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# From HIPAA to HITECH: A Case Study of Stakeholder Influences on the Shift in Government Response to Patient Privacy Violations

Heather N. Smith

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FROM HIPAA TO HITECH: A CASE STUDY OF STAKEHOLDER INFLUENCES ON THE  
SHIFT IN GOVERNMENT RESPONSE TO PATIENT PRIVACY VIOLATIONS

A Dissertation

Submitted to the School of Graduate Studies and Research

in Partial Fulfillment of the

Requirements for the Degree

Doctor of Philosophy

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Title: From HIPAA to HITECH: A Case Study of Stakeholder Influences on the Shift in Government Response to Patient Privacy Violations

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This study explores the policy shift from voluntary to punitive enforcement of privacy violations of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 by the U.S. Department of Health and Human Services' Office of Civil Rights. Specifically, I examined why policymakers altered the enforcement of HIPAA and how different stakeholders influenced policy change. I apply the multiple-streams framework, social movements and countervailing powers, and bounded rationality to this question. The qualitative inquiry involved purposively sampling documents of various types, two levels of coding, and thematic analysis.

I found policymakers modified the enforcement of the HIPAA privacy regulation, despite the opposition of industry, because consumer/privacy advocacy groups worked together and were prepared for a window of opportunity for policy change. Such a window opened in 2008 amid the confluence of a transition in Presidential administrations, Democrats taking a majority in both houses of Congress, and widely supported legislation at the height of the Great Recession, the American Recovery and Reinvestment Act (ARRA), to which to attach the policy change, HITECH.

Stakeholders promoted their policy positions differently. Industry groups wrote letters to policymakers while privacy advocates and governmental officials used the media to disseminate views. Stakeholder group representatives provided congressional testimony and some accepted or left government positions. Consumer/privacy groups worked together, and government

stakeholders indicated they would collaborate with other government and consumer/privacy groups. Industry and professional groups made unsuccessful attempts to influence the policy shift through suggestions in public comment letters. Stakeholder groups opposed to a change in policy enforcement argued that fines are unnecessary and ineffective. Proponents of the policy enforcement shift, consumer/privacy and government groups, consistently pointed to the lack of fines as a reason why the shift was needed.

The findings of this study suggested that the absence of meaningful consequences for privacy violations made for ineffective policy. Industry groups recommended increased transparency from the government enforcement agency. Privacy groups opposed voluntary compliance, arguing it lacked a persuasive element. These findings parallel the policy literature and my professional observations. Stakeholders' preparation to capitalize on an open policy window parallels Kingdon's (2011) multiple-streams framework.

## ACKNOWLEDGEMENTS

Throughout my academic progression, I have found inspiration in certain words of wisdom. My late grandmother, Edna Mae Empfield Serro, repeatedly told me that knowledge is the one thing that other people cannot take away from you. Therefore, I express deep gratitude to my parents, Donna J. and Gerald F. Smith, who encouraged and supported my pursuit of knowledge.

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## LIST OF ACRONYMS

Acronym		Page
OCR	U.S. Department of Health and Human Services Office for Civil Rights .....	1
HHS	U.S. Department of Health and Human Services .....	1
HIPAA	Health Insurance Portability and Accountability Act of 1996.....	1
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## CHAPTER 1

### INTRODUCTION

#### **Introduction**

If a policy is not working, what provokes policymakers to change it? This question encapsulates the topic of this case study. Specifically, this study focuses on the policy shift in how the Office for Civil Rights (OCR) under the U.S. Department of Health and Human Services (HHS) enforces the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and how OCR handles violations. The Privacy Rule pertains to health plans, health care clearinghouses, and certain health care providers who electronically send or receive health information (U. S. Department of Health and Human Services, Office for Civil Rights [OCR], 2003, 2006, 2017d). Thus, these parties must safeguard patient information. The Privacy Rule also stipulates that applicable parties protect any identifying health information or protected health information that encompass any identifiable information involving mental and physical health conditions, care provisions, and payments regarding treatment (OCR, 2003).

Since the Privacy Rule was finalized, enforcement responsibility had to be assigned. OCR enforces the Privacy Rule (OCR, 2017c; Standards for Privacy, 2000). The original enforcement process had multiple steps. First, the receipt of complaints drove the enforcement process. The enforcement of HIPAA was based on complaints reported by individuals who stated that covered entities had committed violations (Maliniak & Mitchel, 2006). Second, OCR officials only investigated complaints if individuals registered them within 180 days of knowing about an incident, an incident occurred after the adherence deadline, if an incident qualified as a violation, and if a complaint pertained to a covered entity (OCR, 2017b). Third, OCR officials utilized informal solutions, such as voluntary compliance. HHS adopted an enforcement method

centered on cooperation that included permitting the settlement of situations through informal measures (Standards for Privacy, 1999). OCR also uses an enforcement approach that promotes voluntary compliance with civil rights violations. If evidence shows that an entity covered under civil rights discrimination laws did not follow the applicable regulation, OCR tries to settle the case through procuring corrective activities via a voluntary arrangement (OCR, 2015). However, the use of informal means such as, voluntary compliance, as an enforcement philosophy became an issue of debate resulting in modified philosophy that stresses penalties.

As with any debate, parties had opposing opinions regarding whether the original enforcement philosophy appropriately addressed Privacy Rule violations. Parties who agreed with original enforcement philosophy included government officials, the health care industry, and covered entities; whereas, parties who disagreed with original enforcement philosophy included privacy advocates, privacy experts/attorneys, and health care consumers. For example, government officials and privacy advocates expressed differing views concerning the success of gaining voluntary compliance from those individuals, groups, and organizations accountable for maintaining patient privacy under the HIPAA regulations. In responding to public comments submitted on the HIPAA Enforcement Rule, HHS stated “encouraging voluntary compliance is the most effective and quickest way of obtaining compliance in most cases” (HIPAA Administrative Simplification, 2006, p. 8394). HHS went on to try and to support the claim with statistics. HHS asserted that as of 2006 the agency’s experience with privacy complaints shows the efficiency of voluntary compliance with a 68 % closure or resolution rate which the agency interprets as a demonstration of privacy issues being resolved (HIPAA Administrative Simplification, 2006). Whereas, privacy advocates do not favorably view voluntary compliance (Gray, 2008). Therefore, I decided to focus this case study on different stakeholder perspectives

regarding the handling of privacy violations and highlight how these perspectives influenced a policy shift through legislation from enforcement through voluntary compliance to a more punitive approach that involves penalties.

### **Background Issues**

This section addresses background issues regarding why privacy is important and details about the HIPAA Privacy Rule.

**The importance of privacy.** E. L. Godkin (1890), a newspaper editor in the late nineteenth century, argued that curiosity is the main adversary that privacy faces. During his examination of privacy, Godkin (1890) highlighted two concepts pertaining to control, which individuals may deeply hold. The first concept is maintaining control over the personal aspects of one's life. The right to determine the level of information regarding personal emotions, beliefs, or inclinations that is publicly accessible is a right comparable to the right to determine what one consumes or how one dresses (Godkin, 1890). The second concept is having control over other people's opinion of a person. Godkin (1890) commented on dignity by stating that "without privacy its cultivation or preservation is hardly possible" (p. 66). Godkin summarized why individuals would want to control the personal aspects of their lives along other people's opinion of them. How members of a social group regard an individual's virtue is the highest valued item an individual possesses (Godkin, 1890).

The two concepts of control and privacy may be linked. Americans prize an individual's right to privacy and autonomy (Saxon, Jacinto, & Dziegelewski, 2006). For instance, individuals may exercise autonomy when considering what information should be conveyed to health care personnel in order to safeguard against invasions of personal privacy. The issue of trust is a key component of the physician-patient relationship. Annas (2003) stated that "(t)he chief public-

policy rationale is that patients are unlikely to disclose intimate details that are necessary for their proper medical care to their physicians unless they trust their physicians to keep that information secret” (p. 1486). A passage in the proposed Privacy Rule addressed this concept and referenced a survey by the California HealthCare Foundation (CHCF) in the discussion of how privacy concerns influence consumer behavior. In the CHCF survey, one-sixth of people who completed the survey responded that they took measures to prevent the inappropriate use of personal data, including switching providers, evading treatment, and giving providers erroneous data (Standards for Privacy, 1999). If mistrust or uncertainty regarding privacy protections exists in the health care sector mistrust may grow among patients, which in turn may influence treatment effectiveness in terms providers giving mistaken diagnoses. Individuals who have reservations regarding their privacy may offer erroneous information when they pursue care, resulting in professionals assigning incorrect diagnoses and care protocols due to receiving flawed information (Standards for Privacy, 1999).

Additionally, individuals who have reservations regarding their privacy being maintained may not pursue care (Standards for Privacy, 1999); this negatively influences the health care system that in turn impacts society (Collins, 2007). For example, an individual who has a contagious illness not seeking treatment, because they worry that a curious neighbor who works for their physician will see test results and share that information with other neighbors. The proposed Privacy Rule contained a passage that expanded upon this concept of privacy being important by addressing the provision of care for vulnerable diagnostic populations providing additional examples when describing the benefits of privacy standards. The four populations (HIV/AIDS, other sexually transmitted diseases, cancer, and mental health or substance abuse

treatment) are the populations who would gain greater levels of certainty or trust from having privacy practices (Standards for Privacy, 1999).

- 1996
  - August 21, 1996: President Clinton signed the HIPAA provisions into law (U.S. Congress, n.d.).
- 1999
  - November 3, 1999: The proposed Privacy Rule was published for public comment on November 3, 1999 (OCR, 2003).
- 2000
  - December 28, 2000: The original final Privacy Rule was published (Standards for Privacy, 2000).
- 2002
  - October 15, 2002: The final Privacy Rule that took effect (Standards for Privacy, 2002).
- 2003
  - April 14, 2003: The compliance date for Privacy Rule standards (Solove, 2013).
- 2009
  - February 17, 2009: The Health Information Technology for Economic and Clinical Health Act (HITECH), part of the American Recovery and Reinvestment Act of 2009 (ARRA), was enacted, and the proposed rule was published on July 14, 2010 (Modifications to the HIPAA Privacy, 2010).
  - October 30, 2009: The interim final rule regarding HIPAA enforcement was published and became effective on November 30, 2009 (Modifications to the HIPAA Privacy, 2010).
- 2011
  - February 22, 2011: OCR issued the first civil monetary penalty for Privacy Rule violations (U. S. Department of Health and Human Services Press Office [HHS Press Office], 2011a).
- 2013
  - January 25, 2013: The final rule resulting from HITECH was published and became effective on March 26, 2013 (Modifications to the HIPAA Privacy, 2013)

*Figure 1.* HIPAA timeline. This figure is a timeline that illustrates the evolution of HIPAA and the Privacy Rule by marking milestones dates.

**Impetus of the HIPAA Privacy Rule.** The modified final version of the Privacy Rule was effective in October 2002 (Standards for Privacy, 2002). Policymakers designed HIPAA to protect health care consumers' information. Legislators passed HIPAA with ambitions that involved more protection of personal medical information (Breux & Anton, 2008). Such legislation is important, because it decreases potential bias. The proposed Privacy Rule stated that "the proposed privacy protections may prevent or reduce the risk of unfair treatment or discrimination against vulnerable categories of persons, such as those who are HIV positive, and thereby, foster better health" (Standards for Privacy, 1999, p. 60010).

Beckerman and her coauthors (2008) agreed with the importance of privacy protection and explained the ramifications of an inappropriate disclosure for a person who has delicate information in their medical history. The wrongful release of health information concerning sensitive matters such as genetics and psychological disorders may result in significant detriment to the effected individual in the form of discrimination regarding insurance coverage and employment as well as public shame (Beckerman et al., 2008). Also, the proposed Privacy Rule addressed how privacy standards would be of importance to people who are not members of vulnerable diagnostic populations: "Even for relatively minor conditions, an individual still might be concerned with maintaining privacy, and even a person with no significant health problems is going to value privacy, because of the possibility at some time they will have a condition that they want to keep private" (Standards for Privacy, 1999, p. 60020).

**Handling privacy violations under HIPAA.** The purpose of the Privacy Rule is to safeguard private health-related information while still promoting the exchange of information to guarantee effective treatment. A main objective of the Privacy Rule is protecting personal health information, permitting the required trading of information needed to ensure quality health care

while guarding public health (OCR, 2003). The Privacy Rule pertains to covered entities. A covered entity is a health care clearinghouse, health plan, or health care providers who electronically send or receive health information related to a transaction applicable under HIPAA (OCR, 2003, 2006, 2017d). Since the Privacy Rule was finalized, the HHS secretary assigned the responsibility of enforcement to OCR. OCR is tasked with enforcement of the Privacy Rule (OCR, 2017c; Standards for Privacy, 2000). OCR is one of fourteen offices and boards which the HHS Office of the Secretary oversees (U. S. Department of Health and Human Services, Assistant Secretary for Public Affairs, 2018). OCR is responsible for ensuring that the rights of individuals are not limited or violated. The mission statement of OCR reads in part “to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination, and to protect the privacy and security of health information in accordance with applicable law” (OCR, 2017a).

As a part of this responsibility to protect privacy, HIPAA regulations mandate that the secretary of HHS and OCR, by extension, seek to settle violations through voluntary compliance. The Privacy Rule dictates that OCR must attempt to garner voluntary compliance (Gray, 2008; OCR, 2006). Furthermore, parties referred to as covered entities under HIPAA, such as providers, hospitals, and health insurance plans, are aware of the possible consequences and tend to prefer voluntary compliance to the alternative. Covered entities favor the enforcement process that urges voluntary compliance instead of having formal administrative procedures and assessing civil monetary fines (Hill, Langvardt, & Rinehart, 2009).

“Covered entity” is an umbrella term used in texts and discussions regarding HIPAA. It describes parties who are responsible for observing patient privacy and are accountable for violations outlined in the regulations. Due to the prolific use of “covered entity” in sources, I use

the term throughout this text to remain consistent. However, the alternative terms can be substituted for “covered entity.” The alternative terms include; group practices, health care clearinghouses, health insurance plans, hospitals, medical clinics, and physicians.

Policymakers assigned a set of consequences to accompany Privacy Rule violations but not all violations and subsequent consequences are equal. When officials determine a civil violation of privacy standards has occurred, options for an outcome exist before monetary fines are considered. OCR tries to settle violating incidents through voluntary compliance, resolution agreements, or corrective actions (OCR, 2017c). If a covered entity does not meet settlement conditions, consequences progress in seriousness. OCR may assign civil monetary penalties when the entity fails to negate the noncompliant situation in a suitable manner (OCR, 2017c).

*Voluntary compliance.* The enforcement process is a multi-faceted endeavor with complaints driving the process. The enforcement of HIPAA is based on complaints reported by individuals who think that covered entities have committed violations (Maliniak & Mitchel, 2006). OCR officials have relied on informal solutions, such as voluntary compliance, when possible. The Privacy Rule affords HHS the authority to settle privacy complaints through informal means, an authority that HHS commonly employs (Hill et al., 2009). OCR officials only consider civil monetary penalties after unsuccessful attempts at voluntary compliance. According to the regulations, covered entities may informally settle violations through exhibiting compliance or finishing corrective action plans; however, fines may be assessed if informal settlements cannot be reached (Maliniak & Mitchel, 2006; OCR, 2006).

A basis of support for voluntary compliance as a viable enforcement approach directly comes from government officials and regulatory texts. Hutton and Barry (2005) included comments from government officials that tout the success and effectiveness of voluntary

compliance. The view that voluntary compliance is a success also appears in a HIPAA regulatory text. The final HIPAA Enforcement Rule included a statement that touted voluntary compliance as a swift and successful means of resolving compliance issues (HIPAA Administrative Simplification, 2006). Health care clearinghouses, health plans, and providers have encountered minimal enforcement of HIPAA and face a negligible risk of fines due to violations (Davis, 2009). However, voluntary compliance without repercussions such as monetary fines is perceived as a deficiency (Gray, 2008) that hinders adherence to the HIPAA Privacy Rule (Collins, 2007; Gray, 2008).

### **Audiences**

Several audiences may find this study of interest. The first audience is professionals and students in the fields of sociology, psychology, health care administration, public policy, and law given the focus on the HIPAA Privacy Rule and patient privacy. A second audience is health care compliance/privacy officers and other health care administrators, who work to minimize the risk of violations and address the consequences when violations do occur. A final audience is health care attorneys, because the study offers insights into future enforcement and policy activities.

### **Problem Statement**

My research problem concerns stakeholder influences on the shift in government response to privacy violations in health care. The Privacy Rule affords HHS with the authority to settle privacy complaints through informal means; HHS employs informal means to settle complaints (Hill et al., 2009). Participation in voluntary compliance includes the responsibility of addressing the violating situations. In fact, covered entities are obligated to record and report

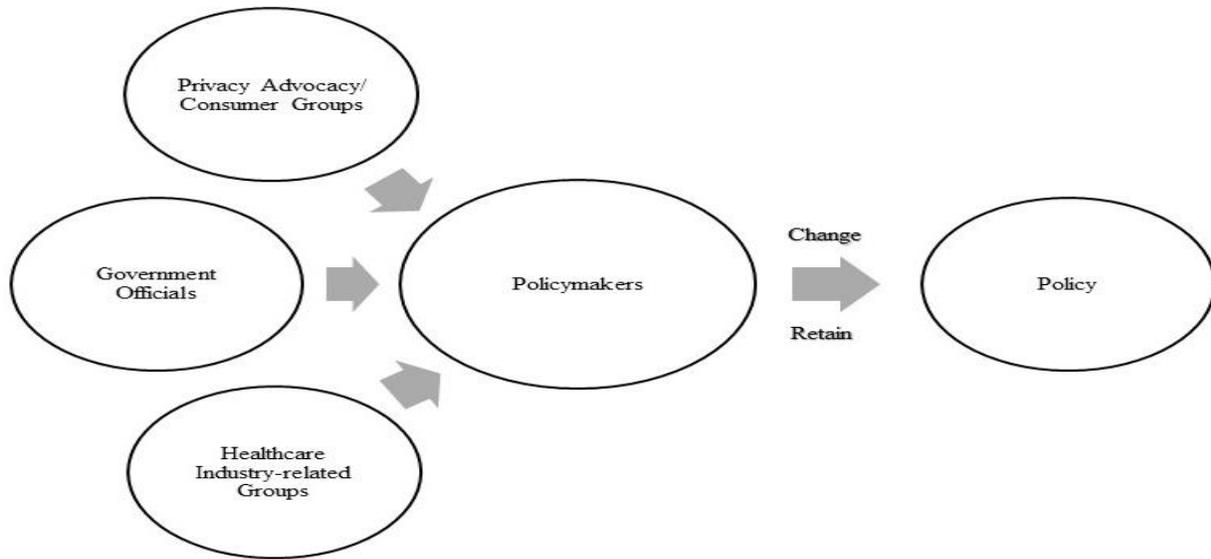
on completed remedies. With informal resolutions, HHS secures guarantees from violators that the issues in question were addressed through agreements and corrective plans (OCR, 2006).

Nevertheless, privacy advocates and health care consumers believed that OCR focusing on voluntary compliance defeats the purpose of the HIPAA regulations (Gray, 2008). Other critics of voluntary compliance asserted that the approach does not possess the incentives or the consequences necessary to promote implementation of change by offending organizations. OCR instructs violators to take corrective actions, but voluntary compliance lacks persuasive influence (Gray, 2008). Rebecca Herold, CEO of The Privacy Professor, echoed this sentiment while commenting on the original enforcement philosophy focusing on voluntary compliance. According to Solove (2013), Herold contended that numerous covered entities failed to revise privacy policies after the initial implementations, because the covered entities recognized that OCR was not issuing penalties in response to noncompliant activities. OCR officials consider civil monetary penalties after attempts at voluntary compliance are unsuccessful. Based on the regulations, covered entities may informally settle violations through exhibiting compliance or finishing corrective action plans; however, fines may be assessed if informal settlements cannot be reached (Maliniak & Mitchel, 2006; OCR, 2006). Thus, the use of voluntary compliance as an enforcement approach has been an issue of debate between different policy stakeholders.

### **Purpose and Objectives of the Case Study**

The purpose of this study is to explore how policy stakeholders influenced the policy shift from the original enforcement philosophy focused on voluntary compliance to a punitive philosophy. The objectives of the study are rooted in the expectations and the research questions, which address how stakeholders contributed to the policy shift regarding the handling of privacy violations.

**Expectations and research questions.** As a qualitative case study, the study contains expectations and related research questions. My expectations include (1) the argument for change stems from a dearth in penalties for violations, (2) the decision point for policymakers' concerns change not being easily discernible, and (3) the stakeholder groups seeking a policy change are more influential with lawmakers.



*Figure 2.* Model of stakeholder influence. This figure is a model that illustrates I how envisioned stakeholder influence regarding the policy shift.

Figure 2 depicts how I consider stakeholder influence regarding the policy shift with different groups promoting their views. The stakeholder groups are on the left and the policymakers are in the center. The arrows represent influence with the groups influencing policymakers and policymakers influencing the policy. The positioning of the stakeholder groups relates to their views on the policy and policy shift with advocacy groups promoting change and industry-related groups promoting retainment. I placed government officials in the middle since I think the view of this group as being changeable based on circumstances.

My study includes one overarching question with three subquestions on aspects of stakeholder influence concerning the policy shift. The research questions parallel the idea that

individuals in the field of sociology “are inherently interested in determining whose interests might be furthered by any legislation and why some groups fail while others succeed in achieving their objectives” (Quadagno, 2010, p. 134). The study’s primary research question is as follows: Why did policymakers alter the original enforcement philosophy under the HIPAA Privacy Rule to the enforcement philosophy outlined in the modifications under HITECH? Subquestions include: (a) In what ways did policy stakeholders influence the policy shift from the original enforcement philosophy to a more punitive philosophy? (b) How did stakeholder groups collaborate to promote certain perspectives and concepts? (c) How did stakeholder perspectives on the lack of civil money penalties or fines influence the policy shift?

### **Significance**

The policy shift in question can influence opinions about the value of privacy safeguards. The case study adds to the existing information about Privacy Rule enforcement as well as factors that assist in creating policy shifts. The study provides scholarly evidence on how stakeholders influence the decisions of policymakers. Finally, the study uses different theoretical perspectives to understand policy development.

### **Statement of Researcher Positionality**

I wanted to acknowledge my positions on certain concepts associated with the research topic.

**Viewpoint statement.** I need to acknowledge that my professional experiences and observations as a corporate compliance officer for a privately-owned behavioral health provider led me to an interest in the enforcement process that inspired this study. Moreover, I recognize that these experiences and observations were at the individual and organizational levels and have influenced my numerous beliefs, values, biases, and opinions that pertain to the HIPAA Privacy

Rule and related enforcement procedures. My beliefs regarding the federal government's enforcement of the Privacy Rule are negatively slanted due to my professional experiences. I believe that the Privacy Rule has a well-intended goal, but the original enforcement procedures have shortcomings. By extension, I believe that voluntary compliance has some deficiencies and, thus was not an effective enforcement approach. I believe that some defiance of rules always exists; therefore, I am not confident that every organization with substantiated violations would address the issues that permitted the violations to occur without more punitive consequences than voluntary compliance.

I have a few opinions and related biases regarding privacy and the HIPAA Privacy Rule. I have two opinions relevant to how OCR handles privacy violations. First, I think that voluntary compliance is not a viable approach to enforcing the HIPAA Privacy Rule. I developed this informed opinion based on my review of the scholarly literature (e.g., Collins, 2007; Gray, 2008). Second, I think that improvements to enforcement via voluntary compliance were needed. I developed this opinion from the view that no procedure is implemented perfectly; however, flaws can be addressed within reason. Therefore, I have a bias towards voluntary compliance not being a successful enforcement strategy and argue that a policy shift was appropriate. Also, I have a bias toward the modified policy being successful. Since privacy protection has been a focus in my professional life, I want the HIPAA and HITECH provisions to remain in place and relevant, because I plan to resume my career in health care compliance.

I also personally value medical privacy. Like most people, I do not want anyone not directly associated with my treatment having knowledge of my medical information. Also, I believe that the risk of improper use or disclosure positively correlates with the number of people who know the information. However, I understand that mistakes and oversights occur, and I

appreciate admissions of mistakes and attempts to resolve the issues. As a trained clinician and compliance officer, I respect and value consumer privacy. I always try to keep in mind how I would feel if the patient in question was my family member.

### **Assumptions**

Due to my professional background in psychology, I think that individuals actively attempt to comprehend the surrounding environment and their place in that environment. I also believe in the existence of multiple realities. In several psychology courses, my professors conveyed the concept that every person has his or her own reality due to how each person perceives events. Thus, the concept of multiple realities may be applicable to how stakeholder groups view policies, which in turn, encourages efforts either for or against policy changes.

### **Delimitations**

This study has four delimitations. First, the scope of the study is limited to a single policy shift between the HIPAA Privacy Rule and the HITECH modifications. Second, the study is limited to Privacy Rule violations rather than all HIPAA violations, because the volume of information would be too cumbersome. Third, I have chosen to pursue particularity over generalizability. This choice is due to the study addressing a particular change in policy with specific stakeholder groups. During the research process, a fourth delimitation pertaining to potential data sources emerged. I initially thought that internet-based discussion boards and/or blogs would be a robust data source. The ability to garner useful information from these sources proved to be problematic in that the sources did not address relevant topics or did not have entries dating back far enough. Thus, the delimitations associated with my study also influenced the findings and what information could be interpreted from those findings.

## **Overview of Remaining Chapters**

The case study focuses on why policymakers altered the enforcement philosophy from enforcement through voluntary compliance to a punitive approach that includes established criteria for activities garnering monetary penalties and for assessing levels of penalties. The study addresses the overarching research question of why policymakers altered the enforcement philosophy along with three subquestions concerning different aspects of stakeholder influence regarding the policy shift. Chapter 2 addresses the relevant scholarly literature. Chapters 3, 4, and 5 covers the methods, findings, and interpretations of this study. The study also highlights (1) the multiple-streams framework, which addresses how factors within the spheres of policy, politics, and social problems affect agenda setting; (2) the theory of rulemaking and regulation, which addresses policy development; (3) concepts related to social movements and countervailing powers, which pertain to how stakeholders utilize influence; (4) the theory of bureaucracy with attention to legal-rational authority and its consequences; and (5) the theory of bounded rationality, which seeks to understand decision making in the context of flawed or incomplete knowledge. I use qualitative methods and coding procedures for document review and textual analysis, as well as, a validation process that employs data triangulation, acknowledgment of bias, and thick description. I present findings pertaining to voluntary compliance are discussed considering the scholarly literature on how policy develops and in terms of my professional experiences on individual and organizational levels as a compliance officer. Finally, I discuss my interpretations of the findings pertaining to the research questions and present suggestions for future research including suggestions that stem from supplemental findings.

## CHAPTER 2

### LITERATURE REVIEW

#### **Chapter Overview**

This chapter contains an outline of the background of HIPAA and the Privacy Rule along with a review of the relevant literature and theories that inform my conceptual framework. This review covers policy development, social movements, and stakeholder participation as well as shifts in how privacy violations are handled. It concludes with the conceptual framework.

#### **Background**

Two central questions regarding HIPAA and the Privacy Rule are pertinent to this study. The first question is how HIPAA and the Privacy Rule, by extension, came about. The second question is why the policy shifted in terms of how OCR handles violations. These questions are relevant to the structure and organization of the United States (U.S.) health care system and privacy in America. HIPAA is the preeminent legislation on health care privacy. HHS implemented the Privacy Rule as the nationwide criterion for safeguarding personal health data (Standards for Privacy, 2002). Violations of privacy in health care may contribute to mistrust of providers, which, in turn, may affect treatment effectiveness. Individuals who distrust providers may offer erroneous information when they pursue care, which result in misdiagnoses (Standards for Privacy, 1999). Additionally, people who distrust privacy protections refrain from seeking treatment, which disturbs the social order. Individuals with reservations regarding their privacy being maintained may not pursue care, and avoidance of treatment negatively affects the health care system and society (Collins, 2007).

**Privacy before HIPAA.** It is useful to understand the right to privacy in U.S. society, to provide a context for the discussion. There are three related concepts to consider. Privacy

encompasses how people should respect personal boundaries. For example, when a patient and a physician privately discuss a personal health matter, privacy is operating. Second, security shapes how information is protected and how a physician stores patient charts in a locked limited access file room. Third, confidentiality denotes restrictions on certain knowledge; for example, only particular individuals are permitted to know and discuss certain patient information.

In general, personal privacy gained attention in the late nineteenth century. Journalists' methods prompted "The Right to Privacy" written by Warren and Brandeis in 1890 (Solove, 2003). Warren and Brandeis (1890) posited that newspapers resorted to reporting rumors: "Gossip is no longer the resource of the idle and of the vicious, but has become a trade, which is pursued with industry as well as effrontery" (p. 196). Godkin (1890) succinctly summarized the connections among newspaper reporting, rumors, and threats to personal privacy, stating that the main adversary of privacy is the curiosity of others, which feeds gossip.

Within a medical context, privacy was relevant long before HIPAA became policy. Expectations of privacy has existed within the field for centuries. Individuals' right to privacy regarding health information dates to Hippocrates with physicians being required to maintain privacy (Annas, 2003). Eventually, this expectation moved from a professional standard of medical practice to a legal concept: "Privacy matters deeply in American society and law, no aspect of privacy is more important than the privacy of health information" (Beckerman et al., 2008, p. 2). Simply, people desire and expect personal privacy: "The right to privacy is one of the rights most widely demanded today" (McCloskey, 1980, p. 17). Individuals wish their right to privacy to be acknowledged, and object to intrusions of that privacy (McCloskey, 1980).

**Intent of HIPAA.** Legislators passed HIPAA with ambitions that involved more protection of personal medical information (Breux & Anton, 2008). Yet, policymakers did not

create HIPAA solely to ensure privacy of health information. According to the preamble to the legislation, the U.S. Congress enacted HIPAA to modify the Internal Revenue Code adopted in 1986 as a means of increasing stability pertaining to insurance coverage (Health Insurance Portability and Accountability Act, 1996). The proposed Privacy Rule addressed possible discrimination through promoting safeguards that “may prevent or reduce the risk of unfair treatment or discrimination against vulnerable categories of persons” (Standards for Privacy, 1999, p. 60010). In addition, lawmakers designed the legislation to serve several other functions: to streamline administration of insurance; to increase the availability of long-term care insurance and promote medical savings accounts; and to decrease insurance abuse and fraud (Health Insurance Portability and Accountability Act, 1996). In fact, policymakers only addressed privacy under one subtitle of the legislation. Subtitle F of HIPAA, which modifies the provisions within the Social Security Act, outlines the administrative simplification standards that include privacy provisions (Health Insurance Portability and Accountability Act, 1996). Moreover, lawmakers did not appear concerned with developing medical privacy standards. Congress failed to provide privacy regulations within the timeframe specified under HIPAA and left HHS to draft standards in time for a required comment period (OCR, 2003). Hence, HHS developed the stipulations and elements that comprise medical privacy and was responsible for establishing privacy standards (OCR, 2003).

**The HIPAA Privacy Rule.** The revised Privacy Rule became effective in October 2002 (Standards for Privacy, 2002). The modified rule is the product of a multistage progression which included; moving from a proposed version, to a first final version, two comment periods, and subsequent alterations with corrective releases published in the *Federal Register*. Policymakers designed HIPAA regulations to protect patient information and encourage the

exchange of information needed for effective treatment (OCR, 2003). HIPAA can be interpreted as a means of balancing the privacy needs of consumers with the information that the health care industry needs in order to facilitate care. Policymakers planned for HIPAA to create a legal structure for personal health related data merging the desire for personal privacy with the required transfer of data (Beckerman et al., 2008). However, the Privacy Rule only pertains to those providers that qualify as covered entities. A covered entity is a health care clearinghouse, health plan, or health care provider that electronically sends health information in relation to a transaction applicable under HIPAA (OCR, 2003, 2006). Though the electronic transmission caveat for providers may appear outdated given the current prevalence of electronically exchanging information, HHS via OCR still retains the caveat within the description of a covered entity. On the HHS web page entitled “Covered Entities and Business Associates,” the description of an applicable provider includes the caveat of using electronic transmission of information in relation to transactions regulated by HHS (OCR, 2017d).

Thus, providers who are considered covered entities under the Privacy Rule must protect patient information. The Privacy Rule stipulates that covered entities protect identifying health information that encompasses any identifiable information involving mental and physical health conditions, care provisions, and payments regarding treatment (Standards for Privacy, 2002). Since the Privacy Rule was finalized, enforcement responsibility had to be assigned. OCR was tasked with the enforcement of the Privacy Rule (OCR, 2017c; Standards for Privacy, 2000). As part of enforcement responsibility, the HHS secretary tries to settle violations through voluntary compliance. The final Enforcement Rule contained in the HIPAA Administrative Simplification stresses an informal nondisiplinary method rooted in education and cooperation (Brown, 2009). HHS and OCR personnel are familiar with an enforcement approach that promotes voluntary

compliance, such as incidents of civil rights violations. If evidence shows that an entity covered under civil rights discrimination laws did not follow regulations, OCR tries to settle the case through procuring corrective activities via a voluntary arrangement (OCR, 2015).

***Informal resolutions.*** Even after OCR verifies a violation, the agency gives the covered entity an opportunity to remedy the situation. A passage in the final HIPAA Enforcement Rule stated that “opportunities will precede a determination of a violation, however, that will permit the Secretary to exercise his discretion to not impose a penalty” (HIPAA Administrative Simplification, 2006, p. 8400). This reflects how HHS through OCR uses informal solutions, such as voluntary compliance. The Privacy Rule affords HHS the authority to settle privacy complaints through informal means (Hill et al., 2009). HHS and OCR use the term “informal means” which appears in regulatory texts to describe a subset of resolutions. Regulatory texts list examples of informal means as “demonstrated compliance or a completed corrective action plan or other agreement” (Modifications to the HIPAA Privacy, 2013 p. 5690; OCR, 2013, p. 21). The emphasis on voluntary compliance and reliance on informal methods for settling a violation is compatible with prior HHS enforcement (Rahman, 2006).

***Criticisms of voluntary compliance.*** HHS denies “that encouraging voluntary compliance and seeking informal resolution of complaints in individual cases constitutes lax enforcement” (HIPAA Administrative Simplification, 2006, p. 8394). Nonetheless, criticism of the practice involves that exact issue. Privacy advocates do not view voluntary compliance favorably, because it is not a punitive approach (Gray, 2008). HHS has failed to penalize covered entities that have violated HIPAA (De Armond, 2008). OCR received complaints and engaged in settlements, but officials released few details; ironically, the enforcement process safeguards the privacy of privacy violators (Gray, 2008). Voluntary compliance is devoid of

motivation for covered entities to change privacy practices. Gray (2008) asserted that OCR instructed violators to take corrective actions, but voluntary compliance lacks persuasive influence. These criticisms may stem from the belief that voluntary compliance encourages ambivalence about privacy practices and violations leading to the regulations being useless. If no guarantee of rule enforcement exists, the rules attached to HIPAA will be ineffective and pointless (Collins, 2007).

An extension of this critique involves the dearth of financial penalties assessed due to privacy violations. OCR does not levy civil monetary fines for Privacy Rule violations (Rahman, 2006). Critics contended that the lack of monetary penalties make covered entities careless about observing privacy. Murphy (2008) concluded that OCR's focus on assistance contributes to complacency among covered entities. In other words, voluntary compliance without penalties does not motivate covered entities to comply with regulations. The logic is that providers do not follow privacy standards because of insufficient incentives (Collins, 2007). Without citing instances, Rebecca Herold, CEO of The Privacy Professor, expanded on this stating that covered entities have not amended policies (after the original implementations) because the covered entities recognized that OCR was not assessing penalties (Solove, 2013).

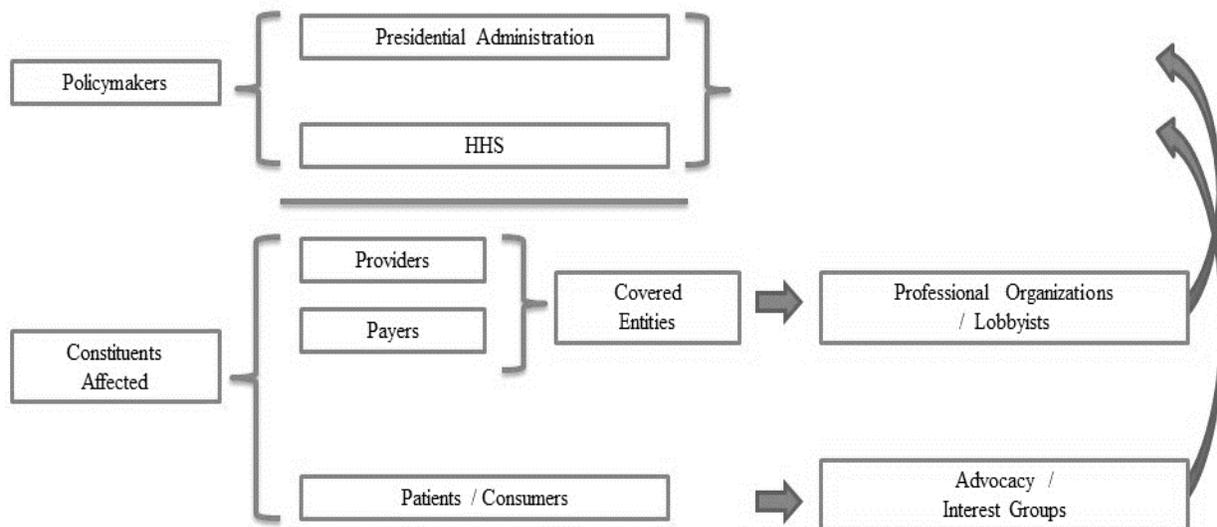
Another critique is that complainants are overlooked and do not experience a complete resolution (Gray, 2008). Individuals whose privacy was violated may report their concern to OCR but cannot sue the violator. Under the Privacy Rule, individuals only may register a complaint with OCR (Gray, 2008; Letzring & Snow, 2011). People do not have a right to private action against covered entities (Collins, 2007; Gray, 2008; Letzring & Snow, 2011). Therefore, covered entities are not held accountable through the legal system. Covered entities need not worry about lawsuits from patients whose privacy has been violated, because the HIPAA statute

does not stipulate whether people can sue providers regarding violations (De Armond, 2008). When OCR does assess penalties, complainants do not receive remuneration. Despite any enforcement actions, victims of privacy violations in the health care sector are not compensated (Collins, 2007). Beckerman et al. (2008) agreed that the legal options under HIPAA were limited for someone affected by a privacy violation. HIPAA does not establish a private right of action at the federal level allowing individuals to sue covered entities in order to receive compensation for breaches of privacy. Even so, Beckerman et al. (2008) posited that HIPAA might aid in pursuing private remedies by creating a benchmark for providers behavior where other statutes address liability allowing for private remedies. A policy shift manifests in different ways: “Influencing the policy process may entail a variety of goals from the adoption of a new policy to minor adjustments to institutional arrangements in current policies” (Weible, Heikkila, deLeon, & Sabatier, 2012, p. 1). In sum, the critiques of voluntary compliance center on lacking a compelling influence in terms of changing in privacy practices, no fines, and no way for complainants to obtain a direct legal resolution that holds violators accountable.

