was going to die without it. Certainly that made sense.”

In the case of prostate cancer, the disease was thought of as slow growing, so there was time to try various treatment options, to use what was considered standard of care and waiting for off-label medicines to prove their safety over time.

The MCOP&T spoke of the importance of enrolling patients into clinical trials vs just providing coverage for an off-label medication. The benefit of a clinical trial is that it will over time benefit all patients with a given condition and not just the one-off patient being treated because the MCO made an exception to cover the medicine.

“If patients like this should be ideally enrolled if they want to go on off-label medications; should be done in confines of an approved study not just some experiment by some oncologist who may be playing fast and loose with a medication vs others so you know from a plan perspective for off-label use should be done ideally within confines of a study with an approved investigation.” (MCOP&T_10)
At the same time MCOP&T_10 readily acknowledged that cost factors into decision-making. The MCOP&T spoke of the use of Avastin off-label to treat Diabetic Retinopathy vs the more expensive on-label use of Lucentis. The MCO sees the products having similar efficacy and hence do not limit coverage just because it is off-label. As stated by MCOP&T_10, “...we turn a blind eye if it is something being used… the MD is asking for something off label and we are allowing it because it is a lot cheaper.” The MCOP&T spoke of the plan placing its focus on economic value. The example of NCQA HEDIS measures was referenced; if HEDIS started to measure off-label use and there was a negative impact on the MCO, the MCO would take steps to change use. Otherwise the MCO is spending money to make a change that does not bring economic value. As stated by MCOP&T_10,

“If… HEDIS NCQA starts measuring our utilization of Avastin vs Lucentis for revascularization of the retina than we are going to start… we will start to correct the misuse of it; if you want to call it misuse… I suppose it is not FDA approved for use for that.”

**EBDDM Perspective (PCa)**

For some of the EBDDMs there was no difference in approach across the various case studies. However, one EBDDM expressed the importance to have a patient advocate who can reach out to the MCO or the employer to see what treatment options are available for use by the patient. The EBDDM felt that this patient would be unique given their medical condition and hence EBDDM_02 “would rely on a panel of peer physicians to review records and make a recommendation to us as an organization on what we should do”. The independent panel would have been built by the EBDDM’s MCO or consultant. If coverage was denied, the evidence used by the panel to make their decisions would be communicated back to the treating physician and patient. Cost was not a criteria for coverage as stated by EBDDM_02; coverage was based solely on what was considered medically appropriate. The EBDDM also perceived rule of rescue at play in that if the MCO denied coverage it was based on a panel decision; it was not supporting the treating physician’s recommendation, so the patient is made aware that experts are not in agreement with the treating physician’s treatment strategy. There was not enough compelling
evidence for use; even if there was a 50-50 split in the panel, the net result would be lack of coverage. The MCO is not denying access to the medication, only payment for use under the plan. At the other end of the spectrum was the EBDDDM point of view that the treatment is expensive and not yet approved and that was not the role of the EBDDM to experiment; however, it would be virtuous if employers decided to provide coverage in such situations. As stated by EBDDM_03,

“...I applaud the employer for covering them. But at the same time, I wouldn’t say it’s immoral or unethical for them to not provide it. And it’s not a justice issue either since justice implies that you were wrong, and I don’t think it’s right or wrong, I just think it would be nice if more employers did this.”

EBDDM_07 spoke to the point that there should not be a denial just because the policy states there is no coverage; it should review the evidence and make a determination accordingly. “I would say that if they made a best effort attempt to determine if there was a reason to approve it, then they’re fine; if they just said no, the rule says this, then stopped there, then I would say that was not ethical behavior.”

The EBDDM wanted to ensure that whomever did the clinical review should have no financial benefit from the decision eventually made.

However, as stated by EBDDM_10, there was concern of the liability of an off-label medication being covered by the MCO.

