

Investigating the Economic Impact of Mandatory Electronic Prescribing Requirements in the United States

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ABSTRACT

Purpose

Technological advancements applied to healthcare may holistically improve the economic burden of prescription medication costs. United States legislative actions requiring utilization of electronic prescribing (e-prescribing) will drive provider utilization to decrease healthcare spending. Federal and state e-prescribe requirements have been met with resistance by the prescribing community, due to claims that the requirements create an economic burden for them. This research intends to demonstrate the long-term economic value of electronic prescribing regulations across the healthcare spectrum.

Methods

Research methodology included a systematic literature review across the spectrum of regulatory action in the United States, government electronic prescribing resources, and applicable studies which review electronic prescribing impacts. An exploratory mixed methods design focusing on a holistic qualitative review using thematic analysis, followed by quantitative investigation and cost-benefit analysis was performed (Creswell, 2010).

Results

Economic impacts of legislation requiring the e-prescribing channel were found to be positive and negative. Initial costs were higher for healthcare providers as electronic prescribing was implemented, however, maintenance costs and value gained over the long-term is recognized for patients, the government, providers, and the healthcare system. Improved patient outcomes also create holistic cost reductions.

Conclusion

Regulatory actions in the United States driving a shift in prescription channels to electronic prescribing have an initial short-term cost investment resulting in a long-term cost reduction for the overall healthcare system.

GLOSSARY OF TERMS

DEA	The Drug Enforcement Administration is the agency under the US Department of Justice responsible for enforcing federal laws and regulations regarding controlled substances.
EHR	The Electronic Health Record is the comprehensive medical profile for a patient across all providers of services for that patient.
EMR	The Electronic Medical Record is a standalone medical record for a patient from one provider of services.
E-prescribe	Electronic Prescribing
ERx	Electronic Prescribing
Medicare	The United States federally funded health insurance program for qualified individuals over 65 years old or with certain disabilities and medical conditions.
Medicaid	The United States health insurance program administered by the individual states and funded by the federal government for qualified individuals with low incomes.
NCPDP	A standards development organization responsible for standards development for electronic transmissions associated with pharmacy and healthcare services.
SCRIPT	This is an annually published standard from NCPDP that outlines electronic transmission requirements for electronic prescribing between prescribers, pharmacies, payers, and others.
Surescripts	An organization providing the Information Technology framework for electronic prescribing technology transmissions.
Specialty	A United States terminology for pharmacy services for complex and chronic conditions treated with drugs requiring special handling, contracting, government safety programs, and/or expense.

ACRONYMS

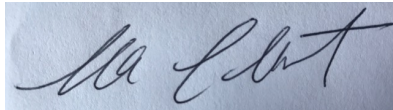
ACA	Affordable Care Act
AMCP	Academy of Managed Care Pharmacies
APhA	American Pharmacists Association
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CMS	Centers for Medicare & Medicaid Services
CPOE	Computerized Prescriber Order Entry
DEA	Drug Enforcement Administration
DMEPA	Division of Medication Error Prevention and Analysis
EHR	Electronic Health Record
EMR	Electronic Medical Record
FDA	Food and Drug Administration
HHS	United States Department of Health & Human Services
HITECH	Health Information Technology for Economic and Clinical Health Act
ISMP	Institute for Safe Medication Practices
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
NABP	National Association of Boards of Pharmacy
NCPDP	National Council for Prescription Drug Programs
US	United States of America
WHO	World Health Organization

DECLARATION

I declare that this thesis that I now submit for assessment on the programme of study leading to the degree Master of Science in Pharmacy Administration and Policy Regulation has not been submitted for the purpose of a degree at this or any other higher education institution. It is entirely my own work and has not been taken from the work of others, save the extent that such work has been cited and acknowledged within the text of my work.

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A rectangular image showing a handwritten signature in black ink on a light blue background. The signature is cursive and appears to read 'M. E. O.'.

Dated

September 25, 2017

ACKNOWLEDGEMENTS

I would like to acknowledge all that have influenced, supported, and guided this research effort including my family, educators, leaders, preceptors, and mentors. Additionally, I dedicate the efforts of my research to my mother, who perished on August 29, 2017 following a lengthy battle with colon cancer.

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CHAPTER 1 INTRODUCTION

Economic burdens on the United States (US) government and individual patients from prescription medicines and administrative costs are significant (Catlin, Cowan, Hartman, & Heffler, 2008; Trish, Joyce, & Goldman, 2014). Technological advancements applied to the healthcare system have the opportunity to reduce those costs (Ducker, Sanchez, & Taylor, 2013). Electronic prescribing (e-prescribe) is one such technological advancement that has radically changed the practice of pharmacy in the retail and ambulatory setting (Ducker, Sanchez, & Taylor, 2013). Governmental regulations requiring utilization of electronic prescribing for legend medications will drive an economic improvement on healthcare spending in the United States (Porterfield, Engelbert, & Coustasse, 2014). Recent examples of e-prescribe requirements have surfaced through federal incentive acts for government-funded health insurance programs and regulations passed in the state of New York (Centers for Medicare & Medicaid Services, 2014; NY State Department of Health, 2016; Ogundimu & Tommasculo, 2011). Additional US states have demonstrated an interest in following New York with e-prescribing mandates and therefore it is imperative to understand the economic impact that can be recognized with these changes (NABP, 2016).

Healthcare expenditure related to prescription drug has changed since the turn of the century. The shift has been from traditional prescription medications to new modalities available for complex and chronic conditions that require special administration, monitoring, patient counseling, and product storage. These newer modalities include higher cost biologicals and injectables which made up over 70% of the drug trend in 2010 (Jacobs & Johnson, 2012). Health coverage insurers have employed various programs to cut costs associated with prescription drugs including rising costs for complex and chronic conditions. Strategies have included drug formularies, prior authorizations, and shifting drugs distribution channels (Patel & Audet, 2014; Wehrwein, 2015). As the frequency of these strategies increases the need to better manage the prescription channel between the prescriber and the pharmacy becomes more critical. Pharmacoeconomic management strategies have therefore expanded to government payer and state regulatory

oversight through electronic exchange of health information including e-prescribing (Centers for Disease Control and Prevention, 2016).

Electronic prescribing is defined in the United States Code of Federal Regulations (CFR) as the “transmission using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser” (United States Government Publishing Office, 2016). Current electronic prescribing federal requirements in the United States were enacted as a part of the Health Information Technology for Economic and Clinical Health (HITECH) Act. The HITECH Act was enacted in 2009 and includes three stages that provide incentives for healthcare providers to exchange health information electronically. Penalties occur in the form of reduced payments for services rendered for government insured patients (Centers for Disease Control and Prevention, 2016). E-Prescribing is one of the specific requirements that the HITECH Act promotes as an extension of the Medicare Modernization Act of 2003 administered by the Center for Medicare and Medicaid Services (Centers for Medicare & Medicaid Services, 2014). Beyond the insurer mandated electronic prescribing, more restrictive regulatory mandates through the state of New York began in March 2015 (NY State Department of Health, 2016).

Electronic prescribing benefits include a reduction in adverse drug events and quality improvements derived from eliminating interpretation of handwritten prescriptions and electronic databases that guide users on appropriate drug and dose selection. Many electronic prescribing software packages also include immediate drug utilization review applications and prior authorization management at the point of prescriber transmission. Systems also have the opportunity to track and report on patient medication adherence. Improvements in patient access through immediate transmission benefit the patient with shorter wait times for medication. Additional benefits include the resultant e-prescribing functionality decreasing interpretative and administrative pharmacy roles to move towards more cognitive functions that benefit the healthcare system. Collectively all of these benefits contribute to improved economic outlooks

for pharmacies, prescribers, and consumers (Powers, Gabriel, Encinosa, Mostashari, & Bynum, 2015; Esmacil Zadeh & Tremblay, 2016; Qureshi et al., 2015).

Establishing electronic prescribing capabilities is a significant shift for the medical community. Hospital systems, physician practice groups, and independent physicians require a transition from paper records or standalone computer software to more elaborate certified electronic health record (EHR) systems. Hundreds of different electronic systems are available and they vary in cost and complexity of transitioning existing records to the new systems (Health Resources & Services Administration, 2016). Systems must also meet regulatory security encryption requirements and certifications to legally transmit prescriptions to a licensed pharmacy. Integration and communication with external partners in the healthcare supply chain, therefore, drive the system set-up requirements to insurers, pharmacy benefit managers, and finally the pharmacy dispensing the prescription. Therefore the initial equipment and administrative costs across the prescription supply chain are economically impactful.

E-prescribing has been met with distrust and resistance by some members of the prescribing community (Crosson, Schueth, Isaacson, & Bell, 2012). Those resisting mandatory change and regulations for e-prescribing have indicated that it creates an economic burden for their practices and facilities. The economic burden stems from changes to the management of electronic medical records and software required to facilitate e-prescribe. Additional staff to support e-prescribe is also an administrative economic burden cited as impacting prescribers (Gagnon, Nsangou, Payne-Gagnon, Grenier, & Sicotte, 2014). This research intends to demonstrate the long-term economic impact of mandatory electronic prescribing technology across the healthcare spectrum.

Research also intends to demonstrate the qualitative aspects of e-prescribe to patients, prescribers, and regulators. Although some aspects of improved care can be extrapolated to cost savings through lost time at work or long-term medical spend, the sustainable healthcare network generated with e-prescribe technology does not have a distinct price tag.

CHAPTER 2 LITERATURE REVIEW

2.1 INTRODUCTION

Electronic prescribing utilization has increased in the United States following pivotal government policies that started an e-prescribe trend that has become embedded in regulatory frameworks throughout the country (Gabriel & Swain, 2014). This literature review will show the evolution of that regulatory transition. There are five sections explored in the literature review to demonstrate healthcare economics, e-prescribe technology, federal requirements in the US, individual state requirements in the US, and finally the motivation that regulatory bodies have provided for bringing about e-prescribe requirements.

The environment of healthcare spending is the first area explored, to set the stage for demonstrating the opportunity that exists in the United States with regard to rising health care expenditures. Following that the technology of electronic prescribing as used in the United States will be described in detail. The technology details are critical because the regulatory framework is dependent on the details and furthermore the required monetary output for the technology user is dependent on those details. Federal requirements resulting from that framework will then be explained as well as the economic impact of incentives tied to those requirements. Mandated requirements of individual states of the country will subsequently be explored since in the United States the majority of laws and regulations governing the practice of pharmacy are left to the discretion of the individual states. Finally, the motivations provided by the regulatory bodies for the e-prescribe requirements will be explored in preparation for understanding the relationship between those motivations and the qualitative and quantitative factors of overall economic impact.

2.2 HEALTH CARE SPENDING

The United States Centers for Medicare & Medicaid Services (CMS) reports that total expenditure growth for national health is expected at a rate of 5.6% each year from 2016 to 2025 (Keehan, et al., 2017). This is an increase following a 2016 total spend of almost \$3.4 trillion. Prescription medicine spend has a higher expected average expenditure growth over that same period of 6.4%. Inflationary rates specific to medical spending during that time period are also projected to rise from 0.8% to 3%. It is notable that prescription medicine costs contributing to healthcare spending in the United States differs from other countries. Prescription medicine costs in the United States are higher than other industrialized nations by more than double (Kesselheim, Avorn, & Sarpatwari, 2016). The opportunity to assess and reduce prescription medicine costs in the United States has therefore been demonstrated.

2.3 E-PRESCRIBE TECHNOLOGY

Electronic prescribing, also termed in literature as e-prescribe and E-RX, did not become legal across all 50 US states until 2007. Prior to that time, many forms of it existed sparked by Pharmacy Benefit Managers (PBM's), pharmacies interested in physician steering, and as a product of computerized pharmacy systems (Salmon & Jiang, 2012). Regulatory acceptance of e-prescribe required a sophisticated set of functional requirements. These requirements include the ability of the information sent from the prescriber's software to be in the same technological language translated to the pharmacy software through a set of standards (Leavitt, 2007). In addition, certification of the pharmacy application through audit at a routine frequency, record keeping requirements, access requirements and reporting, and two factor authentication are all aspects of e-prescribe technology under the microscope of regulators (United States Government Publishing Office, April 2016).

The Health Information Network (HIN) for e-prescribing consists of an exchange of information between pharmacies, payers, and prescribers (Agency for Healthcare Research and Quality, US Department of Health & Human Services, 2011). Prescription transactions within the e-prescribe workflow can include new prescription transmission, refills, renewals, and change requests

(NCPDP, 2014). Additional transactions can include notification of patient receipt, DUR, benefits check, medication profile review, and drug formulary review (Agency for Healthcare Research and Quality, US Department of Health & Human Services, 2011). The NCPDP, an accredited standards development organization, published their SCRIPT standard in 1997 (National Council for Prescription Drug Programs, 2014). SCRIPT helps the sender and receiver by standardizing the different data fields required for prescription transmission (Drug Enforcement Administration, 2010). It brings alignment and defines different segments of the HIN and also defines the type of transaction such as a new or a refill prescription. SCRIPT is a requirement by the Federal government for Medicare programs according to §423.160 Standards for electronic prescribing as of January 2012 (United States Government, 2012).