**The HITECH Act.** A policy shift occurred in the form of modification by the HITECH Act. The resulting final rule was effective as of March 26, 2013; however, September 23, 2013 (180 days) was the deadline for covered entities and business associates to reach compliance with the modifications including those involving the Privacy Rule (Modifications to the HIPAA Privacy, 2013). This simple declaration of a compliance deadline may leave some individuals with the impression that altering the established regulations to mirror HITECH provisions was a straightforward process. However, my research for this study indicates the policy shift was complex. I explore the policy shift in subsequent chapters, but before detailing my methods and findings, I review the literature and discuss theories that inform my study.

## Theoretical Framework

Theories drawn from separate fields apply to my study of the policy shift on privacy enforcement in the health care sector. First, I review how policy happens drawing heavily from the work of John W. Kingdon (1984, 2011) and regulatory rulemaking highlighted in the work of Deborah A. Stone (1988, 2002). Second, in reviewing how participants shape policy and social change, I use the work of Jill Quadagno (2004, 2005) and Theda Skocpol (1995) on stakeholders and social movements and Donald W. Light's work (2010) on countervailing powers. Third, in thinking about how policy decisions are made, I review a theory of bureaucracy derived from the work of Max Weber (1946/2014, 1947/2009), as well as a theory of bounded rationality based on the work of James G. March (1978, 2006) and Herbert A. Simon (1971, 1979, 1991, 1993).



*Figure 3.* How policy happens. This figure illustrates the flow of stakeholder influence regarding public policy.

**How policy happens.** Figure 3 depicts the flow of stakeholder influence. For this study, a stakeholder is a party who has an interest in how the federal government responds to patient privacy violations. Each box represents a participant or stakeholder group. The top two bracketed boxes on the left represent groups who develop and write policy (policymakers). The

bottom three bracketed boxes on the left represent groups who are affected by policy (constituents affected), and the boxes on the right represent the groups who influence policy on behalf of those groups affected by policy. The line under the “HHS” box represents the separation point between policymakers and the constituents affected by policy. The outside arrows on the right represent organized influence. I view the difference between nonorganized and organized influences is that individual covered entities and consumers are the sources of nonorganized influence; whereas, professional organizations and advocacy groups with established structures and agendas are the sources of organized influence. Policy scholars may focus on the entire phenomenon or different aspects of the phenomenon depicted in Figure 3. For the purposes of this study, the focus is on the participant groups represented by the boxes (i.e., presidential administration, HHS, professional organizations, and advocacy groups) and the organized influences represented by the outside arrows on the right of the figure.

**Multiple-streams framework.** The foundation of the multiple-streams (MS) framework is from organizational theory. Kingdon (1984) created the multiple-streams framework inspired by the garbage can model of action from Cohen, March, and Olsen (Sabatier, 1999, 2007b). The free flow of ideas and people is central to a garbage can model. The model depicts choice as a garbage can where contributors flow in and out of decisionmaking while leaving extraneous issues and answers behind; the process of choice evolves without a particular individual overseeing the process (Sabatier, 2007b). The MS framework alters concepts from the original model to address policy. Kingdon modified the garbage can model for application to the U.S. government and highlighted agenda setting and selecting alternatives (Zahariadis, 1999).

Three streams serve as the foundation of the framework. The framework posits that the policy process contains procedures and parties constituting different streams with unique

conventions and characteristics (Sabatier, 1999, 2007b; Zahariadis, 1999). The political stream, as the name implies, involves politicians. Elections and those officials who hold positions based on election results comprise the political stream (Sabatier, 1999, 2007b). Second, the problem stream pertains to thoughts about an issue. In the problem stream, participants advocate for how issues are delineated with ambiguity regarding these delineations as well as objectives being an assumption of the framework (Sabatier, 1999). The problem stream attends to popular problems. The issues that people most want addressed are part of the problem stream (Zahariadis, 2007). Third, the policy stream concerns how to address a problem. In the policy stream, participants advocate for particular answers to issues (Sabatier, 1999, 2007b).

***Policy participants.*** Participants or stakeholders influence agenda setting organized within operating sectors (i.e., the public sector, the private sector, the public). After discussing the participants, I turn to contextual attributes that influence whether issues appear on agendas.

Participant groups may be designated as visible or hidden (Kingdon, 2011). Involved participants operate within the governmental structure, such as bureaucrats and politicians, or beyond the governmental structure, such as members of interest groups, the public, and media (Kingdon, 2011). Individuals are active but have different levels of exposure. Visibility translates into an impact on agendas (Kingdon, 2011). Visible participants including congressional members, high-level appointees, and the president, capture interest from the media as well as the public (Kingdon, 2011). Conversely, those with less visibility impact policy choices. Hidden participants influence the applicable policy alternatives (Kingdon, 2011). Government officials and civil service employees comprise less visible participants, as they hold lesser positions. Hidden participants are lower-level appointees, bureaucrats, academics, or researchers (Kingdon, 2011). Visibility can fluctuate based on circumstances; thus, the groups

move between categories. Interest groups may qualify under either classification depending on the action the groups are involved in at a given time (Kingdon, 2011). Four stakeholder groups operate within the public sector. Three are visible participants (the president, political appointees, and Congress) and the fourth group (bureaucrats) is a hidden participant. Also, the two initial stakeholder groups are integral pieces of a presidential administration.

*The president.* As depicted in Figure 3, the Office of the President fits into the “Presidential Administration” box regarding policy flow. The president and political appointees comprise the human elements of an administration (Kingdon, 2011). The president and the administration have influence concerning attention for agenda items. If an administration regards an issue as a priority, other participants exhibit the same high regard for the issue; however, if an administration does not regard an issue as a priority, supporters of a proposal must curtail expectations (Kingdon, 2011). In addition to prioritizing agenda items, the president wields influence through other actions. The president has control over certain resources such as public exposure that may compel action, organizational decisiveness, and capabilities on an institutional level such as personnel decisions and veto power (Kingdon, 2011).

*Political appointees.* Political appointee positions fit into the “Presidential Administration” category as depicted in Figure 3, but certain appointees also fit into “HHS” box depending the department of the positions. As the term implies, appointees occupy positions for which individuals are chosen rather than hired. A president selects appointees to be officials who serve in government bureaus, departments, and agencies (Kingdon, 2011). The term also is applicable to persons chosen by other high-level officials. A director of an agency and the vice president select the people classified as political appointees (U.S. Office of Government Ethics [OGE], 2017). Appointees are members of the executive branch and are subject to ethical

scrutiny. Political appointees must observe additional ethical constraints beyond those constraints imposed on the standard personnel of the executive branch (OGE, 2017).

Political appointees are able to affect agenda matters over a wide range of government institutions. Appointees can affect the agendas of influential individuals located either inside or outside of a particular agency (Kingdon, 2011). However, time constraints may accompany this ability. Appointees have experienced relatively brief tenures which contributes to the pressure to initiate changes (Kingdon, 2011). Moreover, adding to this pressure also is the pressure to concentrate on the priorities of the president. Political appointees need to address the issues that the president wants to see addressed, because differences in priorities creates political discomfiture for the president (Kingdon, 2011).

*Members of Congress.* In Figure 3, this stakeholder group fits into the “Policymakers” box on the far left. As with the president and political appointees, members of Congress affect the governmental agenda. Congressional legislators can influence agendas along with the available options; therefore, Congress occupies an important position in regard to policy development (Kingdon, 2011). Members also have legitimate authority at their disposal. Congressional members have legal authority as a resource which is key since significant modifications to policy frequently call for additional statutes (Kingdon, 2011). Additionally, members frequently have assets beyond legal authority. Congressional legislators have different resources including: long tenures, the ability to generate publicity regarding issues, and the receipt of data or information from varied sources (e.g., constituents, bureaucrats, interest groups) which may be combined (Kingdon, 2011).

*Bureaucrats.* For purposes of this study, bureaucrats are HHS or OCR employees; therefore, these individuals are grouped into the “HHS” box in Figure 3. The term “bureaucrat”

often has a negative connotation. However, Kingdon (2011) utilized the term “bureaucrat” when describing a civil servant; in fact, the index refers readers to “civil servants” when looking up “bureaucrats.” Some bureaucrats closely work with policies. Staff bureaucrats in positions within departments that allow those individuals to consider policies and attributes (Kingdon, 2011). Moreover, bureaucrats possess unique advantages that are useful in navigating their work environments. Kingdon (2011) contended that career bureaucrats have three assets: (1) long tenures, (2) knowledge and experience in functioning within the political system and interacting with members of interest groups, and (3) the raptors that develop due to these interactions. The relationships that bureaucrats develop and maintain with other parties operating within their environment are so involved that the relationships are resistant to outside influences. According to Kingdon (2011), “(t)he relationship between these three actors – bureaucrats, committees, and interest groups – is often called an iron triangle, because their interests dovetail nicely and because they are alleged to be impenetrable from the outside and uncontrollable by president, political appointees, or legislators not on the committees in question.” (p. 33).

The following six stakeholder groups operate within the private sector. The first four stakeholder groups are hidden participants while the last two groups are visible participants. Visible participants garner attention from the public and the media while hidden participants complete tasks in the background (Kingdon, 2011).

*Policy entrepreneurs.* Policy entrepreneurs comprise a hidden participant group located throughout politics. Entrepreneurs occupy different positions within the political arena (Kingdon, 2011). In Figure 3, policy entrepreneurs may occupy space in the “Advocacy/Interest Groups” box or the “Professional Organizations/Lobbyists” box depending on the circumstances. Policy entrepreneurs have unique relationships and qualities which may be utilized with

expectations of reciprocation. Kingdon (2011) stated that policy entrepreneurs are “advocates who are willing to invest their resources – time, energy, reputation, money – to promote a position in return for anticipated future gain in the form of material, purposive, or solidary benefits” (p. 179). Even so, the procurement of a policy entrepreneur has some advantages. Entrepreneurs offer benefits including; tenacity, bargaining capabilities, political contacts, and participating in hearings. In sum, policy entrepreneurs contribute to the policy process in various ways. Policy entrepreneurs exercise good timing and are prepared to rely on their character along with putting forth effort and finances to achieve an objective (Weible et al., 2012).

Policy entrepreneurs function both inside and outside of politics. Effective entrepreneurs utilize assets to influence politicians. Zahariadis (1999) stated that “successful entrepreneurs are those who are willing to spend considerable amounts of resources (time, energy, money, etc.) to make their ideas and pet proposals palatable to various policymakers” (p. 84). The promotion of a policy to the public is a function beyond politics. Policy entrepreneurs prime the public and the policy community about a policy through activities such as numerous meeting, composing documents, media involvement, and participating in hearings (Kingdon, 2011).

*Academics and researchers.* Academics and researchers comprise another hidden participant group. Based on Figure 3, either, the “Advocacy/Interest Groups” box or the “Professional Organizations/Lobbyists” box, may pair with the activities of this group contingent on the purpose or funding source. The influence of these participants is widespread. Except for interest groups, academics and researchers are the group of highest importance among the private sector groups and whose impact may be recognized in policy activities (Kingdon, 2011). Scholars may affect policy in various ways based on the focus of the research involved. Academics may have knowledge of the immediate and future ramifications of a policy or have

knowledge regarding policy alternatives (Kingdon, 2011). Researchers also are information sources for policymakers. Policymakers request that researchers share their knowledge during meetings and hearings (Kingdon, 2011). Still, politicians have differing views concerning such knowledge. Some politicians seek the advice of academics pertaining to policy; nonetheless, others regard the work of academics with suspicion and contempt (Kingdon, 2011).

*Interest groups.* Another hidden participant group is interest groups. In reference to Figure 3, this participant group logically falls into the “Advocacy/Interest Groups” box. The purposes of such groups are numerous and varied. Interest groups represent a wide range of population segments including; different public concerns, professions, and industries (Kingdon, 2011). However, experts within all interest groups serve the same purpose in the policy stream. Experts with awareness of an issue are a component of the policy stream and work toward realizing an answer (Odom-Forren & Hahn, 2006). These groups employ various techniques to promote a given concern or issue. Interest groups activate or garner advocates through communications, having representatives, and encouraging associates to engage in similar actions to gain consideration from officials (Kingdon, 2011). Also, the goal of an interest group is focused on producing one of two outcomes. The actions of interest groups are aimed at either hindering the possibility of modifying policy or advocating for new directions in policy with hindering efforts to modify policies being the more common goal (Kingdon, 2011).

*Health care industry.* In Figure 3, the “Professional Organizations/Lobbyists” box includes representatives of the health care industry. I delineated this stakeholder group from interest groups to reflect the difference in populations served. In Figure 3, the “Providers (Covered Entities)” box connects to the “Professional Organizations/lobbyists” box. Kingdon (2011) utilized actions within the health care industry to illustrate interest group activities.

However, for this study, actions within the health care industry are addressed in a separate subsection. Hospitals and physicians each have organizations that promote the concerns of the respective groups. The American Hospital Association and the American Medical Association are professional organizations that serve as industry interest groups in health care (Kingdon, 2011). For example, hospitals and health care workers, by extension, can influence various agenda items. This is because each “congressional district has hospitals and their trustees are pillars of the community” (Kingdon, 2011, p. 51). Kingdon cited how this ability swayed politicians against cost control efforts during the Carter administration. Esteemed physicians and hospital leaders conveyed to elected officials the opposition to these efforts along with information pertaining to how the legislation would affect their particular institution.

Health insurers also have interests to promote and protect within the health care industry. Kingdon (2011) referred to these concerns in terms of the debate over national coverage. Per a congressional staff member, “everybody with any interest in it leaps in to protect his own turf; the commercial insurance industry, the Blues [Blue Cross and Blue Shield]” (p. 51).

*Media.* A visible participant group concerning establishing agenda items is the media. Media is the only participant group without a discernable location in Figure 3 reflecting that media has an overarching influence which potentially involves the other participant groups. Members of the media frequently are portrayed as having influence in terms of agenda setting (Kingdon, 2011). The activities of this participant group are effective in swaying the public: “Mass media clearly do affect the public opinion agenda” (Kingdon, 2011, p. 57). People in positions to make policy decisions does not view the actions of the media in a favorable manner: “Active policy makers often express their disdain for media sensationalism” (Kingdon, 2011, p. 58). Even so, the policy community does not necessarily experience the ramifications of such

coverage. The media engages in concentrated spans of dramatic coverage, but the policy community continues to function beyond the media fray. Moreover, limited attention spans lessen the ramifications of media scrutiny. The media have a penchant for only focusing on a story for a limited time; therefore, media have lesser impact on agendas than is perceived (Kingdon, 2011).

However, media coverage is a means of promoting an issue. A technique for bringing attention to an issue is to have the issue appear in a newspaper of significance (Kingdon, 2011). Even though the capacity for persuasion may be constricted, the capacity still is present. Media may represent a secondary influence on participant groups, but the significance of this influence fluctuates based on the participant group. The impact of media on social movements is an example of this secondary influence. Media coverage also highlights existing social movements (Kingdon, 2011).

*Public.* For this study, the public embodies patients or health care consumers and thus, would comprise the “Patients/Consumers” designation in Figure 3. The public is another visible participant group regarding public policy, and the influence of the public lies in the voicing of an opinion. The opinion of the public can have an adverse or favorable influence on whether issues appear on an agenda (Kingdon, 2011). If that voice is loud enough, public opinion may sway policymakers. Public opinion “might thrust some items onto the governmental agenda because the vast number of people interested in the issue would make it popular for vote-seeking politicians” (Kingdon, 2011, p. 65). Furthermore, if the voice of public opinion is soft or muted, a strong voice for an issue may be found elsewhere, “where public interest in an issue is low, expansion of the issue is largely left to professionals inside and outside government who seek to induce other actors to change policy” (Birkland, 1998, p. 73).

*Contextual circumstances.* The second part of the discussion concerns circumstances that may affect the placement of issues on government agendas. Three factors that influence agenda setting include the political process, critical incidents, and research reports (Kingdon, 2011). Each factor has the potential to either bolster or impede an issue on an agenda. These factors can catalyze or inhibit depending on the level and kind of attention while for the issue. The potential of each factor is connected to how well different parties foresees receptiveness. The ability of individuals in government to gauge the national mood allows certain agenda items to move forward while hindering others (Kingdon, 2011).

Another consideration is what type of agenda is being affected. Governmental agendas contain items that individuals focus on; however, decision agendas contain items that are on the threshold of being decided upon either by the president or through legislation (Kingdon, 2011). Even though an issue appears on a decision agenda, the possibility exists that the issue loses momentum. When the problem, political, and policy streams merge, an item is apt to move up on the decision agenda; however, when one of these factors is absent, the placement of an item on the agenda is brief (Kingdon, 2011). For example, perceived harm can provoke or deter policy change. The more ambiguous the event and the extent of resulting damage, the less chance an issue has of broadening which affects the possibility of the issue appearing on the agenda (Birkland, 1998).

*Policy alternatives.* The existence of policy alternatives also affects the appearance of an issue on an agenda. Hidden participant groups develop policy alternatives (Kingdon, 2011). Parties present policy alternatives in the form of proposals. The process is as follows; “(p)eople recognize problems, they generate proposals for public policy changes, and they engage in such political activities as election campaigns and pressure group lobbying” (Kingdon, 2011, p. 197).

Nonetheless, some participants try limit available alternatives. Alternative specification restricts the number of potential choices into the group of choices that may be selected (Kingdon, 2011).

*Personnel changes.* A personnel change is a circumstance that affects agendas. Election outcomes, the turnover of administrations, and change in civic attitude comprise the political stream (Kingdon, 2011; Odom-Forren & Hahn, 2006). They also comprise the political or partisan composition of the legislature (Kingdon, 2011). Change in presidential administration may mean potential agenda changes. Presidential administrations are a key player in policymaking, and changes in administrations create new ideas for consideration (Kingdon, 2011). However, agenda changes may contribute to an issue losing attention. Changes in personnel impede progress on items that previously were considered worthy (Kingdon, 2011). The change in presidential administrations from Clinton to Bush created doubt about the possibility of HIPAA being implemented since the Bush administration initiated another comment period (Solove, 2013).

*Feedback regarding programs.* The receipt and content of feedback for a current program is another circumstance influencing agenda setting and within the problem stream. Feedback typically based in public perspectives regarding established programs is a part of the problem stream (Odom-Forren & Hahn, 2006). Feedback is a valuable tool of issue recognition. Officials use feedback about how well an ongoing program functions to gain knowledge on issues (Kingdon, 2011). Feedback indicates when programs do not operate as prescribed. Program implementation is an issue if it does not match the espoused purpose. The officials may fail to manage a program in a manner consistent with legislators' aim (Kingdon, 2011).

The nature and extent of dysfunction can help determine a course of action. Even though expected adverse outcomes produce issues, unexpected outcomes that have significant influence

contribute to the perception that an issue exists and requires investigation (Kingdon, 2011). Government officials in higher positions may call for action based on a lack of goal attainment. Individuals in oversight positions may want to examine if an issue is present when program managers fail to achieve established objectives. Kingdon (2011) stated that feedback is important, because it “gives information on current performance that may not square with legislative or higher administrative intent, indicates a failure to meet goals, or suggests unanticipated consequences” (p. 113).

If a program is not functioning as expected, some bureaucrats might recognize and address the problem. Bureaucrats gain knowledge of issues by engaging in the everyday management of the programs (Kingdon, 2011). Reviewing information is a regular activity that can help identify problems. Thus, bureaucrats “constantly issue studies, reports, and other papers, some mandated by statute and some done on their own; these can play a part in preparing the policy community for some future direction” (Kingdon, 2011, p. 129). Due to the regular review of information, bureaucrats may identify possible problems. However, even with program feedback, the policy may remain unchanged despite dysfunction, because “there is some incentive to protect the existing program rather than to open it up to criticism and a possible pandora’s box of changes” (Kingdon, 2011, p. 31).

*Focusing events.* The occurrence of a focusing event is a third circumstance that impacts agenda setting and is a factor in the problem stream. As part of the problem stream, focusing events draw interest to a particular issue (Odom-Forren & Hahn, 2006). These occurrences produce a rapid flow of consideration regarding an issue. Focusing events garner attention more quickly than issues that require prolonged study of statistics such as crime or illness (Birkland, 1998). However, a balance in information comes with the speed in attention. With focusing

events, politicians and the public obtain knowledge at the same time; thus, the ability to frame the issue before the public begins to participate is lessened (Birkland, 1998). Focusing events also bolster the attention given to an issue that previously disappeared from agendas. Birkland (1998) asserted that focusing events spur interest in a latent issue which may result in the reconsideration of a policy due to failure.

*Policy windows.* The availability of an appropriate policy is another circumstance affecting agenda setting. A policy window is a chance for supporters of a proposal to promote their answer or awareness of a specific issue (Kingdon, 2011). Policy windows open and close based on the policy environment. Kingdon (2011) asserted that “(a) shift in climate, according to people who are actively involved in making or affecting public policy, make some proposals viable that would not have been viable before, and renders other proposals simply dead in the water” (p. 149). Thus, open policy windows signal openness to change. Open policy windows are scarce and quickly close; however, open windows lead to significant alterations to policy (Kingdon, 2011). Policy changes also occur when different factors align. Factors align when “(a) problem is recognized, a solution is developed and available in the policy community, a political change makes it the right time for policy change, and potential constraints are not severe” (Kingdon, 2011, p. 165).

Open policy windows do not frequently happen. Open windows may occur in response to politically based factors. Issues or happenings in the political stream create open windows (Zahariadis, 2007). The activities of visible participant groups also play a role in how frequent open window are. Open windows are rare, because Congress and presidential administrations experience backlogs and the overall structure has limited volume (Kingdon, 2011). Despite being rare, individuals may anticipate when windows will open. Certain official standards

stipulate the opening of windows at regular intervals for items such as reports, budgets, and renewals (Kingdon, 2011).

The scarcity and briefness of open policy windows means that policy windows tend to be closed. Policy windows only are open for limited periods (Zahariadis, 1999). Yet policy windows do not close without cause. Policy windows close for several reasons including: interested parties do not receive a response regarding a proposal and drop the matter, the interested parties believe a resolution to the issue has been established, alternatives do not exist, or the precipitating situation has lost attention (Kingdon, 2011). Finally, personnel changes close policy windows. Policy windows also close due to staff shifting in that the individuals holding central positions have changed (Kingdon, 2011).

*Coupling of the three streams.* The concept of coupling concerns the status of the three streams, but the concept also connects with policy windows and entrepreneurs. Kingdon perceived the streams as independently functioning unless policy entrepreneurs can couple the streams during a policy window (Sabatier, 1999, 2007b). The coupling of streams allows for certain issues to gain standing. Therefore, coupling involves when a policy item ascends on the agenda, because the three streams converge at a point in time (Zahariadis, 1999). The factor of who is in power also may affect coupling. Coupling occurs when particular lawmakers hold power in the midst of an open policy window (Zahariadis, 2007).

Policy entrepreneurs rely on stream coupling to increase the probability of success. Thus, “(a) policy’s chances of being adopted dramatically increase when all three streams – problems, policies, and politics – are coupled in a single package” (Zahariadis, 2007, p. 74). As with policy windows, the factor of who is in power at a certain time also affects entrepreneur success through coupling. Coupling describes the pairing of issues and answers offered by entrepreneurs

while interested lawmakers are available (Zahariadis, 1999). However, policy shifts may take place when entrepreneurs correctly approach stream coupling. If an entrepreneur effectively couples the streams, policy change occurs (Sabatier, 1999, 2007b).

*Criticisms of the multiple-streams framework.* Four areas of criticism address shortcomings concerning the MS framework. The first area concerns the origins or basis of the framework. Criticism of the framework involve errors concerning the garbage can model that inspired the framework (Zahariadis, 2007). Therefore, two criticisms of the garbage can model are of interest regarding the MS framework. The criticisms are that the findings stem from the assumptions associated with the model and that discrepancies exist between the computer-based stimulation attached to the original scholarly work and the verbal version of the model (Zahariadis, 2007). Despite any justifications for this criticism, empirical support exists for the actual framework. Zahariadis (2007) asserted “whatever the flaws of the garbage can model, MS is theoretically driven and empirically validated” (p. 80).

The second area focuses on the development and scope of the theory. Kingdon only highlights one phase of the policy process with the theory of agenda setting (Weible et al., 2012). Therefore, the theory has limited focus that requires advancement. Sabatier (1991) asserted that Kingdon “developed an interesting approach to agenda-setting and policy formulation, which may well be expandable to the entire policy process” (p. 151).

A third area of criticism involves theory application and validation. According to Ridde (2009), criticisms of Kingdon’s approach include being too focused on American politics. Due to this penchant, the application of the theory may have constrained validity. Ridde (2009) contended that Kingdon’s approach solely has been validated in terms of agenda setting for policies pertaining to nations with elevated revenue.

A fourth area of criticism pertains to the ability to prove or disprove the theory. This criticism stems from a lack of informative power. According to Ridde (2009), the toughest criticisms “are from those who think the framework, which has hardly been contested, in fact cannot be contested because of its limited, or even non-existent, explanatory capacity” (p. 941). Along with a lack of informative power, misrepresentation of outcomes is possible. Sabatier (2007a) asserted that falsification regarding the MS framework is problematic due to the amount of functional and structural variability along with a lack of clear premises.

**Rulemaking by regulation.** Next, I discuss the emergence of administrative agencies and thus administrative regulations. Agencies are a component of the executive branch; the governmental branch responsible for the implementation and execution of laws (USA.gov, 2018). Administrative agencies came to prominence within the federal landscape during the last century. Anderson and Jackson (2006) pointed out that some individuals regard agencies as a hypothetically separate governmental branch; they stated that during the 1900s, American politics witnessed power being removed from Congress and assigned to government organizations, which academics have labelled the “fourth branch of government - administrative agencies” (p. 78). With this change in roles came a change in duties. Before the shift in power, administrative agencies were to execute the instructions that the legislative and judicial bodies handed down; however, after the shift in power, these agencies were responsible for considering issues and determining the possible repercussions for violators (Anderson & Jackson, 2006).

Administrative agencies use rulemaking to create and distribute regulations. Under regulation-by-rulemaking, “(a)gencies issued written regulations that informed regulated entities how to conduct various aspects of their businesses” (Morriss, Yandle, & Dorchak, 2005, p. 179). Agency officials complete certain tasks or steps: they offer notice regarding a proposed activity,

establish a timeframe for comments pertaining to the proposed activity, and address noteworthy comments from concerned persons or entities within the final notice (Morriss et al., 2005; Yandle & Morriss, 2004). However, this process is not always linear. In regulation-by-rulemaking, an agency may have proceedings and may release multiple versions of a proposed rule before formulating and deciding on the final version of a rule (Morriss et al., 2005). Also, the regulation-by-rulemaking process can have one more element added even after the given agency disseminates the final regulation. The persons and entities impacted by the regulation, may attempt litigation after an agency has finalized the regulation (Yandle & Morriss, 2004).

Officials are supposed to create rules to meet societal goals. Policy design depends on rules to achieve social objectives (Stone, 2002). Policymakers also develop rules that direct actions as a means of social management. Behavioral rules serve as social management (Stone, 2002). Rules targeting behaviors focus on appropriateness under certain conditions. Interactions between policymakers and policy enforcers lead to the creation of rules, but the resulting rules set forth what actions should be taken given a situation and define acceptable actions (Stone, 2002). Simply stated, rules are preventive measures. Rules are in place to deter repeating previous errors (Powers, 2010).

However, the possibility exists for rules to be disregarded or violated. According to Stone (2002), “(s)ince rules are meant to make people do things they might otherwise not choose to do (or refrain from doing things they might choose to do), there is always some pressure on rules from potential evasion or disobedience” (p. 298). Subsequently, policymakers have the task of creating, monitoring, and enforcement procedures. Individuals, who disobey rules and restrictions have to be identified; therefore, societies have methods for monitoring behaviors, examining indiscretions or offenses, and ultimately deciding culpability (Westin, 1967). For that

reason, policymakers include inducements in rules so that citizens will follow the rules. Societies that adopt rules should establish devices for imposing the rules (Westin, 1967); thus, rules contain incentives for individuals to act inside established parameters (Stone, 2002). Policymakers frequently use penalties to support the formal rules. Sanctions, such as fines, prison terms, or the retraction of freedoms, reinforce official rules (Stone, 2002).

Policymakers create regulations to improve society and individual lives. The goal of regulations is to decrease the number of negative results or experiences that occur (Coglianese, 2002). Thus, policymakers incorporated investigative and disciplinary protocols into regulations to address issues and noncompliance. With administrative regulation, officials must complete a three-step process: 1) decide if a violation happened, 2) assess significance of the violation, and 3) determine the appropriate sanction (Anderson & Jackson, 2006). Officials view violations in terms of harm to society. Under administrative regulation, the supposition is that a violation harms the public not just an individual; therefore, the regulatory basis for determining a violation is whether the applicable rule was violated and not whether harm regarding an outside party occurs (Anderson & Jackson, 2006). The penalty for regulatory violations typically is financial. Resolutions involving regulatory infractions traditionally has been the assessment of monetary-based consequences and other civil punishments (Anderson & Jackson, 2006; Coglianese, 2002).

**Social movements and countervailing powers.** Participants in policy development and change do not share a single view or set of interests. Different participants have more sway or influence over the process. In this section, I explore theories on the social movements that push for policy change and the role of countervailing powers in encouraging or discouraging change.

***Social movements.*** The basis of a social movement is striving toward the realization of having a desired issue of concern addressed for instance an enforcement philosophy. A

movement starts to progress the desires of supporters to accomplish certain goals (Benford & Snow, 2000). However, a movement also may have constraints, including having a limited scope (Kingdon, 2011). A social movement aims to resolve concerns; therefore, the focus or activity associated with a social movement depends on ascertaining who is responsible for the targeted concerns (Benford & Snow, 2000).

Once individuals within a movement have details concerning their chosen social issue, movement representatives can approach politicians about addressing the identified issue. The structure of the American political system allows groups to try to influence separate lawmakers to either promote or discourage pieces of legislation or to define what issues the lawmakers consider significant (Quadagno & Street, 2005). Stakeholders on both sides of a social issue use techniques to promote their viewpoint as being popular with the public. Within the American political arena, both influential stakeholders and their less influential counterparts employ grassroots efforts to persuade politicians that their espoused concerns reflect society's desires (Quadagno, 2004). A successful persuasive technique that movement representatives may employ is connecting the issue of focus to commonly held values. Based on different comments from scholars, one can conclude that national or essential values are believed to sway the decisions of politicians and to account for how reform efforts can garner public backing concerning recommended policies without difficulty (Skocpol, 1995).

However, the politicians and officials whom interest groups target also operate as stakeholders they want the involved groups to be content with the outcomes. Government officials and politicians seek conciliation among the involved groups with separate assets such as votes and endorsements (Skocpol, 1995). Politicians and officials want these concessions to fit into existing frameworks. The officials and politicians desire to build such agreements in a

manner that is consistent with how the political structure in which they work already functions (Skocpol, 1995). Government officials and politicians also use the current surrounding infrastructures to formulate policies that interest groups will like. With their futures in mind, politicians and officials attempt to utilize established government-based groups to develop and enact policies, which will be embraced by different socially oriented interest groups (Skocpol, 1995). Nonetheless, individuals should not view such policies as merely the result of catering to interest groups or other stakeholders. By adhering to the perimeters of the established structure in which they already function, government officials and politicians frequently produce unique policies that are more than reactions to the desires of particular interest groups (Skocpol, 1995).

Individuals have started social movements regarding health care as a means of safeguarding deeply held values. People have organized social movements in response to disputes regarding health care in order to protect fundamental views and values (Quadagno, 2010). Therefore, healthcare is not immune to the persuasive efforts of stakeholders. Various stakeholders are able to impress their goals, concerns, and standards on the health care industry (Light, 2001). As an example of stakeholder influence, Quadagno (2011) explained how different stakeholders or interest groups influenced a piece of health care legislation. In her discussion of the debate in 2010 concerning the Patient Protection and Affordable Care Act (ACA), Quadagno (2011) contended that a small number of interest groups witnessed all their desires come to fruition; however, most interest groups were placated via various compromises.

***Countervailing powers.*** Legislation is susceptible to influence from stakeholders and interest groups who hold different views and interests. The topic of countervailing powers similarly is relevant, because parties acting as countervailing powers, specifically regarding health care, are some of the same parties classified as stakeholders for this study. Countervailing

powers are stakeholders in the health care sector that potentially offset or oppose the collective interests of physicians, who have enjoyed and exercised professional dominance throughout most of the twentieth century in the United States (Light, 2010).

Nevertheless, countervailing powers should be cautious about relying on the assets of the group to secure a successful policy campaign. Even though the amount of resources that an interest group possesses may affect the amount of influence that group can exercise concerning an agenda, the amount of resources that an interest group possesses does not always translate into success or failure regarding an objective (Kingdon, 2011). As with any other power, countervailing power, can fade based on circumstances. External sociocultural movements can shift the relationship between countervailing powers (Light, 2010).

The government is a key countervailing power in terms of health policy as it is “the creator and enforcer of regulations” (Light, 2010, p. 271). As with the government, the health care industry involves multiple countervailing powers. Patients now represent an additional countervailing power in health care. Health care consumers have developed into a significant countervailing power, especially due to advocacy groups (Light, 2010).

The assets of a countervailing power may play a role in the successfulness of a stakeholder group. A significant group that has resources often also has the capability to prevent the adoption of a proposal, contradictory to the group’s desires (Kingdon, 2011). In addition, these stakeholder groups must be cognizant of perception when addressing adverse situations. Groups with more influence have to be measured in their reaction to an event, because groups will want to take a defensive position and downplay the ramifications when the event jeopardizes the influence of the groups (Birkland, 1998).

Despite asserting their positions, stakeholders may not accomplish their objectives alone but will need to align with other stakeholders. A profession works together with other groups in the political environment (Light, 2010). Quadagno (2005) offered a health care-based illustration of this need for powerful associates. Physicians had a prevailing perspective in policy arguments, because the espoused political objectives aligned with what important corporate and political allies desired. Therefore, physicians had a political advantage that translated into achieving objectives. When the interests of physicians coincided with the preferences of other stakeholder groups, such as politicians and employers, physicians accomplished political goals (Quadagno, 2005).

**Theory of bureaucracy.** This portion of the theoretical framework pertains to concepts present in or extrapolated from the work of Max Weber (1946/2014, 1947/2009). Due to politicians, government officials, and bureaucrats being policy stakeholders, an exploration of how a bureaucracy functions are relevant to addressing the research questions in the study. The first two topics highlight the concepts of ideal type and legitimate authority. Then, the discussion moves into topics concerning bureaucracy. From concepts of bureaucracy, the discussion proceeds to the topics of compliance and power. This portion of the theoretical framework concludes with a discussion of criticisms surrounding the concepts presented. It is noteworthy that the concept of rationality appears throughout the following discussion.

***Ideal types.*** The concept of ration or rationality appears as a vital component of how people understand behavior. However, to fully understand a behavior, a person must understand the context of that behavior. In the realm of behavior, an activity is rational when individuals attain obtain a well-defined understanding of the activity supported by context (Weber, 1947/2009). The adoption of an ideal type is a way of increasing understanding. Therefore,

building a rational sequence of activities creates an ideal type that has the advantage of clarity and ease of comprehension (Weber, 1947/2009). A party can refer to a given ideal type to help understand irrationality. Using the rational course of action or ideal type as a basis of contrast, a person can determine how illogical aspects such as mistakes and emotions may impact the action in question enough to produce a departure from the rational (Weber, 1947/2009).

**Authority.** Rational-legal authority is a type of legitimate authority and the authority that relevant to this study. As the name suggests, rational-legal authority consists of two main elements; one based in legality, and the other in sensible reasoning. The rational premise for legitimate authority is dependent on individuals believing in the lawfulness of rules and that leaders have the power to give orders (Weber, 1947/2009). In this discussion, the first element, legality, is presented as government and government officials while the second element, sensible reasoning, is presented as a method of goal achievement.

In rational-legal authority, authority lies with the government. Legal authority means that individuals are obligated to comply with a lawfully recognized detached structure (Weber, 1947/2009). In other words, the government itself is the authority figure to be obeyed. Thus, a person in authority only possesses or maintains their authority if their given position entitles them to such authority. Legal authority encompasses the individuals using official authority and their legal orders and solely observed in the extent of their official authority (Weber, 1947/2009). Given the previous explanations about exercising rational-legal authority, people with such authority can be government officials or administrators. Rational-legal leaders include those administrators who have been assigned authority to perform particular tasks (Weber, 1947/2009).

Rational-legal authority is rooted in the observance of rules (Weber, 1947/2009). Also, this type of authority is sustained by a consensus that the adopted system is most favorable

method for obtaining a means to an end. A rational behavior occurs when people anticipate situations and use that knowledge as the methods and circumstances for achieving goals (Weber, 1947/2009). Regardless of rationality, individuals must view the adoption of rational-legal authority as being beneficial or productive. An individual believing in the legitimacy of a law and capability grounded in rational standards creates legal authority (Weber, 1946/2014).