“I think the bottom line is I would never be able, even through my management team, would I be able to get an off-label use of drug approved because FDA is saying no and we certainly are not going to say yes. I think there potentially would be liability issues if we would approve and pay for it. So that is why the safer route is not to approve an off-label use and do not know if there is an ethical consideration when approving off-label use if the decision-makers at the FDA after reviewing all the research; then who are we to say it should be.”
Quality of Life Case Study

Community Practicing Physician Perspective (QoL)

Physicians felt that ideally MCOs would cover all FDA approved medications; but even if covered it always came down to cost to the patient. The physician was seen as needing to discuss with the patient the various treatment options, and then the patient could make the choice. The standard of care as defined by experts in the medical community as appropriate care was seen as the guide post to informing treatment decisions and the standard of care should be covered.

Despite the availability of other medications on the market, the physician felt that there are ethical implications of restricting access to medicines because it affects physician autonomy and the ability of the patient attaining a higher level of happiness and quality of life. At the same time, the physician understood the utilitarian mindset that there were other products available in the marketplace. However, the question was raised on whether the mindset is driven by a utilitarian mindset or whether cost was factoring into decision-making. The cynicism was highlighted recognizing that MCOs needed to be economically viable.

“I have this more of a cynical attitude because I see where healthcare is going and you know its… there is no right answer. But I think that these insurance companies, these health care plans, need to stay afloat so they need to do that by cutting costs.” (Physician_03)

The physician spoke of there was lack of transparency to understand how decisions were made by the MCO and what factored into their coverage decisions; it would be important to understand the rules; MCOs do not communicate effectively.

“…boils down to understanding what the rules are. I think the insurance plans do not communicate it very effectively… it is sort of a black box. It's mysterious. We don’t know how the decisions are made or why the decisions are made or what the decisions are sometimes.” (Physician_04)

Where it was seen as getting complicated is that there are a high number of diseases and treatment options; the differences of these options are marginally better and
hence coverage decisions are less about being black and white, and coverage decisions usually fall into more of a grey area.

The physician felt that there needs to be head to head studies on endpoints that help the decision-makers to understand the difference in outcomes. The MCO should look to understand the difference in outcomes based on the available evidence otherwise, as stated by Physician_05, “the MCO is sort of arbitrarily deciding that quality of life information doesn’t have any clinical significance and most physicians would argue the opposite of that.” However, not providing coverage until that evidence is available was seen as fair and just. The MCO was seen as reasonable; if the patient wants to improve outcomes as it relates to secondary endpoints such as QoL, he should be willing to pay for it. The patient bought a certain level of coverage through his plan and there should not be any expectation for additional levels of coverage beyond what was purchased.

Community Retail Pharmacist (QoL)

The pharmacist recognized that MCOs make decisions at the population level and not at the individual patient level. When a new drug becomes available on the market the product was considered to be more costly than other options that are widely used and so MCOs will disadvantage the product through use of formulary (utilization) management.

“That’s the way the system works. It’s not a question of, you know, of right or wrong; it’s not a question of this or that. It’s the system… Every case has to be done on its own merit. And when you are talking in generalities, you are not always able to come up the right solution to fit everybody.” (Pharmacist_03)

The manufacturer over time needs to be able to demonstrate that the product delivers better outcomes and lowers cost of care. There needs to be historic data to inform evidence-based medicine. MCOs were not seen as focusing on quality of life. As stated by Pharmacist_05, “the payer really doesn’t at all consider that social interaction: sleep, concern, coping are things that you need. To put it bluntly you don’t need any of those things to be a dutiful citizen.” The Pharmacist expressed frustration that patients will not gain the benefits of certain products because they are
not the average patient but recognized that the system does not think it is worth paying for. However, ultimately, it was seen as the patient has responsibility for their own health and healthcare; patient should be made aware of available options but then the patient has to make the choice of what therapy to purchase. At the same time the pharmacist believed that insured members were not educated enough to be able to make informed decisions and that the MCO and the employer should provide the necessary resources to inform decision-making.

Pharmacist_09 raised the point of insured members taking accountability for their health.

"Employers are paying for expensive medications because we didn’t pay attention to it twenty years ago when we should have been paying the company to have an hour of exercise during lunch hour. Think about it." (Pharmacist_09)

The pharmacist did not understand why healthcare is thought of differently; certain things were recognized as costing more and if insured members want access to specific medicines they will need to pay more to access those medicine.