The individual participants within the network have a broad selection of software vendors that can be utilized for e-prescribing technology (Modern Medicine Network, 2013). Electronic Health Record (EHR) software allows for a broad sharing of information across multiple participants in the workflow as opposed to an Electronic Medical Record (EMR) which is specific to one provider (HealthIT.gov, September 2016). Certification of the EHR is outlined with extensive criteria by the US Government in Title 45, Title A, Subchapter D, PART 170—Health Information Technology Standards, Implementation Specifications and Certification Criteria and Certification Programs for Health Information Technology. This criterion includes Functional Standards, Content Exchange Standards, protection of electronic health information, and certification criterion (United States Government Publishing Office, October 2016).

Network organizations facilitating the secure exchange of information are another aspect that brings the technology workflow together. One intermediary, SureScripts/RxHub, certifies electronic prescription and pharmacy applications for compliance with the SCRIPT standard; Surescripts, is one of 105 highly certified intermediary firms that partners with over 700 EHR applications (Surescripts, 2016). They are responsible for assessing if SCRIPT standards are met and the information is produced according to those standards by the transmitter and capable of being opened and read by the recipient of the prescription information (Terry, March 2016). According to Surescripts data on e-prescribing in February 2016, approximately 58% of

prescribers in the United States are enabled to e-prescribe non-controlled substances and 70% of New York prescribers are enabled to e-prescribe non-controlled substances. The numbers are less for controlled substances at 8% and 47% respectively (Odukoya & Chui, 2013). Overall prescription volumes have shifted tremendously since 2008, increasing from only 7% of prescriptions prescribed through an EHR to 70% in 2014 (Gabriel & Swain, 2014).

2.4 E-PRESCRIBE REGULATIONS IN THE UNITED STATES

2.4.1 FEDERAL REQUIREMENTS

2.4.1.1 Medicare Improvements for Patients and Providers Act

CMS, a part of the Department of the Health and Human Services of the United States, initiated federal legislative incentives for e-prescribe utilization with the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). This allowed for diminishing incentives to EP over a 5 year period for using e-prescribe and also created increasing penalties starting in 2012 if e-prescribe was not used by EP (Centers for Medicare & Medicaid Services, 2008). Incentives started at 2% of Medicare Part B claims in 2009 and penalties of 2% of claims for not using e-prescribe by 2014 (Minnesota E-Health, 2009). This program ended in 2014; however, more comprehensive health technology efforts that encompassed e-prescribe were enabled prior to its end (Centers for Medicare & Medicaid Services, 2014).

2.4.1.2 The HITECH Act

The HITECH Act is a significant piece of legislation in the United States that propelled healthcare into the technology age (HealthIT.gov, 2014). It expands e-prescribing efforts of the MIPPA of 2008 to a more comprehensive health technology objective. The Health Information Technology for Economic and Clinical Health Act consists of Title XIII and four subtitles under the 2009 American Recovery and Reinvestment Act. The first subtitle is the most impactful in steps towards positive economic trends in healthcare and is specifically responsible for the promotion of Health Information Technology. Electronic Medical Records (EMR) are the backbone of the HITECH Act that incentivizes healthcare providers to provide “meaningful use”

of the technology in their practices. One of the primary EMR applications is the utilization of electronic prescribing. The effectiveness of the electronic prescribing is further enhanced by other aspects of the meaningful use of the EMR through additional computer applications such as drug utilization review, disease state contraindications, and lab records.

Incentives provided by the HITECH Act were significant at inception for providers serving Medicare and Medicaid recipients. Individual clinicians could benefit over a ten year period to \$44,000 through billing to Medicare and \$63,750 through billing to Medicaid (Blumenthal & Tavenner, 2010; Electronic Health Record Incentive Program & Centers for Medicare & Medicaid Services, 2013). The overall reach of the HITECH Act in 2010 was aimed at EMR use by as many as 700,000 clinicians (EP - eligible professionals). Hospital utilization was also aimed at 5000 acute care hospitals (EH - eligible hospitals) (Electronic Health Record Incentive Program & Centers for Medicare & Medicaid Services, 2013). Being driven by the Centers for Medicare Services (CMS) the HITECH Act incentivizes those prospective administrators of healthcare. Initial requirements in 2011 for mandatory reporting by EP was required at a minimum ten times annually. Failure to comply resulted in reduced compensation to that EP (McBride, 2012). Therefore, it could be considered to have a mandatory aspect as a result of the penalties that it imposes for EP and EH that don't comply, to the tune of an initial 1% reduction in fee reimbursement that is followed by a 3% reduction in 2017 (Centers for Disease Control and Prevention, 2016).

2.4.1.3 Federal E-Prescribe Requirements

The Drug Enforcement Agency (DEA) published a rule for the electronic prescribing of controlled substances in March 2010 (Drug Enforcement Administration, 2010). This rule went into effect in June of that year, paving the way for the expansion of electronic prescribing throughout the United States. The published DEA's Interim Final Rule with Request for Comment titled "Electronic Prescriptions for Controlled Substances" [Docket No. DEA-218, RIN 1117-AA61] provides authority but not mandate for e-prescribing of controlled substances. Requirements to utilize e-prescribing are very specific to ensure secure signature by an

authorized prescriber and transmission of the controlled substance to the dispensing pharmacy. The DEA requires two-factor authentication of the prescriber signature. In addition to transmission, the prescriber must obtain an audit by a third party or certification body of their system that demonstrates compliance with the DEA's requirements and results in a certification to e-prescribe controlled substances. Finally, registration of the software with the DEA is required.

2.4.2 STATE REQUIREMENTS

Federal laws and regulations are supreme to state laws and regulations in the United States according to the US Constitution Article VI, Section 2 (United States Government, n.d.). Therefore each state is required to adhere to the Federal law but can pass laws or regulations that are more stringent for their state. Currently, only three states have statutes that require some aspect of e-prescribe. Active states include New York and Minnesota, with Maine e-prescribe requirements going into effect in mid-2017. Other states that have considerations for e-prescribe regulations include Massachusetts, according to Superscripts representatives (Terry, March 2016).

2.4.2.1 New York E-Prescribe

An update to Title 10 NYCRR Part 80 Rules and Regulations on Controlled Substances laid the framework for the move to mandatory e-prescribing of prescription drugs in the state of New York (NY) when it became effective on March 27, 2016 (New York State, 2016). On March 27, 2016, the State of NY's mandate for mandatory e-prescribing went into effect for all licensed NY healthcare prescribers (Vinciguerra, 2015; Bureau of Narcotic Enforcement, New York State Department of Health, 2016). The start date was delayed a year from the initial target date to provide sufficient time for providers to acquire and implement the necessary resources to facilitate e-prescribing. The e-prescribing requirements apply to non-controlled and controlled (Schedule 2 to 5) substances, following the federal requirements for a certified e-prescribing system. Providers are also required to register their systems with the NY Department of Health.

Exceptions to New York's e-prescribing mandate have been added following the original mandate notification, and outlined in Article 2A - Section 281, The Prescription Drug Reform Act- Chapter 447 of the laws of 2012, and Title 10 Part 80 of the Official Compilation of Codes, Rules and Regulations of the State of New York (§80.64(c)(3)) (Bureau of Narcotic Enforcement, New York State Department of Health, 2016). Prescriptions that are not well supported by current e-prescribing technology such as compounded medications, orders with long directions, and orders that have certain FDA requirements, may be exempt by a blanket waiver (Zucker, 2016). Situational exceptions also apply to the blanket waiver including prescribing opioid antagonists, public health emergencies, research protocol prescribing, technology failures, patient health and safety concerns rendering e-prescribing impractical (New York State Department of Health, April 2016), and for certain dispensing activities in nursing home long-term care facilities. Individual prescribers are also permitted to apply to New York for limited waivers on the basis of economic hardships or technological limitations (New York State Department of Health, February 2016).

A significant aspect of the NY e-prescribing mandate is that it includes enforcement protocols that can result in prescriber fines or penalties managed by the Office of Professional Misconduct (Terry, March 2016). It also places the burden of compliance on the prescriber rather than the pharmacy to report instances of prescriptions issued outside of the e-prescribe regulations.

2.4.2.2 Minnesota E-Prescribe

In 2008 the state of Minnesota enacted requirements that would take effect in January 2011 for mandatory e-prescribing according to Minnesota Statutes 62J.497 Electronic Prescription Drug Program Subd. 2 (Minnesota Department of Health, 2015). The mandate is applicable to pharmacies, healthcare providers, and healthcare facilities, with the exception of long-term care (LTC) and system compliance can follow NCPDP or HL-7 according to federal standards (Office of Health Information Technology Minnesota Department of Health, 2011). As an incentive for prescribers to utilize e-prescribing in conjunction with an electronic health record (EHR) the Minnesota Department of health offers an interest-free financing option to establish an EHR

(Minnesota Department of Health, 2015). There are however no penalties or disciplinary actions at this time by the Minnesota Department of Health (MDH) for violators of the mandate. Instead, the MDH warns of punitive factors such as increased provider liability and negatively impacted patient outcomes (Office of Health Information Technology Minnesota Department of Health, 2011). Additionally, the MDH acknowledges the continued use of paper prescriptions as acceptable under necessary circumstances, which is much less restrictive than the New York requirements for prescribers to notify the state whenever a paper prescription is utilized.

2.4.2.3 Maine E-Prescribe

In March 2016 the state of Maine passed the requirement for mandatory e-prescribing utilization by January 1, 2018 (Maine Medical Association, March 2016). The Legislative Document “An Act to Prevent Opiate Abuse by Strengthening the Controlled Substances Prescription Monitoring Program”, LD 1646, is the public law that requires licensees to only prescribe opioids through e-prescribe channels. Additionally, this law has requirements for monitoring of patients’ opioid utilization, advertising restrictions, and opioid quantity limitations. The motivation for Maine is clearly opioid abuse reduction (Maine Legislature, 2017). Maine’s mandate will also have waiver exceptions, like New York, for physicians that have technology limitations impacting their ability to e-prescribe (Terry, 2016).

Additional states have also been exploring legislation for e-prescribe. The State of New Jersey in July 2016 proposed legislation for mandatory electronic prescribing of all substances. As with New York and Maine, the New Jersey legislative proposal has been associated with initiatives to reduce opioid addiction (NJAOPS, 2016).

2.4.3 REGULATORY MOTIVATION FOR MANDATORY E-PRESCRIBE

The motivation for e-prescribe laws and regulations has differed among federal programs and individual states. The United States Department of Health and Human Services spoke to advantages such as improved formulary selections to reduce cost, reduced phone calls between pharmacies and physicians offices, and improved patient convenience and compliance (Health Resources & Services Administration, 2016). Also from the federal side, the DEA cited multiple reasons for e-prescribe utilization (Drug Enforcement Administration, 2010). Patient-centric reasons include the reduction of prescription errors and reduced wait times at the pharmacy. Prescriber and pharmacy advantages cited by the DEA include reduction of paperwork for controlled substances, reduced paper record storage, reduced processing time, and reduced callbacks. The key to their primary interest they emphasized as a reduction in prescription forgeries.

The individual states have focused on similar advantages such as the reduction in diversion as well as fraud and abuse for New York (Balick, 2016). Maine has expressed their motivation to crack-down on opiate abuse as their reason behind e-prescribing regulations (Maine Medical Association, 2016). Minnesota's perspective is a little different and interesting from the perspective that they are not assessing penalties for non-compliance with e-prescribe. Minnesota's reasons for imposing the e-prescribe statutes include improved medication management, error reduction, patient satisfaction, and overall improved clinical decision making (Division of Health Policy, Office of Health Information Technology & e-Health, Minnesota Department of Health, 2015).

2.5 STUDIES EXAMINING THE ECONOMIC IMPACT OF E-PRESCRIBE

Review of literature included examination of existing literature reviews or similar studies that demonstrated economic impact of e-prescribe. Several studies were examined and included two literature reviews with results speaking to e-prescribe costs. One systematic review study, **Electronic Prescribing: Improving the Efficiency and Accuracy of Prescribing in the Ambulatory Care Setting**, assessed the quality impact and consequential cost of e-prescribe in the United States (Porterfield, Engelbert, & Coustasse, 2014). Another, **A review of the literature and proposed classification on e-prescribing: Functions, assimilation stages, benefits, concerns, and risks**, had a focus on the risks and benefits of e-prescribe which concluded that cost savings was a benefit (Esmail Zadeh & Tremblay, 2016). Although these studies did include an economic aspect of e-prescribe, the comprehensive study intents were much different from this study which is based on the more holistic economic impact of the US regulatory framework e-prescribe motivation.

CHAPTER 3 METHODOLOGY

The methodology outlined in this chapter is intended to demonstrate the step by step process utilized to investigate e-prescribing regulations in the US, the factors motivating those regulations, and how those motivating factors translate to firstly qualitative and secondly quantitative economic impact. The objective of the methodology is to provide an unbiased and broad investigation of the economic impact of e-prescribe that is specifically based on the regulatory framework and requirements of governing bodies in the US.