. ***Administration.*** Bureaucracy is the method by which social act is converted into a rationally structured act (Weber, 1946/2014). The bureaucratic form of administration complements rational-legal authority. For Weber, rationality is a key feature of bureaucracy. The purest application of rational-legal authority is a bureaucratic administration (Weber, 1947/2009). Knowledge drives the rationality of a bureaucratic administration. A bureaucracy is rational based on the control being derived from knowledge (Weber, 1947/2009).

The agencies act as vehicles for the application and enforcement of the various policies that politicians create. All legal structures exist in deliberately formed systems of conceptual rules with the management of the legal standards being in the application of these standards (Weber, 1947/2009). However, agencies and officials require power in order to apply the policies. Control over numerous people necessitates having a team or a particular group that can be relied upon to implement overarching policies and explicit directives (Weber, 1947/2009). Individuals within these bureaucratic agencies are not only concerned with policy implementation and enforcement, but also with how such tasks can be continued. Weber (1946/2014) contended that three factors comprise a bureaucratic authority: the assignment of formal responsibilities, the authority to issue directives associated with those responsibilities while observing established perimeters, and careful forethought is carried out to ensure the responsibilities keep being performed.

**Compliance.** Rational-legal authority also promotes compliance. Compliance is the anticipated fulfilling of legal responsibilities (Weber, 1946/2014). People are more likely to comply when they believe the directive has credence. The legitimacy of authority depends on if individuals view the assertion as binding (Weber, 1947/2009). Bureaucracies rely on the exercising of power to gain compliance. As a device for structuring power relationships, bureaucracy is preeminent mechanism for the individuals who manage bureaucratic systems (Weber, 1946/2014). The existence and the application of power shapes social relations as well as compliance levels. Power dynamics are present in all relationships and influence the executing an agenda. For carrying through with an agenda, power is the likelihood that within a social relationship one individual will be able to complete a desired behavior regardless of opposition (Weber, 1947/2009).

Society anticipates that individuals will conform to laws and social agreements. The law, the reasonable assessment of tangible goals, and the dedication to these concepts will remain a behavioral standard (Weber, 1946/2014). However, individuals do not always observe behavioral expectations, and the possibility of individuals choosing to be noncompliant should not be overlooked. Deviation from the law will result in penalties intended to encourage compliance and admonish noncompliance (Weber, 1947/2009). Individuals in authoritative positions use coercion as a tactic to garner compliance. Coercion is a punitive measure used to ensure adherence to rules (Weber, 1947/2009). Finally, a belief in the issuing authority and the desire to avoid negative consequences can serve as motivational factors for individuals to comply with directives. Optimism, anxiety, and potential reprisal drive compliance (Weber, 1946/2014).

*Criticisms of the theory of bureaucracy and associated concepts.* Criticisms involving time and historical considerations exist regarding Weber's work concerning bureaucracies and the legal compliance strategy. According to Tompkins (2005), Weber's concept of bureaucracy has a time-based limitation. This criticism suggests that the explanations of rationality, which Weber presents, should be considered within the bounds of history. In other words, "(w)hat seemed highly rational to Weber in the early 1900s, such as strict obedience to authority and limited discretion, cannot be viewed as the embodiment of rationality today" (Tompkins, 2005, p. 56). The time-sensitive basis of this criticism also extends to the implementation of the legal compliance strategy. Government managers or officials are not dependent on the strategy of legal compliance to garner wanted actions with less invasive means of control and other motivational approaches being accessible (Tompkins, 2005).

Another criticism focuses on compliance in relation to power and authority. Critiques of bureaucratic institutions are rooted in the supposition that such organizational arrangements have the power to control people, and people cannot counter such power (Jaffee, 2001). However, such criticisms may not be considering Weber's complete body of work. In his work, Weber focused on how bureaucracy creates consequences for people in that people fight against the iron cage of bureaucratic influence which leads to tension (Jaffee, 2001). Moreover, Jaffee (2001) pointed to studies by Gouldner and Blau as showing how people can exhibit opposition and inventiveness within bureaucratic structures. Acts of individualism within a bureaucracy possible and compel people in authoritative positions to alter the established approaches to compliance. Jaffee (2001) further contended that people "employ alternative means to achieve goals, they force supervisory personnel to revise strategies for compliance, and their actions generate tensions that result in the reformulation of bureaucratic procedures" (p. 102).

**Theory of bounded rationality.** Policymakers as responsible for decision-making regarding laws and regulations must balance interests and influence of constituent stakeholders. In this section, I explore the theory of bounded rationality to understand how government organizations make decisions.

Organizations prefer rational decision-making (Choo, 1996). Behaviors are rational based on adherence to objectives, and decisions are rational based on whether the resulting behaviors accomplish objectives (Simon, 1993). Ideally rational decision-making relies on complete and full information based on an exhaustive examination of all possibilities. However, the ideal of a rational decision-making process often is impractical and rationality flawed (Choo, 1996; March, 1978). Assumptions regarding what people did prior to actions contribute to flaws. People assume that behavior follows standards developed from reasonable procedures (March, 1978). In other words, flaws are the product of unrealized expectations. When actions diverged from expectations, people customarily viewed these actions as mistakes or fixable flaws (March, 1978). Flawed rationality is theoretically framed as bounded rationality.

The ideal circumstances for rational decision-making are unrealistic, because people, who serve as organizational members, experience constraints. March (2006) stated that “widespread replication of model-based rational choice as a technology of action and the sanctification of rational choice as a technique of problem solving testifies, in part, to a record of successes of rationality as an instrument of intelligence” (p. 207). Constraints on information, cognitive abilities, and potential outcomes and such constraints influence how organizations and their agents act and decide (Choo, 1996; Simon, 1993). Bounded rationality involves seeking alternative resolutions and assessing the results connected to the alternatives based on flawed or

incomplete knowledge due to cognitive limitations (Simon, 1979). The theory of bounded rationality addresses these constraints.

*Constraints.* Limited information constrains rational decision-making. The complexity of information and circumstances inhibits people from determining the best choice (Simon, 1972). Informational constraints also influence other constraining factors. Adaptive rationality or adaptation demonstrates how flawed information contributes to errors in choice selection occur and influences outcomes. Adaptive rationality promotes the concept that stability in preference and lengthy experiences contribute to actions approximating the actions which would be selected if people possessed flawless information, but preferences can fluctuate, which makes foreseeing preferences problematic (March, 1978). Also, adaptive behavior relies on previous choices and outcomes to guide current choices. Adaptation reacts to past actions rather than the underlying distribution of potential action; therefore, the procedures overstate the potential of past occurrences and understate the potential of events that may have occurred (March, 2006).

Another constraint on rationality involves consideration of alternatives. The limitation concerns possible decision options. People only possess partial knowledge regarding such alternatives (Simon, 1972). Without complete information about alternative outcomes, results may be unanticipated. Thus, errors in judgment emerge. Miscalculations of anticipated results can lead to dissatisfaction and inflated expectations (Harrison & March, 1984). Even when parties may apply cost-benefit comparisons in the decision-making process, results may be unclear (Harrison & March, 1984; March, 1978). In such circumstances, there may be attempts to justify the outcomes, because logical reasoning is often taken for granted. People assume that behavior ensues after rational calculation of goal achievement (March, 1978). In other words, individuals “see” wisdom in choices to reason away unexpected outcomes.

The second assumption of rational choice concerns preferences. Parties will attempt to account for preferences when making decisions. Organizations seek intelligence by selecting actions that produce satisfactory results while adjusting for possible changes in tastes and perceptions (March, 2006). However, as with the first assumption about the prediction of outcomes, predictions about preferences may prove troublesome. Suppositions regarding how current knowledge includes details about the tastes of people and causes in the environment drive the models; thus, minor errors concerning the calculations in these abstractions can expand into major errors and also expand with the degree of complexity (March, 2006).

*Addressing the constraints.* The first suggestion focuses on the decision-making process. In the decision-making process, objectives are established then alternatives and the associated results are pursued concluding with an assessment of results based on the organizational objectives (Choo, 1996). However, alternative solutions may have to be developed or designed (Simon, 1993). A second suggestion for dealing with constraints is that organizations introduce decision premises. The application of decision procedures and premises decreases the difference between the bounded rationality of a person and organizational rationality (Choo, 1996). A third suggestion for diminishing the influence of bounded rationality on decision-making is for organizations to promote problem representations, which set limits on information searches. Problem representation involves how organizational participants define the search perimeters for possible resolutions, but if confronting a novel situation, an organization has to develop a new representation and educate employees how to use the representation (Simon, 1991). In the context of constraints on rationality, organizational practices may include simplification of the decision-making process; satisficing or attempts to

find satisfactory, not necessarily ideal solutions; suppressing personal or specific differences for a collective good; and emphasis on a logical process even when it is circular.

The adoption of solution options also addresses constraints. The development of a satisficing a solution involves the use of past knowledge, such as problem representations. The pursuit of a satisfactory resolution centers on previous resolutions and mirrors the prior understandings, education, and objectives (Choo, 1996). A satisficing solution also indicates that a threshold for sensibility and suitability has been met. A satisfactory resolution denotes reasonableness and being above the lowest level of appropriateness (Choo, 1996).

### **Conceptual Framework**

The conceptual framework contains assumptions, suppositions, and expectations. The assumptions are that the standing policy had flaws or was undesirable in some manner, policymakers do not change policies without prompting, and policy changes occur due to the parties advocating for change exercise greater influence than the parties advocating for the current policy to remain unchanged.

Why did policymakers alter the original enforcement philosophy under the HIPAA Privacy Rule? The stakeholder group(s) perceives the policy has having flaws which required the adoption of a new policy or least modifications to the standing policy. The original policy for handling privacy violations had clear flaws. Murphy (2008) cited the results of a survey by Healthcare Information and Management Systems Society (HIMMS) and Phoenix Health Systems supporting evidence that voluntary compliance lacks a reinforcing influence that promotes observance of the privacy standards. Survey results indicated that the approach could deter covered entities who fail to adhere to privacy provisions and have not encountered complaints from employing privacy practices (Healthcare Information and Management

Systems Society [HIMSS] & Phoenix Health Systems, 2006). Stakeholders may try to focus on salient events to spur interest in reconsideration of flawed policy. Such actions may prompt lawmakers to shift policy (Birkland, 1998). Proponents of policy change appeared more influential or persuasive arguments than others; therefore, policymakers adopted the modifications contained in HITECH. How stakeholders mobilized to influence the change in enforcement regarding HIPAA privacy violations is the focus of this study.

How OCR originally handled violations contributed to the perception of flaws in the policy that were the crux of the argument for a policy shift with a stark lack of repercussions for verified violations. The lack of civil money penalties is probably due to the strategy that HHS employs for considering and resolving a HIPAA violation (Brown, 2009). HHS previously had handled enforcement informally by voluntary compliance (Rahman, 2006), yet punitive consequences through fines and penalties also were possible (OCR, 2006).

What prompted the shift in policy? Although, I am unsure of a clear demarcation point, a policy window is a chance for supporters of a proposal to promote their answer or awareness of a specific issue (Kingdon, 2011). A focusing event in conjunction with the opportunity of an open policy window may have aided the policy shift. The combination is a possibility given that HITECH was folded into ARRA.

Obviously, the stakeholder groups seeking a policy change were more influential with lawmakers than the stakeholder groups wanting to maintain the standing policy. However, an aspect of the debate regarding how OCR handled enforcement that is of interest is what stakeholder groups were on which side of the enforcement debate? I also anticipate that stakeholders; such as consumer groups, the media, and academics, comprised those participant groups favoring a policy shift; whereas, stakeholders such as; political appointees, industry

groups, and professional organizations, comprised those participant groups denying the need for a policy shift. Stakeholder groups with similar objectives collaborated and combined assets to realize the objective. A profession works together with other stakeholders in the political environment (Light, 2010). Therefore, different stakeholder groups with similar views on enforcement may coordinate their activities to persuade policymakers.

### **Summary**

This chapter includes background information regarding privacy, the intent of HIPAA, and details concerning the Privacy Rule. A persistent topic is how OCR does not assess civil monetary fines when dealing with Privacy Rule violations (Rahman, 2006). Critics focused on complainants not receiving compensation and lack a private right to action, both of which additional legislation addresses. These topics leads into discussing the HITECH modifications.

The theories and work that comprise the theoretical framework parallel themes in the literature and will assist in addressing the research questions of this study. Concepts in the multiple-streams framework identify and address how factors within the spheres of policy, politics, and social problems affect agenda setting. The framework posits that the policy process contains procedures and parties that constitute different streams (Sabatier, 1999, 2007b) with each stream possessing unique conventions and characteristics (Zahariadis, 1999). The concepts related to rulemaking by regulation address why officials develop and manage regulations. Policy design depends on rules to achieve social objectives (Stone, 2002). The goal of regulations is to decrease the number of negative results or experiences that occur (Coglianese, 2002). The concepts related to social movements pertain to how social issues receive political attention. Both influential stakeholders and their less influential counterparts utilize grassroots efforts to persuade politicians that their espoused concerns reflect society's desires (Quadagno,

2004). The concepts related to countervailing powers address how stakeholders act regarding the political attention. Proponents for policy change asserted that the current policy failed as an effort to gain attention for a matter from a larger group; whereas, proponents of maintaining the current policy want to block the advancement of a matter that potentially impedes their concerns (Birkland, 1998). The concepts of rational-legal authority and bureaucratic administration within the theory of bureaucracy involve rationality. The rational premise for legitimate authority is dependent on individuals believing in the lawfulness of rules and that leaders have the power to give orders (Weber, 1947/2009). Finally, bounded rationality involves seeking alternative resolutions and assessing the results connected to the alternatives based on flawed or incomplete knowledge due to cognitive limitations (Simon, 1979).

The conceptual framework highlights different ideas about why the policy shift occurred and foreshadow findings. The ideas address the functionality of voluntary compliance, policies change only with pressure, and the groups seeking change exercise enough influence to obtain the change. Others claim that stakeholder view the policy in question as possessing errors, these stakeholders pressure policy makers for the wanted change, and arguments by the stakeholders seeking change are persuasive to policymakers. Finally, predictions include the argument for change stemming from a dearth in penalties for violations, having the decision point for policymakers concerning change not being easily discernible, and the stakeholder groups seeking a policy change were more influential with lawmakers. These predictions informed my choice of research questions and provided a guide for me during the research process.

In the next chapter, I explain my choices regarding the research design and methods. I focus on why this study is a case study and address relevant ethical considerations. I describe the research methods used, including data collection, analysis, and validation procedures.

## CHAPTER 3

### METHODS

#### **Chapter Overview**

Chapter 3 provides an overview of the methods I used to explore how the policy shift in HIPAA privacy enforcement happened. It details my data collection, qualitative analysis, validation procedures, and discusses ethical considerations pertinent to the case study.

#### **Research Design or Strategy of Inquiry**

The objective of this study is to explore how stakeholders influenced the shift in government response to privacy violations through a qualitative case study utilizing archival documents. A case study approach explores factors that contributed to the shift in policy while maintaining a focus on the influence of stakeholder perspectives. Case studies are a type of inquiry in which qualitative researchers examine a process, action, or incident (Creswell, 2009). The circumstances or context of the policy shift are explored in terms of stakeholder actions.

#### **Data Collection Procedures**

This section highlights the sampling and data collection procedures that I used.

**Sampling.** Qualitative researchers often use purposeful selection of participants that will most assist researchers comprehend the issues and research questions, or circumstances being studied (Bloomberg & Volpe, 2008; Creswell, 2009). A case study stresses obtaining data about the actions of stakeholder groups identified in the reviewed documents. The strategy is grounded in purposeful sampling, in which researchers employ reasoning and previous information to select participants who fit the intentions of the project (Monette, Sullivan, & DeJong, 2011). The sample is based on the selection of pertinent documents including congressional testimony, government-issued texts and reports, and news articles. These documents likely include views

from different stakeholder groups and facts regarding enforcement rather than including only a single view and potentially biased information. Also, I remained open to including documents produced by advocacy or industry groups based on content while mindful of the sources.

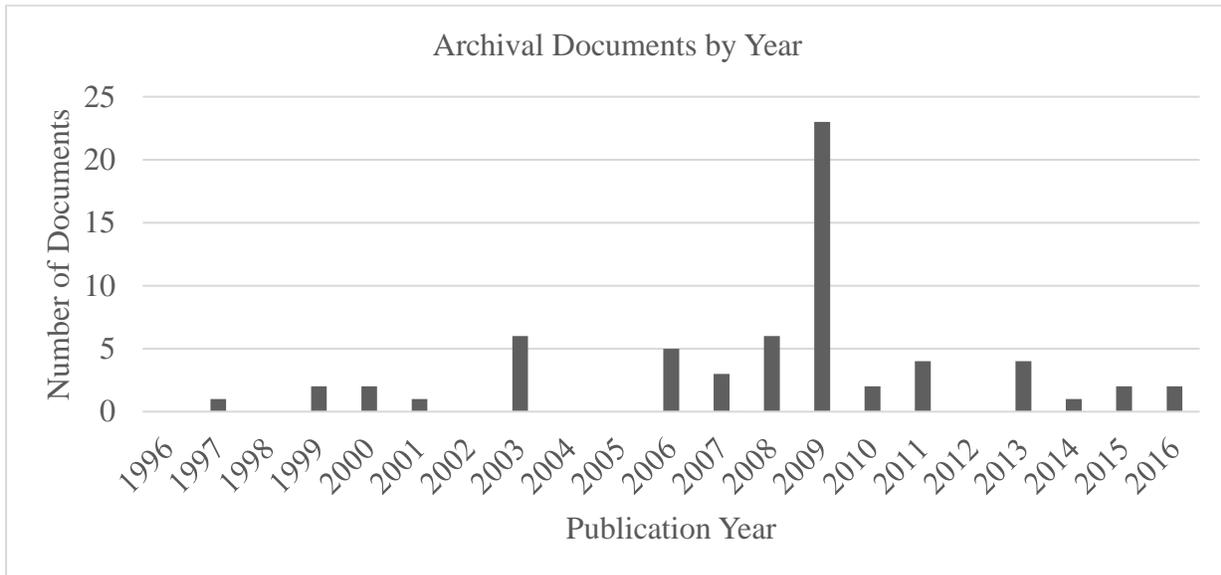


Figure 4. Distribution of archival documents. This figure illustrates the distribution (by year) of the archival documents used.

In addition, I was mindful of temporal order when selecting archival documents for inclusion in the sample. Temporal order is a factor of consideration particularly when exploring policy, because policy concerns are fluid. Zahariadis (2007) contended that “(w)ho pays attention to what and when is critical” (p. 68). I was aware of the “what” and “when” of perspectives and opinions expressed in the archival documents that I used for the purposeful sample. The “what” is addressed in the findings of this study; Figure 4 addresses the “when” regarding the archival documents that I used for the sample. Figure 4 reflects the distribution of the archival documents used. The peaks in the distribution are indicative of periods of interest regarding HIPAA. For example, there is a peak for 2003, the year that the Privacy Rule became effective, and a peak for 2009, the year that the modifications under HITECH were adopted. Figure 4 shows that the distribution includes a few years with no archival documents of interest.

**Data collection.** Data collection occurred by retrieving archival data and conducting document reviews. Qualitative documents include materials such as reports and newspaper articles (Creswell, 2009). Researchers use documents as an alternative for observing activities (Stake, 1995). I used information sources that focus on the types of archival documents named as the desired sample. Table 1 contains databases selected for their content (e.g., congressional records, testimony, reports, news articles). I used government websites to access documents such as federal government reports. I employed these government materials, newspaper articles, and other media sources such as online news publications to gather information regarding stakeholder activities and opinions. I reviewed reports from additional stakeholder groups and other sources of stakeholder perspectives such as comment letters, and editorials. Finally, I refrained from using journal-based databases because I wanted to review original sources.

**Data collection process.** To aid organizing data collection, I created Table 1 and Table 2. Table 1 includes the databases I searched for archival documents which I selected based on content and accessibility through the Indiana University of Pennsylvania (IUP) libraries.

Table 1

*Research Databases Used to Locate Research Documents*

Database Topic	Database Name
Government/Political Science	Catalog of U.S. Government Publications CQ E-library CQ Weekly FDSys
Law	Legal Collection ProQuest Social Science Premium Collection Sage Premier
News	Newspaper Source (EBSCO) Newsstand (ProQuest) ProQuest Newsstream Wall Street Journal The Washington Post

In the research databases provided in Table 1, I used the following search terms.

Table 2

*Search Terms Used in the Research Databases to Locate Documents*

Search Terms		
The American Recovery and Reinvestment Act	ARRA	Civil monetary penalties
HIPAA	HIPAA criticisms	HIPAA enforcement
HIPAA fines	HIPAA and interest groups	HIPAA Privacy Rule
HIPAA omnibus rule	HIPAA reform	HIPAA stakeholders
HIPAA violations	HITECH	HITECH Act
HITECH modifications	Privacy advocates	Privacy reform
Privacy Rule changes	Privacy Rule enforcement	Privacy Rule reform
Privacy stakeholders	Privacy violations	Voluntary compliance

Table 2 is an organized presentation of the used search terms. I printed the tables on a single sheet of paper to use for tracking document searches. I assigned each database listed in Table 1 a color put a hash mark in the assigned colors next to the searches terms in Table 2 as I completed document searches. I worked through the search terms in Table 2 systematically from left to right in alphabetical order to ensure that I did not skip any search terms. I did conduct document searches outside of the database searches. I found a project report and two electronic articles as the result of internet searches regarding a stakeholder group referred to in an article that I read. I conducted a search on [www.regulations.gov](http://www.regulations.gov) to locate material submitted during the comment period for the modifications under HITECH. I conducted this search thinking that it would yield documents in which stakeholders expressed ideas or opinions beyond what stakeholders were willing to express in public. Finally, I performed another search on [www.hhs.gov](http://www.hhs.gov) to obtain compliance and enforcement reports from OCR.

I saved the documents in subfolders labeled for the search term with the folder for the applicable database. After I more thoroughly reviewed the documents, I created “questionable”

subfolders into which I moved documents that I had doubts about applicability or usefulness but did not want to delete. This procedure aided in document tracking and retrieval. I followed these steps for every database except CQ Weekly and CQ E-library, because these databases sent the documents via email rather than having downloadable versions. I did not record the number of results that each search garnered because I recognized that result numbers fluctuated when reopening a search or navigating the main results pages.

I did encounter unanticipated or complicating circumstances during the collection process. I experienced the issue of availability due to database access and document irretrievability. The database list in Table 1 was revised to reflect those databases that were available at the time of data collection. Also, some document searches within different databases produced overlapping results; therefore, I disregarded duplicate documents.

### **Data Recording and Coding Procedures**

This section addresses the data recording and coding procedures that I used to conduct this study.

**Recording procedures.** The following subsection highlights the notetaking and data recording procedures that I employed in completing this study.

**Notetaking.** I recorded information regarding stakeholder perspectives gathered from the previously mentioned sources of documentation based on a notetaking procedure that I developed and consistently applied. The basis for the notetaking procedure stems from advice by Creswell (2009). The notes include main ideas expressed in the gathered information. Creswell (2009) recommended that qualitative researchers record the essential concepts in the documents or materials. In addition, the notes included how the pertinent information was communicated and assessments of reliability regarding information sources. Notes should

contain references to whether the information came from a direct or indirect source as well as impressions regarding reliability (Creswell, 2009). The notes also contain additional information that I find interesting or unique. Finally, I reviewed the notes regarding the materials within a few weeks of the original notetaking to ensure the accuracy of the notes.

***Recording of data.*** I manually coded the data and used a database program to store and organize the data, which aided in the coding process. I used an Access database to record and track data. I built a reference database table to record details about the archival documents including; assigned document identification number, abbreviated title, document type, whether the document came from a direct or indirect source, and document date. I included the document date being mindful of temporal ordering. Then, I entered the coded extracts into an Access database table constructed for the data, following the initial coding process for the entries: the assigned color code, the individual or group associated with the extracted information, and details regarding the document of origin into the database table. After checking for duplicate entries, I converted the database table to an Excel spreadsheet in preparation for focused coding.

For recording the data after focused coding, I completed steps similar to those I did in recording data after the initial coding process. I constructed a separate Access database table for each research subquestion then entered the coded extracts into the relevant Access database table. All entries contained information regarding the extracts including; the original assigned color code from the initial coding stage, the individual or group associated with the extracted information, the document date, and the numeric identifier for the document of origin. I sorted each table by document date keeping temporal order in mind. After checking for duplicate entries, I converted the four database tables to Excel spreadsheets for ease of review in preparation for the analysis process.

As an aside to recording the coded data, I constructed another Access database table. This database table contained extracts that evoked ideas and /or comments. I used this table as a way of recording and organizing my insights after the focused coding process. I did not create this table for analytic purposes, but rather as an additional notebook preserve my thoughts.

**Coding procedures.** The coding process occurred in two phases with the objective of producing themes. Coding is a technique that organizes disordered text into ideas (Richards & Morse, 2007). The process also involves segmenting text-based data into labeled categories or themes (Creswell, 2009). Coding is applicable to the case study since data collection focused on archival data such as documents.

The first phase involved the data being coded using initial coding. Initial coding is suitable for studies utilizing documents and provides a base from which researchers obtain indications for additional study with codes being subject to revision (Saldana, 2016). This coding procedure emphasizes data being divided for investigation. Initial coding separates data into discreet pieces for examination including comparisons (Saldana, 2016). For the initial coding, I decided to review the archival documents, and code the information in the documents according to stakeholder groups or activity. I highlighted passages or extracts with different colors based on the stakeholders involved. For example, an extract from congressional testimony given by an advocacy group representative was denoted with purple (the designated color for advocacy groups). See Appendix B for a complete list of the coded items and the associated colors used in the initial coding process. I then entered the color-coded extracts into an Access database table; I entered the extracts accompanied by information regarding the document of origin into the database table. Finally, I converted the database table to an Excel spreadsheet for ease of review in preparation for focused coding.

The second phase consisted of the initially coded data undergoing focused coding. Focused coding is a second cycle process suitable for cultivating themes or categories (Saldana, 2016). Data examined using initial coding can be utilized in focused coding to build themes. Focused coding occurs after initial coding and classifies the coded data according to thematic parallels while seeking for the most noteworthy initial codes in order to cultivate the most relevant categories (Saldana, 2016). I prepared for focused coding by reviewing the results of the initial coding. I based the focused coding of extracts on what research subquestion the extracts addressed. After beginning to code the extracts, I recognized that some extracts addressed concepts pertaining to Subquestion 3 on fines but offered information beyond the scope of the subquestion. Therefore, I added another code, “other circumstances,” related Subquestion 3 regarding fines. See Appendix B for a complete list of the research subquestions and the associated colors used in the focused coding process. Also, I coded some extracts or part of extracts under multiple focused codes based on content. After coding the extracts and reflecting on the codes to ensure accuracy, I created Access database tables for each focused code, which only contained the extracts associated with the respective focused codes. Finally, I converted the four database tables to Excel spreadsheets in preparation for thematic analysis.

### **Data Analysis Procedures**

This section focuses on components of the data analysis procedures that I followed for this study.

**Preparation for data analysis.** Data analysis is a multi-stage process. The data analysis procedures began with arranging the information for analysis by reviewing the notes and separating the information based on the research question concerned. Creswell (2009) suggested preparing data for the analysis process by typing notes and sorting the data in an organized

manner. I examined all data to establish familiarity with the information as well as think about what the information denotes. Creswell (2009) proposed that qualitative researchers should review the obtained data and gain an understanding of the information by considering what the information indicates. I made notes about thoughts while progressing through the data review. This process parallels the first step in thematic analysis presented later in this chapter.

**Unit of analysis.** The unit of analysis for the case study is the “case of interest.” Even though, I reviewed documents and records that are considered social artifacts, the actual unit of analysis is policy stakeholders (in terms of organized influence and not the documents). A unit of analysis concerns the entity regarding which data gathered and interpretations are made, but it is not inevitably the data source (Monette et al., 2011). This means that even though I utilized archival data as data sources, the actual unit of analysis is the involved case in terms of the decision to change enforcement responses from the government. Yin (2014) stated that the unit of analysis for a case study is the “case,” and that a case of a decision may be the focal point.

**Method of analysis.** Themes are significant to the analytic component of this study. While themes cannot be coded, they are the result of coding (Saldana, 2016). The selection of thematic analysis for this study aligns with the selection of the coding processes. Saldana (2016) recommended thematic analysis as a possible method for further analyze initial and focused codes. This approach to qualitative analysis allows for data to be coded and presented in a longer format. Thematic analysis is the synopsis and analysis of data via phrases or sentences (Saldana, 2016). As the name implies, thematic analysis also allows for themes to emerge that guide the formation of categories. Researchers may code document-based data to isolate themes and, in turn, produce categories and discern patterns (Coffey, 2014). In summary, thematic

analysis involves a researcher reviewing the collected data for category development and coding to determine themes (Bowen, 2009).

I employed a systematic method to the analysis process, using the multistep approach to thematic analysis offered by Braun and Clarke (2006). After completing the processes of initial coding, focused coding, and recoding the data, I moved into the analytic process which focuses on the discernment of themes (Braun & Clarke, 2006). To determine themes, I reviewed the entries in the four Excel spreadsheets for each research subquestion. Then, I went back and assigned summary labels to each entry. These labels became preliminary themes.

The next step in thematic analysis encompasses a two-level review that includes verifying themes are congruent with the coded data and the whole data set as well as producing a map of the analysis (Braun & Clarke, 2006). After assigning the preliminary themes, I reviewed the extracts again to ensure that the content matched the assigned themes and the applicable research subquestion. I also had the opportunity to review and confirm themes when I added “theme” fields to the Access database tables. Regarding the theme maps, I drew an informal version of a map for each subquestion. Then, I edited the informal theme maps based on a review of the themes and created formal electronic versions of the theme maps. Table 3 in Chapter 4 provides more detail; the themes and subthemes that emerged in the theme maps are presented in table form for ease of review; however, I did include the final theme maps in Appendix D.

The next step in the thematic analytic process emphasizes honing themes along with the overarching narrative (Braun & Clarke, 2006). I started this step by reviewing and modifying the formal theme maps. I wrote “thought pages” about themes and subthemes for each research subquestion in order to have a final period of contemplation regarding appropriateness and

placement in the overarching narrative. After reviewing all of the entries, I sorted the four Excel spreadsheets by theme then date to produce organized final copies.

The final step involves creating the analysis report including the selection of examples or extracts (Braun & Clarke, 2006). I considered how to present those themes, and which extracts to include as examples while wanting to show temporal ordering. I made duplicates of each spreadsheet and added a column indicating the extracts that were most appropriate to use as examples then printed final copies. I reviewed the themes and subthemes then created outlines for groupings and an order of presentation regarding each research subquestions. These outlines included notes on why I paired certain themes as well as transitions between themes. The final product of this step is incorporated into Chapter 4.

**Narrative structure.** Since I wanted to present the information regarding a case study in literary style, I used a narrative structure. The choice to use qualitative methods to complete the case study influenced the structure of the narrative. The central approach to reporting the outcomes of a qualitative study is to create a narrative that cultivates descriptions and themes (Creswell, 2009). The use of a case study as the research design affected the narrative presentation. I looked to descriptions of how narratives are constructed for guidance. The narrative for the qualitative outcomes may contain a detailed analysis of the event involved (Creswell, 2009). The narrative includes extracts or excerpts from reviewed documents or materials, such as portions of available testimony or pertinent quotations. A presentation style for narratives is to indicate extracts and to cluster these extracts according to themed groupings (Bloomberg & Volpe, 2008). The extracts are presented chronologically under each finding in being mindful of temporal ordering. Finally, I chose to incorporate a unique element into the presentation. I framed the information presented in the results chapter as if revealing the plot of

a mystery novel by using the different findings as developmental steps to introduce the findings for the overarching research question.

### **Data Interpretation Procedures**

The interpretation procedure involved comparing the findings of my study to concepts contained in the relevant literature. Interpretations involve developing connotations from findings when they coincide with or deviate from the existing concepts or literature (Creswell, 2009). My professional experiences and observations as a compliance officer and what I have witnessed on a small scale pertaining to policy development and modifications along with the handling of privacy violations may influence my interpretation. Creswell (2009) stated that qualitative interpretations can be placed within the context of the researcher's background or experiences. Nonetheless, I want to note that my interpretations call on my professional experiences and observations that occurred on the individual and organizational levels

### **Validation of Findings (With Reliability and Generalization)**

This case study's methods involved validation of findings through the technique of data triangulation. Data triangulation is a validation technique that concerns collecting data from several sources (Russ-Eft & Preskill, 2009). Data triangulation also is a means of substantiating the highlighted themes. Triangulation occurs when evidence from various sources is employed to establish support for themes, and researchers substantiate those themes by bringing together multiple sources of data (Creswell, 2009). Given the archival nature of the data, multiple forms of documents may be used to achieve triangulation. Bloomberg and Volpe (2008) asserted that triangulation is a method, by which researchers utilize several viewpoints to clarify meaning, and researchers employ various collection techniques to accomplish triangulation from sources including examining the content of incident reports and completing reviews of other documents.

Data triangulation began by reviewing government-issued texts or reports, professional journals, news reports, and advocacy-based information. I foresaw differences in tone between a report that agency officials created and a news article; however, information from these sources still can be congruent and mutually validating. Furthermore, I conducted document reviews on materials such as articles appearing in, newspapers, news wires, scholarly journals, and electronic or online media. Kingdon (2011) grouped members of the media as one policy stakeholder, but media members have differing agendas and can disseminate slanted information.

The validation of findings incorporated the practices of creating rich or thick descriptions and acknowledging biases. The method by which the findings communicated is thick descriptions. Thick descriptions can engage readers and may contribute to validity (Creswell, 2009). I utilized thick descriptions to aid in building the narrative so that readers may develop a sense of what has occurred.

Furthermore, I addressed the biases that I bring to the case study. Creswell (2009) asserted that well-conducted qualitative research includes statements from the researcher about how biases influence their interpretation of findings. My biases in interpretation come from my professional and educational experiences involving privacy regulations and resolution procedures. Personal viewpoints and the associated biases only can be managed not eliminated (Machi & McEvoy, 2009). Thus, I tried to prevent my biases from affecting the research by utilizing two techniques. First, I recorded my thoughts in a journal, which I regularly reviewed. Journaling prompts a contemplative attitude that provides the researcher with a chance to create a record of their thoughts, queries, apprehensions, and experiences (Bloomberg & Volpe, 2008). Beyond aiding reflection, my journaling activities also served as an audit trail: “Keeping careful records also implies an open-minded and critical approach and can contribute to what Lincoln

and Guba (1985) refer to as an ‘audit trail,’ which provides useful material for making validity claims for your study” (Bloomberg & Volpe, 2008 p. 4).

Second, I paid attention to my tendencies during the data collection and analysis processes as to help avoid unintentionally skewing the research by writing memos. Researchers can write memos regarding ethical and methodological issues as a way of better comprehending the research topic or the entire study (Maxwell 2005). I combined my journaling and memo writing activities as the respective purposes are described in a similar manner. Bloomberg and Volpe (2008) stated that maintaining a research journal allows the researcher to preserve their thoughts and reasoning and describe the evolution of their concept. Maxwell (2005) contended that memos are a vital tool available for researchers to use in evolving their thoughts and stated that researchers can record memos in journals. Finally, I reviewed my writing when I completed distinct sections of each chapter to help limit the influence of my biases.

In addition, the validation procedures addressed issues of reliability and generalization. The keeping of documentation regarding the research process addresses reliability. As the study involves one specific policy shift, aspects of the study parallel elements of case study research; therefore, documentation of the research processes is key. Qualitative researchers should record their techniques during case studies (Yin, 2014). Generalization can be applicable in qualitative research. Generalization can occur when researchers investigate more cases and apply the findings to the new case (Creswell, 2009). However, I favored particularity rather than asserting generalizability, since the proposed case study focuses on one policy shift and potentially involved a unique set of stakeholders.

## **Role of the Researcher**

My role as researcher was to describe policy stakeholder perspectives regarding the handling of privacy violations, which potentially suggested multiple realities. In my psychology courses, professors taught the concept that every person has their own reality due to how each person perceives events. The concept of multiple realities may be applicable to how stakeholder groups view occurrences that concern policies. During my tenure as compliance officer, I adopted a candid approach in handling information requests and resolving privacy-related issues. I also interacted with attorneys who specialized in health care law, and these attorneys stressed addressing and resolving incidents or issues. These experiences potentially influenced my data interpretation depending on what situations and circumstances the data highlight.

## **Ethical Considerations**

Though the study did not have human participants and did not require IRB approval, three ethical concerns exist. The first concern is about how my beliefs influenced my interpretation of the data. The second concern pertains to the selection of documents being biased or the documents being inaccurate, incomplete, or inaccessible. Even though documents may serve as an abundant data source, researchers must critically examine documents and exercise caution (Bowen, 2009). The use of reflection and journaling were attempts to limit the influence of these two ethical concerns. Taking a systematic approach to data collection assisted in limiting the potential for biased selection. The third concern involves the identification or naming of specific stakeholder groups. I refrained from naming the individual stakeholder groups to focus on how general stakeholder groups as identified in Figure 3 used influence. When needed, I used pseudonyms in brackets in place of the actual names.

## Summary

The methods for this study are qualitative in nature, which allow for data collection via documentation and text reviews. Sampling and data collection procedures started with the purposeful selection of documents and an orderly approach to data collection, including specifying research databases and initial search terms. My recording procedure involved extensive note taking to aid in thick description and use of Access database tables to aid thematic analysis. The coding process included initial coding and focused coding, with the goal of helping to discern themes. I followed the steps and procedures for thematic analysis; my interpretation procedure had two components (a comparison of the findings to concepts in relevant literature and a comparison of findings on individual and organizational levels to my professional experiences and observations as a compliance officer). Extensive documentation of research process addresses reliability; the particularity rather than generalizability matches this study's focus on one policy shift.

The first ethical consideration that I addressed is how my beliefs may affect the interpretation of the data. The second involves data collection using archival data and document reviews, since documents may be inaccurate, incomplete, or inaccessible. I addressed the ethical concerns by journaling to reflect on my awareness of these issues. The third concern involves the naming of stakeholder groups. I do not name individual groups or their representatives, since the focus is on how general stakeholder groups utilized influence.