"People accept this and every other facet of life except health care. Why do they challenge health care? Why is health care always the bad guy? When it is what it is. You know. You had ten wrecks you are going to pay. Okay." (Pharmacist_09)

MCOP&T_Perspective (QoL)

The MCOP&T spoke of the need to have evidence that shows differentiation vs the standard of care. If a given product is not covered there should be appeal to cover the product to assess if there is true need for the product given the patient’s medical condition and the available evidence.

"And part of that P&T committee, because there is expert opinion in that, our P&T like everybody else is made up of a mix of specialists that are, you know, that sort of cover the full range of medicine. I think you really would like to understand that literature from the perspective of that specialty about what is purported, about whether there is really evidence of that." (MCOP&T_02)
The patient’s need for a specific product with certain QoL attributes might be necessary because of his occupation such as being a performer or a politician. Hence in these cases it was important to request a formulary exception.

The opinion of the specialist on the P&T Committee has greater weight than the non-specialist when it comes to specific medical conditions. However, most medications were seen as being more similar than different hence products already on the formulary should suffice being able to provide care to the patient.

One MCOP&T spoke to the point that not all decision-makers focused on QoL and that it also needed to be in context of the medical condition. For example, QoL for managing hypertensive patients was not seen as important as there was the belief there were several good agents on the market; however, for treating arrhythmia there was need for medicines that improved QoL. Either way the MCOP&T felt he would need to work diligently to get the other committee members to understand his point of view.

“It would not matter in the P&T I work with. I can assure you that. I would be fighting for that. I would have to go probably over and beyond my usual interest in the meeting to get them to listen to something there. Probably the biggest way I would have is trying to make this work is going from the cost perspective and trying to find a way to show that whatever the difference in cost would be something back for us. Like, less time off work. Less trips to the emergency room things like that. Which I think probably get some help form the company making the drug; they would have that available.”

(MCOP&T_03)

The MCOP&T spoke of words like “fighting” and “battle”; that there was a tradeoff that always took place between patient care and cost; that there needed to be a give and take and that was probably a sign of a good P&T committee. However, MCOP&Ts spoke of that QoL was not something they generally based their decisions on.

P&T committee decisions were affected by contract requirements that were in place with other manufacturers. Adding medications to formularies could impact the rebates of other products and hence these types of factors needed to be considered in the formulary decision-making process. There would need to be savings from
other areas in order to account for the additional cost of coverage for a specific medication and it would need to be important to understand the implications of those trade-offs.

**EBDDM Perspective (QoL)**

As stated by the EBDDMs, there needs to be clinical data to support the business case. There are medications on the market that are being used to treat the primary disease; QoL is secondary to that in terms of determining treatment choices.

“…there is no medical necessity that we pay for a little better quality of sleep or social interaction. We are just trying to fix the medical issue here and in that respect we are going to do it in the most efficient way we can.” (EBDDM_10)

One of the EBDDMs spoke of the need to establish a framework that lays out the definition of roles; who is responsible for what and this will lead to greater clarity around coverage decisions and responsibility to outcomes.

“The framework, once we define… once we have a good definition of what our role is, decisions when you challenge them against your definition of role should become more apparent. Should be more apparent when you defined your role and where your role stops and when an employee’s role starts.” (EBDDM_02)