In order to accomplish the objectives, the study was structured with an initial sampling of government publications that were coded for regulatory motivations as they pertain to e-prescribe. The resulting regulatory motivations established the sample selection criteria for a Mixed Methods Model of Exploratory Sequential Research Design (Creswell, 2010). Samples related to economic impact of e-prescribe were selected based on the regulatory motivations. Following sample selection, data collection proceeded with qualitative data being gathered, followed by quantitative data. Following data collection, qualitative samples were analyzed using Thematic Analysis and quantitative samples were analyzed using a Cost Benefit Analysis (CBA).

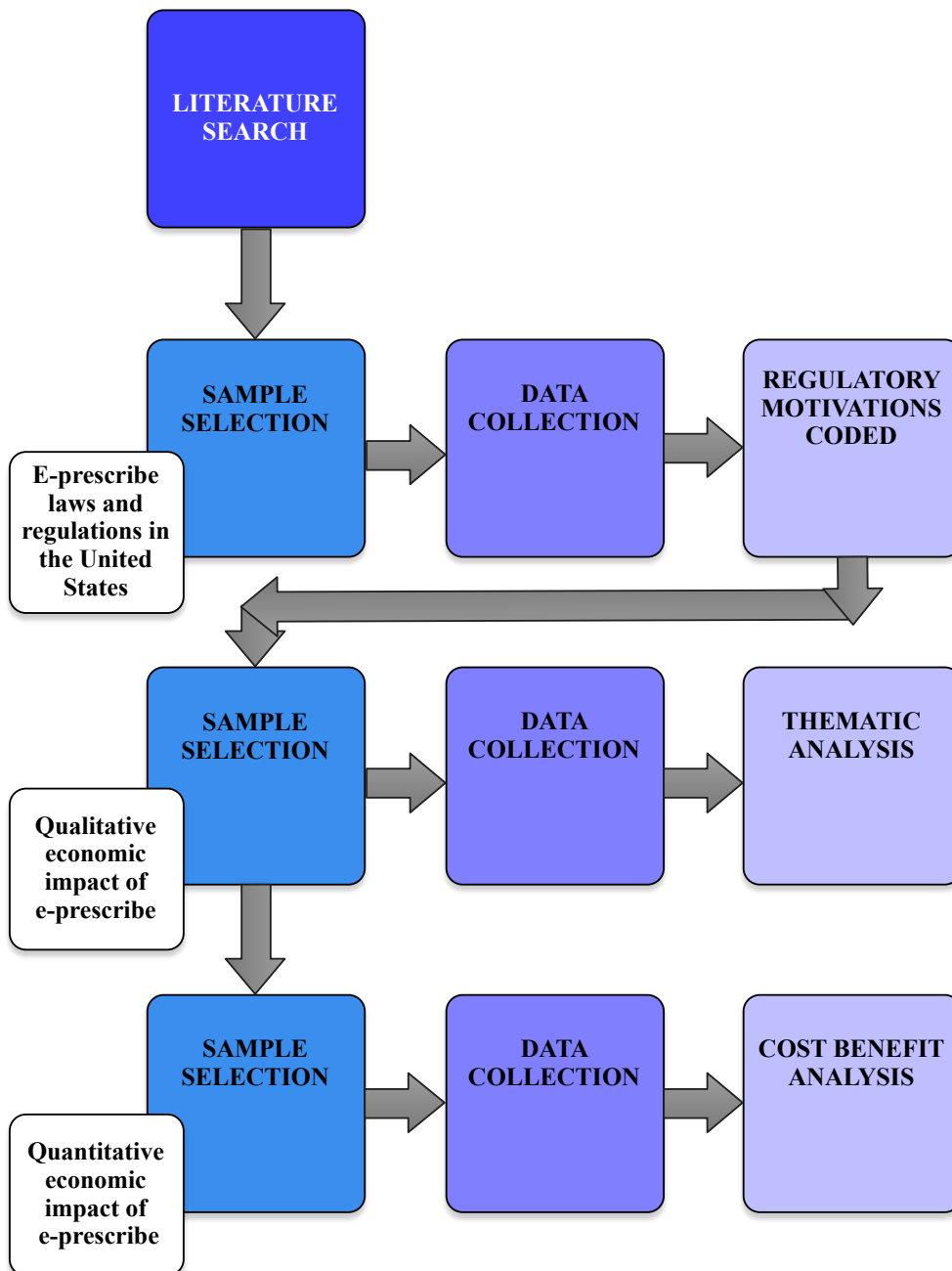
3.1 STUDY DESIGN

Public safety and well-being are at the heart of laws and regulations associated with the practice of pharmacy in the United States (FDA, 2016). Public safety and quality of life as a whole require a subjective approach that does not tend exclusively to monetary assessment. Although economic values can be estimated for the value of a human life, the comprehensive value of that life can't be completely measured. Therefore, the philosophy for this research was based on a preference for firstly a qualitative review to establish the scope of public impact resulting from e-prescribe regulations. Secondly, quantitative details are valuable to demonstrate economic impact and can be used to demonstrate the long-term economic impact of investment in e-prescribing technology, which does have a measurable cost. A Mixed Method of Exploratory Sequential Research Design was therefore selected for the systematic literature review (Creswell,

2010). Within that mixed method research design, a qualitative review was completed first using thematic analysis and a subsequent quantitative review was completed using a cost benefit analysis (Harden & Thomas, 2007; The University of Auckland New Zealand, 2017). This research process for the literature search is outlined in Figure 3.1.

Figure 3.1

LITERATURE SEARCH METHODOLOGY



3.2 SAMPLING FRAMEWORK

Available literature on e-prescribing is diverse including the introduction of regulatory requirements, impacts on patient health and safety, different pharmacy practice settings, pharmacy benefit management, provider impacts, and economic impacts. Literature available from the early years of e-prescribe technology introduction is geared to federal requirements for government insured beneficiaries. With the introduction of the first pharmacy regulations in a state of the US, and discussions within other states, it is important to identify the broader impact to a larger population rather than an isolated insured population. Therefore the systematic review scope covers a comprehensive review across federal and state regulatory requirements, pharmacy practice settings, provider settings, and the resultant economic impacts.

The research was therefore conducted through a scientific approach using a systematic review (Davies & Crombie, 2009) of firstly qualitative and secondly quantitative literature available on e-prescribing. The approach included the selection of resources, targeted research terms in a hierarchy based on an exploratory sequential research design, and inclusion criteria. The sources selected for the literature search were based on professional organizations for the practice of pharmacy in the United States, search engines available to the public, government web-sites regulating prescription drugs, and library resources from two collegiate institutions. The resources utilized for the literature search are broken down by resource type in Table 3.2.

LITERATURE SEARCH

Table 3.2

Type of Literature	Literature Identification			
University Library	Hibernia College	University of Missouri		
Government Publications	FDA	DEA	HHS	CMS
Search Engines	Google	Bing	PubMed	
Professional Notifications	APhA's Pharmacy Today	Specialty Pharma Notification	Pharmacy Times e-News	AMCP
Professional Resources	The Joint Commission	ISMP	Surescripts	NCPDP

3.3 SAMPLE SELECTION

The information available, using the literature resources and search terms found, was included based on a hierarchy of criteria aimed at government publications, peer-reviewed journals and professional publications. Excluded materials included any searches that produced a journalistic publication from a non-professional resource, in the form of an editorial, opinion centric content, or non-factual supported content. Searches that produced immediately apparent advertisement or biased resources were not engaged for review. Examples include a for-profit vendor of e-prescribe software or hardware. Search exclusions by resource origin were based on the following:

- Commercial Medical and Prescription Medicine Insurance Plans (e.g. Aetna, Humana, Express Scripts)
- Commercial businesses with e-prescribe software or technology hardware as a product line
- Any search in an internet search engine producing results title “Ad”
- Independent for-profit healthcare consultant organizations
- Foreign e-prescribe government agencies

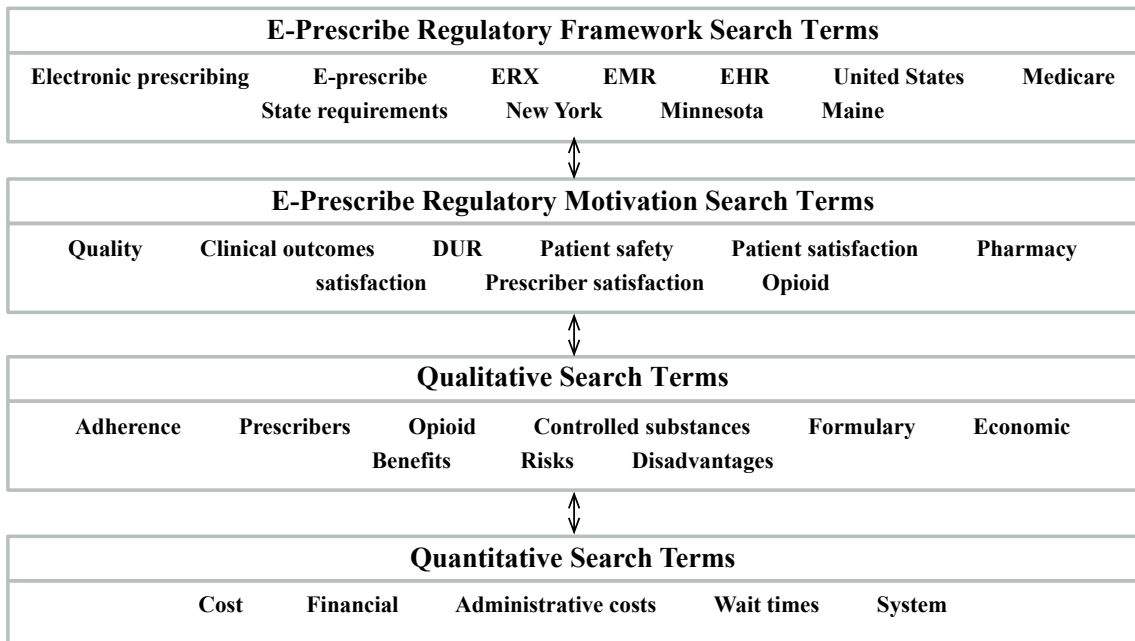
The literature search was conducted with search terms targeted in the following progression:

1. E-Prescribe Regulatory Framework
2. E-Prescribe Regulatory Motivation
3. Qualitative Search Terms
4. Quantitative Search Terms

Therefore, primary search terms were based on key words associated with e-prescribe, to draw an initial review of available resources specifically related to government requirements. Secondary search terms were based on key words associated with e-prescribe regulations, including regulatory motivating factors. The qualitative sample selection proceeded next and was followed by the quantitative sample selection. Search terms from each progression were also included together in one thread to expand available literature. Combinations and strings of the search terms were also applied to sharpen the availability of applicable literature. For example, e-prescribe + clinical outcomes + adherence + cost, to extract a comprehensive review of quantitative information. Specific search terms for the systematic review and their hierarchy are included in Table 3.3. This process was completed for all resources outlined in Table 3.2.

Table 3.3

LITERATURE SEARCH TERMS



3.4 DATA COLLECTION

According to the Mixed Methods Model of Exploratory Design, the investigation proceeded from a qualitative investigation followed secondly by a quantitative investigation (Creswell, 2010). Proceeding from that structure, the initial step of the data collection attempted to examine all of the available e-prescribing laws and regulations in the United States. Regulatory motivations were coded based on the data collected. The regulatory motivation of the legislative action, as described by legislators, was identified and coded from each of the laws and regulations. These regulatory motivations were subsequently used to perform data collection of firstly qualitative aspects of economic impact based on the legislative motivation. Secondly, data collection of quantitative economic impacts were compiled. These specifically included the available economic cost factors corresponding with each of the legislative motivations.

3.5 DATA ANALYSIS

3.5.1 QUALITATIVE ANALYSIS

Thematic analysis was the form of data analysis used to examine the qualitative research. This method of qualitative analysis was selected because an initial review of the literature demonstrated that motivations for e-prescribe legislative action can be identified and coded with corresponding themes. The process of thematic analysis is completed in six phases including the following:

- Phase 1 Familiarize with Data
- Phase 2 Preliminary Coding
- Phase 3 Search for Themes
- Phase 4 Review Themes
- Phase 5 Define Themes and Name
- Phase 6 Reporting

The final phase of thematic analysis proceeded with qualitative results of the literature review examined and documented within the analysis of each of the coded regulatory motivations, themes, and sub-themes. This reporting step completed the thematic analysis phases. The resulting framework from the thematic analysis was now ready to layer in the quantitative assessment in keeping with the mixed methods approach of exploratory design (Creswell, 2010).