In the next chapter, I identify the themes within the findings of this study. I present the findings by subquestion while pairing some findings for ease of reading. I consider temporal ordering regarding how excerpts are presented within the findings.

## CHAPTER 4

### FINDINGS

#### **Introduction**

Before beginning the narrative outlining the findings of this case study, I want to reiterate my research questions for reference.

#### **Overarching Question**

Why did policymakers alter the original enforcement philosophy under the HIPAA Privacy Rule to the enforcement philosophy outlined in the modifications under HITECH?

#### **Subquestions**

1. In what ways did policy stakeholders influence the policy shift from the original enforcement philosophy to a more punitive philosophy?
2. How did stakeholder groups collaborate to promote certain perspectives and concepts?
3. How did stakeholder perspectives on the lack of civil money penalties or fines influence the policy shift?

In the following sections, I review information and decisions that affect the narrative. First, I was more interested in factors that contributed to the policy shift than in which party exercised enough influence to bring it. The layout of the narrative is akin to a mystery novel with each finding revealing more information. Second, I do not name the stakeholders since the focus is on how influence was exercised and not on who exercised the influence; I refer to individuals from stakeholder groups or entire stakeholder groups in generic terms. Third, I separated the data addressing the subquestion of how perspectives about the lack of civil money penalties/fines played a role in stakeholder arguments for or against the policy shift. I divided them into two items during the research process, because enforcement strategies other than fines

were presented. Fourth, I distinguished themes and subthemes according to research subquestions and included Table 3, a table of themes and subthemes for reference. Finally, I often grouped themes and subthemes for ease of presentation and reading.

Table 3

*Theme and Subtheme Labels for Each Subquestion*

Themes/Subthemes for Subquestion 1: Stakeholder influence	Themes/Subthemes for Subquestion 2: Stakeholder collaboration	Themes/Subthemes for Subquestion 3: Influence of the lack of fines	Themes/Subthemes for other circumstances from Subquestion 3
1. Communicate in writing	6. Q & A/Testimony	Voluntary compliance	18. Private right of action
Communicate by speaking	7. Partnering statements	11. For 13. Against	19. State attorneys general
2. News media		12. Policy of the administration	
3. Testimony			
4. Employee movement among groups	8. Work groups/ Initiatives	14. Lack of fines	20. Transparency/ Monitoring
5. Participation through connections	9. Association/ Industry groups	15. Not adequate/ Motivating	
		16. Recommendations from industry with explanations	21. Staffing - resources
	10. Opposition to HIPAA/HITECH	17. Recommendations from other	

**Findings (Themes and Subthemes)**

Instead of including the theme maps for each subquestion, I present the theme and subtheme labels combined in Table 3 for ease of reference. Each subquestion has a dedicated column with a vertical listing of the labels for the themes and subthemes pertaining to the subquestion. When present, I listed subtheme labels with a bullet point under the relevant theme

labels. The labels listed under Subquestion 1 denote the ways in which stakeholders could have influenced the policy shift regarding enforcement philosophies. The labels listed under Subquestion 2 denote the ways in which stakeholder groups with coinciding objectives collaborate to promote certain perspectives and concepts. The labels listed under Subquestion 3 denote the ways in which perspectives regarding the lack of civil money penalties or fines play a role in stakeholder arguments for or against the policy shift. Finally, the labels listed under other circumstances from Subquestion 3 denote supplemental findings based on other circumstances that emerged from addressing Subquestion 3.

### **Narrative Layout**

I set up the incorporated narrative to present as a mystery with each finding revealing more information. The layout design includes presenting findings by the assigned theme labels as listed in Table 3 followed by explanations of the codes which I subsequently use when introducing the findings. I also pair some findings due to the complementary nature of the data.

### **Findings for Subquestion 1**

The findings for this subquestion include a caveat. I was not able to find direct statements or references addressing the exercise of stakeholder influence. However, the data indicated findings related to the exercise of influence.

**Communicate in writing and news media (communicate by speaking).** This pair highlights how different stakeholder groups utilized methods of communication to convey perspectives regarding HIPAA and enforcement practices.

*Communicate in writing.* This finding emerged as stakeholder groups directly communicated with members of Congress or agency officials by writing letters. Industry representatives initially expressed support for voluntary compliance in the media. In a

newspaper article, a representative from a large health care industry association said that the approach was “an opportunity for hospitals to understand better what their requirements are and what they need to do to come into compliance” (Stein, 2006a, p. A.01, 2006b, p. 1A, 2006c, p. A-1). Yet, industry stakeholders opted to directly address policymakers after policymakers introduced the new legislation. For example, three years following the first extract, a corporate officer from a national professional organization stated in a letter to congressional leadership that “I write today to convey our concerns with specific provisions included in H.R. 1, the American Recovery and Reinvestment Act of 2009” (Pharmaceutical Care Management Association [PCMA], 2009, Introductory section, para. 1). The same year, industry stakeholders wrote letters to HHS offering opinions and suggestions during the comment period for the HIPAA Enforcement Rule: Interim Final Rule (IFR), which included the modifications under HITECH. Two groups connected through a shared member submitted comment letters asserted that “(w)e generally support the proposed rule but offer feedback and recommendations to improve the rule” (Aging Services of Minnesota, 2009, Introductory section, para. 2; Minnesota Department of Health [MDH], 2009, p. 1).

*News media (communicate by speaking).* This finding involves members of stakeholder groups speaking to the news media in an effort to promote the group’s viewpoint or agenda. Early on, some non-industry stakeholders were outspoken about potential pitfalls concerning HIPAA enforcement. In a profile newspaper article, the leader of a prominent privacy group stated that the group “will be working on tightening up the new regulations, which took effect earlier this month. She sees numerous challenges ahead, including monitoring HIPAA enforcement” (Goldstein, 2003, p. A.21). Six years later during the transition to the new or

modified enforcement approach, an agency press office released a statement with the following quote from a person in leadership at the agency:

This strengthened penalty scheme will encourage health care providers, health plans and other health care entities required to comply with HIPAA to ensure that their compliance programs are effectively designed to prevent, detect and quickly correct violations of the HIPAA rules. (HHS Press Office, 2009, Full text, para. 4)

To underscore the possible scope of influence that speaking to the media generates, an official from a government-based research entity wrote a report to policymakers and cited Stein (2006a) as citation 79 when discussing HIPAA enforcement. Stevens (2008), the author, provided that “(c)oncerns have been raised by some that the HIPAA Privacy Rule is being underenforced by the U.S. Departments of Health and Human Services (HHS) and Justice (DOJ)” (p. 14).

Additionally, it is of note that various newspapers published Stein (2006a) under other titles and sometimes with different ancillary details. I included two such as articles, Stein (2006b) and Stein (2006c) in this study, because the variations may offer added information.

**Testimony (communicate by speaking).** The finding denotes how members of stakeholder groups presented testimony in congressional hearings. Stakeholders had chances to testify before Congress; however, chances to be heard does not equate to people listening to the offered viewpoint. For example, the leader of a prominent privacy group clearly expressed a concern. The leader testified that the group were “very concerned about the weak enforcement and the weak remedies that are available under the proposed regulation. Again, HHS was constrained because of HIPAA” (Confidentiality of Patient Records, 2000, p. 56). Other witnesses were not as precise such a corporate officer from a Mid-Atlantic hospital conglomerate as seen in the following statement:

I reviewed the current draft privacy legislation included in the Health Information Technology for Economic and Clinical Health Act. While the act attempts to address evolving privacy and security requirements that have arisen since the implementation of HIPAA, it falls short of providing the necessary and comprehensive and workable framework that we now need. (Health Information Technology, 2009, p. 16)

Furthermore, witnesses sometimes offered testimony that denoted hesitation or lack of information. The following set of extracts highlights this hesitation. The first extract is from a policymaker during a hearing regarding privacy and health care information systems:

There has been significant criticism of the agency's enforcement of HIPAA and lack of civil penalties enforced on identified violations. Are the enforcement activities of HHS being carried out in accordance with the statute and the legislation and regulations? Are the current regulations adequate to ensure that violating entities are being sanctioned appropriately? (Protecting Patient Privacy, 2007, p. 37)

The second extract is from a leading official from an office/agency of the federal government responding to questions about enforcement activities posed in the previous extract from a hearing on health care information systems and privacy: "I have to say, first of all, that we have not studied HHS' enforcement actions; however, I think it has been widely reported that there have been few enforcement actions on their part" (Protecting Patient Privacy, 2007, p. 37).

**Employee movement among groups and participation through connections.** The findings in this pairing address how members of stakeholder groups potentially exercised influence through professional or personal contacts.

***Employee movement among groups.*** The finding highlights how members of stakeholder groups left the groups by changing employers and by changing employers moved

among the different groups. Different data entries showed some parties moved between stakeholder groups; at one time or another these parties had positions within government. For instance, parties who assisted in the development of HIPAA had transitioned into other sectors and were quoted in news articles. The following two extracts dated approximately three years apart refer to the same person. The party “was directly involved in the drafting of the Privacy Rule while working for the government. Now, as a private consultant with [Company XYZ], he advises health care entities and assists with HIPAA compliance” (Lawson, Orr, & Klar, 2003, p. 129 footnote 3). A few years later in a newspaper article, the same party, described as being from an advocacy and research group, said regarding HIPAA, "(i)t's not being enforced very vigorously" (Stein, 2006a, p. A.01, 2006b, p. 1A, 2006c, p. A-1). Some versions of the news article included a quote about different enforcement approaches from a party who also had held positions with academic, advocacy, and governmental groups:

The Securities and Exchange Commission, the Federal Trade Commission - they find significant and high-profile cases and send a message to industry about what is permitted and what isn't,' said [Jones], an [University XYZ] law professor who helped write the HIPAA regulations during the Clinton administration. (Stein, 2006a, p. A.01, 2006b, p. 1A)

The final extract is from an online health news magazine and refers to a party from a well-known privacy advocacy group being appointed to positions within the federal government:

At OCR, [Jones] will lead policy, enforcement and outreach efforts related to the HIPAA Privacy, Security, and Breach Notification Rules. . . . In 2009, she was appointed by former HHS Secretary Kathleen Sebelius to the federal Health IT Policy Committee, for

which she chaired the Committee's Privacy and Security Workgroup and co-chaired its Tiger Team. (Miliard, 2015, para. 2, 4)

***Participation through connections.*** The finding developed as professional and personal connections between members of different stakeholder groups were acknowledged within the archival documents. This finding also dovetails with the previous finding in that it addresses the possibility of parties exercising influence through circumstances. In the following extracts, parties may have influence through human connections rather than moving job positions. The first two extracts describe the same person who was in a leadership role with a Washington D.C.-based advocacy group. The first extract is from a newspaper article profiling a privacy advocate that refers to their professional connections. They have prominent associates: a former leader of a civil rights organization, bioethics professional with ties to academia, and a former White House chief of staff (Goldstein, 2003). The next extract is from an article in a professional journal published five years later that highlighted influential individuals in privacy. The same person described in the previous extract is described as “instrumental in shaping the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and subsequent regulations” (“Who’s Who in Privacy”, 2008, p. 1).

The next two extracts are both from the same 2009 Senate hearing and are different senators introducing witnesses. These extracted quotes reference informal ties, which in turn, denotes the possibility of increased social capital and influence. The potential for increased social capital and influence is reflective of the old adage of influence is based on who someone knows rather than what they know. The first extract is a senator introducing a witness from a consumer advocacy group in the hearing on health information technology: “She earned her Bachelor of Arts degree from the Colorado College - where she was a classmate of my sister”

(Health Information Technology, 2009, p. 12). The final extract is another senator introducing a witness from who was an officer with a hospital-based corporation during the same hearing:

I appreciate the opportunity to say a few words on health IT this morning and, of course, welcome our distinguished panel, and especially you, Mr. [Jones], from my alma mater, the University of Pittsburgh, I'm pleased to have you here, and all of you. (Health Information Technology, 2009, p. 2)

In sum, the findings for this subquestion indicate that stakeholders exercised influence through indirect methods. The methods included talking to the media with testifying in government hearings being the most direct method of stakeholders exercising influence.

### **Findings for Subquestion 2**

As with the findings for Subquestion 1, the findings for this subquestion have a caveat. I was not able to find outright statements addressing collaboration about the policy shift. Still, the data did contain references to collaboration and indicated findings.

**Q&A/testimony and partnering statements.** This pair of findings address the possibility of collaboration via the content of exchanges and statements by stakeholders.

**Q&A/testimony.** This finding emerged from reviewing congressional testimony; policymakers and witnesses engaged in question and answer exchanges. The section contains sets of extracts from testimony in which policymakers pose questions followed by answers from agency officials. The following set is from a hearing about the confidentiality of patient files and highlights how government stakeholders foresaw the issue of enforcement. The first extract is a member of Congress posing questions to an assistant secretary for a government agency:

So the question I have for you, Secretary [Jones], is that one of the issues that we are having a great deal of difficulty is, how do you enforce whatever standards we come up

with? How have you done that in your regulations and how do you think is the best way for us to make sure that these standards, whatever standards are developed, that all parties that are affected by it comply with the standards? And how do you go about making sure that becomes reality? (Confidentiality of Patient Records, 2000, pp. 34-35)

The next extract is the assistant secretary responding and confirming that a concern existed:

There are a set of enforcement standards that I believe were given to us through the HIPAA statute in terms of our opportunities for enforcement. And that is one of our concerns, one of the reasons why we feel that in fact national legislation would provide benefits that we cannot achieve through the reg process. (Confidentiality of Patient Records, 2000, p. 35).

The second set of extracts from a hearing held nine years later focuses on the presence of an issue regarding enforcement. The policymaker posed the question of how the issue would be resolved while assigning blame during a nomination hearing for an agency directorship position:

How will you revitalize the Office of Civil Rights at HHS? In particular, how will you ensure that the Office provides sufficient oversight over the HIPAA Privacy Rule, both in terms of enforcement of current rules (which was lax under the Bush administration) as well as ensuring that the regulations keep up with developments in health IT?

(Nomination of Governor Kathleen Sebelius, 2009, p. 54)

In response, the individual nominated for the directorship addressed the enforcement issue: “As you know, a recent HHS Office of the Inspector General report found that the Department has done little to ensure that entities covered by HIPAA use sufficient measures to stop privacy breaches before they occur” (Nomination of Governor Kathleen Sebelius, 2009, p. 55).

*Partnering statements.* The finding is based on statements of representatives from stakeholder groups expressing a desire to partner with other groups on endeavors regarding health information privacy or enforcement. The following extracts illustrate the presence of statements regarding potential stakeholder collaboration. During a Senate subcommittee hearing on medical record privacy, a policymaker stated that a group “is working with various stakeholders, including government, industry and health care experts, to address the challenges of creating a Nationwide Health Information Network” (Private Health Records, 2007, p. 27). Conversely, OCR produced a report four years later that contained a statement directly referencing partnering activities concerning enforcement:

OCR will continue to work diligently to enforce both the current protections under the Privacy and Security Rules and the new protections provided by the HITECH Act, especially by leveraging state and federal partnerships including those OCR has already established with other federal agencies. (OCR, 2011, p. 20)

Finally, during a hearing on health information privacy in the computer age held the same year, a policymaker alluded to the prior activities of an advocacy group and encouraged the group to once again be active regarding an item which the policymaker supports:

you came here to lobby us, but I’m going to lobby you back. [Organization XYZ] is an important voice in these issues, and I feel very strongly that we stand to gain immense advantage from a much more robust health information infrastructure. ... So I hope that [Organization XYZ] will be an energetic advocate for the propagation of a robust health information infrastructure, knowing that there are these critical fault lines where patients have to be protected not only in their individual data, but also when it’s being looked at in the aggregate. (Your Health and Your Privacy, 2011, pp. 23-24)

**Work groups/initiatives and association/industry groups.** This pairing of findings reflects levels of collaboration among groups. The activities took different forms from working on a joint project to groups representing an industry or profession producing universal statements on behalf of group members. Again, the topic of collaboration required an indirect approach.

*Work groups/initiatives.* The finding focuses on how members of different individual stakeholder groups worked together on a project. The next extracts span six years, and I chose these extracts to highlight how work groups and initiatives made efforts to produce change. The first extract is from a newspaper profile article and refers to the work of the privacy group that the policymaker “lobbied” for continued activity under the previous finding. The group:

became central to the advocacy during the rulemaking process by organizing a coalition of 100 consumer groups, including representatives of disabled people, seniors, AIDS patients, and the mentally ill. The coalition's constituents generated more than 30,000 of the 52,000 comments on the proposed rules that were filed with the Department of Health and Human Services. (Goldstein, 2003, p. A.21)

The next extract is from a report produced for a research organization associated with a university law school, and the extract highlights this organization. The author of this report has ties to the stakeholder group highlighted in the prior extract: “For select high-priority issues, [Organization XYZ] organizes reflective problem-solving initiatives in which the Institute seeks to bridge the gap between key policymakers in the public, private, and civil society sectors and the intellectual talent and knowledge that resides in academia” (McGraw, 2009, p. i).

The final extract details a work group that is a function of a state-level industry stakeholder: “The privacy and security workgroup as a part of the [Group XYZ] represents a

broad spectrum of stakeholders and representatives from over 25 health care organizations from across the state” (MDH, 2009, p. 2).

**Association/industry groups.** This finding involves attempts by stakeholder groups representing a profession or industry to influence the policy shift. The extracts, all from the same year, demonstrate how the association/industry groups encapsulated collaborative efforts that tried to influence the details of the modified enforcement philosophy. The first highlighted industry group is a managed care organization that:

serves more than 70 million Americans each year across the country. Partnering with more than 650,000 physicians and other care providers, 5,200 hospitals, 80,000 dentists and 65,000 pharmacies in all 50 states, we touch nearly every aspect of health care delivery and financing. (UnitedHealth Group, 2009, p. 1)

The next association group acts on behalf of “more than 100 academic health centers nationwide, is dedicated to improving the nation's health care system by mobilizing and enhancing the strengths and resources of the academic health center enterprise in health professions, education, patient care, and research” (Association of Academic Health Centers, 2009, para. 1). The final industry group “is a national not-for-profit organization that provides support services to 91 separately incorporated affiliates that operate 850 reproductive health care centers in almost every state” (Planned Parenthood Federation of America [Planned Parenthood], 2009, p.1).

**Opposition to HIPAA/HITECH.** The finding is derived from statements by stakeholder groups expressing opposition to an aspect of enforcement. The extracts for this finding are dated eight years apart and illustrate the history of influence by industry stakeholders. The first extract is from a newspaper article and represents how industry stakeholders were committed to have

HIPAA not succeed even before the regulations in effect: “Industry leaders vowed to press HHS officials to reconsider provisions in the rule that they argue would hurt care and raise costs by making the industry less efficient” (Goldstein, & O’Harrow, 2001, p. A.1). The second extract is from a newspaper article and details the perspective of a health care industry consultant that industry stakeholders achieved the espoused objective: “I believe it is because of the power the medical and pharmaceutical lobby has wielded to discourage enforcement” (Kanigher, 2009, p. 1).

In sum, the findings for this subquestion suggest that stakeholder collaboration occurred indirectly through activities. Participation in work groups and professional associations opened the possibility of collaboration, and partnership statements and testimony addressed for future collaboration.

### **Findings for Subquestion 3**

The findings for Subquestion 3 address themes and subthemes that involved aspects of stakeholder perspectives regarding fines.

**For voluntary compliance and policy of the administration.** This pair highlights different avenues of stakeholder support for the original enforcement approach.

*For voluntary compliance.* The finding emerged as a result of the archival documents containing stakeholder statements that supported voluntary compliance. The extracts in this section span six years and exemplify how industry stakeholders and government officials promoted voluntary compliance. A newspaper article included the following statement from a corporate officer of a professional medical association: “‘We’re more used to the government coming down with a heavy hand where it’s unnecessary,’ said [Jones of Organization XYZ]. ‘I applaud HHS for taking this route’” (Stein, 2006a, p. A.01, 2006b, p. 1A, 2006c, p. A-1). The

same news article also contained a supportive quote from a person in leadership at the government agency: “Our first approach to dealing with any complaint is to work for voluntary compliance. So far it's worked out pretty well” (Stein, 2006a, p. A.01, 2006b, p. 1A, 2006c, p. A-1). Agency officials also continued to support voluntary compliance in the year prior to passing of the HITECH Act. A news article stated that a spokesperson for HHS “said the department's approach has led to ‘improvements that were constructive and were achieved more quickly than through imposition of monetary penalties’” (Rubenstein, 2008, p. D.1).

During 2009, the year which the modifications under HITECH were proposed and discussed, some industry stakeholders promoted non-enforcement options. The following extract is a statement a corporate officer with a hospital-based organization during a Senate committee hearing: “We clearly need an organization to oversee privacy and security, and I think not from an enforcement perspective, but from an oversight” (Health Information Technology, 2009, p. 28). Meanwhile, other industry stakeholders still supported a voluntary approach. One group including a state-level agency recommended that HHS “(c)onsider remediation and prevention mechanisms instead of relying on penalties and additional monetary burdens on organizations to ensure compliance” (MDH, 2009, p. 1). The final extract is from a letter written by a private citizen that I included for the unique view expressed:

The possibility of fines should only be used as a LAST resort not first. This opens the government to the accusation that it is not using its power to gain compliance but as a revenue enhancement device. The Department of Health and Human Services is not a revenue generating agency and should not be placed in this position. (Hurley, 2009, Public Comment Submission, para. 2)

***Policy of the administration.*** This finding features statements made by members of stakeholder groups about how a presidential administration viewed violations. These extracts feature how the policy of a presidential administration influenced the handling of privacy violations and potential for a policy shift with a change in administration. The first extract is from the congressional testimony of another law professor and privacy expert. The party stated:

the current administration has adopted the policy of “one free violation”. In the 2006 enforcement rule adopted by HHS, the decision was made that a covered entity would simply not be subject to civil penalty for its first violation. Instead, the first offense always results in a plan to correct actions going forward. (Protecting Patient Privacy, 2007, p. 92)

The next extract is from a report generated two years later for a research group and references the possibility of upholding the status quo started by the prior presidential administration: “The new Administration should and will set its own enforcement policies with respect to criminal and civil HIPAA violations” (McGraw, 2009, p. 32). The final extract is statement made by a law professor published in a newspaper article: “The enforcement regulations under HIPAA give people one free bite of the apple with respect to civil violations” (Kanigher, 2009, p. 1).

**Against voluntary compliance and lack of fines.** This pair emphasizes disapproval for maintaining the original enforcement approach.

**1. Against voluntary compliance.** The finding emerged as a result of the archival documents including stakeholder statements that opposed voluntary compliance. The following extracts represent sentiments before and after the passage of HITECH and illustrate what opponents of voluntary compliance perceive as a weakness in the enforcement approach. The first extract is from a newspaper article and points to privacy advocates viewing the resolutions

as weak: “Critics say the government's approach which focuses on getting providers to correct violations may be too lenient” (Alonso-Zaldivar, 2008, A.10). The second extract is from a report prepared by an official from a government-based research entity and highlights the perceived weaknesses. The official wrote “(p)rivacy advocates have been critical of HHS’ enforcement of the HIPAA Privacy Rule which has focused on technical assistance and voluntary cooperation for the covered entity with HHS” (Stevens, 2008, p. 14). The last extract is from a report seven years later by another official from the same entity as the previous extract and typifies what trend this lenient approach creates. The official stated that “(p)rivacy advocates criticized the agency for not being more aggressive in its enforcement activities and for not penalizing noncompliant organizations” (Redhead, 2015, p. 20).

***Lack of fines.*** The finding concerns statements made by members of stakeholder groups about the lack of fines associated with voluntary compliance. All extracts for this finding are from congressional hearings either testimony or comments. An agent of an advocacy group stated during a hearing on privacy and health care information systems that “the batting average for HHS is pretty low. There has been 27,000 complaints and zero civil or monetary penalties, so over 27,000. That doesn’t create a lot of confidence” (Protecting Patient Privacy, 2007, p. 87). The next extract is from a congressional hearing one year later and shows how the number of complaints increased but the number of penalties did not. A congressman remarked that:

the privacy rule has now been in effect for half a decade and there have been 30,000 or so complaints alleging violations reportedly filed with HHS, yet I understand there has not been one instance in which HHS has imposed a civil penalty for a violation of the rule.

(Discussion Draft, 2008, p. 137)

The last extract is from four years after the policy shift and pertains to the answers of a leading OCR official in response to questions that the committee chairperson submitted in relation to a congressional hearing. The agency official explained the measured use of penalties even after the adoption of the modified enforcement approach:

The ultimate goal of our enforcement efforts is to protect the privacy rights of all individuals under the HIPAA Privacy and Security Rules through compliance by covered entities and business associates. Strategic use of our civil money penalty authority and high-profile resolution agreement cases draw attention to longstanding, systemic failures to comply with security or privacy requirements and raise the awareness of all covered entities and business associates of their obligations in these areas. (Does HIPAA Help, 2013, p. 119)

**Not adequate/motivating.** This finding focuses on how some perceived the original enforcement approach as not having a persuasive element that would encourage covered entities to abide by the regulations. The ensuing set of extracts focuses on statements made a few years before the modifications under HITECH. In a newspaper article, an industry consultant made the following comparison when discussing the original enforcement philosophy:

It's like when you're driving a car, said [Jones] of [Company XYZ] another consultant. If you are speeding down the highway and no one is watching, you're much more likely to speed. The problem with voluntary compliance is, it doesn't seem to be motivating people to comply. (Stein, 2006a, p. A.01, 2006b, p. 1A)

The next extract is from the prepared congressional testimony of a prominent privacy group representative:

When Congress enacted HIPAA in 1996, it included civil and criminal penalties for failure to comply with the statute—and these penalties applied to the subsequent privacy and security rules implemented years later. Unfortunately, the HIPAA rules have never been adequately enforced. (Hearing on Promoting the Adoption, 2008, p. 70)

The following extract is from the congressional testimony of a law professor representing an advocacy group. This testimony, not only, addresses the issue of motivation, but also, denotes the issue has received media attention. The professor stated that “lack of enforcement has been the subject of major stories in the Wall Street Journal and the Washington Post. One expert was quoted in the post saying, ‘HHS really isn’t doing anything, so why should I worry?’” (Protecting Patient Privacy, 2007, p. 87).

This pair of extracts focuses on statements made by government officials after the modifications under HITECH. The first extract is from an agency-issued press release regarding a covered entity being assessed a monetary penalty: "We hope the health care industry will take a close look at this agreement and recognize that OCR is serious about HIPAA enforcement. It is a covered entity's responsibility to protect its patients' health information" (HHS Press Office, 2011b, Full text, para. 3). The second extract is from the written answers offered by a leading agency official to accompany congressional testimony: “The purpose of higher penalties for HIPAA violations is to increase the incentive for covered entities and business associates to comply with their privacy and security obligations” (Does HIPAA Help, 2013, p. 119).

**Recommendations from industry including explanations and recommendations from other.** This pair of findings focus on the suggestions made by stakeholders regarding how policymakers and government officials should handle enforcement.

*Recommendations from industry including explanations.* This finding developed from the archival documents including recommendations by industry stakeholders regarding the policy shift and the handling of violations. The recommendations concern how the stakeholders wanted explanations and sometimes reconsideration of the revised penalty structure. The extracts in this section are from comment letters regarding IFR submitted to HHS/OCR from industry stakeholders in 2009 and exemplify the desire for participation in and knowledge of the penalty determination process. The first extract is a from a document submitted by a work group associated with a state-level industry stakeholder and addresses engagement:

HHS can make available the proposed process and who will be involved with determining what tier any given violation would fall under and at a minimum provide or engage mechanisms to educate or inform people and organizations about the process.

(MDH, 2009, p. 7)

The next extract is from a letter submitted by a professional association and concerns a more detailed request that could result in covered entities (e.g., industry stakeholders) gaining more insight into the assignment of penalties. In the letter, the group stated, “we believe that specific examples of the Department’s thinking regarding the categories of violations and the levels of CMPs it contemplates would be helpful” (American Medical Informatics Association [AMIA], 2009, p. 3). The third extract highlights how groups offered recommendations that if taken would give industry stakeholders information on how escape fines. In this extract, an industry group made a recommendation regarding communication about potential penalties:

“The Secretary should make clear that penalties for violations due to lack of knowledge can be waived” (Planned Parenthood, 2009, p. 2).

The following set of extracts also is from the comment letters submitted by association or industry groups and illustrates how these stakeholder groups offered recommendations concerning the use of judgment when assessing penalties. The extracts provide differing views on the matter. One stakeholder association wrote that “we are concerned that the wide range of discretion that HHS has proposed in the enforcement rule will lead to inconsistency in enforcement among HHS/OCR’s Regional Offices, and subsequently lead to arbitrary results” (National Association of Chain Drug Stores, 2009, p. 2). Conversely, an industry stakeholder “believes that HHS should exercise the discretion granted to it by law by establishing maximum penalties for each category of violation on a proportionate basis” (American Council of Life Insurers, 2009, p. 1). A final extract is from a group that includes a state-level agency and demonstrates how some industry groups still offered veiled recommendations calling for the continuation of voluntary compliance or a like approach. The group wrote “(w)hile this rule outlines the tiers of penalties for violations, the group members would suggest that remediation and prevention measures can assist with compliance and promote change as effectively and consistently as punitive mechanisms” (MDH, 2009, p. 3).

***Recommendations from other.*** The finding developed from the archival documents containing recommendations by non-industry stakeholders regarding the policy shift and the handling of violations. These recommendations mainly focused on having mandated fines when violations were the result of deliberate disregard for privacy standards. This pair of extracts are dated eight years apart and highlights statements addressing the concept of willful neglect. The first extract is from the congressional testimony of a deputy assistant secretary for an agency and offers perspective, because the testimony was given prior to the Privacy Rule going into effect: “The Secretary’s recommendations in 1997 suggested that we thought there should be civil

money penalties for violations criminal penalties for knowing and wrongful conduct” (Confidentiality of Patient Records, 2000, p. 35). The second extract is from the prepared statement from a privacy group official that accompanied testimony and is from the year before policymakers passed HITECH: “Congress should act to clarify that the Secretary must investigate all complaints for which a preliminary inquiry into the facts indicates possible willful neglect and pursue civil monetary penalties in willful neglect cases” (Hearing on Promoting the Adoption, 2008, p. 71).

In sum, the findings for this subquestion indicate what was anticipated. Stakeholder groups who favored voluntary compliance also contested modifying enforcement and assigning fines. Stakeholder groups who opposed voluntary compliance also focused on the lack of fines.

### **Findings for the Other Circumstances From Subquestion 3: Supplemental Findings**

These findings emerged from the data for Subquestion 3, but the content was outside the purview of the question.

**Private right of action.** The supplemental finding emerged from members of stakeholder groups making statements pertaining to the possibility of private lawsuits based on privacy violations. This finding addresses how individuals whose privacy was violated *originally* could not take legal action against covered entities. The following extracts span eight years and exemplify the longevity of this topic. A leading agency official asserted in a prepared statement to accompany congressional testimony that “any individual whose privacy rights have been violated should be permitted to bring a legal action for actual damages and equitable relief” (Confidentiality of Patient Records, 2000, p. 17). The debate over the adoption of a private right of action also had parties ready to dismiss the concept. During a congressional hearing, a representative of the health care industry testified “that it is outside the Secretary’s authority to

impose an implied private right of action” (Confidentiality of Patient Records, 2000, p. 65). Nonetheless, a privacy advocacy group was still drawing attention to the concept through a prepared statement submitted during congressional testimony years later:

We recognize that providing a private right of action to pursue every HIPAA complaint no matter how trivial would be inappropriate and disruptive, but Congress should further consider giving consumers some right to privately pursue recourse where there are intentional violations of the law, or in circumstances of willful neglect. (Hearing on Promoting the Adoption, 2008, p. 72)

**State attorneys general.** This supplemental finding developed as a result of members of stakeholder groups making statements about the possibility of giving enforcement authority to State attorneys general. This finding in the data emphasizes how the modifications under HITECH expanded the potential legal consequences that violating covered entities may encounter at the state-level of government. The next extract is from a member of Congress during an exchange about the option of allowing enforcement to be handled by state officials:

You are raising concerns about the existing law and the enforcement by the Secretary under that existing law. I was also posing the idea of letting the State agencies enforce the law. You think both need to be looked at? (Discussion Draft, 2008, p. 138)

The subsequent extract is the response from a representative of a leading privacy group: “Yes, I would look at it. Because arguably if you give the State AGs the authority, they have to abide by the statutory provisions that the OCR has to follow” (Discussion Draft, 2008, p. 138). The next extract is from a letter by national professional association to the House of Representatives and contains a call for caution. The association stated that “allowing State Attorneys General to enforce federal privacy laws has the potential to result in myriad civil actions for the same

incident and lead to costly and unnecessary litigation expenses for health care providers (PCMA, 2009, Sec. 4410(e) Enforcement by State Attorneys General, para. 1). Despite the calls for caution, policymakers did give state attorneys general the authority to pursue civil remedies for privacy violations as an attorney representing the DOJ pointed out during a Senate subcommittee hearing. The attorney for the DOJ asserted that “(t)hrough the Health Insurance Portability and Accountability Act, or HIPAA, as recently strengthened by the HITECH amendments ... State attorneys general can initiate civil proceedings for injunctive relief and financial penalties” (Your Health and Your Privacy, 2011, p. 6).

**Transparency/monitoring.** The supplemental finding emerged from members of stakeholder groups making statements pertaining to the need for transparency or monitoring at OCR. This finding emerged from data that contained calls for more insight into how OCR handles enforcement. Some stakeholders desired transparency for informational purposes. A comment letter from a workgroup/initiative functioning within a stakeholder group including a state-level agency requested that HHS “(c)ontinue to provide open and transparent process for the rulemaking process including opportunities, where feasible and possible, for stakeholders to provide feedback prior to compliance dates of new regulations” (MDH, 2009, p. 1). In written testimony submitted to the U.S. Senate two years later, a representative from a privacy advocacy group suggested adopting “(s)trenghened accountability through greater transparency about enforcement of privacy and security rules (Your Health and Your Privacy, 2011, p. 55).

The finding also highlights calls for monitoring practices that coincided with desire for additional insight. The first two extracts represent the desire for monitoring before and after the policy shift. Advocacy stakeholders wanted increased government culpability for abiding by updated enforcement procedures if the government was promoting the implementation of the

updated procedures. The following extract is from a prepared statement a hearing in which a senior representative of a privacy group made recommendations: “Congress can take a number of actions to secure more meaningful enforcement of the HIPAA rules, including ... Requiring OCR to report to Congress on a regular basis on enforcement of the rules” (Hearing on Promoting the Adoption, 2008, p. 79).

The next extract is from a professional journal article whose authors are attorneys who focus on health or medical areas of practice: “The biggest complaints by critics of HIPAA are that there is insufficient oversight” (Kempfert & Reed, 2011, p. 269). In the end, policymakers allowed for both greater transparency and monitoring through the modifications under HITECH. The ensuing extract is from a report prepared by an official from a government research entity and details the reporting responsibilities of HHS/OCR per the modifications under HITECH:

The HITECH Act requires the Secretary annually to submit a report to Congress that summarizes the number and types of complaints received; the compliance reviews and enforcement actions taken; the number of audits performed and their findings; and the Secretary’s plan for improving HIPAA compliance and enforcement for the following year. (Redhead, 2015, p. 21)

**Staffing - resources.** The supplemental finding developed as a result of members of stakeholder groups making statements regarding OCR staffing issues. The extracts chosen to illustrate for this finding span eleven years and show staffing practices as an issue of concern. However, the concern does not receive much attention even though the imbalance of OCR staff to covered entities was cited in an early newspaper article: “Fewer than 100 inspectors have been assigned to police tens of thousands of doctors' offices, clinics, hospitals and pharmacies and other sites that HIPAA calls ‘covered entities’” (Boodman, 2003, p. F.01). An agency official

later admitted to staffing deficiencies affecting enforcement. The writer of a news article asserted that a leading OCR official made claims about “the size of his staff limits its ability to do much more than respond to complaints” (Stein, 2006a, p. A.01, 2006b, p. 1A). An editorial published shortly after the previous article contained a less than sympathetic view of the issue: “The U.S. Department of Health and Human Services is responsible for enforcing the Health Insurance Portability and Accountability Act, but complains that a limited staff hinders executing HIPAA, as the law is commonly known. That's no excuse” (Nice Law, No Teeth, 2006).

The issue of staffing remained an ongoing concern as the modifications under HITECH were becoming reality. In fact, a person nominated for HHS secretary addressed the subject: “As Secretary, I will work to ensure that the Office of Civil Rights has the necessary leadership and resources to protect effectively the rights of individuals to preserve the confidentiality of their medical information” (Nomination of Governor Kathleen Sebelius, 2009, p. 55). Even after the modifications under HITECH were in place, OCR officials continued to be cognizant of staffing matters. The following extract is from a report produced by OCR that included a statement referencing resources and enforcement activities:

Given OCR’s experience with an ever-increasing volume of complaints, without a corresponding increase in resources, OCR is determining ways to “work smarter,” that is, to increase the effectiveness of its allocation of staff time and other resources to achieve the most industry compliance with the HIPAA Rules. Many complaints can be resolved more effectively through early intervention and technical assistance than through an investigation. (OCR, 2014, p. 23)

In sum, the supplemental findings suggest that different stakeholders endorsed ideas that were beyond the purview of Subquestion 3. Different groups promoted establishing a private

right of action, allowing state attorneys general to enforce HIPAA, increasing transparency and monitoring at OCR, and increasing awareness that staffing at OCR is an issue.

### **Findings for the Overarching Question**

The following findings address an event that emerged from the data regarding the overarching question.

**Open policy window.** The event of having an open policy window aiding in the policy shift emerged early in the analysis process. These extracts span two years and represent the briefness of an open policy window and show how a policy window opening due to a change in presidential administrations helped to precipitate a shift in enforcement philosophies. In congressional testimony from before the policy shift, a law professor and privacy expert asserted:

The current administration has adopted the policy of one free violation. In an enforcement rule last year, HHS said that the first violation simply won't lead to a penalty; instead, it will lead to a planned correct going forward. This sends the signal that medical privacy shouldn't be taken seriously. If you are a covered entity, just wait until they come the first time and then you can fix it, but you don't face any exposure.