However, the EBDDM acknowledged that there should be follow-up by the EBDDM with the MCO decision-makers to understand the reasons for lack of coverage.
<table>
<thead>
<tr>
<th>Code Book</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to Rx Medicines Impacted by the Financials</td>
</tr>
<tr>
<td>Encroaching on the physician’s judgement</td>
</tr>
<tr>
<td>Defining the job of the physician</td>
</tr>
<tr>
<td>Diverging expert opinion</td>
</tr>
<tr>
<td>Having an independent panel of experts</td>
</tr>
<tr>
<td>Having differences of opinion</td>
</tr>
<tr>
<td>Having one’s hands tied</td>
</tr>
<tr>
<td>Having the ability to prescribe whatever physician wants</td>
</tr>
<tr>
<td>Having the necessary expertise</td>
</tr>
<tr>
<td>Impacting prescribing (ability to practice medicine)</td>
</tr>
<tr>
<td>Limiting decision-making</td>
</tr>
<tr>
<td>Loosing autonomy</td>
</tr>
<tr>
<td>Making decisions independent of the physician</td>
</tr>
<tr>
<td>Making generalizations based on personal experience</td>
</tr>
<tr>
<td>Not interfering with the physician-patient relationship</td>
</tr>
<tr>
<td>Overstepping bounds of expertise</td>
</tr>
<tr>
<td>Physician working with a limited set of drugs</td>
</tr>
<tr>
<td>Code Book</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Practicing medicine as physician deems best</td>
</tr>
<tr>
<td>Practicing medicine as plan deems best</td>
</tr>
<tr>
<td>Prescribing patterns of physicians vary</td>
</tr>
<tr>
<td>Recognizing evidence interpretation is subjective</td>
</tr>
<tr>
<td>Redirecting physician prescribing decision</td>
</tr>
<tr>
<td>Relying (consulting) on expertise of others</td>
</tr>
<tr>
<td>Respecting (accepting) opinion of expert</td>
</tr>
<tr>
<td>Turning physicians into robots</td>
</tr>
<tr>
<td>Understanding the physician's perspective</td>
</tr>
<tr>
<td>Varying attitudes of treating physicians</td>
</tr>
<tr>
<td>Overcoming access restrictions</td>
</tr>
<tr>
<td>Advocating on behalf of others</td>
</tr>
<tr>
<td>Advocating on behalf of self</td>
</tr>
<tr>
<td>Being resourceful</td>
</tr>
<tr>
<td>Causing additional burden for others</td>
</tr>
<tr>
<td>Creating barriers vs providing access</td>
</tr>
<tr>
<td>Creating inertia</td>
</tr>
<tr>
<td>Discouraging advocacy</td>
</tr>
<tr>
<td>Documenting</td>
</tr>
</tbody>
</table>