3.5.2 QUANTITATIVE ANALYSIS

The quantitative economic evaluation was completed by leveraging available cost information and tangible quantitative social factors (Ma, Liu, Hunter, & Zhang, 2008; Thomas, 2009). The method of economic evaluation selected for the research was a Cost Benefit Analysis (CBA). A CBA is performed by assessing the quantitative impact when costs are subtracted from benefits, to arrive at a decision regarding the best “course of action” (Entrepreneur Staff, 2017). In this evaluation, the benefits may be measurable from a revenue standpoint, but may also be from more abstract sources of evaluation. Costs are also evaluated across a broad range of measurable costs and unquantifiable costs that may be estimated (Investopedia, 2017).

A CBA was selected for the quantitative aspect of the economic evaluation because of the broad scope of the economic impact of e-prescribing legislation across populations. Social aspects of the e-prescribe benefit and the government involvement in e-prescribe mandates were also factors in the selection of a CBA (Mishan & Quah, 2007). There were several potential limitations of a CBA considered throughout the assessment (Portney, 2008). The direct and indirect costs imposed upon users of e-prescribe services, as a result of the regulations, are an important consideration. This is in contrast to the potential differences in costs for the beneficiary of the e-prescribe economic impacts. The time factor of when costs are realized versus benefits recognized was also considered. Furthermore, the long-term nature of the impact of e-prescribing and how to measure that in present values was a potential limitation. This was mitigated by leveraging resources that provided present values and the vast disparity versus total costs and revenues.

Quantitative data evaluation was structured by reviewing directly measurable economic cost impacts associated with each coded regulatory motivation. These were subdivided into direct and indirect costs for evaluation purposes. Cost and benefit data is limited to direct cost information available in the literature and indirect costs estimated based on literature when directly measurable figures are not available. This information was incorporated in the CBA to achieve a calculated negative or positive total for e-prescribe implementation. The calculated comprehensive outcome drives the overall evaluation of quantitative economic impact. Limitations of this approach are the broad net applied to the overall societal impact rather than individual populations impacted by e-prescribe costs.

3.6 ETHICAL CONSIDERATIONS

The study methodology focused strictly on a comprehensive literature review and therefore ethical considerations were focused on the researcher's review and analysis of that literature (Economic & Social Research Council, n.d.). Literature was evaluated for ethical standards and utilized only if deemed consistent with those standards. Additionally, literature was only utilized in the review that met criteria for studies with informed consent where applicable and did not exceed the scope of the original consent.

Researcher literature review references all resources and data with accurate sources and the research is void of plagiarism. Only information available to the public is utilized as a literature resource and no contact has been made with the original authors or participants. No suspected ethical circumstances were recognized throughout the course of the research and therefore did not require escalation by the researcher to the college sponsor.

CHAPTER 4 RESULTS AND FINDINGS

This chapter serves to present the qualitative and quantitative results of the systematic literature review examining the economic impact of e-prescribe regulations in the United States. Literature search details for the government publications and resulting regulatory motivations will be presented first. This will be followed by the literature search details for the corresponding qualitative economic impact and quantitative economic impact. Data analysis of government publications and documented regulatory motivations will be presented first. Data analysis and corresponding results will then be presented for qualitative economic impact, followed by quantitative economic impact.

4.1 EXAMINING E-PRESCRIBE IMPACT

4.1.1 REGULATORY MOTIVATION LITERATURE SEARCH RESULTS

Government publications are the baseline research resource used to establish e-prescribe regulatory motivation to perform the economic impact research. Table 4.1.1 provides an overview of those government publications that contributed to establishing the regulatory motivations related to qualitative themes for e-prescribing regulations and quantitative cost benefit analysis. It is important to note that each regulatory body had variances in their identified motivation for establishing regulatory action as it relates to e-prescribe. Initial regulatory motivations identified focused heavily on patient safety. Later regulations have focused on concerns with opioid abuse in the US and corresponding safety or economic implications.

Coded regulatory motivation categories resulting and named from this phase of the literature search included the following:

- Benefits
- Costs
- Opioid Abuse
- Implementation Tool to Establish E-prescribe (Incentives)

E-PRESCRIBE REGULATORY MOTIVATION SEARCH

Table 4.1.1

Government Publication Title	Motivation Code or Requirements	Regulatory Body
A Toolset for E-Prescribing Implementation in Physician Offices	<ul style="list-style-type: none"> • Implementation Tool to Establish E-Prescribe 	Department of Health and Human Services
Frequently Asked Questions for Electronic Prescribing	<ul style="list-style-type: none"> • Requirements 	NY State Department of Health
Meaningful Use	<ul style="list-style-type: none"> • Implementation Tool to Establish E-Prescribe (Incentives) 	CDC
E-Prescribing	<ul style="list-style-type: none"> • Requirements 	CMS
Electronic Prescribing Incentive Fact Sheet	<ul style="list-style-type: none"> • Implementation Tool to Establish E-Prescribe (Incentives) 	CMS
Electronic Prescribing (eRX) Incentive Program	<ul style="list-style-type: none"> • Implementation Tool to Establish E-Prescribe (Incentives) 	CMS
2015 Physician Quality Reporting System (PQRS): Understanding 2017 Medicare Quality Program Payment Adjustments	<ul style="list-style-type: none"> • Requirements • Implementation Tool to Establish E-Prescribe (Incentives) 	CMS
Economic Impact Analysis of the Interim Final Electronic Prescription Rule	<ul style="list-style-type: none"> • Costs 	DEA
The Opioid Epidemic by the Numbers	<ul style="list-style-type: none"> • Opioid Abuse 	HHS
Electronic Prescribing Exceptions	<ul style="list-style-type: none"> • Requirements 	NY State Department of Health
Waiver Request for Electronic Prescribing	<ul style="list-style-type: none"> • Requirements 	NY State Department of Health
Electronic Prescribing in Minnesota	<ul style="list-style-type: none"> • Requirements 	Minnesota Department of Health
Electronic Prescriptions for Controlled Substances	<ul style="list-style-type: none"> • Requirements 	DEA
Medicare Electronic Health Record Incentive Payments for Eligible Professionals	<ul style="list-style-type: none"> • Implementation Tool to Establish E-Prescribe (Incentives) 	CMS
HealthIT Legislation and Regulations	<ul style="list-style-type: none"> • Requirements 	The Office of the National Coordinator for Health Information Technology (ONC)
What is an Electronic Medical Record (EMR)?	<ul style="list-style-type: none"> • Benefits 	The Office of the National Coordinator for Health Information Technology (ONC)

E-PRESCRIBE REGULATORY MOTIVATION SEARCH

Table 4.1.1

Government Publications Title	Motivation Code or Requirements	Regulatory Body
Electronic Prescribing of Controlled Substances	<ul style="list-style-type: none"> • Requirements • Benefits 	The Office of the National Coordinator for Health Information Technology (ONC)
What are some of the benefits of e-prescribing?	<ul style="list-style-type: none"> • Benefits 	US Department of Health and Human Services
EHR State Incentive Program	<ul style="list-style-type: none"> • Implementation Tool to Establish E-Prescribe (Incentives) 	Maryland State Health Care Commission
SOS Rx Coalition	<ul style="list-style-type: none"> • Requirements 	NABP
Electronic Prescribing in Minnesota	<ul style="list-style-type: none"> • Benefits 	Minnesota Department of Health
NCPDP Electronic Prescribing Standards	<ul style="list-style-type: none"> • Requirements 	NCPDP
History of NCPDP	<ul style="list-style-type: none"> • Requirements 	NCPDP
An Act To Prevent Opiate Abuse by Strengthening the Controlled Substances Prescription Monitoring Program	<ul style="list-style-type: none"> • Requirements 	Maine Legislature
Mandatory Electronic Prescribing	<ul style="list-style-type: none"> • Requirements 	New York State
New Jersey Legislative Update (July 2016)	<ul style="list-style-type: none"> • Requirements 	State of New Jersey
Understanding the 2011 e-Prescribing Mandate (2011)	<ul style="list-style-type: none"> • Requirements • Implementation Tool to Establish E-Prescribe (Incentives) 	Minnesota Department of Health
E-prescribing Toolkit 2011 - A Practical Resource for Providers	<ul style="list-style-type: none"> • Benefits • Implementation Tool to Establish E-Prescribe (Incentives) 	Oregon Health Authority
E-Prescribing Work Group Report and Recommendations	<ul style="list-style-type: none"> • Benefits • Costs • Barriers 	State of Nebraska
Consumer satisfaction surveys.	<ul style="list-style-type: none"> • Requirements 	United States Government Publishing Office
Standards for electronic prescribing.	<ul style="list-style-type: none"> • Requirements 	United States Government Publishing Office
Health Information Technology Standards	<ul style="list-style-type: none"> • Requirements 	United States Government Publishing Office

4.1.2 QUALITATIVE LITERATURE SEARCH AND DATA COLLECTION RESULTS

Further research samples were drawn from published scientific studies on e-prescribing. Studies were selected that corresponded to the e-prescribe legislation motivations identified in the government resources. Table 4.1.2 outlines those studies that were reviewed and included for applicability. Data collection was completed following sample selection. Information identified within the studies that corresponded to the regulatory action and qualitative economic impact was also utilized to perform further searches.

4.1.3 QUANTITATIVE LITERATURE SEARCH AND DATA COLLECTION RESULTS

Following the conclusion of the qualitative aspect of research, an additional literature search was performed to identify or expand upon any economic impacts that could be quantified as a part of a CBA using the regulatory motivations. Table 4.1.3 provides those additional literature resources that were reviewed and included to establish the quantitative assessment of e-prescribe economic impact. Data collection also was performed and collated based on the initially identified regulatory motivations.

QUALITATIVE LITERATURE SEARCH

Table 4.1.2

Study	Theme	Results
Abramson et al., 2011	<ul style="list-style-type: none"> • Clinical Outcomes - Quality 	Prescription errors overall were 35.7 per 100 prescriptions at baseline and one year post-implementation 12.2 per 100 prescriptions. Non-abbreviation errors not significant from baseline to implementation but higher at 12 weeks post-implementation.
Adamson, Suarez, & Gorman, 2017	<ul style="list-style-type: none"> • Clinical Outcomes - Adherence 	Reduction in non-adherence to prescriptions of 47% for electronic prescriptions versus paper prescriptions.
Amirfar et al., 2011	<ul style="list-style-type: none"> • Barriers to Implementation 	Prescriber telephone survey regarding e-prescribe implementation. Barriers identified included pharmacy readiness and patients wanted paper prescriptions.
Bates, 1995	<ul style="list-style-type: none"> • Clinical Outcomes - Quality 	Prescription error incidence in hospital setting of 4031 adults. Incidence from ordering and transcription (56% and 6%) were identified.
Byrne, et al., 2010	<ul style="list-style-type: none"> • Comprehensive - Cost 	Cost benefit analysis of Health IT in US Veterans system with \$309 billion in savings projected.
Craig & Strassels, 2010	<ul style="list-style-type: none"> • Opioid Abuse 	Cost of average opioid prescription was \$10 between 1999 to 2004.
Craxford, Taylor, Duguid, Shivji, & Pickering, 2015	<ul style="list-style-type: none"> • Clinical Outcomes - Quality • Administrative impacts 	Quality improvement in e-prescribe of 2.7 to 5.3% following implementation and learning curve. Workflow improvement of 62 seconds after 2 months, however initial increase of learning curve.
Devine et al., 2010	<ul style="list-style-type: none"> • Administrative Impacts 	E-prescribing point of care takes 20 seconds longer per patient.
Duffy, Yiu, Molokhia, Walker, & Perkins, 2010	<ul style="list-style-type: none"> • Administrative Impacts • Patient Satisfaction • Barriers to Implementation 	Family Medicine practice site study found that e-prescribing decreased the total number of after hours calls by 22%. Additional end-points from e-prescribing included an increased percentage of total medication question calls, positive prescriber satisfaction, and patient satisfaction.
Feifer, Nevins, McGuigan, Paul, & Lee, 2003	<ul style="list-style-type: none"> • Administrative Impacts 	Handwritten prescriptions requiring clarification in one week study were 8.7% for a mail-order pharmacy.
Fischer et al., 2008	<ul style="list-style-type: none"> • Formulary Selection 	Study found a 3.3% increase in Tier 1 formulary selection and reduction in Tier 2/3 when e-prescribed was used. Study found there would be an estimated savings of \$845,000 per 100,000 patients.
Hansen et al., 2006	<ul style="list-style-type: none"> • Administrative Impacts 	Study of 22 primary care practices examined call trends related to prescription clarifications from a pharmacy.
Crosson, Schueth, Isaacson, & Bell, 2012	<ul style="list-style-type: none"> • Barriers to Implementation 	Study of 8 primary care practices that demonstrated prescriber distrust and dissatisfaction in e-prescribing documentation and formulary selection.