(Protecting Patient Privacy, 2007, p. 87)

The next extract is from a report written by a privacy advocate for a research group and denotes the possibility for change with a new administration taking power:

The new Administration and new Congress present us with new opportunities to break the privacy "gridlock." Notwithstanding other critical national issues that need urgent attention, we have never had a better opportunity to pursue reform of our health care system, facilitated by interoperable health IT with protections for privacy and security.

(McGraw, 2009, p. 33)

The ensuing extract is from a newspaper article and signals the arrival of change through the new administration and the new legislation: “When President Barack Obama signed the American Recovery and Reinvestment Act in February to help stimulate the economy, the legislation included provisions to increase HIPAA’s civil penalties” (Kanigher, 2009, p. 1).

The following pair of extracts address the results of utilizing the open policy window. The first extract is from a journal article authored by parties associated with a privacy advocacy group and conveys a guarded optimism concerning enforcement under the new administration:

Overall, it is within the power of the new administration to implement an enforcement policy that is robust without making covered entities so overly cautious that they fail to share information even for those purposes where it is permissible and facilitates the provision of good care. (McGraw, Dempsey, Harris, & Goldman, 2009, p. 425)

The second extract is from a newspaper article and expresses a wait and see view of enforcement under the new administration. An attorney with knowledge of HIPAA stated that the “administration is giving the impression that it will make the most of its strengthened HIPAA, but whether it will follow through remains to be seen” (Kanigher, 2009, p. 1).

### **Summary**

The findings for Subquestion 1 pertain to activities that stakeholders carried out to exercise influence. Even though I was not able to find direct statements or references addressing the exercise of stakeholder influence, the data indicated findings related to the exercise of influence. The data for the finding dealing with industry groups writing letters to policymakers and officials as well as the finding involving group representatives speaking with members of the news media indicate privacy advocates and governmental officials utilized the media to disseminate views more than industry stakeholders. However, all major stakeholder groups in

this study (i.e., privacy advocates, government officials, and the health care industry) had representatives provide congressional testimony. Major stakeholder groups also had employees migrate from one group to another group or have connections to someone who influences policy.

The findings for Subquestion 2 concern potential collaboration among stakeholders to exercise influence. Again, I was not able to find outright statements addressing stakeholder collaboration regarding the policy shift. Nonetheless, the data did contain references to collaboration and indicated findings with government stakeholders made statements referencing the possibility of collaboration. Conversely, the data for the findings of members from different individual stakeholder groups working together on a project and attempts to influence the policy shift by groups representing a profession or industry indicate forms of stakeholder collaboration.

The findings for Subquestion 3 involve perspectives on the lack of civil money penalties or fines playing a role in stakeholder arguments for or against the policy shift were delineated based on support for or opposition to the assessment of fines. The finding concerning stakeholder statements that supported voluntary compliance and the finding highlighting stakeholder statements regarding how a presidential administration viewed violations suggest that industry stakeholders supported by the policy of a presidential administration promoted an enforcement philosophy not focused on the assessment of fines; whereas, data for the findings regarding stakeholder statements opposing voluntary compliance. The finding concerning stakeholder statements regarding the lack of fines associated with voluntary compliance and the finding concerning how some perceived the original enforcement approach as not having a persuasive element signaled that privacy advocacy stakeholders pointed to circumstances created by the original enforcement philosophy as reasons to support a modified enforcement philosophy that promoted the assessment of fines. The recommendations offered by stakeholder groups

reflect the role of fines played in the perspectives. Finally, industry stakeholders sought information about the use of discretion in the assessment of fines, while other stakeholders promoted the concept of willful neglect cases warranting fines.

Four supplemental findings emerged from the data for Subquestion 3, but the content was beyond the perimeters of the question. Privacy advocates and government officials promoted the establishment of a private right of action that allows persons affected by privacy violations to sue covered entities. Different stakeholders urged caution from policymakers regarding allowing state attorneys general to enforce the HIPAA regulations, and urged policymakers to increase level of transparency and monitoring at OCR. Finally, the issue of staffing at OCR emerged as a longstanding concern and continued to be a focus for government officials after the policy shift.

Having an open policy window was central to addressing the overarching question along with aspects of some findings from the subquestions. The change in presidential administrations aided by the introduction of the ARRA legislation provided policymakers with the opportunity to modify the original enforcement philosophy. The event of an open policy window also adds perspective to the findings regarding stakeholder statements on how a presidential administration viewed violations and stakeholder statements about the lack of fines related to voluntary compliance. In other words, policymakers were aware that the original enforcement philosophy had not resulted in any fines but waited until the change in presidential administrations occurred to have the support required for the policy shift.

In the next chapter, I discuss my interpretations of the findings in a presentation order that matches the presentation of findings in this chapter. I address the limitations, and describe the implications associated with this study and provide suggestions for future research.

## CHAPTER 5

### DISCUSSION AND CONCLUSION

#### **Discussion**

##### **Interpretations of Findings**

This section highlights my interpretations of the findings of this study along with broad applications of theories from the theoretical framework.

**Interpretations of findings for subquestion 1.** The data did not include direct statements or references addressing the exercise of stakeholder influence. I viewed this detail as paralleling Kingdon's (2011) concept of hidden versus visible participants. I think that stakeholders engaged in influencing activities, but the archival documents did not include acknowledgements of these activities. Thus, these influencing activities remained "hidden". Yet, the data did indicate findings pertaining to "visible" instances of exercising influence.

*Communicate in writing and news media (communicate through speaking).* The data for this pair indicate that privacy advocates and governmental officials utilized the media to disseminate views more than industry stakeholders.

*Communicate in writing.* This finding emerged as stakeholder groups directly communicated with members of Congress or agency officials by writing letters. Given that a substantial number of the archival documents that I reviewed are records of what stakeholders said (e.g., news articles and testimony), I did not anticipate this finding. In fact, the practice of directly communicating in writing rather than publicly promoting views contradicted what I expected to find before starting the research process. I initially thought that all stakeholder groups would want to have public platforms from which to espouse their views as a means of garnering support. During the research process, I realized that if groups knew their views would

not be well received by the public then the groups may want to circumvent having to broadcast those views while still trying to influence the policy shift.

My interpretation of this finding is tied to the interpretation of the next finding given the juxtaposition of the two findings. I interpret the use of letter writing in response to aspects of the proposed policy shift as industry stakeholders limiting their own potential influence by directly writing to policymakers and government officials. Industry stakeholders may have shied away from using the media to share opinions fearing public reaction. The opinion of the public can have an adverse or favorable influence on whether issues appear on an agenda (Kingdon, 2011). Thus, industry stakeholders may have opted for a communication path that would not draw attention. The reaction of groups with more influence on an event must to be measured; groups may take a defensive position and downplay the ramifications when the event jeopardizes their influence (Birkland, 1998). However, in limiting the audience, the industry stakeholders limited the scope of potential influence. Industry groups failed to use the media to present a defense for maintaining the original enforcement approach resulting in a missed opportunity. The media have a penchant for only focusing on a story for a limited time (Kingdon, 2011)

*News media (communicate through speaking).* This finding involves members of stakeholder groups speaking to the news media in an effort to promote the group's viewpoint or agenda. My interpretation of this finding is a juxtaposition to my interpretation of the previous finding. Parties opposing voluntary compliance and/or encouraging a more punitive philosophy frequently used the media to disseminate ideas and information. The interpretation is congruent with why I did not include the media as a stakeholder in Figure 3 (Chapter 2). Media is the only participant group without a discernable location in Figure 3, because they have an overarching influence that potentially involves other participant groups. These parties wanted the issue in the

spotlight as a means of political pressure. In other words, public awareness of the issue may contribute to the desired political scrutiny, which would facilitate change. This thought parallels how Kingdon (2011) perceived media influence. Media does influence public opinion, and coverage also highlights existing social movements (Kingdon, 2011)..

The ability of the media to disseminate information demonstrates the potential to influence opinion. For example, Stein (2006a) was widely published under other titles including Stein (2006b) and Stein (2006c) which contained statements from parties critical of the original enforcement philosophy. Sources in the literature review (e.g., De Armond, 2008; Gray, 2008; Murphy, 2008) as well as the research documents (i.e., Stevens (2008) cited the information in Stein (2006a). Therefore, I interpret the publication of Stein (2006a) as being a focusing event in the policy shift process. Focusing events draw interest to a particular issue (Odom-Forren & Hahn, 2006). They also spur interest in a latent issue which may result in the reconsideration of a policy due to failure (Birkland, 1998). Finally, the interpretation of Stein (2006a) as a focusing event aligns with the second supposition presented in the conceptual framework. I posited that the actions of an interested party such as a policy participant (stakeholders) in conjunction with an event likely was the prompting activity.

***Testimony (communicate through speaking).*** The finding denotes how members of stakeholder groups offered testimony in congressional hearings. Even so, all major stakeholder groups in this study (i.e., privacy advocates, government officials, and the health care industry) had representatives provide congressional testimony.

My interpretation of this finding is that stakeholder groups had the opportunity to be heard and advance certain agendas. Through my review of testimony, I noticed that witnesses thanked the policymakers for the invitation to testify. I researched the process for selecting

witnesses to assist in completing my interpretation and found a practice in attempted fairness. Congressional committees usually endeavor to invite witnesses who represent different perspectives on a subject; however, at times, committees will invite only witnesses with specific perspectives (Davis, 2015; Heitshusen, 2017). Additionally, even though various stakeholder groups with differing viewpoints testified in hearings, some parties were better at expressing thoughts or opinions. For instance, two stakeholders provided testimony, yet the expression of thoughts differed. The first extract is from the testimony of health care industry representative. The industry representative stated that “I think what we need is, again, some type of oversight organization that provides support, almost like an ombuds - I can't even say the word - ombudsman to do as much support as an enforcement” (Health Information Technology, 2009, p. 28). Conversely, the second extract is from testimony that a privacy advocacy group representative offered two years later. The representative stated:

We also are very much on board with more transparency with respect to how HIPAA is enforced, both on the DOJ and the HHS side. Summary statistics don't really tell you very much about what's really going on in the field in terms of compliance with HIPAA, and particularly where the Department is likely to continue to try to seek voluntary corrective action on the part of institutions. (Your Health and Your Privacy, 2011, p. 19)

The content of the second extract is more polished and practiced than the content of the first extract; a factor which influences the effectiveness of the conveyed thoughts. I was surprised to recognize a lack of polish in formal testimony; however, this could have indicated that witnesses simply were nervous. Nonetheless, sometimes how individuals perceive the people making statements is just as influential as what the people actually say.

*Employee movement among groups and participation through connections.* All major stakeholder groups had representatives move from one group to another group or have connections to someone who influences policy.

*Employee movement among groups.* The unexpected finding highlights how members of stakeholder groups left the groups by changing employers and by changing employers moved among the different groups. When I initially recognized this finding, I considered the moving among groups during careers to be normal given in my experience that employees move among providers. However, after reflection, I now think that with movement comes the possibility of influencing opinion by speaking as a former insider. The first two parties highlighted in the extracts illustrate how the perspectives from knowledgeable parties draw attention by appearing in print. The newspaper reporter quoted both parties giving opinions in the article, which was published in various newspapers (Stein, 2006a, p. A.01, 2006b, p. 1A, 2006c, p. A-1).

This aspect of movement parallels a concept in the theory of bounded rationality. The loss of employees with pertinent knowledge, affects information availability. Employee turnover significantly hampers organizational recall (Simon, 1991). Moreover, I interpret from the data that the opposite scenario of employees bringing useful information may be influential to policy work. Additionally, individuals who move among groups also may exercise influence on the current work product and environment based on experiences at previous workplaces. These parties may possess information regarding policy weaknesses that the current workplace can utilize to advance an agenda. In other words, information due to movement could be a contributing influence on “killing” a policy.

Movement among stakeholder groups also is a concept related to the “garbage can” model that inspired Kingdon’s MS framework. The “garbage can” model posits that persons in

government often move positions and, therefore, experience changes in influence. Participants in decisions change with “bureaucrats, especially high-level servants, often move from public service to private practice” (Zahariadis, 2007, p. 67). A bureaucratic leaving the public sector to work in the private sector is exactly what is described in Lawson et al. (2003).

*Participation through connections.* The finding developed as professional and personal connections between members of different stakeholder groups were acknowledged within the archival documents. The data indicate the possibility of stakeholder group representatives having access to policymakers. I did not expect the direction that this finding took. Privacy stakeholders gaining access to policymakers is not surprising. Yet, statements conveying direct connections between stakeholder representatives and policymakers or people having established political standing was surprising. I interpret connections and access as being a path to potential influence. One extract pertaining to a witness being the classmate of a politician’s sibling illustrates how connections may contribute to access and, by extension, exercising influence through expressing the perspectives of a stakeholder group during testimony before policymakers.

I interpret the finding as highlighting activities and details as paralleling how Kingdon (2011) described policy entrepreneurs. Policy entrepreneurs offer benefits including political contacts and participating in hearings (Kingdon, 2011). The explanation offered by Kingdon (2011) regarding relationships among interest groups, committee members, and bureaucrats. According to Kingdon (2011), these relationships involve overlapping concerns and are unaffected by more visible stakeholder groups in the political realm. Such relationships may lead to more hearing appearances before committees. At times, committees will invite only witnesses with specific perspectives (Davis, 2015; Heitshusen, 2017).

**Interpretations of findings for subquestion 2.** The data did not contain outright statements addressing stakeholder collaboration regarding the policy shift. Again, I interpreted this fact as paralleling Kingdon's (2011) concept of hidden versus visible participants. I think that stakeholders probably engaged in more collaborative activities; however, the archival documents did not acknowledge these activities. Thus, these collaborative activities stayed "hidden", but the data did contain "visible" references to collaboration and indicated findings.

*Q&A/testimony and partnering statements.* Even though I interpreted that data for these findings as not being collaboration, government stakeholders made statements referencing the possibility of collaboration.

*Q&A/testimony.* This finding emerged from reviewing congressional testimony; policymakers and witnesses engaged in question and answer exchanges. Throughout the review of testimony, I constantly thought that some answers were already determined based on the questions. My interpretation is that some questions were leading with a purpose. In these exchanges, the leading participants were congressional members and the responding participants were representatives of other stakeholder groups. During the data analysis process, I wondered if the appearance of these exchanges being prearranged indicates that the policymakers involved also had predetermined conclusions about the policy. The prospect of policymakers having prearranged exchanges is interesting to me given the sway that policymakers have. Kingdon (2011) asserted that legislators possess the capacity to influence agendas along with the available options; therefore, Congress occupies an important position in policy development. Yet, the activity falls short of being collaborative.

*Partnering statements.* The finding is based on statements of representatives from stakeholder groups expressing a desire to partner with other groups on endeavors regarding

health information privacy or enforcement. My interpretation has two parts. First, some documents included statements that a party worked with other parties on a given project. The activity falls short of being collaborative, because these statements usually are vague without direct references to enforcement in offers to collaborate. Second, I did interpret a hint of collaboration in statements from government stakeholders. However, the statements were grounded in what will be done not what was done; therefore, I interpret these activities as willingness to influence enforcement. For example, a government official offered to work with congressional members during testimony: “We are hoping to be working closely with you to develop national privacy protection legislation, and within that context addressing the issue of enforcement” (Confidentiality of Patient Records, 2000, p. 35).

***Work groups/initiatives and association/industry groups.*** The data for these two findings did indicate forms of stakeholder collaboration.

*Work groups/initiatives.* The finding focuses on how members of different individual stakeholder groups worked together on a project. Based on the data, work groups and initiatives were an effective means of stakeholder collaboration throughout the timeframe of interest (2000-2013). The work groups and initiatives often were an offshoot or a subgroup of a larger stakeholder group. I initially considered this finding to be comprised of advocacy-based or non-industry stakeholders; however, I recognized that industry stakeholders also utilized work groups and initiatives. The extract from Goldstein (2003) describes stakeholder activities, which are consistent with concepts related to the organizing of social movements: “the coalition's constituents generated more than 30,000 of the 52,000 comments on the proposed rules that were filed with the Department of Health and Human Services” (p. A.21).

Within the American political arena, both influential stakeholders and their less influential counterparts utilize grassroots efforts to persuade politicians that their espoused concerns reflect society's desires (Quadagno, 2004). People organize social movements in response to disputes regarding health care in order to protect fundamental views and values (Quadagno, 2010). It is of note that some populations mentioned in the extract are the same populations mentioned in the regulatory text regarding trust and privacy. Population examples of HIV/AIDS and mental health or substance abuse treatment are populations who would gain greater levels of certainty or trust from having privacy practices (Standards for Privacy, 1999).

*Association/industry groups.* This finding involves attempts by stakeholder groups represent a profession or industry to influence the policy shift. Based on the data, association/industry groups were not an effective means of stakeholder collaboration during and after the introduction of the modifications under HITECH (2009-2013) even though the groups already were established collaborative groups. The association groups mostly were profession or industry-based stakeholder groups; whereas, the corporate groups were company-based groups embedded in the health care industry. These groups are the same stakeholders who wrote letters to the policymakers and government officials offering comments on the modified enforcement rule. Upon reviewing the letters, I denoted a touch of "do you know who we are" via statements pertaining to organizational holdings or statistics. I interpreted this as the groups attempting to show authority which coincides with concepts related to countervailing powers. I interpreted the stating of resources and reach as veiled warnings about potential lobbying if HHS officials ignored the concerns of these groups. A significant group that possesses resources frequently has the capability to prevent the adoption of a proposal which are contradictory to the group's

desires (Kingdon, 2011). Even so, association/industry groups should employ caution. The need for caution when relying on resources is examined in the interpretation of the next finding.

***Opposition to HIPAA/HITECH.*** The finding is derived from statements by stakeholder groups expressing opposition to an aspect of enforcement. My interpretation of this finding connects to my interpretation of the finding about attempts by stakeholder groups representing a profession or industry to influence the policy shift. This finding supports my impression that association/industry groups wanted to convey “do you know who we are.” The data indicated that industry stakeholders had prior success in asserting influence regarding HIPAA. Thus, industry stakeholders believed reputations and past influence would be enough to sway policymakers. Even though the amount of resources that an interest group possesses may affect the amount of influence that group can exercise concerning an agenda, the amount of resources that an interest group possesses does not always translate into success or failure regarding an objective (Kingdon, 2011). I view the policy shift as partially due to industry stakeholders including association groups not effectively using resources (i.e., the finding addressing stakeholder groups writing letters as a means of directly communicating with policymakers and agency officials).

**Interpretations of findings for subquestion 3.** The findings for this subquestion regarding perspectives on the lack of civil money penalties or fines playing a role in stakeholder arguments for or against the policy shift were delineated based on support for or opposition to the assessment of fines.

***For voluntary compliance and policy of the administration.*** Data for this pairing suggested that industry stakeholders supported by the policy of a presidential administration promoted an enforcement philosophy not focused on the assessment of fines.

*For voluntary compliance.* The finding emerged as a result of the archival documents containing stakeholder statements that supported voluntary compliance. I anticipated this finding based on material in the scholarly literature and in the theoretical framework. This finding is present in the data from documents dated from both before and after the introduction of the modified enforcement philosophy. My interpretation is that industry stakeholders initially supported voluntary compliance as an enforcement option, because the approach was favorable to covered entities, which parallels the scholarly literature. Covered entities favor the enforcement process that urges voluntary compliance instead of having formal administrative procedures and assessing civil monetary fines (Hill et al., 2009). Furthermore, the industry support continued through the adoption of the HITECH modifications. One group recommended that HHS “(c)onsider remediation and prevention mechanisms instead of relying on penalties and additional monetary burdens on organizations to ensure compliance” (MDH, 2009, p. 1).

Another group related to the previous group through a member also touted voluntary compliance. The group encouraged HHS to use preventative and remediation techniques, because the techniques support changes more readily than punitive techniques (Aging Services of Minnesota, 2009). In sum, I interpret this finding as industry stakeholder groups recognizing that voluntary compliance is an enforcement approach without significant consequences attached, and those groups sought to retain the approach due to the lack of consequences. The data for this finding coincides with what I experienced at the organizational level as a compliance officer. The corporate policy for addressing privacy violations included remedial training for the employee as the first step in the progressive disciplinary process. Employees grumbled about being caught but would attend the training to avoid additional discipline.

Additionally, I interpret agency officials offering support for voluntary compliance as understandable and obligatory. The first piece of interpretation highlights how the espoused support was understandable. I interpret the finding as matching the socially expected norm that people will act in accordance with laws and customs. The law, the reasonable assessment of tangible goals, and the dedication to these concepts will remain a behavioral standard, and compliance is the manifestation of people fulfilling their legal responsibilities. (Weber, 1946/2014). In other words, the inherent expectation is that individuals will fulfill their social duty to follow the rules and observe laws. Therefore, government stakeholders created and promoted an enforcement approach focused on compliance with thinking that covered entities would comply since complying was the socially acceptable response. Much like as a compliance officer, I expected on an organizational level that most employees would adhere the policies, because the employees were aware that the policies existed.

The next two pieces of interpretation address why OCR's support of voluntary compliance may have been obligatory. Before completing this case study, I thought that OCR officials touted voluntary compliance, because the approach worked in addressing most violations. Therefore, I did not foresee the second piece of interpretation. This piece of interpretation coincides with the limits on bureaucratic roles. Officials are relegated to specific duties, the proverbial gears in the machine without the ability to halt the entire machine once it is operating (Weber, 1946/2014). For this study, OCR officials are the gears and the unstoppable machine is the enforcement approach. I view this interpretation as paralleling the concept of constraints on rationality as offered in the theory of bounded rationality.

This third piece of interpretation addresses how OCR officials dealt with meeting goals. In the decision-making process, objectives are established then alternatives and the associated

results are pursued concluding with an assessment of results based on the organizational objectives (Choo, 1996). If the aim of the presidential administration is to not pursue penalties in response to privacy violations, OCR meets that goals through promoting voluntary compliance. The content and interpretations of this finding partially coincide with the third expectation presented in the conceptual framework regarding what stakeholder were against voluntary compliance. I anticipated that stakeholders; such as political appointees, industry groups, and professional organizations would be the groups that denied the need for the policy shift.

*Policy of the administration.* This finding highlights statements made by members of stakeholder groups about how a presidential administration viewed violations. This finding was unexpected despite the topic appearing in the theoretical framework and the scholarly literature, because I initially viewed the influence of a presidential administration on policy as being less than the influence of the Senate or the House of Representatives since those legislative bodies collectively have policymaking duties. My interpretation calls on two different pieces from the theoretical framework. First, I interpret the finding as relevant to explaining the adoption of the original enforcement philosophy and why the push for the shift in philosophy was successful. Kingdon (2011) posited that personnel changes contributed to fluctuations in policy agendas. Changes within politics such as the introduction of a presidential administration may alter agendas (Kingdon, 2011).

Second, I interpret this finding as paralleling concepts in the theory of bureaucracy. The research documents address the functional impact of how a presidential administration approaches enforcement. During congressional testimony, a law professor representing an advocacy group critical of how the Bush administration handled enforcement said, “the current administration has adopted the policy of one free violation” (Protecting Patient Privacy, 2007, p.

87). Additionally, the finding appeared as a topic in the scholarly literature and addressed the impact the Bush administration had on HIPAA. A change in presidential administrations from Clinton to Bush created doubt about the possibility of HIPAA's implementation since the Bush administration initiated another comment period; nonetheless, the administration issued the Privacy Rule with some modifications (Solove, 2013). I interpret this element of the finding as an indication of presidential power being embedded in the bureaucrat structure of the federal government. Again, OCR officials only could enforce privacy violations by methods available to them with the available method being voluntary compliance. Therefore, someone with greater authority had to modify the enforcement philosophy allowing OCR to pursue additional enforcement methods. This concept matches the description of what a bureaucratic leader is capable of doing. Officials cannot start or stop the entire machine once it is operating only people with the highest authority can carry out such actions (Weber, 1946/2014). I interpret the president as being the individual in the government with the level of authority, because the president has the power to veto legislation. The president has control over certain resources such as public exposure that may compel action, organizational decisiveness, and capabilities on an institutional level such as personnel decisions and veto power (Kingdon, 2011).

Again, this finding had an unanticipated level of importance to the study. In retrospect, I should have not been surprised by the general concept of individuals in positions of complete authority affecting policy implementation. On an individual and an organizational level, I experienced a leadership change that impacted how I carried out my duties. When I was named compliance officer, the company's owner was in control, and he trusted me with the authority to develop policies, conduct confidential investigations or audits, and reprimand employees when needed. Then, the owner ceded control to a senior officer. The senior officer almost

immediately constricted my authority so that I was not allowed to conduct investigations or to contact the owner to discuss compliance activities.

This finding also helped to frame other findings such as stakeholder statements that oppose an aspect of enforcement and stakeholder statements regarding the lack of fines associated with voluntary compliance. The finding provides a thought-provoking gateway into the forthcoming discussion of how Kingdon's concept of policy windows applies to this study. Thus, I interpret this finding as being an "ah-ha" moment in addressing the overarching question.

*Against voluntary compliance and lack of fines.* Data for this pair signaled that privacy advocacy stakeholders pointed to circumstances created by the original enforcement philosophy as reasons to support a modified enforcement philosophy that promoted assessing fines. Also, the content and interpretations of these findings coincide with the third expectation presented in the conceptual framework about what stakeholders were against voluntary compliance. I expected stakeholders such as advocacy/consumer groups and academics wanted the policy shift.

*Against voluntary compliance.* The finding emerged as a result of the archival documents including stakeholder statements that opposed voluntary compliance. This finding was anticipated and compatible with the information I read for the literature review as well as my professional experiences. I interpret the data and subsequent finding as being straightforward. My interpretation is that opponents of voluntary compliance were consistent in focusing on how the philosophy contained an inherent tolerance of wrongdoing by covered entities (e.g., industry stakeholders) by not being proactive in nature. In a speech, one policymaker summarized the argument against voluntary compliance; the senator commented that the designers of HIPAA intended the HHS to enforce the regulations through audits, legal activities, and fines; however, the agency investigates situations only after receiving complaints (Clinton, 2006). The scholarly

literature contained statements with similar thoughts. Gray (2008) stated that voluntary compliance does not have the compelling influence to facilitate change. My interpretation also calls on my experiences as a compliance officer. Some employees petitioned me that since the government relied on complaint-based enforcement that I should adopt the same approach and not worry about compliance unless I received a complaint. I view this finding as corroborated by the content of the next finding.

*Lack of fines.* The finding concerns statements made by members of stakeholder groups regarding the lack of fines associated with voluntary compliance. This finding was expected and congruent with the information in the scholarly literature. For example, Rahman (2006) asserted that a persistent topic of concern was how OCR does not assess civil monetary fines when dealing with Privacy Rule violations. The finding also focuses on the phenomenon created by a lenient enforcement approach. My interpretation is that this finding was central to why the shift in policy occurred. As with any legal case, detectives must offer evidence regarding the charges before the government will prosecute a party. I interpret the lack of fines as being the evidence required by policymakers to address the flawed enforcement philosophy.

The number of complaints without a civil monetary penalty was another contributing factor in the policy shift. For instance, in *Discussion Draft* (2008), a policymaker stated in a hearing that HHS received 30,000 complaints without assigning a single fine. In my experience, tangible numbers garner attention, and people remember numbers. I also view the numbers as an indicator of functioning. Kingdon (2011) viewed program feedback in a similar manner; it “gives information on current performance that may not square with legislative or higher administrative intent, indicates a failure to meet goals, or suggests unanticipated consequences” (p. 113). I perceive the lack of fines as an unanticipated consequence of OCR focusing on

voluntary compliance. Unexpected outcomes that have significant influence contribute to the perception that an issue exists and requires investigation (Kingdon, 2011).

I also perceive the mandate in HITECH that requires OCR to report activities as a means of program feedback. Bureaucrats produce required reports that affect the direction of policy (Kingdon, 2011). According to OCR (2011, 2014, 2016), OCR is to report to Congress various statistics and details regarding HIPAA-related enforcement activities. This interpretation coincides with the first expectation presented in the conceptual framework. This expectation involves how OCR originally handled violations adding to the flaws in the policy in terms of the stark lack of repercussions for confirmed violations.

*Not adequate/motivating.* This finding focuses on how some perceived the original enforcement approach as not having a persuasive element that encouraged covered entities to abide by the regulations. Data for this finding indicate that privacy advocacy stakeholders pointed to situations created by the original enforcement philosophy as reasons to support a modified enforcement philosophy.

Again, this finding was expected and consistent with the information in the scholarly literature and my professional experiences. Murphy (2008) summarized points made by critics of voluntary compliance in stating how OCR stressed assistance over the assessment of civil fines contributed to complacency and differences between covered entities and unmotivated covered entities. The finding also reinforces the finding about the lack of fines attached to voluntary compliance. My interpretation is that this finding moves beyond the fact that enforcement efforts were not yielding fines to the dearth of penalties sending a message to covered entities. Having concrete repercussions attached to an action is needed to eliminate the given action, according to psychology. This finding addresses the importance of anticipated

penalties by highlighting what could occur when consequences are absent which parallels my professional observations on an organizational level in dealing with employees who had issues with compliance. I disciplined employees for similar issues despite prior warnings or training; those employees tended to be more conscientious when faced with greater consequences.

The finding also coincides with concepts explored in the theoretical framework regarding the work of Weber (1946/2014, 1947/2009) and Stone (2002). Optimism, anxiety, and potential reprisal drive compliance (Weber, 1946/2014). In other words, worry regarding negative outcomes compels compliance with rules. Accordingly, if negative outcomes are not attached to violating the Privacy Rule, covered entities are not motivated to comply with the Privacy Rule. In sum, penalties for violations act as motivation to adhere to laws and regulations. Societies that adopt rules should establish devices for imposing the rules (Westin, 1967); thus, rules contain incentives for individuals to act inside established parameters (Stone, 2002). Additionally, Weber (1947/2009) asserted that departure from the law must result in penalties intended to encourage compliance and admonish noncompliance.

*Recommendations from industry including explanations and recommendations from other.* The recommendations offered by stakeholder groups also reflect the role of fines played in their perspectives. Industry stakeholders sought information about and the use of discretion in the assessment of fines, while other stakeholders promoted the concept of willful neglect cases definitively warranting fines.

*Recommendations from industry including explanations.* This finding developed from the archival documents including recommendations by industry stakeholders about the policy shift and the handling of violations. The finding highlights requests for information from industry stakeholders, which is consistent with my professional experiences on an organizational

level. I had numerous requests from employees during routine semi-annual training sessions to specify punishable actions and the corresponding consequences. I usually could decipher by the way an employee asked a question or by the amount of the detail they gave if the situation already had occurred. I answered those requests for information by offering global answers and referring the employees to the corporate compliance manual. Yet, material from the literature review offered a different perspective on disseminating enforcement information. Sanctions lose the deterring influence if individuals can determine which violations are prosecuted; therefore, formal rules rely on concealment concerning rules of thumb to be effective (Stone, 2002).

Industry stakeholders recommended discretion regarding regulations and penalties rather than focusing on the probability of penalties. I interpret this finding as industry stakeholders opting to not promote the continuation of voluntary compliance but wanting to gather information to minimize the potential for penalties. For instance, the stakeholders who produced AMIA (2009) and MDH (2009) requested that HHS/OCR offer information regarding enforcement activities including examples. My interpretation is based on the data with the change in direction is logical. If a party understands that a highly favorable practice is being abandoned, the party would want to promote the adoption of a next best option to secure some favorability while maintaining a participatory presence.

*Recommendations from other.* The finding developed from the archival documents containing recommendations by non-industry stakeholders regarding the policy shift and the handling of violations. This finding was anticipated based on the scholarly literature. Westin (1967) promoted the concept that having an outside party exchange someone else's information produces unique responsibilities for the outside party. More recently and specifically, Gray (2008) suggested a modification to internal policy that includes a reconsideration of relying on

informal means, because voluntary compliance may be appropriate in some cases while other cases call for more stringent forms of corrective actions. My interpretation is that policymakers considered the proposed recommendations to be useful enough to incorporate the concepts into the modified enforcement philosophy. For example, policymakers included considerations for violations involving willful neglect, “there may be circumstances (such as circumstances indicating willful neglect), where the Secretary may seek to proceed directly to formal enforcement” (Modifications to the HIPAA Privacy, 2010, p. 40876, 2013, p. 5578). However five years before the passage was published in the regularly text, a representative of privacy advocacy group asserted in a prepared statement for a 2008 congressional hearing that “Congress should act to clarify that the Secretary must investigate all complaints for which a preliminary inquiry into the facts indicates possible willful neglect and pursue civil monetary penalties in willful neglect cases” (Hearing on Promoting the Adoption, 2008, p. 71).

At times, I also was surprised how closely the HITECH regulations mirrored recommendations from government and privacy advocacy stakeholders. Therefore, I interpret the finding as being influential in the policy shift. For example, a privacy group representative recommended in a written statement for a 2008 hearing that Congress should direct “OCR to report to Congress on a regular basis on enforcement of the rules” (Hearing on Promoting the Adoption, 2008, p. 79). Policymakers included a similar condition into the modifications under HITECH. OCR must report to Congress on various statistics and details regarding HIPAA-related enforcement activities (OCR, 2011, 2014, 2016). This requirement of OCR also parallels how Kingdon (2011) described a function of bureaucrats in analyzing programs; they “constantly issue studies, reports, and other papers, some mandated by statute and some done on their own; these can play a part in preparing the policy community for some future direction” (p. 129).

**Interpretations of findings for other circumstances from subquestion 3.** These supplemental findings emerged from the data for Subquestion 3, but the content was beyond the perimeters of the question. However, the first three supplemental findings are relevant to the study in that the findings draw on information present in the scholarly literature, as well as the regulatory texts. Therefore, I was familiar with the concepts; however, I failed to recognize the potentiality for themes until the data analysis process.

*Private right of action.* The supplemental finding emerged from members of stakeholder groups making statements about the possibility of private lawsuits based on privacy violations. Privacy advocates and government officials promoted establishing a private right of action that allows persons affected by privacy violations to sue covered entities. I was not surprised that a private right of action emerged as a finding. People do not have a right to private action against covered entities (Collins, 2007; Gray, 2008; Letzring & Snow, 2011). In other words, the potential recourse options for individuals affected by privacy violations did not evolve much during the previous century. Godkin (1890) asserted that publicly discrediting intrusions of privacy is the sole recourse an individual has concerning an infraction against their right to have personal privacy. The concept of not allowing for personal avenues of recourse is a complementary concept to the handling of administrative regulations such as the HIPAA Privacy Rule. The regulatory basis for determining a violation is whether the applicable rule is violated and not whether harm regarding an outside party occurs (Anderson & Jackson, 2006). This view is reminiscent of thoughts articulated over a century ago. In discussing enforcement of the right to privacy, Warren and Brandeis (1890) stated that “(i)t is not for injury to the individual’s character that redress or prevention is sought, but for injury to the right of privacy” (p. 218).

Therefore, my interpretation of the establishment of a private right of action is straightforward. A private right of action is a longstanding concept regarding Privacy Rule enforcement that parties debated and dismissed only to be presented again. For example, *Confidentiality of Patient Records* (2000) is a record of a congressional hearing from 2000 and contained testimony concerning a private right of action, and years later, government official and privacy advocates cited the concept as a topic of concern. One government agency official testified that the concept should be considered:

Under HIPAA, for example, there is no individual right of action. If someone isn't satisfied with what happens at HHS, they cannot go to the courts for resolution. I think this is an issue that, you know, we will need to look at over time, but we haven't studied it in depth. (Protecting Patient Privacy, 2007, p. 37)

A representative from a privacy group submitted testimony three years later advocating for Congress to consider the concept:

With respect to a private right of action for privacy and security violations, [Organization XYZ] recognizes that providing such a right for every HIPAA complaint - no matter how trivial - would be inappropriate and disruptive. However, Congress should give consumers some right to privately pursue recourse in specific circumstances. (House Science and Technology Subcommittee, 2010)

***State attorneys general.*** The supplemental finding developed as a result of members of stakeholder groups making statements about the possibility of giving enforcement authority to State attorneys general. I always have envisioned government agencies and levels of government as being territorial about responsibilities and functions. Therefore, I was surprised to recognize a finding that dealt with granting enforcement authority outside of the federal

government. Yet, I was not surprised to recognize a finding involving the need to expand possible avenues for enforcement. Warren and Brandeis (1890) asserted that the scope of legal protections regarding privacy should be revised and stated that “it has been found necessary from time to time to define anew the exact nature and extent of such protection” (p. 193). I also was not surprised that state attorneys general were the law enforcement body who received the authority. For example, the text for the final rule for the HITECH modifications included that HHS “will be working closely with State Attorneys General to coordinate enforcement in appropriate cases, as provided under section 13410(e) of the HITECH Act” (Modifications to the HIPAA Privacy, 2013, p. 5579).

My interpretation of the finding is that I understand the need for expanded avenues of enforcement, but I question the motivation behind the expansion. Different stakeholders urged caution from policymakers regarding allowing state attorneys general to enforce the HIPAA regulations. That is, different stakeholder groups identified the need to approach the concept with caution as reflected in the extracts presented in Chapter 4. The attorney for the U.S. Department of Justice stated during a Senate subcommittee hearing that “(s)tate attorneys general can initiate civil proceedings for injunctive relief and financial penalties” (Your Health and Your Privacy, 2011, p. 6). This statement provoked a thought from me concerning this supplemental finding. Could policymakers have instituted the inclusion of state attorneys general into the updated enforcement approach as a means of alleviating OCR from total responsibility, and, by extension, total blame if the updated scheme does not produce result?

Moreover, I view the concept of allowing state attorneys general to enforce the HIPAA regulations as another issue of debate between stakeholders; privacy advocates encouraged the concept, and industry representatives discouraged the concept. One privacy group representative

testified via a prepared statement that policymakers “should also consider authorizing State Attorneys General to also enforce HIPAA” (Hearing on Promoting the Adoption, 2008, p. 72). Conversely, a corporate officer on behalf of national professional organization addressed the concept in a letter to congressional leaders by stating that “HIPAA enforcement should be aimed at encouraging compliance, not punitive actions” (PCMA, 2009).