369
<table>
<thead>
<tr>
<th>Code Book</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gaining support of decision-maker</td>
</tr>
<tr>
<td>Having time to help everyone</td>
</tr>
<tr>
<td>Intervening (advocating) takes time</td>
</tr>
<tr>
<td>Jumping through hoops creates a lag time</td>
</tr>
<tr>
<td>Making an appeal to gain access to medicines</td>
</tr>
<tr>
<td>Taking a stance</td>
</tr>
<tr>
<td>Underlying intentions (motivations)</td>
</tr>
<tr>
<td>Understanding multiple influencers that impact on access</td>
</tr>
<tr>
<td>Understanding perspective of stakeholder</td>
</tr>
<tr>
<td>Voicing one's concerns</td>
</tr>
<tr>
<td>Reconciling business with need for providing care</td>
</tr>
<tr>
<td>Characteristics that may be contraindicated for a business</td>
</tr>
<tr>
<td>Conflicting interests</td>
</tr>
<tr>
<td>Understanding the environment of the company</td>
</tr>
<tr>
<td>Understanding where the business stops</td>
</tr>
<tr>
<td>Taking a collaborative approach</td>
</tr>
<tr>
<td>Being the go-between</td>
</tr>
<tr>
<td>Being the messenger (middle man)</td>
</tr>
<tr>
<td>Code Book</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Dealing with difficult people</td>
</tr>
<tr>
<td>Defining roles</td>
</tr>
<tr>
<td>Defining the job of the physician</td>
</tr>
<tr>
<td>Leveraging role of physician as educator</td>
</tr>
<tr>
<td>Understanding needs of others</td>
</tr>
<tr>
<td>Utilizing a team-based approach to treating the patient</td>
</tr>
<tr>
<td>Working as a team</td>
</tr>
<tr>
<td>Working at odds to each other</td>
</tr>
<tr>
<td>Working within the system</td>
</tr>
<tr>
<td>Dealing with reality</td>
</tr>
<tr>
<td>Working within the constraints of the system</td>
</tr>
<tr>
<td>Drug Formularies Means to an End</td>
</tr>
<tr>
<td>Assessing role of ethics in access decision-making</td>
</tr>
<tr>
<td>Compromising ethics for economics</td>
</tr>
<tr>
<td>Keeping your promise</td>
</tr>
<tr>
<td>Lacking compassion</td>
</tr>
<tr>
<td>Needing ethics because cost matters</td>
</tr>
<tr>
<td>Practicing ethics is not the remit of P&amp;T Committees</td>
</tr>
<tr>
<td>Taking emotions out of decision-making</td>
</tr>
<tr>
<td>Code Book</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td><strong>Dealing with economics</strong></td>
</tr>
<tr>
<td>Getting what you pay for</td>
</tr>
<tr>
<td>Granting access if bringing value to the organization</td>
</tr>
<tr>
<td>Having the ability to pay (willingness to pay)</td>
</tr>
<tr>
<td>Identifying who should pay for access</td>
</tr>
<tr>
<td>Limiting (controlling) care to increase profit</td>
</tr>
<tr>
<td>Making decisions based on dollars</td>
</tr>
<tr>
<td>Making decisions best for the organization</td>
</tr>
<tr>
<td>Making money (running a business)</td>
</tr>
<tr>
<td>Managing profits</td>
</tr>
<tr>
<td>Minimizing liability</td>
</tr>
<tr>
<td>Patients who are sick having to pay more</td>
</tr>
<tr>
<td>Realizing that access comes at a price</td>
</tr>
<tr>
<td>Recognizing cost is a factor</td>
</tr>
<tr>
<td>Shifting cost to the patient</td>
</tr>
<tr>
<td>Spending less</td>
</tr>
<tr>
<td>Staying economically viable</td>
</tr>
<tr>
<td>Defining the minimum acceptable level</td>
</tr>
<tr>
<td>Defining (providing) what is acceptable (appropriate)</td>
</tr>
<tr>
<td>Code Book</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>Differentiating between needs and wants</td>
</tr>
<tr>
<td>Having access to more than reasonable care a privilege</td>
</tr>
<tr>
<td>Making the plan affordable</td>
</tr>
<tr>
<td>Providing affordable care</td>
</tr>
<tr>
<td>Exercising fiduciary responsibility</td>
</tr>
<tr>
<td>Acting responsibly (accountable)</td>
</tr>
<tr>
<td>Allocating resources</td>
</tr>
<tr>
<td>Being reasonable</td>
</tr>
<tr>
<td>Being trustworthy</td>
</tr>
<tr>
<td>Defining fiduciary responsibility (due diligence)</td>
</tr>
<tr>
<td>Ensuring patients do not overuse services</td>
</tr>
<tr>
<td>Finding a balance (compromise)</td>
</tr>
<tr>
<td>Providing (company) oversight</td>
</tr>
<tr>
<td>Recognizing one’s obligation</td>
</tr>
<tr>
<td>Understanding consequences of choice</td>
</tr>
<tr>
<td>Wasting resources</td>
</tr>
<tr>
<td>Informed Decision-making Essential to Understanding Implications of Choice</td>
</tr>
<tr>
<td>Enabling decision-making</td>
</tr>
</tbody>
</table>
**Code Book**