QUALITATIVE LITERATURE SEARCH
Table 4.1.2

Study	Theme	Results
Kaushal, Kern, Barrón, Quaresimo, & Abramson, 2010	• Clinical Outcomes - Quality	Study of 15 providers demonstrating improved prescription quality of 6.6 per 100 for e-prescribe compared with 38.4 for traditional methods.
Kilbridge, 2006	• Clinical Outcomes - Quality	Evaluation of hospital computerized physician order entry symptoms as they relate to adverse drug event frequency and cost.
Lander, Klepser, Cochran, Lomelin, & Morien, 2012	• Barriers to Implementation	Study of 23 pharmacy providers examining barriers of pharmacies to e-prescribing implementation and associated prescriber barriers.
Lapane, Dube, Schneider, & Quilliam, 2007	• Patient Satisfaction	Study of 35 providers examining geriatric patient perceptions of e-prescribing and the impact to overall prescription communication with providers.
McGuire & Iuga, 2014	• Clinical Outcomes - Adherence	Study evaluating costs of non-adherence and e-prescribing impacts. The study concluded that e-prescribing increased prescription pick-ups by 10% and associated cost improvement of \$140 billion over ten years.
Gagnon, Nsangou, Payne-Gagnon, Grenier, & Sicotte, 2014	• Barriers to Implementation	Systematic review of prescriber barriers related to e-prescribing.
Moniz et al., 2011	• Clinical Outcomes - Quality	Study of computerized prescriber order entry's impact on dispensing errors showed a reduction in almost half the errors from baseline.
Qureshi et al., 2015	• Clinical Outcomes - Quality	Systematic review of e-prescribing impact on medication errors.
Odukoya & Chui, 2013	• Clinical Outcomes - Quality	A focused review examining new errors associated with e-prescribing technology and human factors.
Patel & Audet, 2014	• Comprehensive - Cost	Journal article that examines costs of pharmaceuticals and economic modalities to reduce costs in the US.
Porterfield, Engelbert, & Coustasse, 2014	• Clinical Outcomes - Quality	Systematic review examining the quality impact of e-prescribing and consequential cost.
Esmail Zadeh & Tremblay, 2016	• Comprehensive - Benefits and Risks	Literature review examining benefits and risks of e-prescribing.
Powers, Gabriel, Encinosa, Mostashari, & Bynum, 2015	• Clinical Outcomes - Quality	Study of Medicare patients with diabetes examines adverse drug event incidence by high or low e-prescriber characteristics. Result is 5% versus 6.5% for high and low e-prescribers respectively.
Prakash, 2010	• Patient Satisfaction	Journal article examines different factors in patient satisfaction including wait times, telephone service, and interaction with doctor.

QUALITATIVE LITERATURE SEARCH**Table 4.1.2**

Study	Theme	Results
Rasu et al., 2014	<ul style="list-style-type: none">• Opioid Abuse	Study examined the cost of non-malignant pain treatment in the US with \$3.6 billion annually spent on opioids.
Ryan, Shih, Winther, & Wang, 2014	<ul style="list-style-type: none">• Barriers to Implementation	Study examines physician attitudes to e-prescribe in new users versus those 2 years post-implementation. The study found 2.02 times more acceptance of e-prescribe in more seasoned users.
Schleiden, Odukoya, & Chui, 2015	<ul style="list-style-type: none">• Patient Satisfaction	Telephone survey of 75 patients over 50 yo showing 81% satisfaction rate with e-prescribing.
Salmon & Jiang, 2012	<ul style="list-style-type: none">• Barriers to Implementation	Literature review examines history of e-prescribe and pharmacy barriers.
Smith, 2006	<ul style="list-style-type: none">• Barriers to Implementation	Study examines barriers slowing e-prescribe implementation and spread in US.
Teich et al., 2000	<ul style="list-style-type: none">• Clinical Outcomes - Quality• Formulary Selection	Study examining computer order entry in medical centers found a positive 15.6 to 81.3% change in formulary selection. The study also looked at improved entry accuracy.
Weingart et al., 2009	<ul style="list-style-type: none">• Barriers to Implementation	Study of 25 physicians using a focus group to examine qualitative factors to evaluate their attitudes on the impact and safety of e-prescribe.
Westbrook et al., 2012	<ul style="list-style-type: none">• Clinical Outcomes - Quality	Study evaluating incidence of quality events in a hospital system before and after e-prescribing. A statistically significant reduction was found with e-prescribing.

QUANTITATIVE LITERATURE SEARCH

Table 4.1.3

Publication	Corresponding Regulatory Motivation	Economic Impact
American College of Preventative Medicine, 2011	<ul style="list-style-type: none"> • Benefits 	Resource tool examining the cost and incidence of medication adherence. Cost reported at \$100 to \$300 billion per year or \$2000 per patient in required practitioner visits and impacts 20 to 50% of patients.
Blumenthal & Tavenner, 2010	<ul style="list-style-type: none"> • Implementation Tool to Establish E-Prescribe (Incentives) 	Journal article references Medicare and Medicaid incentive payments and requirements.
Centers for Medicare & Medicaid Services, 2017	<ul style="list-style-type: none"> • Opioid Abuse 	Government publication provides ACA reimbursable prices for covered medications in assistance programs.
Keenan et al., 2017	<ul style="list-style-type: none"> • Costs 	Journal article about prescription medicine spend projections and historical spend.
Dallas, 2016	<ul style="list-style-type: none"> • Opioid Abuse 	CDC report of \$78.5 billion impacting US economy annually from opioid abuse.
Drug Enforcement Administration, 2014	<ul style="list-style-type: none"> • Comprehensive Costs 	Government publication of record keeping requirements for prescriptions.
Hansen, Oster, Edelsberg, Woody, & Sullivan, 2011	<ul style="list-style-type: none"> • Opioid Abuse 	Journal article examines costs of non-medical opioid use in the United States.
HealthIT.gov, 2014	<ul style="list-style-type: none"> • Implementation Tool to Establish E-Prescribe 	Government publication advisement on EHR implementation costs.
Health Manag Techno, 2012	<ul style="list-style-type: none"> • Benefits 	Study projecting \$140 billion in savings over ten years from relationship of e-prescribing and medication adherence.
Birnbaum et al., 2011	<ul style="list-style-type: none"> • Opioid Abuse 	Journal article reporting costs of Opioid Abuse \$55.7 billion in 2007.
ISMP, 2000	<ul style="list-style-type: none"> • Benefits 	Professional organization safety publication on the costs of prescription errors and drug related events with a recommendation to eliminate handwritten prescriptions.
Maine Medical Association, 2016	<ul style="list-style-type: none"> • Opioid Abuse 	Professional organization review of future Maine e-prescribe requirements and benefits.
McBride, 2012	<ul style="list-style-type: none"> • Implementation Tool to Establish E-Prescribe 	Journal article providing EHR vendor information.
MGMA, 2016	<ul style="list-style-type: none"> • Implementation Tool to Establish E-Prescribe 	Professional organization article on the current costs per physician for EHR implementation reported as \$32,500.
Murphy, 2016	<ul style="list-style-type: none"> • Benefits 	Journal article presents costs of patient satisfaction.

QUANTITATIVE LITERATURE SEARCH**Table 4.1.3**

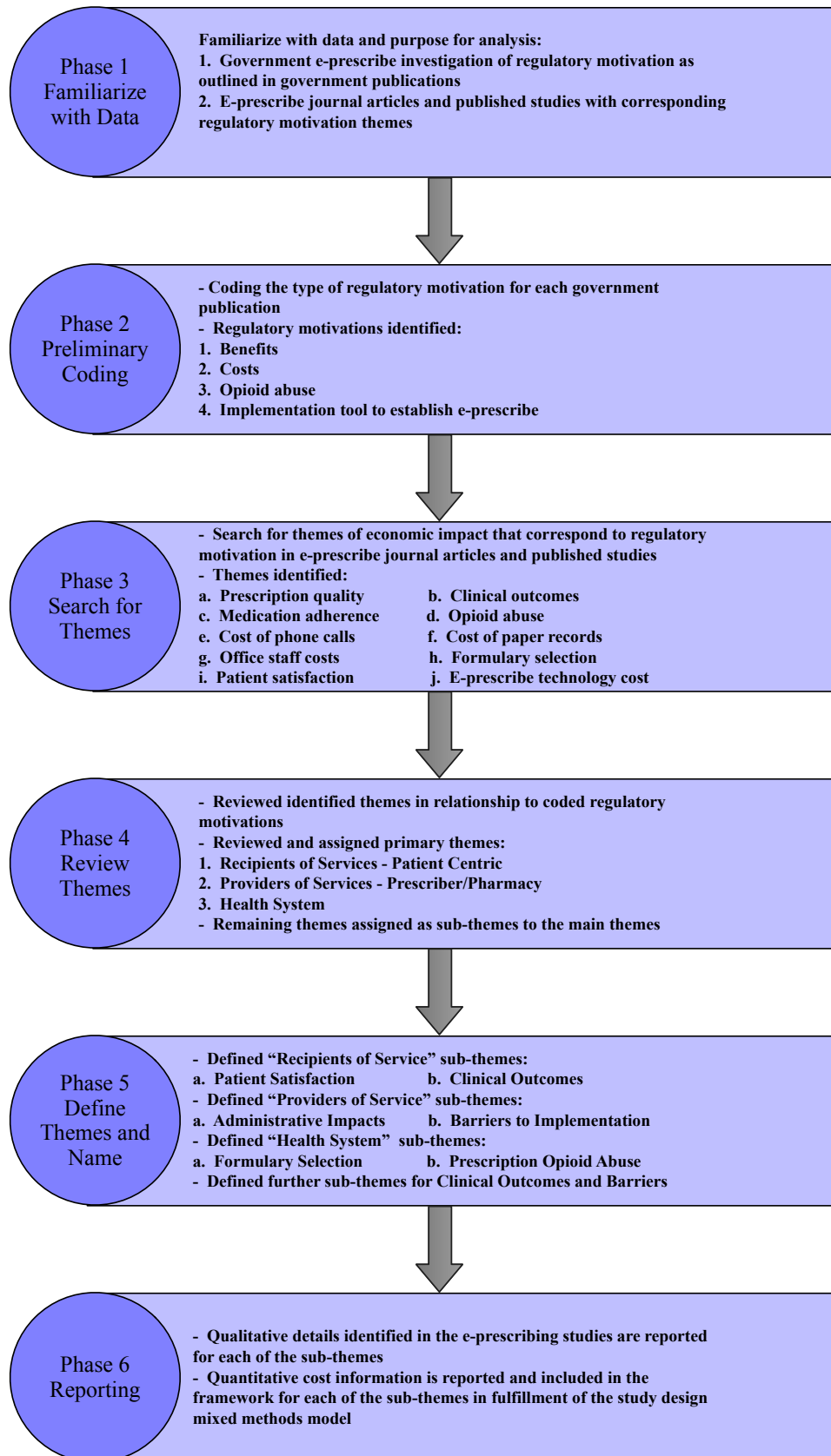
Publication	Corresponding Regulatory Motivation	Economic Impact
Ogundimu & Tommasculo, 2011	<ul style="list-style-type: none">• Costs	Industry article on the barriers to e-prescribe discussed including technology costs, technology limitation, and prescriber attitudes.
Surescripts, 2016	<ul style="list-style-type: none">• Implementation Tool to Establish E-Prescribe	Industry article examines aspects of e-prescribing technology that relates to cost.
Terry, 2016	<ul style="list-style-type: none">• Requirements• Costs	Industry news perspective in reputable professional resource examined e-prescribe implementation in New York and Maine.
The Center for Improving Medication Management, 2011	<ul style="list-style-type: none">• Requirements• Implementation Tool to Establish E-Prescribe	Professional association support and overview of e-prescribe including implementation resources.
Trish, Joyce, & Goldman, 2014	<ul style="list-style-type: none">• Comprehensive Costs	Journal article examines healthcare spending specific to Medicare beneficiaries; those in the e-prescribe prescriber incentive population.
World Health Organization, 2003	<ul style="list-style-type: none">• Benefits	Professional organization examines aspects of adherence to prescription medications.