***Transparency/monitoring.*** The supplemental finding emerged from members of stakeholder groups making statements pertaining to the need for transparency or monitoring at OCR. I was not surprised that government transparency and/or monitoring was emerging as a finding. OCR does not practice transparency concerning enforcement (Gray, 2008).

This finding also was not surprising in terms of my individual professional experiences as a compliance officer. My colleagues in senior management repeatedly requested total transparency concerning my activities; however, transparency was not always possible based on the objectives of activities. I routinely conducted confidential investigations that only were known to company’s owner and occasionally the human resources director. I had to investigate complaints and employee activities while the employees were still working at the company. Due to the nature of these investigations, the company’s owner required me to observe security measures including working behind locked doors. During one investigation, he required me to leave my belongings in my office and work in an unoccupied office so that I would not easily be found. These security and confidentiality measures unnerved some of my coworkers, but the measures prevented information leaks.

My interpretation has two components. The first is stakeholders viewed transparency as a key to knowledge. This interpretation ties to the finding of recommendations by industry stakeholders regarding the policy shift and the handling of violations. For example, one

association group commented that “some of our members are interested in the metrics that OCR uses as it investigates a potential violation” (American Health Information Management Association [AHIMA], 2009, p. 3). Some stakeholders want additional information for self-interested reasons. The same association group explained that “members believe that such information may assist covered entities and business associates in their compliance planning and education activities” (AHIMA, 2009, p. 3). In other words, stakeholders could determine enforcement thresholds if OCR provides enough enforcement data. In interpreting this finding, I thought of Stone’s (2002) rules of thumb. Stone (2002) stated that informal rules of thumb uphold and impose formal rules, and enforcers convey rules of thumb to recipients via direct clues and indirect observation regarding enforcement patterns.

The second component is that stakeholders viewed OCR as needing to be monitored with a system of checks and balances. In other words, some stakeholders saw transparency as a tool for responsibility. This interpretation ties to the finding of having recommendations by non-industry stakeholders regarding the policy shift and the handling of violations. In a 2003 newspaper profile article, a prominent privacy advocate foresaw “numerous challenges ahead, including monitoring HIPAA enforcement” (Goldstein, 2003, p. A 21). Several years later, another representative from the same privacy group stated during testimony that “challenges in health IT result from gaps in current law and a lax approach to enforcement, accountability and oversight” (House Science and Technology Subcommittee, 2010, Introductory section, para. 2). The next year, the person repeated the desire for monitoring by asserting that the group is “very much on board with more transparency with respect to how HIPAA is enforced, both on the DOJ and the HHS side” (Your Health and Your Privacy, 2011, p. 19). I also interpret this finding as a factor in the adoption of the modifications under HITECH in that after reviewing the statistics

policymakers decided the original enforcement philosophy was not functioning as intended and enforcement procedures require monitoring.

*Staffing - resources.* Finally, the issue of staffing at OCR emerged as a longstanding concern and continued to be a focus for government officials after the policy shift. Unlike the other supplemental findings, staffing at OCR or lack of was an unexpected finding that emerged from the data. The finding was unexpected in two ways. First, I did not expect inadequate staffing to be a contributing factor in why OCR used voluntary compliance to resolve privacy violations. Second, I did not expect inadequate staffing and/or resources to remain an acknowledged issue after the modifications under HITECH. Therefore, my interpretation is that staffing was an underlying issue regarding enforcement. In fact, I interpret this finding as indicating that HIPAA enforcement as a perpetually underfunded mandate. A privacy group representative who repeatedly testified before Congress authored a report that includes the topic of resources. The author stated that inadequate resources regarding enforcement was one reason for OCR not effectively enforcing HIPAA regulations (McGraw, 2009).

Furthermore, I interpret this finding as explaining why voluntary compliance remains an enforcement option. Policymakers keeping enforcement efforts underfunded benefits covered entities (e.g., industry stakeholders). The agency sent the *Las Vegas Sun* email confirming the benefit: “Voluntary compliance and informal resolution are an efficient mechanism to resolve noncompliance and save resources for both (the civil rights office) and a covered entity” (Kanigher, 2009, p. 1). This finding remained relevant five years later. If the agency cannot afford to conduct investigations, the optimal enforcement method is one that emphasizes self-correction. A government report stated that “(m)oving forward, OCR intends to realign its

enforcement efforts to focus its limited resources on cases that present OCR with the maximum opportunity to effect change within the health care industry” (OCR, 2014, p. 22).

**Interpretations of findings for the overarching question.** Having an open policy window was essential to addressing the overarching question along with aspects of some findings from the subquestions. The change in presidential administrations aided by the introduction of the ARRA legislation provided policymakers with the opportunity to modify the original enforcement philosophy. The event of having an open policy window also adds perspective to the findings of statements about how a presidential administration regarded violations and about the lack of fines. In other words, policymakers were aware that the original enforcement philosophy had not resulted in fines but waited until presidential administrations changed for the support required for the policy shift.

**Open policy window.** I deliberately placed the data entries referencing the possibility of window or change due to a new administration or legislation into a spreadsheet separate from those designated for each subquestion to limit the potential for bias in interpreting the subquestion findings. I recognized that the open policy window may be the key factor in policymakers altering the enforcement philosophy. A policy window is a chance for supporters of a proposal to promote their answer or awareness of a specific issue (Kingdon, 2011).

This event adds perspective to subquestion findings such as the findings highlighting how a presidential administration regarded violations and the lack of fines associated with voluntary compliance. For example, policymakers were aware that the original enforcement philosophy had not resulted in any fines. This thought parallels the concept of program feedback. Officials utilize feedback concerning the functioning of an ongoing program to gain knowledge on issues (Kingdon, 2011). However, the presidential administration at the time encouraged the practice

of allowing covered entities have one “free” privacy violation without repercussions. I interpret the presence of a policy window as the opportunity policymakers were waiting for to alter the enforcement approach. In other words, policymakers had the evidence required to support the policy shift but needed the correct circumstances to facilitate the shift. Kingdon (2011) asserted that changes occur when different streams in the political environment meet: In the streams meeting, “(a) problem is recognized, a solution is developed and available in the policy community, a political change makes it the right time for policy change, and potential constraints are not severe” (p. 165).

As a compliance officer, I encountered organizational situations in which I had to wait for opportunities to introduce policies due the likeliness that colleagues with different agendas would stifle the policies. For example, I wanted to introduce a policy for matching clinical documentation to timesheets with the dual purposes of immediately addressing staff documentation issues and preventing financial penalties based on negative audit results. Yet, the senior officer who I reported to did not approve the policy until the government announced a structural change to program oversight and the possibility of a full audit greatly increased.

My interpretation captures the second expectation in the conceptual framework; nevertheless, the prediction about which stakeholder group would be waiting for the policy window was slightly incorrect. The expectation was that advocates for change recognized a policy window was opening and took advantage of the opportunity. I initially thought that privacy advocates would be the group taking advantage of an open policy which did occur. For example, the report written by privacy advocate for a research group addressed the possibility for change with a new administration taking power (McGraw, 2009). However, policymakers also viewed the change in administrations as an opportunity. For instance, the policymaker, who

posed the question of how the issue of enforcement would be resolved during the nomination hearing for an agency directorship position, wanted to know how enforcement would be improved on from the previous administration (Nomination of Governor Kathleen Sebelius, 2009). This inquiry indicated a policy window. Personnel changes at a monitoring agency open policy windows by way of garnering favorable hearings regarding proposals (Kingdon, 2011).

*Contextual circumstances surrounding the open policy window.* No event occurs in isolation. This section highlights circumstances that already were in place or denote some planning for the policy shift. Open policy windows require anticipation and planning, so stakeholders are able to use the opportunity to create change; therefore, being prepared when an opportunity arises is key. People cannot direct events; however, they can foresee events and use them to an advantage (Kingdon, 2011). This section offers an overview of other activities or circumstances in politics that added context to the policy shift.

The first contextual circumstance is changes to policymaker status. Due the 2008 election results, congressional democrats started 2009 in a similar position to what they experienced in 1993 as President Clinton took office (Stathis, 2014). The Democrats gained partisan control of the legislature. In 2009, Democrats assumed power in the White House along with possessing majorities in the House of Representatives and the Senate (Stathis, 2014). The ability to control legislation may have contributed to Kingdon's policy, political, and problem streams converging which allowed for the policy shift. A policy window opens due to a shift occurring in politics such as a philosophical rearrangement of Congress or a new presidential administration (Kingdon, 2011)

A second contextual circumstance was the availability of potential overarching legislation. The new administration was concerned with the condition of the American

economy. The administration introduced ARRA as their first legislation aimed at assisting individuals confronted with a very bleak economy while stopping an ongoing recession (Stathis, 2014). President Obama laid the groundwork for ARRA to be passed even before taking office. President Obama, as president-elect, met with policymakers to promote the economic legislation (Stathis, 2014). This activity indicates planning for an open policy window, and this planning may have extended to the modifications under HITECH. HITECH is a component of ARRA of 2009 (Modifications to the HIPAA Privacy, 2013). ARRA housed the modifications under HITECH with changes to the penalty structure. ARRA not only attempted to boost the economy, but also boosted the civil penalties associated with HIPAA violations (Kanigher, 2009).

A third contextual circumstance that aided the policy shift was the availability of other legislation that diverted attention away from the shift. In this instance, stakeholders focused their attention on the issue health care reform. Quadagno (2010) asserted that “(t)he health care reform debate of 2009–2010 highlighted the relevance of institutions, interest groups, and ideology in understanding the dynamics of policymaking in the United States.” (p. 132). The reform debate involved the ACA. The debate drew controversy stemming from issues such as the viability of insurance offered through employers, whether the government would pay for abortion procedures, and having a public insurance choice (Quadagno, 2010). Despite the attention associated with the debate, policymakers passed the legislation. The Democrats obtained approval of the act only after overcoming opposition from Republicans who cited public opinion against the legislation (Stathis, 2014). Nonetheless, the stakeholders who sought the policy shift in enforcement philosophies regarding HIPAA privacy violations benefited from the distraction that the reform debate created.

**Broad applications of theory.** As I reviewed the interpretation pieces regarding the findings, I pondered taking a broader approach to the interpretations. In the end, I decided against explaining my interpretations in broad terms for the individuals who potentially will read the study. I cannot foresee what aspect of these findings and associated interpretations a reader would want to know about; hence, I refrained from only taking a broad approach with presenting my interpretations. However, this section highlights broad applications of the theories and related concepts matched with ideas within the scholarly literature and the study findings.

*Application of the multiple-streams framework.* The application of the MS framework includes policy windows. The occurrence of a policy window being open at the time when lawmakers adopted the HITECH modifications was a reason for the modifications being passed. The modifications were the result of an open policy window; thus, symmetry is present in the evolution of the HIPAA provisions. The proposed legislation now known as HIPAA was a countermeasure to another bill, the Kassebaum Kennedy Roukema Act (KKR), which lawmakers abandoned due to the introduction of caveats or additions as recommended in a *Washington Post* editorial (1996). Republican House members promised to introduce addendums that would endanger KKR, and if Congress accepted these addendums, KKR needed to be blocked (Bad Move on Health Care, 1996). Similarly, lawmakers included the HITECH modifications into an overarching piece of legislation, ARRA. HITECH is a component of ARRA of 2009 (Modifications to the HIPAA Privacy, 2013).

The concept of having a policy window also emerged as a finding. The following extract from a 2008 government research report and indicates the possibility of a policy window:

Lawmakers and others are examining the statutory and regulatory framework for enforcement of the HIPAA Administrative Simplification standards, and ways to ensure

that agencies use their enforcement authority to the fullest extent under HIPAA to address improper uses and disclosures of protected health information. (Stevens, 2008, summary page)

***Application of the concepts in rulemaking by regulation.*** The presence of the administrative rulemaking process directly impacted the development and enforcement of the Privacy Rule. In December 2000, HHS published the final Privacy Rule after studying the received comments (Standards for Privacy, 2002). However, as Morriss et al. (2005) stated as happening with proposed rules, HHS decided to create a second version of the final rule. Due to difficulties in comprehending the Privacy Rule, the HHS secretary reopened the comment period after the final rule was issued, and the revised version of the Privacy Rule became effective in October 2002 (Standards for Privacy, 2002). The previous situation exemplifies how the policy process can be unpredictable. Policies are not linear or uniform with policy employment frequently not following the original strategy (Ridde, 2009). However, one author offered an alternative explanation for this decision to re-open the final rule to potential modifications that involved influence from the executive branch. A change in presidential administrations from Clinton to Bush created doubt about the possibility of HIPAA being implemented since the Bush administration initiated another comment period; nonetheless, the administration issued the Privacy Rule with some modifications in 2002 (Solove, 2013).

The emergent data indicated that how a policy progresses, or regresses is largely dependent on who is in charge of the policy. As with how the Bush administration, the Obama administration's approach to policy development also influenced the Privacy Rule. The first extract is from a report written by a privacy advocate for a research group and represents how administration changes can mean changes in policy. The report stated that "(t)he new

Administration and new Congress present us with new opportunities to break the privacy ‘gridlock’” (McGraw, 2009, p. 33). The second extract is from a nomination hearing for a potential head of HHS and illustrates a philosophical change regarding how privacy violations should be handled. The nominee stated that in addition to “being reviewed and updated, the privacy rules must be enforced” (Nomination of Governor Kathleen Sebelius, 2009, p. 55).

*Application of social movements and countervailing powers.* As Quadagno (2011) examined how stakeholders influenced the ACA in some manner, I explored how stakeholders influenced the policy shift regarding the handling of privacy violations. The call to change how OCR handles privacy violations spurred a form of social movement among privacy advocates which may have aided the policy shift. Privacy advocates desire harsher enforcement rather than voluntary compliance (Maliniak & Mitchel, 2006). A movement starts as a means to progress the desires of movement supporters by accomplishing certain goals (Benford & Snow, 2000). Nonetheless, the structure of the American political system allows groups to try to influence separate lawmakers to either promote or discourage pieces of legislation or to define what issues the lawmakers consider significant (Quadagno & Street, 2005).

Countervailing powers may have played a role in why the policy on the handling of privacy violations shifted. Moreover, capabilities associated with the concept of countervailing powers parallels the content and functions of this study. In the instance of handling violations, privacy advocates, as a countervailing power, are the proponents of policy change. Privacy advocates hold unfavorable views regarding voluntary compliance (Gray, 2008).

This concept matches with the findings related to stakeholder statements that opposed voluntary compliance. The findings suggest that parties were displeased with the original enforcement approach. The following paraphrased comment from a senator during a speech on

health care privacy given three years before the policy shift. The senator commented that HIPAA was supposed to promote the assessing of fines, lawsuits regarding violations, but officials rely on complaints then start investigations (Clinton, 2006). The next extract is from a news article one year before the passage of the modifications under HITECH and summarizes the view of patient advocates. The writer stated that “advocates criticize as too lax institutions' enforcement of a federal privacy law” (Rubenstein, 2008, p. D.1).

Nonetheless, policymakers also considered the views of industry stakeholders regarding the handling of privacy violations. Covered entities were the opposing countervailing power that sought to maintain a focus on voluntary compliance. Covered entities tend to prefer voluntary compliance to the alternative. Health care industry officials agree that voluntary compliance is the optimum enforcement strategy to employ regarding the Privacy Rule (Gray, 2008). Officials prefer this enforcement process that urges voluntary compliance instead of having formal administrative procedures and assessing civil monetary penalties (Hill et al., 2009).

This concept parallels the findings related to stakeholder statements supporting voluntary compliance. The findings indicate that covered entities were pleased with voluntary compliance and wanted the approach to remain in practice. The following pair of extracts is from three years before the policy shift. The first extract is succinct. The approach is “praised by hospitals, insurance plans and doctors” (Stein, 2006b, p. 1A). The second extract is a direct quote from a representative of the hospital sector of health care and appeared in the same news article and elaborates on why covered entities liked the original enforcement approach. The representative viewed that the approach as “an opportunity for hospitals to understand better what their requirements are and what they need to do to come into compliance” (Stein, 2006c, p. A-1).

*Application of the theory of bureaucracy.* This section addresses how concepts related to the theory of bureaucracy align with the study. Utilizing the rational course of action or ideal type as a basis of comparison, a person can determine how illogical aspects such as mistakes and emotions may influence the action in question enough to produce a departure from the rational course (Weber, 1947/2009). An individual may posit that voluntary compliance served as the rational ideal type for HIPAA enforcement given previous experience and success with that enforcement approach. HHS uses voluntary compliance as a method of resolving civil rights violations. If evidence shows that an entity covered under civil rights discrimination laws did not follow the applicable regulation, OCR tries to settle the case through procuring corrective activities via a voluntary arrangement (OCR, 2015). However, what is rational can shift. If the ideal type of enforcement is ineffective, would it be rational to adjust what the ideal type is? While voluntary compliance might be a successful approach with covered entities that had formal complaints, survey results indicated that the approach could deter covered entities who fail to adhere to privacy provisions and have not encountered complaints from employing privacy practices (HIMSS & Phoenix Health Systems, 2006).

These concepts match with the findings related to stakeholder statements concerning the lack of fines attached to voluntary compliance and of how some perceived the original enforcement approach as lacking persuasion. The findings suggest that voluntary compliance and the lack of fines associated with the approach failed to produce an ideal type of enforcement. The following extract is a quote from a privacy advocate that was published in a new article a few years before the policy shift. The advocate stated that government officials "have done almost nothing to enforce the law or make sure people are taking it seriously. I think we're dangerously close to having a law that is essentially meaningless" (Stein, 2006a, p. A.01). The

next comment exemplifies how voluntary compliance may not be an ideal type of enforcement due to the absence of a motivating influence for covered entities to change privacy practices. The paraphrased comment is from a policymaker during a speech that occurred within two weeks of the news article referenced for the previous extract. The politician stated that due to lenient enforcement, compliance is decreasing since covered entities realize they will not be made accountable (Clinton, 2006).

*Application of the theory of bounded rationality.* The concepts in the theory apply to the decision processes and actions of OCR officials concern the suggestions and a method for addressing issues derived from bounded rationality. One suggestion focused on the decision-making process and helps in exploring the process behind the decision to modify Privacy Rule enforcement through provisions in HITECH. The process of creating decision choices entails thinking of concepts followed by more fully developing on those concepts. Designing solutions may involve cultivating and expanding ideas about resolving important issues (Simon, 1972, 1993). The HHS secretary, at the time that the legislation was written, had an idea that would have expanded resolution options. HHS Secretary Shalala recommended that the legislation should include a legal remedy for individuals affected by violations (Standards for Privacy, 1999). Yet, the idea was not included in the legislation. Congress failed to include a provision within the HIPAA legislation stipulating a private right to action; hence, the HHS secretary cannot offer people affected by violations that particular recourse (Standards for Privacy, 1999).

The need for a private right of action emerged as a finding. The concept was a discussion point before and after HITECH. The first extract is from the congressional testimony of a privacy advocate given nine years before HITECH. The advocate stated that “the Secretary is unable to confer on individuals a private right of action in the event the rules are violated”

(Confidentiality of Patient Records, 2000, p. 59). The second extract is from the congressional testimony of another privacy advocate given one year after the passage of HITECH. The advocate asserted that the law “never included a private right of action, leaving individuals dependent on government authorities to vindicate their rights“ (House Science and Technology Subcommittee, 2010, Strengthen Accountability/Enforcement section, para. 2).

The concept of working under or with a satisficing solution may applicable to understanding voluntary compliance as an enforcement approach. The development of satisficing a solution involves the use of past experiential knowledge, such as problem representations. The pursuit of a satisfactory resolution centers on previous resolutions and mirrors the prior understandings, education, and objectives (Choo, 1996). This explanation of a satisfactory resolution coincides with how OCR handles civil rights violations concerning discrimination. A satisficing solution indicates that a threshold regarding sensibility and suitability has been met; a satisfactory resolution denotes reasonableness and being above the lowest level of appropriateness (Choo, 1996). The following extract is from a government issued report after the policy shift, and the extract illustrates a focus on efficacy over in-depth inquiries. The report stated that “(m)any complaints can be resolved more effectively through early intervention and technical assistance than through an investigation” (OCR. 2014, p.23).

### **Limitations**

The study had three limitations with two of the limitations involving the research design/strategy of inquiry. The first limitation is that a case study has inherent boundaries by focusing on one policy shift. A case study involves exploring one case while comprehending the conditions surrounding the case (Stake, 1995). The second limitation involves the data collection method, specifically the use of archival data and document reviews in terms of what

databases and, in turn, documents I was able to access. Access and retrievability affect the study of documents (Altheide & Schneider, 2013). A third limitation emerged during the research process. This limitation relates to the second limitation and concerns two research subquestions. The questions regarding the exercising of stakeholder influence and stakeholder collaboration proved difficult to completely explore. These questions required examination through indirect information. For example, I was unable to locate information about conversations stakeholder groups may have had with policymakers. Instead, I relied on findings such as professional and personal connections between members of different stakeholder groups and statements expressing a desire to partner with other groups for activities to explore the potential for influence. Therefore, the limitations associated with the study influenced the findings and what information could be interpreted based on those findings.

### **Implications**

The findings of this study have implications which suggest that the reason for this policy shift and how stakeholders contributed to the policy shift compliance was multifaceted. The number of themes and subthemes that emerged during the process of analysis suggests the reasons behind and the factors contributing to a policy shift may be just as numerous. Nevertheless, the findings imply a few factors had more prominent roles in the policy shift.

The first implication addresses how a presidential election opens a policy window. I view the change in presidential administrations as fueling the presence of an open policy window. Weber (1946/2014) contended that officials cannot start or stop the bureaucratic machine once it is operating only people with the highest authority can carry out such actions. The findings imply that stakeholder groups who sought a policy shift used ideas such as those in the findings of statements about how a presidential administration viewed violations and

statements about the lack of fines associated with voluntary compliance to promote their objective leading up to and directly after the change in presidential administrations. I keep recalling one extract that encapsulates this implication. The extract is from 2009 report written by a privacy advocate and addressed the potential for change with a new administration and legislature taking control. The report included the view that “(t)he new Administration and new Congress present us with new opportunities to break the privacy ‘gridlock’” (McGraw, 2009, p. 33). This expectation that a new administration may introduce policy changes is realistic. Change is a fixation during the first year of a presidential administration (Kingdon, 2011). Policymakers passed the modifications under HITECH encapsulated in the ARRA legislation in 2009, the first year of the Obama administration. Therefore, the findings suggest that policy entrepreneurs and those stakeholders who want to promote a proposal should prepare well in advance of a presidential election, so that a proposal is not only ready, but recognized by policymakers to increase the chances of being considered within the first year of an administration.

A second implication is that the findings related to how a presidential administration regarded violations suggest that OCR officials may have been limited in what remedies were available, not only, due to the adopted regulations, but also, how the presidential administration wanted privacy violations to be handled. At first, the shift in how OCR officials viewed enforcement confused me. Before the policy shift, OCR officials touted the effectiveness of voluntary compliance. In 2006, the OCR Director stated in a news article that enforcement through voluntary compliance had “(s)o far it's worked out pretty well” (Stein, 2006a, p. A.01). However, OCR officials championed stronger enforcement after the policy shift. In 2013, a subsequent OCR Director stated in a HHS news release that the modifications under HITECH

“strengthen the ability of my office to vigorously enforce the HIPAA privacy and security protections, regardless of whether the information is being held by a health plan, a health care provider, or one of their business associates" (U.S. Department of Health and Human Services, 2013, para. 6). This change indicates OCR officials are subject to what a presidential administration supports and are obligated to follow those wishes including publicly promoting the administration’s policies. In sum, OCR handles enforcement of the HIPAA Privacy Rule (OCR, 2017c; Standards for Privacy, 2000); however, the findings imply that attention should be given to who “handles” OCR when considering this policy shift.

A third implication is that despite the policy shift voluntary compliance remains an available enforcement option. I equate the situation to reading a novel and realizing at the conclusion that character who supposedly died is alive and in good health. I recognize there are possible explanations for why voluntary compliance still is an enforcement practice. First, the approach actually may be affective in most instances. The agency sent the *Las Vegas Sun* an email confirming the use of the approach: “Voluntary compliance and informal resolution are an efficient mechanism to resolve noncompliance and save resources for both (the civil rights office) and a covered entity” (Kanigher, 2009, p. 1). Years after policymakers passed the modifications under HITECH, a 2014 report to Congress stated that complaints may be settled more successfully by interceding than by conducting investigations (OCR, 2014).

Second, OCR may use voluntary compliance out of necessity. Inadequate resources regarding enforcement was one reason for OCR not effectively enforcing HIPAA regulations (McGraw, 2009). The issue of resources also was mentioned in the 2014 report to Congress:

Given OCR’s experience with an ever-increasing volume of complaints, without a corresponding increase in resources, OCR is determining ways to “work smarter,” that is,

to increase the effectiveness of its allocation of staff time and other resources to achieve the most industry compliance with the HIPAA Rules. (OCR, 2014, p. 23)

This description leads me to think that privacy enforcement efforts are underfunded and that equipping OCR with the resources required for stronger enforcement approaches is not a priority.

### **Beyond the Implications**

The study provided theoretical perspectives through which future researchers may contemplate policy development and shifts. The theories and related concepts presented in the theoretical framework helped to place and understand the findings. Explanations offered by Kingdon (2011) regarding the MS framework particularly were helpful exploring what groups and factors influence policy. Specifically, public policy is an evolving creation; therefore, what is persuasive reason for a policy shift today can lose persuasiveness tomorrow. I think that recognizing the presence of a policy window as the result of a presidential administration change exemplifies the concept of fluidity in the policy process. Yet, future researchers should view the applicability of the theories and concepts I selected as an indication of possibilities rather than an instructional guide on what theories to use when studying policy. The application of different theories and concepts only contributes more information to the available scholarly knowledge.

Finally, the study contributed to the scholarly evidence and added to the field of knowledge. Moreover, the findings added to the existing knowledge concerning the handling of privacy violations. The findings identified factors that assisted in creating policy shifts. The findings with consideration given to the limitations and delimitations of this study implied that certain information about stakeholder groups exercising influence may remain unknown. The findings identified topics for future research in the form of supplemental findings.

## **Suggestions for Future Research**

I would like to see the supplemental findings from this study fully explored. I view these findings as minor characters in one novel but who are interesting enough to appear as main characters in subsequent novels. The concepts of a private right of action and the enforcement authority of state attorneys general could be examined either jointly or separately. A researcher may want to focus on how many times the enforcement authority of state attorneys general has been utilized and/or the circumstances in which the authority was applied.

Nevertheless, I am most interested in having someone explore the issue of staffing within OCR as a research topic. I would describe staffing as an easily overlooked detail that if fully examined may provide a more complete picture of how OCR handles privacy violations. Through in-depth exploration of OCR enforcement staffing, a researcher may be able make inferences about whether the issue does or does not influence enforcement activities and which enforcement approach officials employ. The ensuing findings of this hypothetical future research could further assist in explaining why OCR still uses voluntary compliance as enforcement tool regarding Privacy Rule violations.

## **Conclusion**

Finally, I conclude with three takeaway thoughts. The takeaways involve having a consistency, planning for a policy window, and “why” versus “when”. First, the lack of fines and the need for motivating incentives associated with voluntary compliance were topics that the scholarly literature, the theoretical framework and the archival documents all addressed. For instance, in the scholarly literature, Gray (2008) asserted that OCR instructed violators to take corrective actions, but voluntary compliance lacks persuasive influence. From the theoretical framework, Stone (2002) stated that rules contain incentives for individuals to act inside

established parameters. Weber (1946/2014) also contended that optimism, anxiety, and potential reprisal drive compliance. From the archival documents, testimony from a law professor addressed the issue of motivation. The professor stated that “lack of enforcement has been the subject of major stories in the Wall Street Journal and the Washington Post. One expert was quoted in the post saying, ‘HHS really isn’t doing anything, so why should I worry?’” (Protecting Patient Privacy, 2007, p. 87) Perhaps, the key to successfully promoting a policy proposal is having a consistent thread of information or argument.

Second, those individuals or groups wanting to promote a proposal should be mindful of all presidential elections as well as other federal elections. Stakeholders should plan to act in response to congressional or midterm election. Congressional members have legal authority as a resource which is key since significant modifications to policy frequently call for additional statutes (Kingdon, 2011). The results of the 2008 election illustrate why stakeholders should embrace the potential influence of members of Congress. In 2009, Democrats assumed power in the White House along with possessing majorities in the House of Representatives and the Senate (Stathis, 2014).

Stakeholders also need to realize their group is not alone in seeking attention. Alternative specification restricts the number of potential choices into the group of choices that may be selected (Kingdon, 2011). Therefore, stakeholders need to consider and plan for how to make their proposals “outshine” other proposals. The media can boost the amount of attention a social movement receives but also have a penchant for only focusing on a story for a limited time (Kingdon, 2011). I recognized in reviewing the archival documents that media coverage happened in waves with ebbs and flows. Therefore, stakeholders should welcome any available

positive media coverage to promote their objectives, because such coverage may translate into attention and recognition from policymakers.

Third, my goal in exploring this policy shift was to try to discern why policymakers altered the original enforcement philosophy for handling privacy violation. During the research process, I realized that part of the answer (the findings) was addressing “when” rather than “why”. The finding of an open policy window existing during the policy shift added perspective to other findings and also led me to consider the contextual circumstances that surrounded the policy window contributing to the policy shift. Therefore, I encourage future policy researchers to review the historical and social events that occurred during the timeframe of the policy or policy shift of interest.

### **Summary**

The findings for Subquestion 1 pertain to the ways in which stakeholders exercised influence regarding the policy shift. Interpretations for the finding of industry groups writing letters to policymakers and officials and the finding of group representatives speaking with members of the news media are that privacy advocates and governmental officials utilized the mass media to disseminate views, whereas industry stakeholders limited their potential influence by directly writing to the policymakers and government officials. My interpretation of the finding concerning how members of stakeholder groups presented testimony in congressional hearings is that stakeholder groups had chances to be heard and promote agendas, but some were better at communicating their messages. I interpreted the finding of how stakeholder group members moved groups by changing employers as conveying the possibility of influencing opinion in that “moving” employees may bring useful information to policy work. I interpreted the concepts of connections and access within the finding of connections between members of

different groups as being paths to potential influence and view the activities as paralleling how Kingdon (2011) described policy entrepreneurs as using connections to promote policies.

The findings for Subquestion 2 concern how stakeholder collaborated to promote certain perspectives and concept. I interpreted that data for the findings involving policymakers and witnesses engaged in question and answer exchanges and statements expressing a desire to partner with other groups on endeavors as not being collaboration. I viewed the finding of policymakers and stakeholder witnesses providing testimony having question and answer exchanges as indicating that some questions in exchanges during hearings were leading with a purpose. Regarding the finding of statements concerning potential partnerships with other groups, I viewed the described activities as not being collaboration due to vagueness or the statements containing future-based offers. Based on the data, I interpreted work groups and initiatives as being an effective means of stakeholder collaboration throughout the timeframe of interest; however, I interpreted industry groups as not being an effective means of stakeholder collaboration despite the groups already being established collaborative groups. The finding regarding stakeholder statements expressing opposition to an aspect of enforcement suggested that industry stakeholders experienced previous success in asserting influence regarding HIPAA; therefore, I thought that industry stakeholders believed reputations and past influence would be sufficient to continue influencing policymakers.

The findings for Subquestion 3 involve how perspectives regarding the lack of civil money penalties or fines play a role in arguments for or against the policy shift. My interpretation of the finding pertaining to stakeholder statements supporting voluntary compliance is that industry stakeholders initially supported voluntary compliance as an enforcement, because the approach was favorable to covered entities, and that government

officials offering support for voluntary compliance as obligatory. I interpreted the finding highlighting stakeholder statements regarding how a presidential administration viewed violations as relevant to explaining the adoption of the original enforcement philosophy as well as why the push for the shift in philosophy was successful; an idea, which aligns with the assertion by Kingdon (2011), that changes within politics such as the introduction of a presidential administration may alter agendas. My interpretation of the finding involving stakeholder statements opposing voluntary compliance is that opponents of voluntary compliance were consistent in focusing on how the philosophy contained an inherent tolerance of wrongdoing by covered entities (e.g., industry stakeholders) by not being proactive in nature and was a key reason to why the shift in policy occurred. I interpreted the finding concerning the lack of fines associated with voluntary compliance as being the evidence required by the policymakers to alter the original enforcement philosophy; evidence aided by the number of complaints without a civil monetary penalty. My interpretation of the finding regarding the perception that the original enforcement approach did not include persuasive element is that policymakers and, by extension, government officials sent a message of nonchalant enforcement to covered entities. I viewed the finding of recommendations by industry stakeholders regarding the policy shift and the handling of violations as indicating that industry stakeholders opted to not promote the continuation of voluntary compliance but sought to collect information to curtail the potential for fines. My interpretation of the finding involving recommendations by non-industry stakeholders regarding the handling of violations is that policymakers considered the recommendations to be useful enough to integrate the concepts into the modified enforcement approach, thus I interpreted the finding as being influential in the policy shift.

The findings for other circumstances from Subquestion 3 emerged from the data for Subquestion 3, but the content was outside the scope of the question. My interpretation of the supplemental finding pertaining to the possibility of private lawsuits is that the idea was an enduring concept concerning Privacy Rule enforcement with parties debating the idea then dismissing it only to have the idea appear again. Stakeholder groups identified the need to approach the concept with caution. I view the concept as another issue of debate between stakeholders; privacy advocates encouraged the concept, and industry representatives discouraged the concept. Some stakeholders want additional information for self-interested reasons. In other words, stakeholders could determine enforcement thresholds if OCR provides enough enforcement data. The second interpretative component is stakeholders viewing OCR as needing to be monitored as a system of checks and balances. In other words, some stakeholders viewed transparency as a tool for responsibility. My interpretation is that staffing was an underlying issue regarding enforcement. In fact, I interpret this finding as being an indication that HIPAA enforcement as a perpetually underfunded mandate. Furthermore, I interpret the finding about staffing as explaining why voluntary compliance remains an enforcement option.

The findings and concepts involved in addressing the overarching question are varied. The presence of an open policy window was the finding central to understanding the overarching question and may be the significant aspect of the decision of policymakers to change enforcement philosophies. This event of an open policy window also adds perspective to findings from the subquestions such as the findings concerning stakeholder statements about how a presidential administration viewed violations and about the lack of fines related to voluntary compliance. For instance, policymakers were aware that the original enforcement approach did not result in any fines. This interpretation connects to the concept of program feedback

(Kingdon, 2011) who posited that officials use program feedback to gain knowledge on issues. I also interpreted the policy window as the chance for policymakers to obtain the evidence required to support the policy shift but needed the correct circumstances to facilitate the shift. Finally, the findings suggest that the stakeholder group who was most influential regarding the shift in enforcement philosophies may have been the presidential administration.

This study has three limitations. These limitations are having inherent boundaries by focusing on one policy shift, having difficulty in exploring the exercising of stakeholder influence, and stakeholder collaboration that required examination through indirect information. The limitations influenced the findings and what information could be inferred from the findings.

The study also offers implications and suggestion for future research. The findings have implications in various matters. The findings imply that the reasons for the policy shift and how stakeholders contributed were complex. The implications involve how an open policy window and a change in presidential administrations helped to facilitate the policy shift and why voluntary compliance remains an enforcement option. The findings add to the existing knowledge concerning the handling of privacy violations and the factors that assisted in creating policy shifts and contributed to the scholarly evidence. This study provided theoretical perspectives through which future researchers may contemplate policy development and shifts. The suggestions for future research involve expanding on the supplemental findings. A researcher may want to examine the finding of staffing concerns to make inferences about influences on enforcement activities. Finally, takeaways from this study involve consistency. planning for a policy window and awareness of the contexts surrounding a policy or policy shift.