<table>
<thead>
<tr>
<th>Being informed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communicating information (options)</td>
</tr>
<tr>
<td>Defining (having) processes to inform decisions</td>
</tr>
<tr>
<td>Educating</td>
</tr>
<tr>
<td>Having (providing) options</td>
</tr>
<tr>
<td>Having transparency</td>
</tr>
<tr>
<td>Influencing behaviour (actions)</td>
</tr>
<tr>
<td>Providing choice</td>
</tr>
<tr>
<td>Recognizing benefit of (providing) counselling</td>
</tr>
<tr>
<td>Taking time to understand the plan benefits</td>
</tr>
<tr>
<td>Setting parameters to inform access decisions</td>
</tr>
<tr>
<td>Being consistent</td>
</tr>
<tr>
<td>Benchmarking to the marketplace</td>
</tr>
<tr>
<td>Establishing (adhering to) societal (professional) norms</td>
</tr>
<tr>
<td>Following rules</td>
</tr>
<tr>
<td>Having the ability (willingness) to make changes in coverage</td>
</tr>
<tr>
<td>Making exceptions (setting precedent)</td>
</tr>
<tr>
<td>Making rules for the exceptions</td>
</tr>
<tr>
<td>Code Book</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Recognizing society's role in rule-setting</td>
</tr>
<tr>
<td>Separating clinical decisions from financial interests</td>
</tr>
<tr>
<td>Willing to accommodate (change) given the unexpected</td>
</tr>
<tr>
<td>Understanding the trade-offs</td>
</tr>
<tr>
<td>Handling risk and information</td>
</tr>
<tr>
<td>Rationalizing</td>
</tr>
<tr>
<td>Taking a gamble</td>
</tr>
<tr>
<td>Utilizing evidence to inform decision-making</td>
</tr>
<tr>
<td>Accounting for QoL as important as clinical</td>
</tr>
<tr>
<td>Analyzing the data to understand implications</td>
</tr>
<tr>
<td>Basing decisions on evidence</td>
</tr>
<tr>
<td>Basing decisions on observed outcome</td>
</tr>
<tr>
<td>Choosing less expensive therapy first (step edit)</td>
</tr>
<tr>
<td>Defining what is clinically meaningful</td>
</tr>
<tr>
<td>Having necessary information to inform treatment</td>
</tr>
<tr>
<td>Lacking clear differentiation that is meaningful</td>
</tr>
<tr>
<td>Not knowing tx effect a priori</td>
</tr>
<tr>
<td>Relating to treatment effect including cost</td>
</tr>
<tr>
<td>Trying the least expensive option first</td>
</tr>
<tr>
<td>Code Book</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>Understanding factors that impact on suboptimal outcomes</td>
</tr>
<tr>
<td>Population vs Patient Level Care Not necessarily Reconcilable</td>
</tr>
<tr>
<td>Managing at the population level treats to the average</td>
</tr>
<tr>
<td>Doing what is in the best interest of the many</td>
</tr>
<tr>
<td>Falling into oblivion (not being recognized)</td>
</tr>
<tr>
<td>Meeting 100% of the population's needs</td>
</tr>
<tr>
<td>Providing care at the individual vs population level</td>
</tr>
<tr>
<td>Resolving (making) access decisions based on the population</td>
</tr>
<tr>
<td>Treating the individual patient</td>
</tr>
<tr>
<td>Benefiting the patient</td>
</tr>
<tr>
<td>Compromising patient care</td>
</tr>
<tr>
<td>Giving the patient (employee) the best</td>
</tr>
<tr>
<td>Persuading the patient</td>
</tr>
<tr>
<td>Reflecting patient's preference</td>
</tr>
<tr>
<td>Taking into account consequence to patient</td>
</tr>
<tr>
<td>Treating all patients equally</td>
</tr>
<tr>
<td>Understanding the patient makes the Rx choice</td>
</tr>
</tbody>
</table>
Benevolence vs the economics & business goals of Employers and MCOs

Care is determined by the Contract that has been purchased

Care provided, needs to be reasonable; anything other than reasonable care is a privilege

Formularies are access deterrents: struggle (hassle factor) for HCPs & patients

MCOs look to lower premiums by shifting cost to patients

Physicians believe they have the best interest of the patient in mind

Informed Decision-making Essential to Understanding Implications of Choice

Trusting in the recommendations of experts

Understanding consequences of purchase

Patients ultimately accountable for their health and in making treatment choices

Team-based approach improves healthcare outcomes

Formularies not necessarily fair to the individual patient

HCP follow-up is an important element to improve patient-specific outcomes

Patient autonomy and self-worth potentially compromised due to lack of access
Appendix G: Search Terms

The following search terms were utilized for each of the following search engines.