4.2 THEMATIC ANALYSIS

The process of thematic analysis was completed in six phases that have been outlined as they applied to this research in Figure 4.2. The first phase of the thematic analysis included an in-depth review of the literature resources and familiarization with the data. Resources were stratified according to type and included the following:

- Government publications pertaining to e-prescribe
- E-prescribe references in journals and published studies

THEMATIC ANALYSIS



Phase 2 involved the coding of the qualitative economic impacts to the regulatory motivations for e-prescribe established from the government publications review. The coded regulatory motivations to which coding occurred included the following:

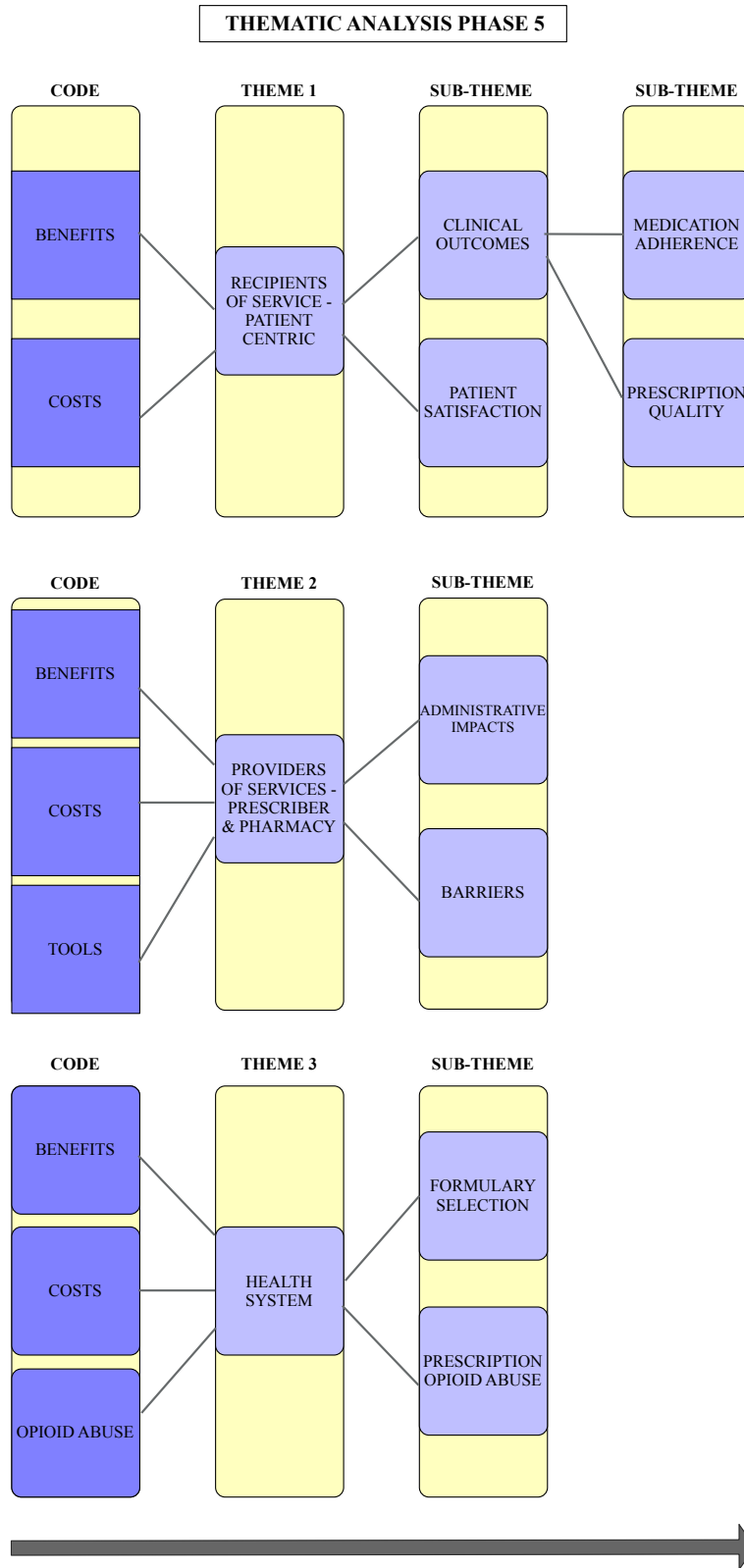
- Benefits
- Costs
- Opioid Abuse
- Implementation tool to establish e-prescribe (Incentives) or “Tools”

The third phase of the thematic analysis involved searching for themes. Here the journal articles and published studies matching coded motivations for legislative action were evaluated for themes that related to economic impact. Themes that emerged included prescription quality, clinical outcomes, medication adherence, prescription opioid abuse, the cost of phone calls, the cost of paper records, office staff costs, formulary selection, patient satisfaction, and e-prescribe technology costs. Following the identification of all themes, the fourth phase commenced with the legislative motivations being matched to the themes economic impact. This resulted in three primary themes being identified:

- Recipients of Services - Patient Centric: Recipients of services and therefore impacted by any determined benefits of e-prescribing
- Providers of Services - Prescriber/Pharmacy: Providers of services and therefore impacted by any economic benefits from e-prescribe utilization and implementation impacts associated with e-prescribe technology
- Health System: Impacted by any recognized e-prescribe benefits applied to the overall healthcare system and society responsible for funding healthcare

In Phase 5 of the thematic analysis, distinct themes identified in Phase 3 were assigned as sub-themes to the primary themes and named. The themes and sub-themes relationship to each other and the coded legislative motivations, as determined by the fifth phase of thematic analysis, are outlined in Figure 4.2.1. In the case of more than one theme applied to a literature source, the determination was made to record this in Table 4.1.2 and 4.1.3 as the individual themes. In the case of three or more themes, the source was labeled as comprehensive. The sub-themes associated with the Patient Centric theme included Patient Satisfaction and Clinical Outcomes. Clinical Outcomes was further broken down into Medication Adherence and Prescription Quality sub-themes. The Providers of Services theme was subdivided into the sub-themes of Administrative Impacts and Barriers. Qualitative Barriers and the Cost of Establishing E-Prescribe Capability were further sub-themes assigned under Barriers. The third theme of Health System was divided into the sub-themes Formulary Selection and Prescription Opioid Abuse. It was determined that Opioid Abuse fits in with the societal theme of health system costs rather than patient-centric impact. This was based on the overarching legislative motivation for opioid control shared by states in their e-prescribe laws and regulations.

Figure 4.2.1



4.3 QUALITATIVE RESULTS AND FINDINGS

4.3.1 INTRODUCTION

An overview of the themes and sub-themes outlined in this presentation of results and findings is outlined in Figure 4.3.1. The themes include:

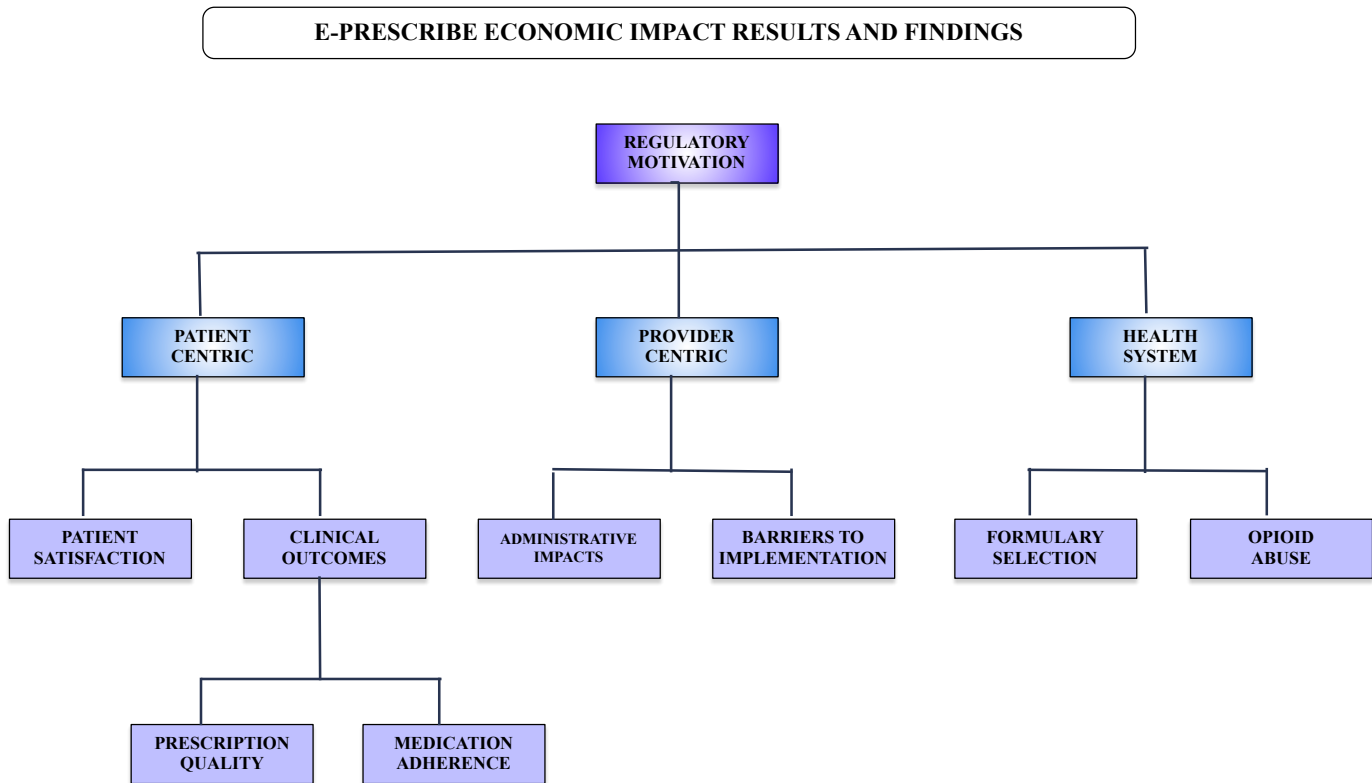
- Theme 1: Recipients of Services - Patient Centric
- Theme 2: Providers of Services - Prescriber/Pharmacy
- Theme 3: Health System

The first economic impact theme explored is the recipient of prescription services, the patient. Sub-themes determined by the literature review include Patient Satisfaction and Clinical Outcomes. Quality is the first type of clinical outcome supported by the literature and Medication Adherence is the second type of clinical outcome supported by the literature.

The second theme represented by the systematic review findings is the provider of prescription services. Here the prescriber authorizing the prescription and the pharmacy fulfilling the prescription order were identified in the literature to have an economic impact by e-prescribe. The sub-themes for the provider group includes Administrative Impact and Barriers to Implementation. It was noted in the literature that these provider impacts include both qualitative and quantitative details that have been included in the findings.

Health System is the final theme identified in the literature review results. The Health System encompasses the holistic economic impact shared in the literature, which touches the patient, providers of healthcare, and society that funds healthcare costs. Two sub-themes emerged with economic impact including Formulary Selection and Opioid Abuse. Opioid Abuse is a strong motivator identified in the literature review thematic analysis step examining regulatory motivators for e-prescribe legislation.

Figure 4.3.1



4.3.2 THEME 1: RECIPIENTS OF SERVICE - PATIENT CENTRIC IMPACT

4.3.2.1 Subtheme 1: Patient Satisfaction

Patient satisfaction influences clinical outcomes which have a value to the patient's healthcare and also financially (Prakash, 2010). Patient satisfaction with e-prescribing has been measured in several studies from its inception until the present. A study conducted within a large family medicine residency clinic in Alabama evaluated patient satisfaction with e-prescribing through a survey (Duffy, Yiu, Molokhia, Walker, & Perkins, 2010). Patient favorability as positive or neutral was 90% of respondents. Furthermore, 71% of patients reported that getting their prescriptions was easier with e-prescribing and 63.3% had the perception that there were fewer errors with e-prescribing (Duffy, Yiu, Molokhia, Walker, & Perkins, 2010). Another convenience sampling review of geriatric patients' perceptions on e-prescribing demonstrated that e-

prescribing was favorable by patients that had experienced both paper and e-prescribe options (Lapane, Dube, Schneider, & Quilliam, 2007). Additionally, the study showed that e-prescribing resulted in improved and earlier patient to prescriber communications. A similar review of patients' preference for e-prescribe in patients over 50 showed a similar preference for e-prescriptions over paper prescriptions by as much as 84% (Schleiden, Odukoya, & Chui, 2015).

4.3.2.2 Subtheme 2: Clinical Outcomes

Improvement in patient clinical outcomes has qualitative value of keeping the patient healthy in addition to economic value. Improvements have been estimated over a ten year period to be as much as \$240 billion when physician centers utilize e-prescribing (Porterfield, Engelbert, & Coustasse, 2014). These clinical outcomes can result from such factors as medication adherence, error reduction, and prescription quality.

4.3.2.2.1 Subtheme 2A: Medication Adherence

Medication adherence is a global problem impacting as much as 50% of the population with chronic diseases in developed countries according to the World Health Organization (World Health Organization, 2003). Lack of medication adherence can result in incorrect treatment decisions and poor clinical outcomes (American College of Preventive Medicine, 2011). It has been demonstrated that primary non-adherence to medication was decreased by 16% when prescriptions were provided electronically rather than by paper (Adamson, Suarez, & Gorman, 2017). An advantage of improving medication adherence and reducing healthcare spend by increased utilization of e-prescribe therefore exists. An additional benefit of utilizing e-prescribe instead of paper prescriptions, that physicians cite, is the ability to create a record that tracks when the patient fills the prescription and to generate an audit capable record of the creation of the prescription (Amirfar et al., 2011). This e-prescribe capability provides visibility and gives control to prescribers to further tip the scales on impacting patient medication compliance.

4.3.2.2.2 Subtheme 2B: Prescription Quality

The Division of Medication Error Prevention and Analysis (DMEPA), a division of the FDA's Center for Drug Evaluation and Research (CDER), defines a medication error as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.” An Adverse Drug Event (ADE) is any injury that may result from medical intervention related to a drug (Becker, 2015).