## References

- Aging Services of Minnesota. (2009, December 29). [Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Attention: HIPAA Enforcement Rule IFR (RIN 0991-AB55)]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0021>
- Alonso-Zaldivar, R. (2008, April 9). Effectiveness of medical privacy law is questioned. *Los Angeles Times*, A.10. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/422206473?accountid=11652>
- Altheide, D. L., & Schneider, C. J. (2013). *Qualitative media analysis*. (2nd ed.). Thousand Oaks, CA: Sage.
- American Council of Life Insurers. (2009, December 29). [Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Re: HIPAA Enforcement Rule IFR RIN 0991-AB55]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0023>
- American Health Information Management Association. (2009, December 29). [Letter to Georgina Verdugo, Re: RIN 0991-AB55: HIPAA Administrative Simplification Enforcement – October 30, 2009 Interim Final Rule]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0022>
- American Medical Informatics Association. (2009, December 24). [Letter to the U.S. Department of Health and Human Services, RIN 0991-AB55 HIPAA Administrative Simplification: Enforcement Interim final rule]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0015>

- Anderson, W. L., & Jackson, C. E. (2006). Criminalization as policy: Using federal criminal law as a regulatory device. *The Journal of Social, Political, and Economic Studies*, 31(1), 75-105. Retrieved from <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.683.6609&rep=rep1&type=pdf>
- Annas, G. J. (2003). HIPAA regulations – A new era of medical-record privacy?. *The New England Journal of Medicine*, 348(15), 1486-1490. doi:10.1056/NEJMLim035027
- Association of Academic Health Centers. (2009, December 29). [Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Attn: HIPAA Enforcement Rule IFR (RIN 0991-AB55)]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0018>
- “Bad Move on Health Care”. (1996, March 18). *The Washington Post*, p. A.16. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/408275758?accountid=11652>
- Beckerman, J. Z., Pritts, J., Goplerud, E. Leifer, J. C., Borzi, P., & Rosenbaum, S. (2008). Health information privacy, patient safety, and healthcare quality: Issues and challenges in the context of treatment for mental health and substance use. *BNA's Health Care Policy Report*, 16(2), 1-13. Retrieved from [https://hsrc.himmelfarb.gwu.edu/cgi/viewcontent.cgi?article=1310&context=sphhs\\_policy\\_facpubs](https://hsrc.himmelfarb.gwu.edu/cgi/viewcontent.cgi?article=1310&context=sphhs_policy_facpubs)
- Benford, R. D., & Snow, D. A. (2000). Framing processes and social movements: An overview and assessment. *Annual Review of Sociology*, 26, 611-639. Retrieved from <http://www.jstor.org/stable/223459>
- Birkland, T. A. (1998). Focusing events mobilization, and agenda setting. *Journal of Public Policy*, 18(1), 53-74. doi:10.1017/S0143814X98000038

- Bloomberg, L. D., & Volpe, M. (2008). *Writing your qualitative dissertation: A roadmap from beginning to end*. Thousand Oaks, CA: Sage.
- Boodman, S. G. (2003, April 8). Privacy, please; New rules may protect patients, alter hospital, office practices. *The Washington Post*, p. F.01. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/409506364?accountid=11652>
- Bowen, G. A. (2009). Document analysis as a qualitative research method. *Qualitative Research Journal*, 9(2), 27-40. doi:10.3316/QRJ0902027
- Braun, V. & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3(2), 77-101. doi:10.1191/1478088706qp063oa
- Breaux, T. D., & Anton, A. I. (2008). Analyzing regulatory rules for privacy and security requirements. *IEEE Transactions on Software Engineering*, 34(1), 5-20. doi:10.1109/TSE.2007.70746
- Brown, B. (2009). A kinder, gentler health and human services: an informal, cooperative resolution process for HIPAA complaints can still result in voluntary payments. *Journal of Health Care Compliance*, 11(1), 35-36 & 72-73. Retrieved from <http://link.galegroup.com.proxy-iup.klnpa.org/apps/doc/A192353315/AONE?u=indi68545&sid=AONE&xid=7d760eca>
- Choo, C. W. (1996). The knowing organization: How organizations use information to construct meaning, create knowledge and make decisions. *International Journal of Information Management*, 16(5), 329-340. doi:10.1016/0268-4012(96)00020-5

- Clinton, H. (2006, June 16). *U. S. Senator Hillary Clinton (D-NY) delivers remarks on privacy rights to the American Constitution Society for Law & Policy convention* [Transcript]. Political Transcript Wire; Lanham. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/467181648?accountid=11652>
- Coffey, A. (2014). Analysing documents, in U. Flick (Ed.), *The Sage Handbook of Qualitative Data Analysis*. (pp. 367-379). London: Sage
- Coglianesi, C. (2002). Bounded evaluation: Cognition, incoherence and regulatory policy. *Stanford Law Review*, 54(6), 1217-1238. doi:10.2307/1229619
- Collins, J. D. W. (2007). Toothless HIPAA: Searching for a privacy right of action to remedy privacy rule violations. *Vanderbilt Law Review*, 60(1), 199-233. Retrieved from <http://search.ebscohost.com.proxy-iup.klnpa.org/login.aspx?direct=true&db=a9h&AN=24630802&site=ehost-live>
- Confidentiality of patient records: Hearing before the Subcommittee on Health of the Committee on Ways and Means, House of Representatives, 106th Cong. (Serial No. 106-89). (2000). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-106hhrg66897/pdf/CHRG-106hhrg66897.pdf>
- Creswell, J. W. (2009). *Research design: Qualitative, quantitative, and mixed methods approaches*. (3rd ed.). Thousand Oaks, CA: Sage.
- Davis, C. M. (2015). House committee hearings: Arranging witnesses. Retrieved from <https://fas.org/sgp/crs/misc/98-304.pdf>

- Davis, J. W. (2009). HITECH HIPAA amendments: New rules on breach notification, business associate compliance, and enforcement. *Health Lawyer*, 21(5), 23-29. Retrieved from <http://search.ebscohost.com.proxy-iup.klnpa.org/login.aspx?direct=true&db=a9h&AN=43245652&site=ehost-live>
- De Armond, E. D. (2008). A dearth of remedies. *Penn State Law Review*, 113(1), 1-53. Retrieved from <http://pennstatelawreview.org/articles/113%20Penn%20St.%20L.%20Rev.%201.pdf>
- Discussion draft of health information technology and privacy legislation: Hearing before the Subcommittee on Health of the Committee on Energy and Commerce, House of Representatives, 110th Cong. (Serial No. 100-122). (2008). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-110hhr55462/pdf/CHRG-110hhr55462.pdf>
- Does HIPAA help or hinder patient care and public safety?: Hearing before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, House of Representatives, 113th Cong. (Serial No. 113-37). (2013). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-113hhr82190/pdf/CHRG-113hhr82190.pdf>
- Godkin, E. L. (1890). The rights of the citizen. IV. - To his own reputation. *Scribner's Magazine*, 8(1), 58-67. Retrieved from <https://babel.hathitrust.org/cgi/pt?id=coo.31924097287480&view=1up&seq=66>

- Goldstein, A. (2003, April 28). A behind-the-scenes force for privacy; For leader of D.C.-based project, protecting confidentiality of medical records is 'lifelong endeavor'. *The Washington Post*, p. A21. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/409425141?accountid=11652>
- Goldstein, A., & O'Harrow, R. (2001, April 13). Bush will proceed on privacy; But Clinton-era rules likely to be modified. *The Washington Post*, p. A.1. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/409087979?accountid=11652>
- Gray, K. (2008). The privacy rule: Are we being deceived?. *DePaul Journal of Health Care Law*, 11, (2), 89-118. Retrieved from <http://via.library.depaul.edu/jhcl/vol11/iss2/2>
- Harrison, J. R. & March, J. G. (1984). Decision making and postdecision surprises. *Administrative Science Quarterly*, 29(1), 26-42. doi:10.2307/2393078
- Healthcare Information and Management Systems Society & Phoenix Health Systems (2006). *U.S. healthcare industry HIPAA compliance survey results: Summer 2006*. Retrieved from <http://www.himss.org/sites/himssorg/files/HIMSSorg/Content/files/SummerSurvey2006.pdf>
- Health information technology: Protecting Americans' privacy in the digital age: Hearing before the Committee on the Judiciary, United States Senate, 111<sup>th</sup> Cong. (Serial No. J-111-3). (2009). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-111shrg54240/pdf/CHRG-111shrg54240.pdf>
- Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996). Retrieved from <https://www.govinfo.gov/content/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf>

Hearing on promoting the adoption and use of health information technology: Hearing before the Subcommittee on Health of the Committee on Ways and Means, House of Representatives, 110th Cong. (Serial No. 110-93). (2008). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-110hhr58278/pdf/CHRG-110hhr58278.pdf>

Heitshusen, V. (2017). Senate committee hearings: Arranging witnesses. Retrieved from <https://www.senate.gov/CRSpubs/045a2fbf-0ad7-434b-9496-ab85db6dae6b.pdf>

Hill, J. W., Langvardt, A. W., & Rinehart, J. E. (2009). Bottom-up or top-down? Removing the privacy law obstacles to healthcare reform in the national healthcare crisis. *Indiana Law Journal Supplement*, 84(5: the supplement), 23-45. Retrieved from <http://www.repository.law.indiana.edu/cgi/viewcontent.cgi?article=11046&context=ilj>

HIPAA Administrative Simplification: Enforcement; Final Rule, 71 *Fed. Reg.* 8390 (Feb. 16, 2006) (codified at 45 C.F.R. pts. 160 and 164). Retrieved from <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/privacyrule/finalenforcementrule06.pdf>

“House Science and Technology Subcommittee on Technology & Innovation hearing: Standards for health IT: Meaningful use and beyond”. (2010, September 30). *Congressional Documents and Publications*. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/756625694?accountid=11652>

Hurley, T. P. (2009, December 14). [Letter to the Department of Health and Human Services, Office of the Secretary, HIPAA administrative simplification: Enforcement: Interim final rule; Request for comments]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0008>

- Hutton, E., & Barry, D. (2005). Privacy year in review: Developments in HIPAA. *I/S: A Journal of Law and Policy*, 1(2-3), 347-384. Retrieved from [https://kb.osu.edu/bitstream/handle/1811/72694/ISJLP\\_V1N2-3\\_347.pdf?sequence=1](https://kb.osu.edu/bitstream/handle/1811/72694/ISJLP_V1N2-3_347.pdf?sequence=1)
- Jaffee, D. (2001). *Organization theory: Tension and change*. New York, NY: McGraw-Hill.
- Kanigher, S. (2009, December 13). Privacy violations seldom punished. *Las Vegas Sun*, p. 1. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/389072807?accountid=11652>
- Kempfert, A. E., & Reed, B. D. (2011). Health care reform in the United States: HITECH Act and HIPAA privacy, security, and enforcement issues. *FDCC Quarterly*, 61(3), 240-273. Retrieved from <http://search.ebscohost.com.proxy-iup.klnpa.org/login.aspx?direct=true&db=lgh&AN=66998712&site=ehost-live>
- Kingdon, J. W. (1984). *Agendas, alternatives, and public policies*. Boston, MA: Little, Brown & Co.
- Kingdon, J. W. (2011). *Agendas, alternatives, and public policies*. (Updated 2nd ed.). Boston, MA: Longman.
- Lawson, N. A., Orr, J. M., & Klar, D. S. (2003). The HIPAA Privacy Rule: An overview of compliance initiatives and requirements. *Defense Counsel Journal*, 70(1), 127-149. Retrieved from <http://search.ebscohost.com.proxy-iup.klnpa.org/login.aspx?direct=true&db=lgh&AN=8984042&site=ehost-live>
- Letzring, T. D., & Snow, M. S. (2011). Mental health practitioners and HIPAA. *International Journal of Play Therapy*, 20(3), 153-164. doi:10.1037/a0023717

- Light, D. W. (2001). Managed competition, governmentality and institutional response in the United Kingdom. *Social Science & Medicine*, 52(8),167-1181. doi:10.1016/S0277-9536(00)00237-9
- Light, D. W. (2010). Health-care professions, markets, and countervailing powers. In C. E. Bird, P. Conrad, A. M. Fremont, & S. Timmermans (Eds.), *Handbook of medical sociology* (6th ed.) (pp. 270-289). Nashville, TN: Vanderbilt University Press.
- McCloskey, H. J. (1980). Privacy and the right to privacy. *Philosophy*, 55(211), 17-38. Retrieved from [www.jstor.org/stable/3750973](http://www.jstor.org/stable/3750973)
- McGraw, D. (2009). *Privacy and health information technology* (RWJF Report No. 36903). Retrieved from the Robert Wood Johnson Foundation website: <https://www.rwjf.org/content/dam/farm/reports/reports/2009/rwjf36903>
- McGraw, D., Dempsey, J. X., Harris, L., & Goldman, J. (2009). Privacy as an enabler, not an impediment: Building trust into health information exchange. *Health Affairs*, 28(2), 416-427. doi:10.1377/hlthaff.28.2.416
- Machi, L. A., & McEvoy, B. T. (2009). *The literature review: Six steps to success*. Thousand Oaks, CA: Corwin Press.
- Maliniak, A. P., & Mitchel, L. A. (2006). Overview of the current state of HIPAA enforcement: three useful tips for avoiding civil monetary penalties. *Journal of Health Care Compliance*, 8(6), 23-24 & 64. Retrieved from <http://link.galegroup.com.proxy-iup.klnpa.org/apps/doc/A155039797/AONE?u=indi68545&sid=AONE&xid=2ab8e0e1>
- March, J. G. (1978). Bounded rationality, ambiguity, and the engineering of choice. *The Bell Journal of Economics*, 9(2), 587-608. doi:10.2307/3003600

March, J. G. (2006). Rationality, foolishness, and adaptive intelligence. *Strategic Management Journal*, 27(3), 201-214. doi:10.1002/smj.515

Maxwell, J. A. (2005). *Qualitative research design: An interactive approach*. (2nd ed.). Thousand Oaks, CA: Sage.

Miliard, M. (2015, June 18). Deven McGraw brings HIPAA expertise to OCR. *Healthcare IT News*. Retrieved from <http://www.healthcareitnews.com/news/deven-mcgraw-brings-hipaa-expertise-ocr>

Minnesota Department of Health. (2009, December 28). [Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Attention: HIPAA Enforcement Rule IFR (RIN 0991-AB55)]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0019>

Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules

Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA rules; Final Rule, 78 *Fed. Reg.* 5566 (Jan. 25, 2013) (codified at 45 C.F.R. pts. 160 and 164). Retrieved from <https://www.govinfo.gov/content/pkg/FR-2013-01-25/pdf/2013-01073.pdf>

Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health

Information Technology for Economic and Clinical Health Act; Proposed rule, 75 *Fed. Reg.* 40868 (Jul. 14, 2010) (codified at 45 C.F.R. pts. 160 and 164). Retrieved from <http://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveridentities/nprmhitech.pdf>

- Monette, D. R., Sullivan, T. J., & DeJong, C. R. (2011). *Applied social research: A tool for the human services*. (8th ed.). Belmont, CA: Brooks/Cole, Carnegie Learning.
- Morriss, A. P., Yandle, B., & Dorchak, A. (2005). Choosing how to regulate. *Harvard Environmental Law Review*, 29(1), 179-250. Retrieved from <https://scholarship.law.tamu.edu/cgi/viewcontent.cgi?article=1105&context=facscholar>
- Murphy, T. M. (2008). Enforcement of the HIPAA Privacy Rule: Moving from illusory voluntary compliance to continuous compliance through private accreditation. *Loyola Law Review*, 54 (1), 155-207. Retrieved from [https://1-next-westlaw-com.proxy-iup.klnpa.org/Document/If98e46da9ad711dd93e7a76b30106ace/View/FullText.html?originationContext=citingReferences&transitionType=Document&contextData=\(sc.Search\)&docSource=da1d0a5b7fdd438dab280baa4b9380b4&rank=1&rulebookMode=false](https://1-next-westlaw-com.proxy-iup.klnpa.org/Document/If98e46da9ad711dd93e7a76b30106ace/View/FullText.html?originationContext=citingReferences&transitionType=Document&contextData=(sc.Search)&docSource=da1d0a5b7fdd438dab280baa4b9380b4&rank=1&rulebookMode=false)
- National Association of Chain Drug Stores. (December 16, 2009). [Letter to the Honorable Kathleen Sebelius, Attention: HIPAA Enforcement Rule IFR (RIN 0991-AB55)]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0009>
- “Nice law, no teeth”. [Editorial]. (2006, June 11). *Knight Ridder Tribune Business News*, p.1. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/465328933?accountid=11652>
- Nomination of Governor Kathleen Sebelius: Hearing of the Committee on Health, Education, Labor, and Pensions, United States Senate, 111<sup>th</sup> Cong. (S. Hrg. 111-804). (2009). Retrieved from GPO’s Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-111shrg48540/pdf/CHRG-111shrg48540.pdf>

Odom-Forren, J. & Hahn, E. J. (2006). Mandatory reporting of health care-associated infections: Kingdon's multiple streams approach. *Policy, Politics, & Nursing Practice*, 7(1), 64-72.  
doi:10.1177/1527154406286203

Pharmaceutical Care Management Association. (2009, January 26). *PCMA letter to the US House of Representatives* [News release]. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/468561318?accountid=11652>

Planned Parenthood Federation of America. (2009, December 28). [Letter to the Honorable Kathleen Sebelius, Re: RIN 0991-AB55, HIPAA Enforcement Interim Final Rule]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0017>

Powers, C. H. (2010). *Making sense of social theory: A practical introduction* (2nd ed.). Lanham, MD: Rowman and Littlefield Publishers.

Private health records: Privacy implications of the federal government's health information technology initiative: Hearing before Oversight of Government Management, the Federal Workforce, and the District of Columbia Subcommittee of the Homeland Security and Governmental Affairs, United States Senate, 110th Cong. (S. Hrg. 111-804). (2007). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-110shrg33874/pdf/CHRG-110shrg33874.pdf>

Protecting patient privacy in healthcare information systems: Hearing before the Subcommittee on Information Policy, Census, and National Archives of the Committee on Oversight and Government Reform, House of Representatives, 110<sup>th</sup> Cong. (Serial No. 110-33). (2007). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-110hrg39023/pdf/CHRG-110hrg39023.pdf>

- Quadagno, J. (2004). Why the United States has no national health insurance: Stakeholder mobilization against the welfare state, 1945-1996. *Journal of Health and Social Behavior*, 45(extra issue), 25-44. Retrieved from <http://www.jstor.org/stable/3653822>
- Quadagno, J. (2005). *One nation uninsured: Why the U.S. has no national health insurance* [Barnes and Noble NOOK book version]. Retrieved from [barnesandnoble.com](http://barnesandnoble.com)
- Quadagno, J. (2010). Institutions, interest groups, and ideology: An agenda for the sociology of health care reform. *Journal of Health and Social Behavior*, 51(2), 125-136.  
doi:10.1177/0022146510368931
- Quadagno, J. (2011). Interest-group influence on the Patient Protection and Affordable Care Act of 2010: Winners and losers in the health care reform debate. *Journal of Health Politics, Policy, and Law*, 36(3), 449-453. doi:10.1215/03616878-1271081
- Quadagno, J., & Street, D. (2005). Ideology and public policy: Antistatism in American welfare state transformation. *The Journal of Policy History*, 17(1), 52-71.  
doi:10.1353/jph.2005.0007
- Rahman, N. N. (2006). Reflections on privacy: Recent developments in HIPAA Privacy Rule. *I/S: A Journal of Law and Policy*, 2(3), 685-714. Retrieved from [https://kb.osu.edu/bitstream/handle/1811/72732/1/ISJLP\\_V2N3\\_685.pdf](https://kb.osu.edu/bitstream/handle/1811/72732/1/ISJLP_V2N3_685.pdf)
- Redhead, C. S. (2015). *HIPAA privacy, security, enforcement and breach notification standards*. Washington, DC: Congressional Research Service. Retrieved from <https://fas.org/sgp/crs/misc/R43991.pdf>
- Richards, L., & Morse, J. M. (2007). *Readme first for a user's guide to qualitative methods*. (2nd ed.). Thousand Oaks, CA: Sage.

- Ridde, V. (2009). Policy implementation in an African state: An extension of Kingdon's multiple-streams approach. *Public Administration*, 87(4), 938-954. doi:10.1111/j.1467-9299.2009.01792.x
- Rubenstein, S. (2008, April 29). Are your medical records at risk?; Amid spate of security lapses, health-care industry weighs privacy against quality care. *Wall Street Journal: Eastern edition*, p. D.1. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/399064207?accountid=11652>
- Russ-Eft, D., & Preskill, H. (2009). *Evaluation in organizations: A systematic approach to enhancing learning, performance, and change*. (2nd ed.). New York, NY: Basic Books.
- Sabatier, P. A. (1991). Toward better theories of the policy process. *PS: Political Science and Politics*, 24(2), 147-156. doi:10.2307/419923
- Sabatier, P.A. (1999). The need for better theories. In P.A. Sabatier (Ed.), *Theories of the Policy Process: Theoretical Lenses on Public Policy* (pp. 3-17). Boulder, CO: Westview Press.
- Sabatier, P.A. (2007a). Fostering the development of policy theory. In P.A. Sabatier (Ed.), *Theories of the Policy Process* (2nd ed) (pp. 321-336). Boulder, CO: Westview Press.
- Sabatier, P.A. (2007b). The need for better theories. In P.A. Sabatier (Ed.), *Theories of the Policy Process* (2nd ed) (pp. 3-17). Boulder, CO: Westview Press.
- Saldana, J. (2016). *The coding manual for qualitative researchers*. (3<sup>rd</sup> ed.). Thousand Oaks, CA: Sage.
- Saxon, C., Jacinto, G. A., & Dziegelewski, S. F. (2006). Self-determination and confidentiality: The ambiguous nature of decision-making in social work practice. *Journal of Human Behavior in the Social Environment*, 13(4), 55-72. doi:10.1300/J137v13n04\_04

- Simon, H. A. (1972). Theories of bounded rationality. In C. B. McGuire & R. Radner (Eds.), (pp. 161-176). *Decision and organization: A volume in honor of Jacob Marschak (studies in mathematical and managerial economics)*. Amsterdam, The Netherlands: North-Holland Publishing Company. Retrieved from [http://innovbfa.viabloga.com/files/Herbert\\_Simon\\_\\_\\_theories\\_of\\_bounded\\_rationality\\_\\_\\_1972.pdf](http://innovbfa.viabloga.com/files/Herbert_Simon___theories_of_bounded_rationality___1972.pdf)
- Simon, H. A. (1979). Rational decision making in business organizations. *The American Economic Review*, 69(4), 493-513. Retrieved from <http://www.jstor.org/stable/1808698>
- Simon, H. A. (1991). Bounded rationality and organizational learning [Special issue: Organizational learning: Papers in honor of (and by) James G. March]. *Organization Science*, 2(1), 125-134. doi:10.1287/orsc.2.1.125
- Simon, H. A. (1993). Decision making: Rational, nonrational, and irrational. *Educational Administration Quarterly*, 29(3), 392-411. doi:10.1177/0013161X93029003009
- Skocpol, T. (1995). *Protecting soldiers and mothers: The political origins of social policy in the United States*. Cambridge, MA: The Belknap Press of Harvard University Press.
- Solove, D. J. (2003). The origins and growth of information privacy law. *PLI/PAT*, 748 (29), 1-51. doi:10.2139/ssrn.445181
- Solove, D. J. (2013). HIPAA turns 10: Analyzing the past, present, and future impact. *Journal of AHIMA*, 84(4), 22-28. Retrieved from [http://scholarship.law.gwu.edu/faculty\\_publications/950](http://scholarship.law.gwu.edu/faculty_publications/950)
- Stake, R. E. (1995). *The art of case study research*. Thousand Oaks, CA: Sage.

Standards for Privacy of Individually Identifiable Health Information; Final Rule, 65 *Fed. Reg.*

82462 (Dec. 28, 2000) (codified at 45 C.F.R. pts.160 and 164). Retrieved from <http://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/privacyrule/prdecember2000all8parts.pdf>

Standards for Privacy of Individually Identifiable Health Information; Final Rule, 67 *Fed. Reg.*

53182 (Aug. 14, 2002) (codified at 45 C.F.R. pts.160 and 164). Retrieved from <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/privacyrule/prprivrulepd.pdf>

Standards for Privacy of Individually Identifiable Health Information; Proposed Rule, 64 *Fed.*

*Reg.* 59918 (Nov. 3, 1999) (codified at 45 C.F.R. pts. 160 through 164). Retrieved from <http://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/privacyrule/1999nprm.pdf>

Stathis, S. W. (2014). *Landmark legislation 1774-2012: Major U.S. acts and treaties.* (2nd ed.).

Washington, D.C.: CQ Press

Stein, R. (2006a, June 5). Medical privacy law nets no fines; Lax enforcement puts patients' files

at risk, critics say. *The Washington Post*, p. A01. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/410126136?accountid=11652>

Stein, R. (2006b, June 5). Privacy law nets no fines over years. *Journal-Gazette*, p. 1A.

Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/411340042?accountid=11652>

- Stein, R. (2006c, June 5). U.S. lax on enforcement of medical privacy law after 19,000 – plus grievances, no fines have been imposed. *Pittsburgh Post-Gazette*, p. A-1. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/390828493?accountid=11652>
- Stevens, G. M. (2008). *CRS report for Congress: Enforcement of the HIPAA Privacy and Security Rules*. Washington, DC: Congressional Research Service. Retrieved from [https://www.everycrsreport.com/files/20080811\\_RL33989\\_9d1068d790c8724c97e4b2c26f8b11153cf693cf.pdf](https://www.everycrsreport.com/files/20080811_RL33989_9d1068d790c8724c97e4b2c26f8b11153cf693cf.pdf)
- Stone, D. (1988). *Policy paradox and political reasoning*. Glenview, IL: Scott, Foresman, & Co.
- Stone, D. (2002). *Policy paradox: The art of political decision making*. (Rev. ed.). New York, NY: W. W. Norton.
- Tompkins, J. R. (2005). *Organizational theory and public management*. Boston, MA: Wadsworth, Cengage Learning.
- U. S. Congress. (n.d.). *H.R.3103 – Health Insurance Portability and Accountability Act of 1996: All action: H.R.3103 – 104<sup>th</sup> Congress (1995-1996)*. Retrieved March 3, 2019 from <https://www.congress.gov/bill/104th-congress/house-bill/3103/all-actions?overview=closed#tabs>
- U. S. Department of Health and Human Services. (2013, January 17). *New rule protects patient privacy, secures health information* [News release]. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/1270600932?accountid=11652>

- U. S. Department of Health and Human Services, Assistant Secretary for Public Affairs. (2018, November 14). *HHS organizational chart*. Retrieved March 3, 2019 from <https://www.hhs.gov/about/agencies/orgchart/index.html?language=es3926/20140108162249/http://www.hhs.gov/news/press/2011pres/02/20110222a.html>
- U. S. Department of Health and Human Services, Office for Civil Rights. (2003). *OCR privacy brief: Summary of the HIPAA Privacy Rule: HIPAA compliance assistance*. Retrieved <https://www.hhs.gov/sites/default/files/privacysummary.pdf>
- U. S. Department of Health and Human Services, Office for Civil Rights. (2006). *HIPAA administrative simplification: Regulation text: 45 CFR Parts 160, 162, and 164 (unofficial version as amended through February 16, 2006)*. Retrieved from <http://www.hhs.gov/sites/default/files/adminsimpregtext.pdf>
- U. S. Department of Health and Human Services, Office for Civil Rights. (2011). *Annual Report to Congress on HIPAA Privacy Rule and Security Rule compliance for calendar years 2009 and 2010*. Retrieved from <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/enforcement/compliancerept.pdf>
- U. S. Department of Health and Human Services, Office for Civil Rights. (2013). *HIPAA administrative simplification: Regulation text: 45 CFR Parts 160, 162, and 164 (unofficial version as amended through March, 26, 2013)*. Retrieved <https://www.hhs.gov/sites/default/files/hipaa-simplification-201303.pdf>
- U. S. Department of Health and Human Services, Office for Civil Rights. (2014). *Annual Report to Congress on HIPAA Privacy, Security, Breach Notification Rule and compliance: For calendar years 2011 and 2012*. Retrieved from <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/enforcement/compliancereport2011-2012.pdf>

- U. S. Department of Health and Human Services, Office for Civil Rights. (2015, September 29). *How OCR enforces civil rights discrimination laws and regulations*. Retrieved March 3, 2019 from <http://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/enforcement-process/index.html>
- U. S. Department of Health and Human Services, Office for Civil Rights. (2016). *Annual Report to Congress on HIPAA Privacy Rule, Security, Breach Notification Rule and compliance: For calendar years 2013 and 2014*. Retrieved from <https://www.hhs.gov/sites/default/files/rtc-compliance-20132014.pdf>
- U. S. Department of Health and Human Services, Office for Civil Rights. (2017a, March 24). *OCR Mission & Vision*. Retrieved March 3, 2019 from <https://www.hhs.gov/ocr/about-us/leadership/index.html>
- U. S. Department of Health and Human Services, Office for Civil Rights. (2017b, June 7). *Enforcement Process*. Retrieved March 3, 2019 from <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/enforcement-process/index.html>
- U. S. Department of Health and Human Services, Office for Civil Rights. (2017c, June 7). *How OCR enforces the HIPAA Privacy & Security Rules*. Retrieved March 3, 2019 from <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/examples/how-ocr-enforces-the-hipaa-privacy-and-security-rules/index.html>
- U. S. Department of Health and Human Services, Office for Civil Rights. (2017d, June 16). *Covered entities and business associates*. Retrieved March 3, 2019 from <https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html>

- U.S. Department of Health and Human Services, Press Office. (2009, October 30). *HHS strengthens HIPAA enforcement* [Press release]. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/443819582?accountid=11652>
- U. S. Department of Health and Human Services, Press Office. (2011, February 22). *HHS imposes a \$4.3 million civil money penalty for violations of the HIPAA Privacy Rule: Action marks first civil money penalty issued by HHS for HIPAA Privacy Rule violations* [Press release]. Retrieved from <http://wayback.archive-it.org/3926/20140108162249/http://www.hhs.gov/news/press/2011pres/02/20110222a.html>
- U.S. Department of Health and Human Services, Press Office (2011, February 24). *Massachusetts General Hospital settles potential HIPAA violations* [Press release].. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/853627640?accountid=11652>
- U. S. Office of Government Ethics. (2017, March 31). *Political appointees*. Retrieved March 3, 2019 from <https://www.oge.gov/Web/oge.nsf/Resources/Political+Appointees>
- UnitedHealth Group. (2009, December 21). [Letter to Secretary Kathleen Sebelius, Re: HIPAA administrative simplification: Enforcement rule]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0012>
- USA.gov. (2018). Branches of government. Retrieved March 3, 2019 from <https://www.usa.gov/branches-of-government>
- Warren, S. D., & Brandeis, L. D. (1890). The right to privacy. *Harvard Law Review*, 4(5), 193-220. Retrieved from <http://www.jstor.org/stable/1321160>

- Weber M. (2009). *The theory of social and economic organization*. T. Parsons (Ed.). A. M. Henderson & T. Parsons (Trans.). [Barnes and Noble NOOK book version]. Retrieved from [www.barnesandnoble.com](http://www.barnesandnoble.com) (Original work published 1947)
- Weber M. (2014). *From Max Weber: Essays in sociology (1946)*. H.H. Gerth & C.W. Mills (Eds. & Trans.). [Barnes and Noble NOOK book version]. Retrieved from [www.barnesandnoble.com](http://www.barnesandnoble.com) (Original work published 1946)
- Weible, C. M., Heikkila, T., deLeon, P., & Sabatier, P.A. (2012). Understanding and influencing the policy process. *Policy Sciences*, 45(1), 1-21. doi:10.1007/s11077-011-9143-5
- Westin, A. F. (1967). *Privacy and freedom*. New York, NY: Atheneum.
- Who's who in privacy?: And who's doing what? (2008). *Privacy Journal*, 34(11), 1,3-4.  
Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/215231863?accountid=11652>
- Yandle, B., & Morriss, A. P. (2004). Regulation by litigation: Diesel engine emission control. *The Independent Review*, 8(3), 401-418. Retrieved from [http://www.independent.org/pdf/tir/tir\\_08\\_3\\_5\\_yandle.pdf](http://www.independent.org/pdf/tir/tir_08_3_5_yandle.pdf)
- Yin, R. K. (2014). *Case study research: Design and methods* (5th ed.). Thousand Oaks, CA: Sage.
- Your health and your privacy: Protecting health information in a digital world: Hearing before the Subcommittee on Privacy, Technology and the Law of the Committee on the Judiciary, United States Senate, 112<sup>th</sup> Cong. (S. Hrg. 112-867). (2011). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-112shrg87166/pdf/CHRG-112shrg87166.pdf>

Zahariadis, N. (1999). Ambiguity, time, and multiple streams, in P.A. Sabatier (Ed.), *Theories of the Policy Process: Theoretical Lenses on Public Policy*. (pp. 73-93). Boulder, CO: Westview Press.

Zahariadis, N. (2007). The multiple streams framework: Structure, limitations, prospects, in P.A. Sabatier (Ed.), *Theories of the Policy Process* (2nd ed.) (pp. 65-92). Boulder, CO: Westview Press.

## Appendix A

### Tables and Figures

Table A1

*Research Databases Used to Locate Research Documents*

Database Topic	Database Name
Government/Political Science	Catalog of U.S. Government Publications CQ E-library CQ Weekly FDSys
Law	Legal Collection ProQuest Social Science Premium Collection Sage Premier
News	Newspaper Source (EBSCO) Newsstand (ProQuest) ProQuest Newsstream Wall Street Journal The Washington Post

Table A2

*Search Terms Used in the Research Databases to Locate Documents*

Search Terms		
The American Recovery and Reinvestment Act	ARRA	Civil monetary penalties
HIPAA	HIPAA criticisms	HIPAA enforcement
HIPAA fines	HIPAA and interest groups	HIPAA Privacy Rule
HIPAA omnibus rule	HIPAA reform	HIPAA stakeholders
HIPAA violations	HITECH	HITECH Act
HITECH modifications	Privacy advocates	Privacy reform
Privacy Rule changes	Privacy Rule enforcement	Privacy Rule reform
Privacy stakeholders	Privacy violations	Voluntary compliance

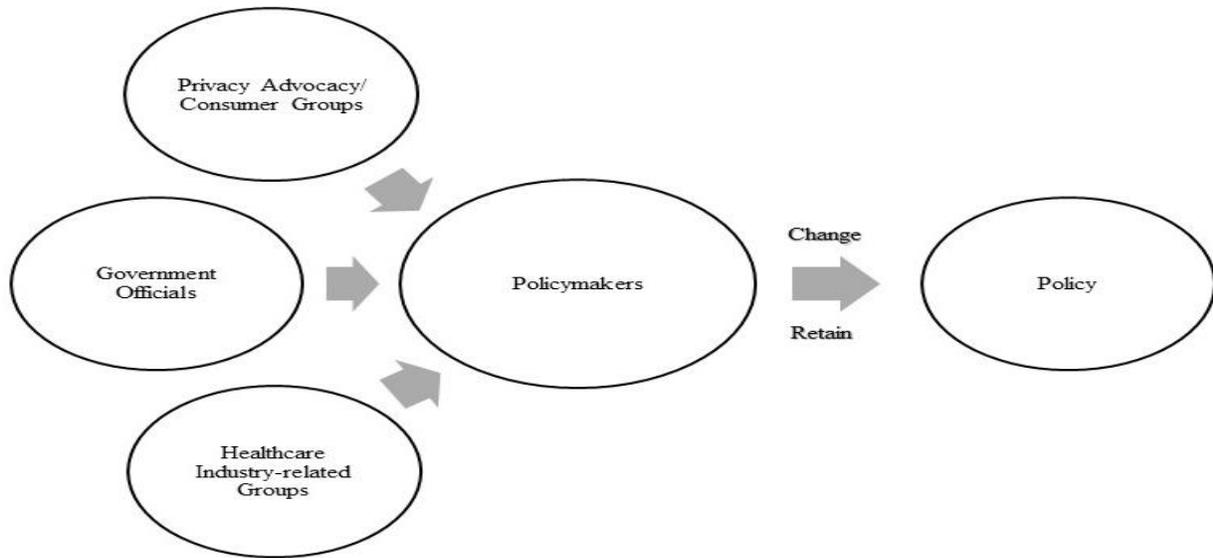
Table A3

*Themes and Subtheme Labels for Each Subquestion*

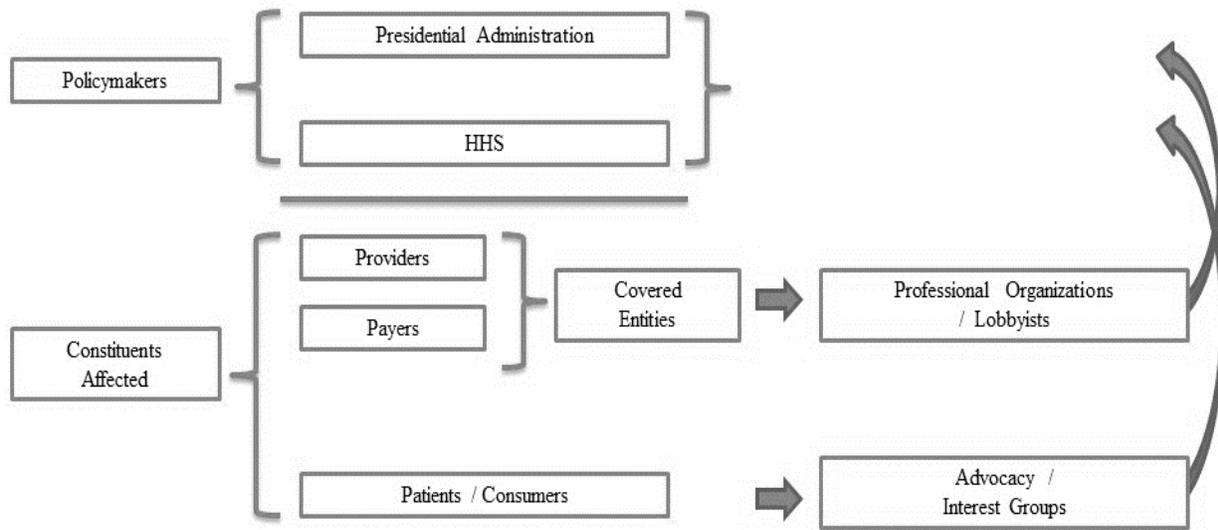
Themes/Subthemes for Subquestion 1: Stakeholder influence	Themes/Subthemes for Subquestion 2: Stakeholder collaboration	Themes/Subthemes for Subquestion 3: Influence of the lack of fines	Themes/Subthemes for other circumstances from Subquestion 3
1. Communicate in writing	6. Q & A/testimony	Voluntary compliance	18. Private right of action
Communicate by speaking	7. Partnering statements	11. For 13. Against 12. Policy of the administration	19. State attorneys general
2. News media			
3. Testimony			
4. Employee movement among groups	8. Work groups/ Initiatives	14. Lack of fines 15. Not adequate/ Motivating	20. Transparency/ Monitoring
5. Participation through connections	9. Association/ Industry groups	16. Recommendations from industry with explanations	21. Staffing - resources
	10. Opposition to HITECH	17. Recommendations from other	

- 1996
  - August 21, 1996: President Clinton signed the HIPAA provisions into law (U.S. Congress, n.d.).
- 1999
  - November 3, 1999: The proposed Privacy Rule was published for public comment on November 3, 1999 (OCR, 2003).
- 2000
  - December 28, 2000: The original final Privacy Rule was published (Standards for Privacy, 2000).
- 2002
  - October 15, 2002: The final Privacy Rule that took effect (Standards for Privacy, 2002).
- 2003
  - April 14, 2003: The compliance date for Privacy Rule standards (Solove, 2013).
- 2009
  - February 17, 2009: The Health Information Technology for Economic and Clinical Health Act (HITECH), part of the American Recovery and Reinvestment Act of 2009 (ARRA), was enacted, and the proposed rule was published on July 14, 2010 (Modifications to the HIPAA Privacy, 2010).
  - October 30, 2009: The interim final rule regarding HIPAA enforcement was published and became effective on November 30, 2009 (Modifications to the HIPAA Privacy, 2010).
- 2011
  - February 22, 2011: OCR issued the first civil monetary penalty for Privacy Rule violations (U. S. Department of Health and Human Services Press Office [HHS Press Office], 2011a).
- 2013
  - January 25, 2013: The final rule resulting from HITECH was published and became effective on March 26, 2013 (Modifications to the HIPAA Privacy, 2013)

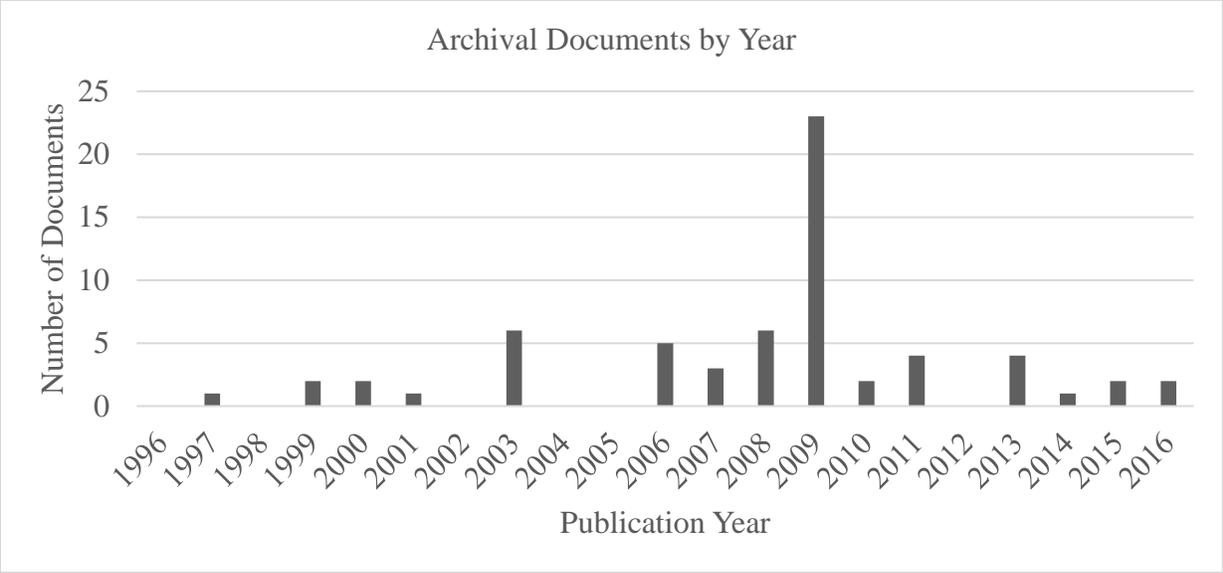
*Figure A1.* HIPAA timeline. This figure is a timeline that illustrates the evolution of HIPAA and the Privacy Rule by marking milestones dates.