EMBASE

1. ethics AND healthcare: 12,156
2. ethics AND healthcare AND ‘managed care’: 135
3. ethics AND healthcare AND ‘formulary’: 9
4. ethics AND ‘formulary management’: 4
5. ethics AND 'access to medicines': 66
6. healthcare AND utilitarianism: 31
7. ‘access to medicines' AND utilitarianism: 0
8. healthcare AND deontology: 58
9. ‘access to medicines’ AND deontology: 0
10. healthcare AND ‘virtue ethics’: 29
11. 'access to medicines' AND ‘virtue ethics’: 0
12. healthcare AND ‘biomedical ethics’: 261
13. ‘access to medicines’ AND ‘biomedical ethics’: 0
14. healthcare AND justice: 2,418

15. ‘access to medicines’ AND justice: 19

16. healthcare AND autonomy: 2,991

17. ‘access to medicines’ AND autonomy: 12

18. healthcare AND beneficence: 367

19. ‘access to medicines’ AND beneficence: 4

20. healthcare AND maleficence: 66

21. ‘access to medicines’ AND maleficence: 2

22. healthcare AND ‘business ethics’: 68

23. ‘access to medicines’ AND ‘business ethics’: 2

24. healthcare AND trust: 28.908

25. ‘access to medicines’ AND trust: 41

26. healthcare AND ‘procedural fairness’: 3

27. ‘access to medicines’ AND procedural fairness’: 0

28. healthcare AND fairness: 212
29. 'access to medicines' AND fairness: 4

30. 'physician rights' AND prescribing: 0

31. 'patient rights' AND 'filling a medication': 0

32. 'community pharmacists' AND ethics: 67

33. 'community pharmacists' AND autonomy: 6

34. 'community pharmacist' AND beneficence: 1

35. 'community pharmacist' AND maleficence: 1

36. 'community pharmacist' AND justice: 4

37. 'P&T Committee' AND ethics: 3

38. 'procedural fairness' AND ethics: 16

39. 'procedural fairness' AND 'formulary management': 0

Web of Science (1990 and Later)

1. ethics AND 'access to medicines': 336

2. ethics AND healthcare: 2,432

3. healthcare AND 'business ethics': 67
4. ethics AND ‘formulary management’: 4

5. healthcare AND utilitarianism: 18

6. healthcare AND deontology: 17

7. healthcare AND ‘virtue ethics’: 38

8. healthcare AND justice: 670

9. healthcare AND autonomy: 1,375

10. healthcare AND beneficence: 85

11. healthcare AND maleficence: 29

12. ‘allocation of resources’ AND ethics: 527

13. ethics AND ‘formulary management’: 4

14. ‘healthcare rights’ AND ‘access to medicines’: 243

15. ‘healthcare rights’ AND formularies: 22

16. ‘healthcare rights’ AND ‘managed care’: 598

17. trust AND ‘managed care’: 1,118

18. ‘informed decision making’ AND formularies: 47

381
19. pharmacists AND ethics AND managed care: 9

20. physicians AND ethics AND managed care: 298

**PubMed**

1. ethics AND healthcare: 55,801

2. ethics AND formularies: 63

3. 'managed care' and "business ethics": 105

4. ‘allocation of resources’ AND autonomy: 1,259

5. ‘allocation of resources’ AND justice: 2,241

6. ‘allocation of resources’ AND beneficence: 462

7. ‘allocation of resources’ AND maleficence: 11

8. 'informed decision making' and formularies: 5

9. ‘allocation of resources’ AND utilitarianism: 573

10. 'allocation of resources' AND deontology: 6

11. 'allocation of resources' AND ‘virtue ethics’: 107

12. 'allocation of resources' AND healthcare AND 'business ethics' 61
13. 'allocation of resources' AND 'managed care' AND 'business ethics': 24

14. physicians AND autonomy AND 'managed care': 354

15. physicians AND justice AND 'managed care': 73

16. physicians AND beneficence AND 'managed care': 25

17. physicians AND maleficence AND 'managed care': 3

18. pharmacists AND maleficence AND 'managed care': 0

19. pharmacists AND beneficence AND 'managed care': 0

20. pharmacists AND autonomy AND 'managed care': 9

21. pharmacists AND justice AND 'managed care': 3

22. 'managed care' AND formularies AND ethics: 17

Global Health 1973 to 2017 Week 40, Books@Ovid October 16, 2017, Your Journals@Ovid, Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily, Ovid MEDLINE and Versions(R)