One aspect of preventable medication errors is verbal and handwritten prescriptions. In 2000 the Institute for Safe Medication Practices issued a call to action for eliminating handwritten prescriptions by advocating electronic prescribing in an effort to reduce medication errors (ISMP, 2000). Regulatory agency support also strongly supports electronic prescribing as a means to improve medication quality. Prescription errors occur at a higher rate in those areas that can be impacted by e-prescribing, evidenced by a study that showed 56% of errors occurred at the stage of ordering and 6% at the stage of transcription (Bates, 1995). One study of prescription errors comparing traditional paper prescriptions versus e-prescribing showed a 50% reduction in errors resulting from a difference in the prescribers intended order and what was dispensed (Moniz et al., 2011).

A study of standalone e-prescribing for 15 providers showed a 7 fold decrease in prescription errors when utilizing e-prescribe versus paper prescriptions (Kaushal, Kern, Barrón, Quaresimo, & Abramson, 2010). Another study of 17 providers in an ambulatory setting demonstrated reductions in rates of errors from 35.7 to 12.2 per 100 prescriptions (Abramson et al., 2011). The types of errors, however, were different, even demonstrating no change in errors other than those related to abbreviation errors one year after implementing electronic prescribing. Further support was recognized in a hospital setting where error reduction ranged from 60.5 to 66.1% across

different wards. Here again, the errors types reduced were those generated by handwriting errors (Westbrook et al., 2012).

Medication error reduction across many studies comparing e-prescribe to traditional methods of prescribing has therefore demonstrated measurable improvement with e-prescribing. When the cost of medication errors and adverse drug events is factored into those reductions, a significant cost savings can be recognized. Beyond errors related to handwriting and transcription, overall physician prescribing patterns and comprehensive quality can be improved by the utilization of e-prescribe including drug selection, dosage frequency, consequent orders, and drug frequency recommendations, for example three times a day is as effective as four times a day (Teich et al., 2000).

4.3.3 THEME 2: PROVIDERS OF SERVICES - PRESCRIBER AND PHARMACY IMPACT

4.3.3.1 Subtheme 1: Administrative Impacts

There are several administrative factors that e-prescribe has on providers of service. One factor that can be examined for impact to administrative activities in healthcare is phone call volume and length of time on the phone between physician centers and the pharmacy when e-prescribe is used versus paper prescriptions. Electronic renewals of prescriptions are less time consuming than calling the renewal to the office of the prescriber (Oregon Health Authority, 2011). It has been shown that 8.7% of handwritten or faxed prescriptions may require phone calls to clarify required prescription elements (Feifer, Nevins, McGuigan, Paul, & Lee, 2003). It is also pertinent to note that callbacks to prescribers for prescription clarifications can result in delayed patient treatment which is also a burden to the healthcare system (Hansen et al., 2006). In addition to quality clarification calls, additional calls for matters such as formulary selections may be required for prescriptions to bring that total to a staggering 30% of prescriptions (Drug Enforcement Administration, 2010).

The DEA has estimated that there could be a 25% reduction in calls with the advent of e-prescriptions (Drug Enforcement Administration, 2010). A study conducted within a large family medicine residency clinic demonstrated a reduction of after hours calls by 22% (Duffy, Yiu, Molokhia, Walker, & Perkins, 2010). That same study showed that for those calls, an increase of 81% for medication-related calls occurred.

An additional administrative area of consideration for providers of services is the time to write prescriptions. A study of 13 primary care practices in Indiana showed evidence that the time spent by physicians to enter prescriptions electronically was greater than traditionally handwritten prescriptions (Overhage, Perkins, Tierney, & McDonald, 2001). The results demonstrated that 2.2 minutes per patient were added when the physician utilized an electronic system for the patient visit, with between 54 to 98% percent of the total system utilization time being dedicated to order entry versus evaluation of clinical information and administrative functions. Additionally, surveys of physician experience were conducted on a 5-point Likert scale and resulted in not only responses of the quality of patient care but they also felt that the use of the prescribing technology was easier and faster.

4.3.3.2 Subtheme 2: Barriers to Implementation

Recognized savings from e-prescribe can be impacted by acceptance and utilization of e-prescribing by the healthcare community. Prescribers perceptions about e-prescribe speed, financial impact, and quality have been proven to improve over time (Ryan, Shih, Winther, & Wang, 2014). Early e-prescribe mandates showed some resistance from the medical community. The position of the American Medical Association was resistance to mandates circa 2007 and physicians were exhibiting resistance to technology (Sipkoff, 2008). A 2009 focus group study of Massachusetts clinicians, in small and medium practices, evaluated the value of e-prescribe technology. They criticized the volume of alerts that could result in alert fatigue (Weingart et al., 2009). They were ambivalent to the improved efficiency of e-prescribing and their attitudes to utilize were impacted by an opportunity for payer incentive systems versus self-purchase.

Many physicians do not desire to take on e-prescribe because they feel that it is inefficient compared with paper prescriptions (Smith, 2006). Evidence, however, has demonstrated that there is a learning curve associated with the utilization of e-prescribe instead of paper prescriptions and e-prescribe related errors also follow a learning curve (Craxford, Taylor, Duguid, Shivji, & Pickering, 2015). A significant reduction of over one minute can be recognized within as little as two months of system utilization as well as quality improvement.

Improvements in perception have been demonstrated two years following implementation in comparison with implementations less than a year underway. A study conducted within a large family medicine residency clinic in Alabama evaluated prescriber satisfaction with e-prescribing through a survey (Duffy, Yiu, Molokhia, Walker, & Perkins, 2010). Prescriber favorability was 93% happy that the clinic had adopted e-prescribing. Despite such a positive response, the prescribers provided negative feedback about e-prescribing including 30% of respondents having difficulty locating a patient pharmacy in the system and 41% feeling that the system did not cut down on overall workload including calls during and after hours. Additionally, 47% of prescribers had an experience with an e-prescription reported as not received by the pharmacy.

Barriers to e-prescribe for pharmacies in non-metro settings can include costs related to start-up implementation, maintenance costs, and associated transaction fees (Lander, Klepser, Cochran, Lomelin, & Morien, 2012). This creates a conundrum for prescribers if e-prescribing is unavailable at patients desired pharmacy, and has been a source of frustration for physicians as they report that they are unable to e-prescribe as much as they could (Amirfar et al., 2011).

4.3.4 THEME 3: HEALTH SYSTEM IMPACTS

4.3.4.1 Subtheme 1: Formulary Selection

A study in a large healthcare center (Brigham and Women's Hospital) demonstrated enhanced formulary selection by as much as 75% with the utilization of computerized physician order entry (Teich et al., 2000). This enhanced formulary selection, therefore, has the opportunity to drive positive health system initiatives.

4.3.4.2 Subtheme 2: Prescription Opioid Abuse

The value that e-prescribe brings to the reduction of opioid diversion includes physician monitoring of filled prescriptions, pharmacy prescription medicine monitoring compiled information, and elimination of altered or forged prescriptions (U.S. Department of Health & Human Services, 2016). E-prescribe utilization allows those technologies, such as prescription monitoring program data, to integrate and provide the prescriber with vital information. Eliminating the potential for forgeries through handwritten prescriptions, by mandating e-prescribe for controlled substances, is another qualitative value of e-prescribe. With as many as 9% of opioid prescriptions, the result of forged prescriptions (O'Donnell, 2016) e-prescribe is, therefore, an opportunity to reduce those forgeries and eliminate circulating opioids in the community. With an average of 650,000 prescriptions written for opioids each day in the US, this would equate to 21.35 million prescriptions each year (U.S. Department of Health & Human Services, 2016).

4.4 QUANTITATIVE ANALYSIS

Regulatory motivations were used to categorize quantifiable economic impacts found in the literature search and subsequently complete the Cost Benefit Analysis. Benefits that emerged from the analysis, that could be quantified, included improved clinical outcomes, formulary selection, patient satisfaction, and reduced consumer waiting times. Both direct and indirect costs were considered in the research. Costs included direct costs of e-prescribing software and software maintenance. Indirect costs, relative to changes in administrative costs considered, included provider training on e-prescribe systems, licensing, auditing, and several administrative provider activities that would shift costs such as making phone calls, faxing, and records storage. The quantitative impact of the opioid abuse regulatory motive was measurable through the costs of forged prescriptions in the US. The final regulatory motivation category, the implementation tool to establish e-prescribe, was quantifiable in the form of payor incentives and penalties.

4.5 QUANTITATIVE RESULTS AND FINDINGS

4.5.1 BENEFITS

Quantitative benefits included several aspects of improved patient clinical outcomes. Financial impact of medication non-adherence is attributed to between 3% and 10% of overall costs in healthcare (McGuire & Iuga, 2014). It has been found that the overall cost benefit of medication adherence with e-prescribing has been estimated over a ten year period to be \$140 billion (Health Manag Techno, 2012). Medication errors have been estimated to cost \$21 billion annually for combined inpatient and outpatient medication errors (National Priorities Partnership, 2011). The number of deaths has been estimated at 7 million annually in the United States as a result of medication errors (National Priorities Partnership, 2011). The cost for an ADE has been estimated at \$2000 to \$2500 (Kilbridge, 2006). Reductions in medication errors, therefore, have a positive economic impact.

Another measurable economic benefit that can result from the utilization of e-prescribing is better formulary drug choices by physicians. A study in community-based settings in Massachusetts of 17.4 million prescriptions utilizing e-prescribing, demonstrated a 3.3% increase in Tier 1 drug selection out of a 3 tier formulary model (Fischer et al., 2008). This increase in effective formulary selections was estimated for 100,000 patients and would equate to \$845,000.

There are additional financial aspects of patient satisfaction for providers of healthcare services that were classified as benefits. The recent federal regulatory initiative of the Affordable Care Act (ACA) ties patient satisfaction scores to reimbursement and therefore has a financial bearing (Murphy, 2016). It has also been shown that hospital revenues increased by 70% when patient satisfaction survey scores improved by just 10% (Revenue 360, 2016). Another key to patient satisfaction, wait times at the pharmacy, has been estimated by the DEA in their March 2010 report to be \$1.08 billion over 15 years at a 7% annualized rate (Drug Enforcement Administration, 2010). Therefore, actions in the healthcare setting such as e-prescribe that improve patient satisfaction, have the potential to generate financial benefit

4.5.2 COSTS

4.5.2.1 Administrative Activity Costs

Providers of services have cost impacts from e-prescribe as a result of changes to administrative processes. Benefits have been estimated at as much as \$1.4 billion a year by the DEA, although acknowledged that this may take many years to fully achieve through expansion of e-prescribe and appropriate utilization tools providing e-prescribe an advantage (Drug Enforcement Administration, 2010). Included in that estimate would be benefits recognized from reduced time spent on the phone with physicians, physician office staff, and pharmacies. Annually, a ten physician practice has been estimated to have an annual cost of \$157,700 for calls with a pharmacy. The US Department of Health and Human Services reports that the annual cost of these phone calls has been estimated at \$20,000 per office (Health Resources & Services Administration, 2016). The cost impact of reducing these cost is therefore significant if we factor in the typical cost of time spent on the phone between physician centers and a pharmacy (MGMA, 2004). The total savings for callbacks has also been estimated at \$420 million at 7% annualized rate for the overall healthcare system in the US over 15 years (Drug Enforcement Administration, 2010).

The time to utilize e-prescribe rather than handwritten administration also needs to be considered in contrast to the cost of phone calls. A study of three patient clinics within a healthcare system that were e-prescribing utilizing a system connected with the EHR, demonstrated an increase in the time to e-prescribe all types of prescriptions versus handwrite the prescription by 25 seconds (Devine et al., 2010). This included various prescribing practitioners within the healthcare system. New prescriptions took 29 seconds longer versus 13 seconds for renewal prescriptions. In addition, there was an increase in the time to e-prescribe in the examining room of 24 seconds. Conversely, an inpatient hospital study which examined all physicians ordering electronically demonstrated a savings of \$887 in charges per admission. Included in those savings was a reduction in drug costs of 15.1%, for 5219 eligible admissions. Annual savings on drug supplies for the hospital system could be extrapolated to \$300,000 per year. Although the study did not

break down the type of orders, there was a conclusion that more time was spent writing orders than the control group.

A further opportunity to reduce administrative costs in healthcare is via the reduction in paper records storage. Pharmacies are required by federal law to maintain prescription records for controlled substances for two years from the last filled date according to the CFR §1304.04 Maintenance of records and inventories (Drug Enforcement Administration, 2014). Other record retention requirements include Medicare Part D which requires plan sponsors to retain records for a minimum of ten years (Drug Enforcement Administration, 2010). The introduction of e-prescribe technologies that reduce paper record storage, therefore, has the opportunity to save the healthcare sector, including total estimated savings for pharmacy paper storage equal to \$1.38 million annualized at 7% over 15 years (Drug Enforcement Administration, 2010).