1. 'managed care' AND formularies AND ethics: 30

2. healthcare AND 'business ethics': 31

3. formularies AND 'informed decision making': 8

383
4. physicians AND autonomy AND 'managed care': 938

5. pharmacists AND formularies AND 'managed care': 68

6. autonomy AND 'allocation of resources' AND healthcare: 66

7. justice AND 'allocation of resources' AND healthcare: 51

8. ‘informed decision making’ AND formularies: 8
Appendix H: REC Approved Application

Royal College of Surgeons in Ireland
The Research Ethics Committee
121 S. Stephens Green, Dublin 2, Ireland.
Tel: +353 1 4022373  Fax: +353 1 4022205  Email: recadmin@rcsi.ie

Dr. David Smith, Acting Chair
Dr. Niamh Clarke, Convenor

20th November 2013

Mr Roy Bentley

Department of General Practice,
Royal College of Surgeons in Ireland,
Beaum Lane House,
Mercers Street Lower,
Dublin 2

<table>
<thead>
<tr>
<th>Ethics Reference No:</th>
<th>REC872</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Title:</td>
<td>Ethical Implications of Market Access to Medicines in the United States</td>
</tr>
<tr>
<td>Researchers Name (lead applicant):</td>
<td>Mr Roy Bentley</td>
</tr>
<tr>
<td>Principle investigator of the project</td>
<td>Dr David Smith (RCSI)</td>
</tr>
<tr>
<td>Other Individuals Involved:</td>
<td>Dr Judith Strawbridge (RCSI)</td>
</tr>
</tbody>
</table>

Dear Mr Bentley,

Thank you for your Research Ethics Committee (REC) application. We are pleased to advise that ethical approval has been granted by the committee for this study.

This letter provides approval for data collection for the time requested in your application and for an additional 6 months. This is to allow for any unexpected delays in proceeding with data collection. Therefore this research ethics approval will expire on 19th November 2014.

Where data collection is necessary beyond this point, approval for an extension must be sought from the Research Ethics Committee.

This ethical approval is given on the understanding that:

- All personnel listed in the approved application have read, understand and are thoroughly familiar with all aspects of the study.
- Any significant change which occurs in connection with this study and/or which may alter its ethical consideration must be reported immediately to the REC, and an ethical amendment submitted where appropriate.
- Please submit a final report to the REC upon completion of your project.

We wish you all the best with your research.

Yours sincerely,

[Signature]

PP Dr. Niamh Clarke (Convenor)
Dr David Smith (Acting Chair)
Bibliography


69 CMS 2016. National Health Expenditures 2016 Highlights


74 COULTER, A. 2007. When should you involve patients in treatment decisions? Br J Gen Pract, 57, 771-772.


391


130 GLOBAL HEALTHY LIVING FOUNDATION 2017. Survey Finds Insurance Companies are Forcing Floridians Off Prescribed Medications During the Plan Year, Providing A Need for New Legislation to Fix the Problem.


394


MANDEVILLE, B. & KAYE, F. B. 1957. *The fable of the bees; or, Private vices, publikk benefits, with a commentary critical, historical, and explanatory by FB Kaye*. 


MASON, M. 2010. Sample Size and Saturation in PhD Studies Using Qualitative Interviews.


MILL, J. S. 1869. On liberty, Longmans, Green, Reader, and Dyer.


NEUMANN, P. C., JAMES; SIMON, FRANÇOISE; MECKLEY, LISA; 2011. Risk-sharing arrangements that link payment for drugs to health outcomes are proving hard to implement. Health Affairs, 30, 2329-2337.


utilization and medication-taking behavior: a systematic literature review. *Current Medical Research and Opinion*, 32, 1281-1290.


SCOTT, W. R. 1900. Francis Hutcheson: his life, teaching and position in the history of philosophy, at the University Press.


STATE OF VIRGINIA CODE OF LAW § 38.2-5800.


STEPHANIE NAM, P. 2016. Ethical Challenges Pharmacists Face When Managing Noncompliant Patients *Pharmacy Times*.