4.5.2.2 Cost of Establishing and Maintaining E-Prescribe Systems

The cost of establishing an e-prescribe system for a prescriber is dependent on the decision to have a standalone system or to integrate with an EHR. The US Department of Health and Human Services, Health Resources and Service Administration (HRSA) provides a resource for determining cost (HRSA, 2016) “How much does an e-prescribing system cost?”. The National e-prescribing Patient Safety Initiative makes the entry cost free for a standalone system up to \$2,500. Costs for an integrated EHR range from \$15,000 to \$70,000 per provider (HealthIT.gov, 2014). Costs, however, do not include all implementation fees for an EHR. HealthIT.GOV, a federal resource, cites five implementation costs including hardware, software, implementation assistance, training, and ongoing network fees and maintenance. Annual maintenance costs and fees have been estimated to range between \$3,000 to \$9,000 per physician annually (The Center for Improving Medication Management, 2011). Overall technology equipment and related costs in 2015 for a physician have topped \$32,500 (MGMA, 2016).

In an economic impact published by the DEA, the annualized costs of establishing qualified systems for e-prescribing of controlled substances is estimated at \$43,329,829.00 where Option 1 is 2-factor credentialing without biometrics, \$53,864,576.00 for Option 2 which includes

biometrics, and \$1,535,922,056.00 for Option 3 which has no 2-factor credentialing and a mandatory pharmacy prescription validation by phone (Drug Enforcement Administration, 2010). Most of the direct practitioner cost in Options 1 and 2 is driven by the requirement to obtain identity proofing, to renew the credential every three years, and by the requirement to check security incident logs. The application provider costs are primarily the costs of the initial reprogramming. These costs are based on a 7% annualized rate. The estimated impact on small entities on an annual basis is estimated at less than 0.2% of the lowest physician salary and less than 0.1% of an independent pharmacy annual sales (Drug Enforcement Administration, 2010). In addition, there is still the cost of the audit and reprogramming fees for systems to be incurred. There are also pharmacy costs to establish and maintain e-prescribe systems. Software systems have been estimated at upwards of \$500 and nominal monthly maintenance survey fees are also required (State of Nebraska, 2009).

We can also examine the costs of total IT as a ratio of IT expenditures to total capital expenditure in an effort to understand the total cost impact of the initial expenditure as well as ongoing maintenance costs. A study by the VA provided estimates of the private sector IT costs (Byrne, et al., 2010). Start up IT system and associated costs had a ratio of 1.48 and ongoing maintenance costs had a ratio of 2.49 in the private sector between the study period 2001 - 2007.

4.5.3 OPIOID ABUSE

Many of the legislative initiatives for e-prescribe have been related to the desire to reduce opioid prescription diversion. The cost to society for prescription opioid abuse in 2007 was estimated to be \$55.7 billion (Birnbaum et al., 2011; HHS, June 2016). Costs included those from crime, lost productivity, drug dependence treatment programs, and hospitalizations for drug abuse treatment. Emergency room and inpatient treatment costs for opioid poisonings were estimated at \$20 billion in 2013 (U.S. Department of Health & Human Services, 2016). Additionally, deaths increased by as much as 85% in the 10 years proceeding the 2011 cost estimates (Hansen et al., 2006). In September 2016, the CDC released information that those cost estimates had increased to \$78.5 billion for the United States (Dallas, 2016).

If we consider the reimbursement permitted by the US Affordable Care Act (ACA) reimbursement for 30 counts of a lower costing opioid, acetaminophen with codeine #3, the cost of a prescription to government patient assistance programs would be \$5.10 (Centers for Medicare & Medicaid Services, 2017). Eliminating the cost of 21.35 million forged prescriptions would be \$108.89 million annually. This is a very conservative estimate with an inexpensive opioid at ACA reimbursement rates; however, those cost savings would expect to be higher based on ACA reimbursement rates for more costly opioids. Existing studies of opioid costs between 1999 to 2004 showed average out of pocket costs for an opioid prescription to be \$10 (Craig & Strassels, 2010). Another study showed that the annual cost for opioids in the US was \$3.1 billion (Rasu et al., 2014). If we utilize the same approach based on the cost for 9% forged opioid prescriptions, the total cost impact would be \$324 million annually.

E-prescribe and associated opioid abuse reduction strategies have been recognized by the US government with \$5 million in presidential budgetary spending being dedicated to the Office of the National Coordinator of Health IT. Despite 88% of pharmacies enabled to accept controlled prescriptions electronically, only 20% of providers are capable and only 3.8% of e-prescription transactions are for controlled substances (HealthIT.gov, November 2016). Although the percentages are small, the volumes overall are impressive if one considers that an 18 month study showed an increase from 1,535 to 52,423 controlled prescriptions submitted electronically through the Surescripts network (Hufstader, Yang, Vaidya, & Wilkins, 2014). Therefore overall economic value in the form of reduced cost of opioid abuse to society has not fully been recognized, however has demonstrated economic cost value ranging from a conservative amount of \$108.89 to \$324 million annually for elimination of forged prescriptions alone.

4.5.4 IMPLEMENTATION TOOL TO ESTABLISH E-PRESCRIBE (INCENTIVES)

Despite the costs of establishing e-prescribe systems, there are means to reducing start-up costs. Financing options are available through individual state programs and technology vendors (The Center for Improving Medication Management, 2011). Free options are also available through vendors and government resources. The State of Maryland started an incentive program for EHR

adoption beginning in April 2011 via the House Bill 706 Electronic Health Records Regulation and Reimbursement (Maryland Health Care Commission, 2016). This incentive program funded by insurance payers can result in a one-time incentive of up to \$15,000 per practice (Maryland Health Care Commission, 2016). Additional downward adjustment of 2% of reimbursement for government payer eligible providers, not utilizing e-prescribe through the reporting of clinical quality measures through EHR Options, is an economic impact to offset technology costs (Centers for Medicare & Medicaid Services, 2015). Prior to 2014 government incentives to e-prescribe could be recognized from \$44,000 to \$63,750 (Agency for Healthcare Research and Quality, US Department of Health & Human Services, 2011). These incentives also provided a technology cost offset (Agency for Healthcare Research and Quality, US Department of Health & Human Services, 2011). These free and incentive options need to be considered carefully though because government incentive programs have minimum functionality requirements of the software (Centers for Medicare & Medicaid Services, 2008).

CHAPTER 5 DISCUSSION AND ANALYSIS

E-prescribe technology utilization has tremendously increased since its origins as a health technology vehicle to improve the available prescription channels. In 2015 9.7 billion transactions were reported by Surescript in their annual report, which is a 47% increase over the prior years transactions and an exponential increase in the less than 120 million transactions reported in 2007. The significance of this is the correlation of the timing of United States federal and state legislation to prescription volume increasing for e-prescribe.

5.1 QUALITATIVE DISCUSSION AND ANALYSIS

Original impressions of e-prescribe by physicians and similar providers of prescriptions was that it was slow, not preferred by patients, and too expensive. Certainly, the work required to convert traditional paper file charting to complex, paperless, IT systems capable of storing paper records might seem necessary given the busy schedules of providers and their desire to dedicate their time to patients versus technology. Changes in workflow include a shift from handwritten prescriptions by prescribers, to standalone computers or handheld devices that require the prescriber to make specific selections of required prescription elements and the patient pharmacy for transmission. The verbal prescription impact might be a much different workflow change for new prescriptions where a designee may call in the prescription, but with e-prescribe, only those with appropriate access levels could enter, sign, and transmit the prescription. Along with the workflow changes, there are training requirements for users. The cost of the efforts for a large healthcare system could be feasible due to the scale. However, costs for independent practitioners and small practices would be more difficult to implement, as shifts in staff to new workflow roles may not translate to headcount savings or may require increased headcount during learning curve implementation and transition. A similar conundrum for small entity pharmacies existed for the initial IT investment.

All of these perceived obstacles and costs to transition to exclusively e-prescribe did not make it a desirable option for many members of the prescribing community and small entities. Evidence of the quality improvement value of e-prescribing versus traditional methods of prescribing, as

early as the turn of the century, was a powerful catalyst for change. The United States legislative environment and that of the individual states, with regard to individual statutes and resultant regulations related to the practice of pharmacy, is geared to protecting the health, safety, and welfare of its citizens. Quality equals patient safety and therefore regulatory action to promote and protect patient safety was an appropriate next step in speeding the transition to the e-prescribe channel across the United States. It is clear that the federal government and individual states have citizen or patient-centric motivations for legislation requiring the e-prescribe channel. Each has a different means by which e-prescribe will benefit its citizens, but the overall incentive of the government is to improve their health, safety, and welfare. If we explore each of their motivations we can clearly see the benefit, although an initial cost investment may be recognized by the prescribing community to drive these long-term benefits.

5.2 QUANTITATIVE DISCUSSION AND ANALYSIS

Regulatory actions in the United States, both Federal and State, have influenced the channel change to prescriptions that are prescribed electronically rather than traditionally handwritten, verbal, or faxed. Some of these actions have mandated the change with significant penalties for non-compliance and others have imposed incentives which can also be viewed as penalties for those not receiving monetary compensation for switching to e-prescribe. All of the legislative activity has accelerated the transition to e-prescribe and eliminated the cost burden choice for the prescribing community. If we compare the specific cost factors outlined in Table 5.2, that are associated with the implementation of e-prescribe, and the cost-benefit outcomes of using this channel versus traditional methods, the hesitancy to pursue e-prescribe does not add up because the positive economic value far exceeds the cost.

COSTS TO ESTABLISH E-PRESCRIBE

Table 5.2

Establishing and Maintaining E-Prescribe Systems	Cost
Standalone System Entry Cost	\$2,500 per system
Integrated EHR	\$15,000 to \$70,000 per provider
Annual System Maintenance	\$3,000 to \$9,000 per provider
Annual Costs of Credentialed System (including system security and credentialing every 3 years)	0.2% of the lowest physician salary and less than 0.1% of an independent pharmacy annual sales based on an annualized rate of 7%

The positive economic value can be proven by examining all of the legislative motivations provided for mandating e-prescribe (with or without penalties). Projected and assessed quantitative economic benefits of e-prescribe have been outlined in Table 5.2.1. The aspect of improved patient quality was the initial impetus for prescription channel change and has the longest studied data to support the positive financial benefit. Financial gains are recognized with the patient clinical outcomes at \$240 billion over a ten-year period and a 7% annualized rate. Initially perceived as a barrier, workflow impacts at the providers level can have a recognized cost savings following the implementation period. If we examine provider benefits there is a nationwide benefit recognized with workflow changes and reduced records storage, resulting in overall reduced administrative costs combined of \$422.38 million nationwide over a 15 year period and a 7% annualized rate. These workflow savings at the pharmacy and prescribers also influence the patient through decreased wait times, a financial benefit to the consumer. Additional financial benefits that impact the patient as well as the overall health system are recognized as the result of formulary selection improvements and improved patient satisfaction. Although not conclusively available in the literature, financial benefits can be extrapolated as related to opiate abuse reduction through e-prescribe technology and has the potential to further augment cost savings benefits from e-prescribe.

E-PRESCRIBE ECONOMIC BENEFITS

Table 5.2.1

Regulatory Motivation	Economic Value
Benefits	
Patient Satisfaction	70% increase in hospital revenues for 10% improvement
Pharmacy Consumer Wait Times	\$1.08 billion nationwide over a 15 year period
Improved Patient Clinical Outcomes	\$240 billion nationwide over a ten year period
Formulary Selection	\$845,000 per 100 patients
Costs	
Provider Administrative Costs (Phone Calls)	\$420 million nationwide over a 15 year period
Pharmacy Records Storage	\$1.38 million nationwide over a 15 year period
Opioid Abuse	
Opioid Prescription Forged Prescriptions	\$108.89 to \$324 million annually
Implementation Tool to Establish E-prescribe (Incentives)	
Government Payer Incentives	Prior to 2014, \$44,000 to \$63,750 over ten years
Government Payer Penalties	After 2013, 2% of reimbursement penalty if not adhering to EHR clinical quality measures

Balancing the standalone benefits of e-prescribe to the healthcare system are the legislative benefits afforded the prescribing community. Individual prescriber benefit of \$100,000 over a ten year period in the form of government payer incentives is a significant aspect to consider. This must also be balanced against the potential for penalties, for not e-prescribing or failing to report per CMS specifications. The incentive savings and potential penalties alone can payback the initial investment for an integrated EHR. If the software selected is a part of a free or incentive program the provider realizes further savings. This therefore alone provides justification for investment in the long-term benefits that can be recognized. If we consider the qualitative aspects of improving patient quality of health through e-prescribe, the comprehensive value of moving to the e-prescribe channel cannot be challenged.

CHAPTER 6 CONCLUSION AND RECOMMENDATIONS

Despite the initial investment and subsequent maintenance costs brought on by legislation for e-prescribe technology, the qualitative and quantitative holistic economic value of the cost savings exceeds the costs of technology in the long term. United States legislative actions taken to date have accelerated the transition of the healthcare community to the e-prescribe channel and are justified by the patient favorable clinical outcomes, patient satisfaction and comprehensive cost savings that e-prescribe generates.

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