*Figure A2.* Model of stakeholder influence. This figure is a model that illustrates I how envisioned stakeholder influence regarding the policy shift.



*Figure A3.* How policy happens. This figure illustrates the flow of stakeholder influence regarding public policy.



*Figure A4.* Distribution of archival documents. This figure illustrates the distribution (by year) of the archival documents used.

## Appendix B

### Coding Manual

Coding Stage	Extract Concerns	Color
Initial code	Activity regarding enforcement	Dark green
Initial code	Advocacy group	Purple
Initial code	Attorneys or legal group	Yellow
Initial code	Governmental group or politician	Red
Initial code	Health care industry group	Blue
Initial code	Work group or initiative	Dark orange
Focused code	Research Subquestion 1: In what ways did policy stakeholders influence the policy shift from the original enforcement philosophy to a more punitive philosophy?	Pink
Focused code	Research Subquestion 2: How did stakeholder groups collaborate to promote certain perspectives and concepts?	Brown
Focused code	Research Subquestion 3: How did stakeholder perspectives regarding the lack of civil money penalties or fines influence the policy shift?	Lime green
Focused code	Other circumstances from research Subquestion 3	Bright orange

Appendix C

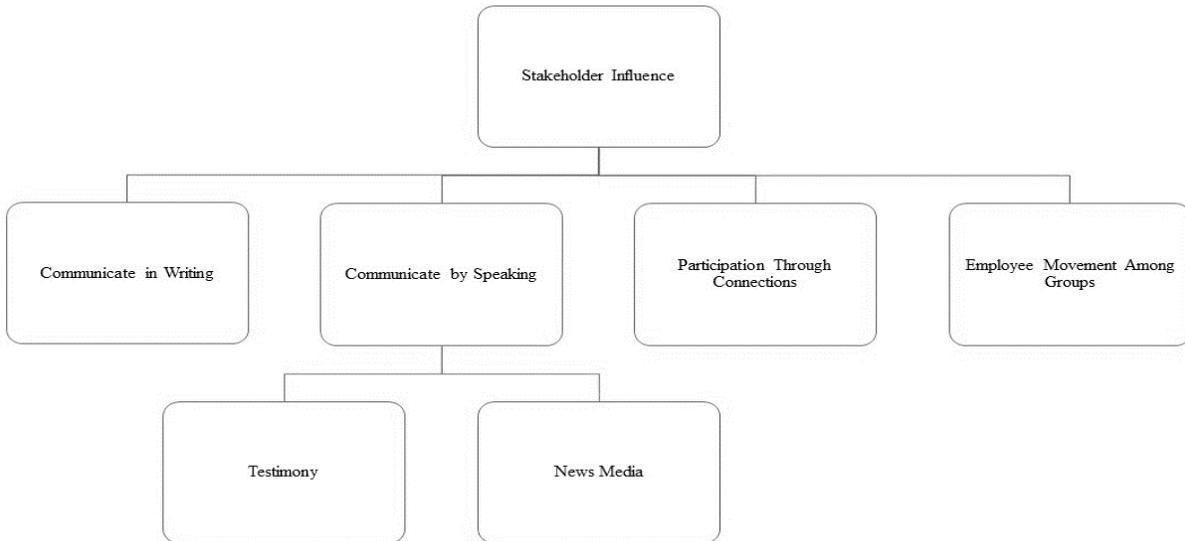
Theme Manual

Question or Subquestion	Coded Theme	Short Description
1	Communicate in writing	Stakeholder groups wrote letters to members of Congress or agency officials
1	News media (Communicate by speaking)	Members of stakeholder groups spoke to the news media
1	Testimony (Communicate by speaking)	Members of stakeholder groups testified in congressional hearings
1	Employee movement among groups	Member of a stakeholder group moved among groups
1	Participation through connections	Members of different stakeholder groups have connections
2	Q & A/Testimony	Stakeholder groups have question and answer exchanges
2	Partnering Statements	Stakeholder groups want to partner with other groups
2	Work Groups/Initiatives	Different stakeholders work together on a project
2	Association/Industry Groups	Stakeholder groups represent a profession or industry
2	Opposition to HIPAA/HITECH	Stakeholder groups oppose an aspect of the enforcement approach
3	For Voluntary Compliance	Stakeholder statements supporting voluntary compliance
3	Policy of the Administration	Stakeholder statements about how a presidential administration viewed violations
3	Against Voluntary Compliance	Stakeholder statements opposing voluntary compliance
3	Lack of Fines	Stakeholder statements about the lack of fines
3	Not Adequate/Motivating	Stakeholder statements regarding the original enforcement approach lacking persuasion
3	Recommendations from Industry	Recommendations from industry stakeholders regarding the policy shift
3	Recommendations from Other	Recommendations from non-industry stakeholders regarding the policy shift
Supplemental to 3	Private Right of Action	Stakeholder statements regarding the possibility of private lawsuits
Supplemental to 3	State Attorneys General (SAG)	Stakeholder statements regarding the possibility of giving enforcement authority to SAG's
Supplemental to 3	Transparency/Monitoring	Stakeholder statements regarding the need for transparency or monitoring at OCR
Supplemental to 3	Staffing – resources	Stakeholder statements about OCR staffing issues

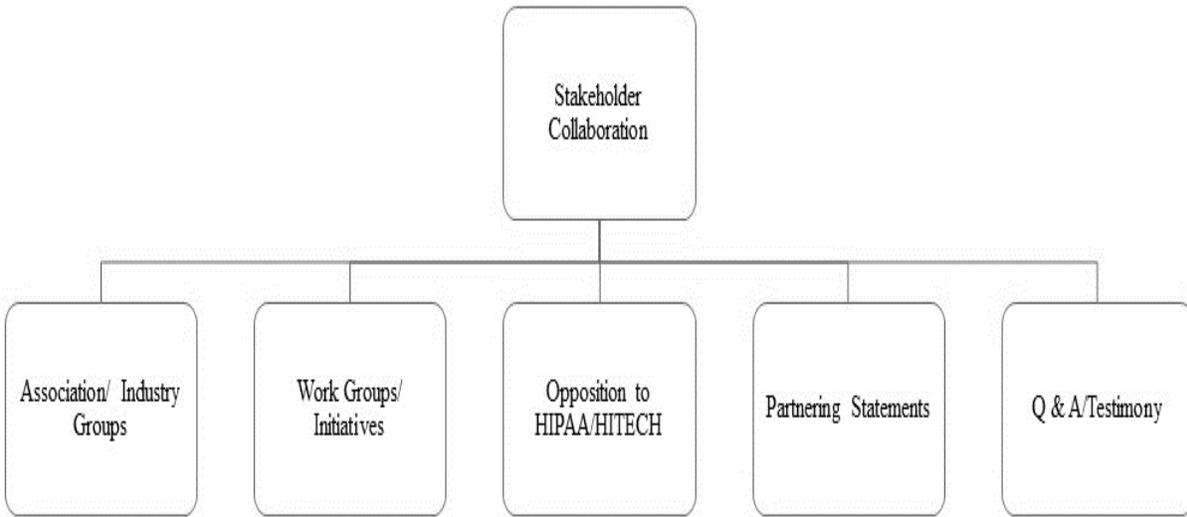
# Appendix D

## Final Theme Maps

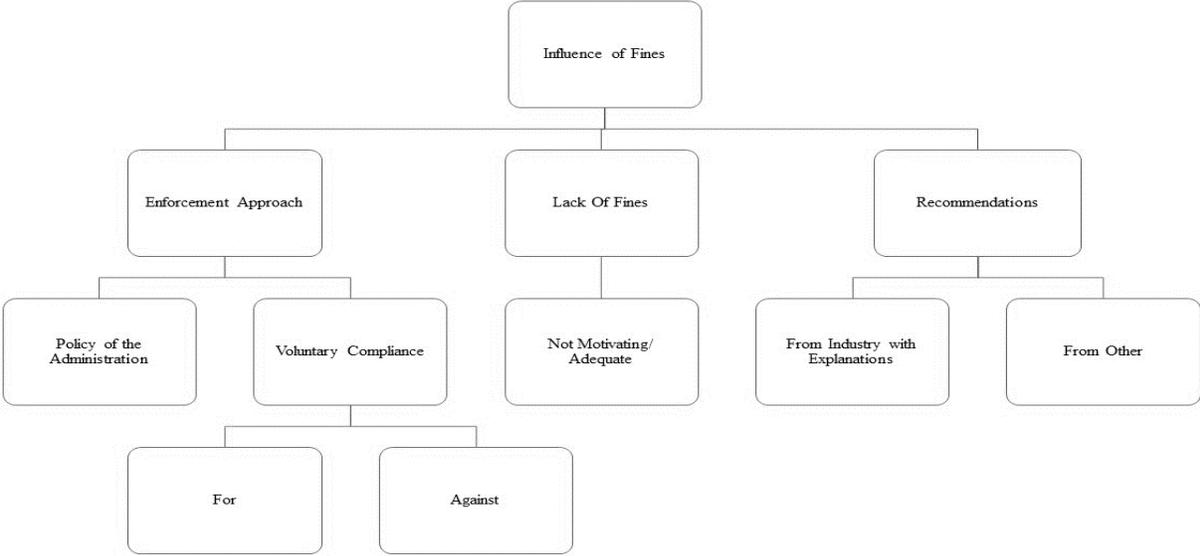
### Theme Map for Subquestion 1



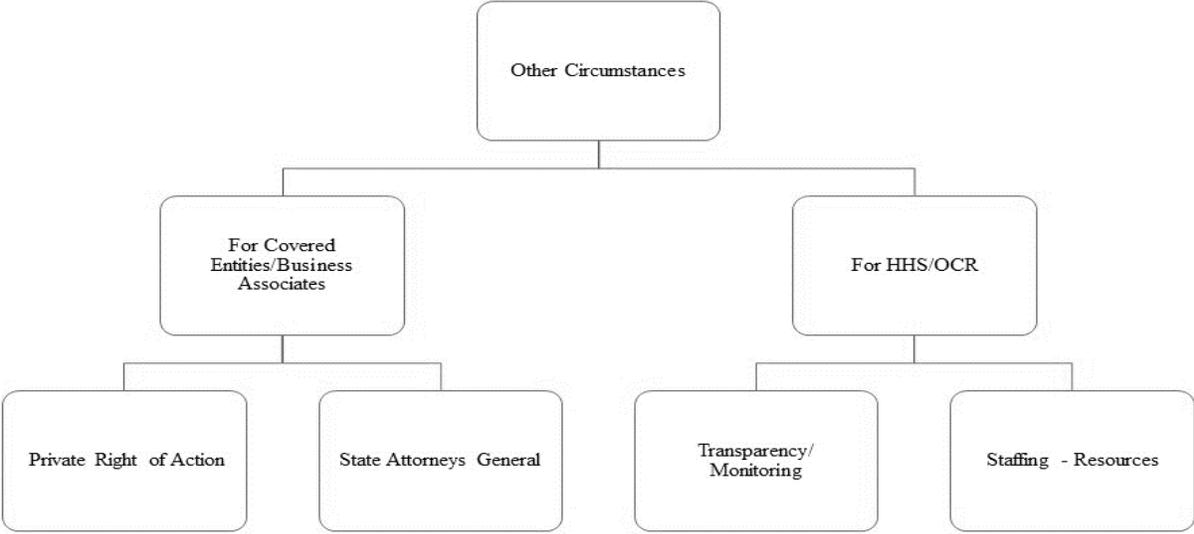
Theme Map for Subquestion 2



Theme Map for Subquestion 3



Theme Map for Other Circumstances from Subquestion 3



Appendix E

Coded Archival Document List (Chronological Order)

Document Code #	Document Title	Author (If Applicable)	Document Date	Document Type
1	Speech by D. E. Shalala, Secretary of Health and Human Services, on medical privacy, National Press Club, Washington, DC	----	July 31, 1997	Speech transcript
2	Best principles for health privacy: A report of the Health Privacy Work Group	Health Privacy Working Group	July 1999	Report
3	Health and the right to privacy	Starr, P.	1999	Journal article
4	Confidentiality of patient records: Hearing before the Subcommittee on Health of the Committee on Ways and Means House of Representatives, 106th Cong.	----	February 17, 2000	Hearing
5	Privacy Standards Issues in HHS' Proposed Rule on Confidentiality of Personal Health Information: Testimony before the Committee on Health, Education, Labor, and Pensions, U.S. Senate:	United States General Accounting Office	April 26, 2000	Testimony
6	Bush will proceed on privacy; But Clinton-era rules likely to be modified	Goldstein, A., & O'Harrow, R.	April 13, 2001	Newspaper article
7	The HIPAA Privacy Rule: An overview of compliance initiatives and requirements	Lawson, N. A., Orr, J. M., & Klar, D. S.	January 2003	Journal article
8	Privacy law sparks medical cover-up	Surendran, A.	April 6, 2003	News wire
9	Privacy, please; New rules may protect patients, alter hospital, office practices	Boodman, S. G.	April 8, 2003	Newspaper article
10	A tougher medical privacy law; Health care providers are hurrying to comply with a federal law that aims to further limit the spread of patient information. Myths and misunderstandings are rampant	Miller, M.	April 14, 2003	Newspaper article

11	Overhaul of privacy regulations sought days after they take effect	Carey, M.A.	April 19, 2003	Magazine
12	A behind-the-scenes force for privacy; For leader of D.C.-based project, protecting confidentiality of medical records is 'lifelong endeavor'	Goldstein, A.	April 28, 2003	Newspaper article
13	Medical privacy law nets no fines; Lax enforcement puts patients' files at risk, critics say	Stein, R.	June 5, 2006	Newspaper article in the Washington Post
14	Privacy law nets no fines over 3 years	Stein, R.	June 5, 2006	Newspaper article in the Journal-Gazette (Ft. Wayne, IN)
15	U.S. lax on enforcement of medical privacy law after 19,000-plus grievances, no fines have been imposed	Stein, R.	June 5, 2006	Newspaper article in the Pittsburgh Post-Gazette
16	Nice law, no teeth	----	June 11, 2006	News wire
17	U.S. Senator Hillary Clinton (D-NY) delivers remarks on privacy rights to the American Constitution Society for Law & Policy convention	Clinton, H.	June 16, 2006	Political transcript wire (of speech)
18	Private health records: Privacy implications of the federal government's health information technology initiative: Hearing before Oversight of Government Management, the Federal Workforce, and the District of Columbia Subcommittee of the Homeland Security and Governmental Affairs, United States Senate, 110th Cong.	----	February 1, 2007	Hearing

19	Confidentiality and privacy in health care from the patient's perspective: Does HIPAA help?	Moore, I. L., Snyder, S. L., Miller, C., An, A. Q., Blackford, J., Zhou, C., & Hickson, G. B.	Spring 2007	Journal article
20	Protecting patient privacy in healthcare information systems: Hearing before the Subcommittee on Information Policy, Census, and National Archives of the Committee on Oversight and Government Reform House of Representatives, 110th Cong.	----	June 19, 2007	Hearing
21	The nation; Effectiveness of medical privacy law is questioned	Alonso-Zaldivar, R.	April 9, 2008	Newspaper article
22	Are your medical records at risk?; Amid spate of security lapses, health-care industry weighs privacy against quality care	Rubenstein, S.	April 29, 2008	Newspaper article
23	Discussion draft of health Information technology And privacy legislation: Hearing before the Subcommittee on Health of the Committee on Energy and Commerce House of Representatives, 110th Cong.	----	June 4, 2008	Hearing
24	Hearing on promoting the adoption and use of health information technology: Hearing before the Subcommittee on Health of the Committee on Ways and Means U.S. House of Representatives, 110th Cong.	----	July 24, 2008	Hearing
25	CRS report for Congress: Enforcement of the HIPAA Privacy and Security Rules.	Stevens, G. M.	August 11, 2008	Report
26	Who's who in privacy? And who's doing what?	----	September 2008	Journal article

27	Legal solutions in health reform: Privacy and security of information	McGraw, D.	January 1, 2009	Report later published as a journal article
28	PCMA letter to the US House of Representatives	Pharmaceutical Care Management Association	January 26, 2009	News wire (of letter)
29	Health information technology: Protecting Americans' privacy in the digital age: Hearing before the Committee on the Judiciary, United States Senate, 111 <sup>th</sup> Cong.	----	January 27, 2009	Hearing
30	'Next generation' of privacy needed for health information technology	The Center for Democracy & Technology	March 10, 2009	News wire (of The Center for Democracy & Technology news release)
31	Nomination of Governor Kathleen Sebelius: Hearing of the Committee on Health, Education, Labor, And Pensions United States Senate, 111th Cong.	----	March 31, 2009	Hearing
32	Privacy as an enabler, not an impediment: Building trust into health information exchange	McGraw, D., Dempsey, J. X., Harris, L., & Goldman, J.	March/ April 2009	Journal article
33	Protecting patients in health information exchange: A defense of the HIPAA Privacy Rule	McDonald, C.	March/ April 2009	Journal article
34	CDT's Deven McGraw named to Federal Advisory Health IT Policy Committee	The Center for Democracy & Technology	May 8, 2009	Press release
35	HHS strengthens HIPAA enforcement	HHS Press Office	October 30, 2009	News wire (of HHS press release)
36	Privacy violations seldom punished	Kanigher, S	December 13, 2009	Newspaper article
37	Letter to the Department of Health and Human Services, Office of the Secretary, HIPAA administrative simplification: Enforcement: Interim final rule; Request for comments	Hurley, T. P.	December 14, 2009	Letter

38	Letter to the Honorable Kathleen Sebelius, Attention: HIPAA Enforcement Rule IFR (RIN 0991-AB55)	National Association of Chain Drug Stores	December 16, 2009	Letter
39	Letter to Secretary Kathleen Sebelius, Re: HIPAA administrative simplification: Enforcement rule	UnitedHealth Group	December 21, 2009	Letter
40	Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Re: HIPAA Enforcement Interim Final Regulations: RIN 0991-AB55	America's Health Insurance Plans	December 23, 2009	Letter
41	Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, RIN 0991-AB55 HIPAA Administrative Simplification: Enforcement Interim final rule	American Medical Informatics Association	December 24, 2009	Letter
42	Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Attention: HIPAA Enforcement Rule IFR (RIN 0991-AB55)	Minnesota Department of Health	December 28, 2009	Letter
43	Letter to the Honorable Kathleen Sebelius, Re: RIN 0991-AB55, HIPAA Enforcement Interim Final Rule	Planned Parenthood Federation of America	December 28, 2009	Letter
44	Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Attention: HIPAA Enforcement Rule IFR (RIN 0991-AB55)	Aging Services of Minnesota	December 29, 2009	Letter
45	Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Re: HIPAA Enforcement Rule IFR RIN 0991-AB55	American Council of Life Insurers	December 29, 2009	Letter
46	Letter to Georgina Verdugo, Re: RIN 0991-AB55: HIPAA Administrative Simplification Enforcement – October 30, 2009 Interim Final Rule	American Health Information Management Association	December 29, 2009	Letter

47	Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Attn: HIPAA Enforcement Rule IFR (RIN 0991-AB55)	Association of Academic Health Centers	December 29, 2009	Letter
48	Letter to Georgina C. Verdugo, Attention: HIPAA Enforcement Rule IFR (RIN 0991-AB55)	Blue Cross Blue Shield Association	December 29, 2009	Letter
49	Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Re: HIPAA Enforcement Interim Final Regulations: RIN 0991-AB55	Kaiser Permanente	December 29, 2009	Letter
50	AHIMA reaction HHS proposed rule on HITECH privacy regulations	American Health Information Management Association	July 8, 2010	News wire (of statement release)
51	House Science and Technology Subcommittee on Technology & Innovation hearing: Standards for health IT: Meaningful use and beyond	----	September 30, 2010	Political transcript wire (of testimony)
52	Massachusetts General Hospital settles potential HIPAA violations	HHS Press Office	February 24, 2011	News wire (of HHS press release)
53	Health care reform in the United States: HITECH Act and HIPAA privacy, security, and enforcement issues	Kempfert, A. E. & Reed, B. D.	Spring 2011	Journal article
54	Annual report to congress on HIPAA Privacy Rule and Security Rule compliance: For calendar years 2009 and 2010	HHS Office for Civil Rights	August 11, 2011 (Submission date)	Report
55	Your health and your privacy: Protecting health information in a digital world: Hearing before the Subcommittee on Privacy, Technology and the Law of the Committee on the Judiciary United States Senate, 112 <sup>th</sup> Cong.	----	November 9, 2011	Hearing
56	New rule protects patient privacy, secures health information	HHS	January 13, 2013	News wire (of HHS press release)

57	Markey praises privacy rules for health records, data	Rep. Ed Markey	January 18, 2013	News wire (of Rep. Ed Markey news release)
58	Does HIPAA help or hinder patient care and public safety?: Hearing before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce House of Representatives, 113th Cong.	----	April 26, 2013	Hearing
59	The HIPAA omnibus rule: Implications for public health policy and practice	Goldstein, M. M., & Pewen, W. F.	November-December 2013	Journal article
60	Annual report to congress on HIPAA Privacy, Security, Breach Notification Rule and compliance: For calendar years 2011 and 2012	HHS Office for Civil Rights	May 20, 2014 (Submission date)	Report
61	HIPAA privacy, security, enforcement, and breach notification standards	Redhead, C. S.	April 17, 2015	Report
62	Deven McGraw brings HIPAA expertise to OCR	Miliard, M.	June 18, 2015	Online magazine article
63	Your medical records aren't as private as they should be	Ornstein, C.	January 3, 2016	Newspaper article
64	Annual report to congress on HIPAA Privacy, Security, Breach Notification Rule and compliance: For calendar years 2013 and 2014	HHS Office for Civil Rights	August 30, 2016 (Submission date)	Report

## Appendix F

### References for Archival Documents

- Aging Services of Minnesota. (2009, December 29). [Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Attention: HIPAA Enforcement Rule IFR (RIN 0991-AB55)]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0021>
- Alonso-Zaldivar, R. (2008, April 9). Effectiveness of medical privacy law is questioned. *Los Angeles Times*, A.10. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/422206473?accountid=11652>
- American Council of Life Insurers. (2009, December 29). [Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Re: HIPAA Enforcement Rule IFR RIN 0991-AB55]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0023>
- America's Health Insurance Plans. (2009, December 23). [Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Re: HIPAA Enforcement Interim Final Regulations: RIN 0991-AB55]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0013>
- American Health Information Management Association. (2009, December 29). [Letter to Georgina Verdugo, Re: RIN 0991-AB55: HIPAA Administrative Simplification Enforcement – October 30, 2009 Interim Final Rule]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0022>

- American Health Information Management Association. (2010, July 8). AHIMA reaction HHS proposed rule on HITECH privacy regulations [News release]. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/603194373?accountid=11652>
- American Medical Informatics Association. (2009, December 24). [Letter to the U.S. Department of Health and Human Services, RIN 0991-AB55 HIPAA Administrative Simplification: Enforcement Interim final rule]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0015>
- Association of Academic Health Centers. (2009, December 29). [Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Attn: HIPAA Enforcement Rule IFR (RIN 0991-AB55)]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0018>
- Blue Cross Blue Shield Association. (2009, December 29). [Letter to Georgina C. Verdugo, Attention: HIPAA Enforcement Rule IFR (RIN 0991-AB55)]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0020>
- Boodman, S. G. (2003, April 8). Privacy, please; New rules may protect patients, alter hospital, office practices. *The Washington Post*, p. F.01. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/409506364?accountid=11652>
- Carey, M. A. (2003, April 19). Overhaul of privacy regulations sought days after they take effect. *CQ Weekly*, 949-950. Retrieved from <http://library.cqpress.com.proxy-iup.klnpa.org/cqweekly/weeklyreport108-000000671309>

Center for Democracy & Technology. (2009, May 8). *CDT's Deven McGraw named to Federal Advisory Health IT Policy Committee* [Press release]. Retrieved from <https://cdt.org/press/cdts-deven-mcgraw-named-to-federal-advisory-health-it-policy-committee/>

Center for Democracy & Technology. (2009, March 10). *'Next generation' of privacy needed for health information technology* [News release]. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/468465624?accountid=11652>

Clinton, H. (2006, June 16). *U. S. Senator Hillary Clinton (D-NY) delivers remarks on privacy rights to the American Constitution Society for Law & Policy convention* [Transcript]. Political Transcript Wire; Lanham. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/467181648?accountid=11652>

Confidentiality of patient records: Hearing before the Subcommittee on Health of the Committee on Ways and Means, House of Representatives, 106th Cong. (Serial No. 106-89). (2000). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-106hhrg66897/pdf/CHRG-106hhrg66897.pdf>

Discussion draft of health information technology and privacy legislation: Hearing before the Subcommittee on Health of the Committee on Energy and Commerce, House of Representatives, 110th Cong. (Serial No. 100-122). (2008). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-110hhrg55462/pdf/CHRG-110hhrg55462.pdf>

Does HIPAA help or hinder patient care and public safety?: Hearing before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, House of Representatives, 113th Cong. (Serial No. 113-37). (2013). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-113hhr82190/pdf/CHRG-113hhr82190.pdf>

Goldstein, A. (2003, April 28). A behind-the-scenes force for privacy; For leader of D.C.-based project, protecting confidentiality of medical records is 'lifelong endeavor'. *The Washington Post*, p. A21. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/409425141?accountid=11652>

Goldstein, A., & O'Harrow, R. (2001, April 13). Bush will proceed on privacy; But Clinton-era rules likely to be modified. *The Washington Post*, p. A.1. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/409087979?accountid=11652>

Goldstein, M. M., & Pewen, W. F. (2013). The HIPAA omnibus rule: Implications for public health policy and practice. *Public Health Reports*, 128(6), 554-558.  
doi:10.1177/003335491312800615

Health information technology: Protecting Americans' privacy in the digital age: Hearing before the Committee on the Judiciary, United States Senate, 111<sup>th</sup> Cong. (Serial No. J-111-3). (2009). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-111shrg54240/pdf/CHRG-111shrg54240.pdf>

Health Privacy Working Group, (1999). *Best principles for health privacy: A report of the Health Privacy Working Group*. Washington, DC: Health Privacy Project. Retrieved from <https://www.cdt.org/files/file/33807.pdf>

Hearing on promoting the adoption and use of health information technology: Hearing before the Subcommittee on Health of the Committee on Ways and Means, House of Representatives, 110th Cong. (Serial No. 110-93). (2008). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-110hhr58278/pdf/CHRG-110hhr58278.pdf>

“House Science and Technology Subcommittee on Technology & Innovation hearing: Standards for health IT: Meaningful use and beyond”. (2010, September 30). *Congressional Documents and Publications*. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/756625694?accountid=11652>

Hurley, T. P. (2009, December 14). [Letter to the Department of Health and Human Services, Office of the Secretary, HIPAA administrative simplification: Enforcement: Interim final rule; Request for comments]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0008>

Kaiser Permanente. (2009, December 29). [Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Re: HIPAA Enforcement Interim Final Regulations: RIN 0991-AB55]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0024>

Kanigher, S. (2009, December 13). Privacy violations seldom punished. *Las Vegas Sun*, p. 1. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/389072807?accountid=11652>

- Kempfert, A. E., & Reed, B. D. (2011). Health care reform in the United States: HITECH Act and HIPAA privacy, security, and enforcement issues. *FDCC Quarterly*, 61(3), 240-273. Retrieved from <http://search.ebscohost.com.proxy-iup.klnpa.org/login.aspx?direct=true&db=lgh&AN=66998712&site=ehost-live>
- Lawson, N. A., Orr, J. M., & Klar, D. S. (2003). The HIPAA Privacy Rule: An overview of compliance initiatives and requirements. *Defense Counsel Journal*, 70(1), 127-149. Retrieved from <http://search.ebscohost.com.proxy-iup.klnpa.org/login.aspx?direct=true&db=lgh&AN=8984042&site=ehost-live>
- McDonald, C. (2009). Protecting patients in health information exchange: A defense of the HIPAA Privacy Rule. *Health Affairs*, 28(2), 447-449. doi:10.1377/hlthaff.28.2.447
- McGraw, D. (2009). *Privacy and health information technology* (RWJF Report No. 36903). Retrieved from the Robert Wood Johnson Foundation website: <https://www.rwjf.org/content/dam/farm/reports/reports/2009/rwjf36903>
- McGraw, D., Dempsey, J. X., Harris, L., & Goldman, J. (2009). Privacy as an enabler, not an impediment: Building trust into health information exchange. *Health Affairs*, 28(2), 416-427. doi:10.1377/hlthaff.28.2.416
- Markey, E. (2013, January 18). *Markey praises privacy rules for health records, data* [News release]. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/1271633007?accountid=11652>
- Miliard, M. (2015, June 18). Deven McGraw brings HIPAA expertise to OCR. *Healthcare IT News*. Retrieved from <http://www.healthcareitnews.com/news/deven-mcgraw-brings-hipaa-expertise-ocr>

Miller, M. (2003, April 14). A tougher medical privacy law; Health care providers are hurrying to comply with a federal law that aims to further limit the spread of patient information. Myths and misunderstandings are rampant. *Los Angeles Times*, F.1. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/421813610?accountid=11652>

Minnesota Department of Health. (2009, December 28). [Letter to the U.S. Department of Health and Human Services, Office for Civil Rights, Attention: HIPAA Enforcement Rule IFR (RIN 0991-AB55)]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0019>

Moore, I. L., Snyder, S. L., Miller, C., An, A. Q., Blackford, J., Zhou, C., & Hickson, G. B. (2007). Confidentiality and privacy in health care from the patient's perspective: Does HIPAA help?. *Health Matrix*, 17(2), 215-272. Retrieved from <http://search.ebscohost.com.proxy-iup.klnpa.org/login.aspx?direct=true&db=mnh&AN=18326392&site=ehost-live>

National Association of Chain Drug Stores. (December 16, 2009). [Letter to the Honorable Kathleen Sebelius, Attention: HIPAA Enforcement Rule IFR (RIN 0991-AB55)]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0009>

“Nice law, no teeth”. [Editorial]. (2006, June 11). *Knight Ridder Tribune Business News*, p.1. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/465328933?accountid=11652>

Nomination of Governor Kathleen Sebelius: Hearing of the Committee on Health, Education, Labor, and Pensions, United States Senate, 111<sup>th</sup> Cong. (S. Hrg. 111-804). (2009).

Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-111shrg48540/pdf/CHRG-111shrg48540.pdf>

Ornstein, C. (2016, January 3). Your medical records aren't as private as they should be. *The Washington Post*, p. B1. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/1753064689>

?accountid=11652

Pharmaceutical Care Management Association. (2009, January 26). *PCMA letter to the US House of Representatives* [News release]. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/468561318>

?accountid=11652

Planned Parenthood Federation of America. (2009, December 28). [Letter to the Honorable Kathleen Sebelius, Re: RIN 0991-AB55, HIPAA Enforcement Interim Final Rule].

Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0017>

Private health records: Privacy implications of the federal government's health information technology initiative: Hearing before Oversight of Government Management, the Federal Workforce, and the District of Columbia Subcommittee of the Homeland Security and Governmental Affairs, United States Senate, 110th Cong. (S. Hrg. 111-804). (2007).

Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-110shrg33874/pdf/CHRG-110shrg33874.pdf>

- Protecting patient privacy in healthcare information systems: Hearing before the Subcommittee on Information Policy, Census, and National Archives of the Committee on Oversight and Government Reform, House of Representatives, 110<sup>th</sup> Cong. (Serial No. 110-33). (2007). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-110hhr39023/pdf/CHRG-110hhr39023.pdf>
- Redhead, C. S. (2015). *HIPAA privacy, security, enforcement and breach notification standards*. Washington, DC: Congressional Research Service. Retrieved from <https://fas.org/sgp/crs/misc/R43991.pdf>
- Rubenstein, S. (2008, April 29). Are your medical records at risk?; Amid spate of security lapses, health-care industry weighs privacy against quality care. *Wall Street Journal: Eastern edition*, p. D.1. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/399064207?accountid=11652>
- Shalala, D. (1998). *Speech by D. E. Shalala, Secretary of Health and Human Services, on medical record privacy, National Press Club, Washington, DC* [Transcript]. Historic documents of 1997. Washington, DC: CQ Press. Retrieved from <http://library.cqpress.com.proxy-iup.klnpa.org/cqpac/hsdc97-0000036324>
- Starr, P. (1999). Health and the right to privacy. *American Journal of Law and Medicine*, 25 (2/3), 193-201. Retrieved from <http://search.ebscohost.com.proxy-iup.klnpa.org/login.aspx?direct=true&db=lgh&AN=2056201&site=ehost-live>
- Stein, R. (2006a, June 5). Medical privacy law nets no fines; Lax enforcement puts patients' files at risk, critics say. *The Washington Post*, p. A01. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/410126136?accountid=11652>

- Stein, R. (2006b, June 5). Privacy law nets no fines over years. *Journal-Gazette*, p. 1A.  
Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/411340042?accountid=11652>
- Stein, R. (2006c, June 5). U.S. lax on enforcement of medical privacy law after 19,000 – plus grievances, no fines have been imposed. *Pittsburgh Post-Gazette*, p. A-1. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/390828493?accountid=11652>
- Stevens, G. M. (2008). *CRS report for Congress: Enforcement of the HIPAA Privacy and Security Rules*. Washington, DC: Congressional Research Service. Retrieved from [https://www.everycrsreport.com/files/20080811\\_RL33989\\_9d1068d790c8724c97e4b2c26f8b11153cf693cf.pdf](https://www.everycrsreport.com/files/20080811_RL33989_9d1068d790c8724c97e4b2c26f8b11153cf693cf.pdf)
- Surendran, A. (2003, April 6). Privacy law sparks medical cover-up. *Knight Ridder Tribune Business News*, p.1. Retrieved from <https://search-proquest-com.proxy-iup.klnpa.org/usnews/docview/461561851/89E3903686B640C6PQ/1?accountid=11652>
- U. S. Department of Health and Human Services. (2013, January 17). *New rule protects patient privacy, secures health information* [News release]. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/1270600932?accountid=11652>
- U. S. Department of Health and Human Services, Office for Civil Rights. (2011). *Annual Report to Congress on HIPAA Privacy Rule and Security Rule compliance for calendar years 2009 and 2010*. Retrieved from <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/enforcement/compliancerept.pdf>

- U. S. Department of Health and Human Services, Office for Civil Rights. (2014). *Annual Report to Congress on HIPAA Privacy, Security, Breach Notification Rule and compliance: For calendar years 2011 and 2012*. Retrieved from <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/enforcement/compliancereport2011-2012.pdf>
- U. S. Department of Health and Human Services, Office for Civil Rights. (2016). *Annual Report to Congress on HIPAA Privacy Rule, Security, Breach Notification Rule and compliance: For calendar years 2013 and 2014*. Retrieved from <https://www.hhs.gov/sites/default/files/rtc-compliance-20132014.pdf>
- U.S. Department of Health and Human Services, Press Office. (2009, October 30). *HHS strengthens HIPAA enforcement* [Press release]. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/443819582?accountid=11652>
- U.S. Department of Health and Human Services, Press Office (2011, February 24). *Massachusetts General Hospital settles potential HIPAA violations* [Press release]. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/853627640?accountid=11652>
- U. S. General Accounting Office. (2000). *Privacy Standards Issues in HHS' Proposed Rule on Confidentiality of Personal Health Information: Testimony before the Committee on Health, Education, Labor, and Pensions, U.S. Senate: Statement of Janet Heinrich, Associate Director Health Financing and Public Health Issues Health, Education, and Human Services Division*. (GAO Publication No. GAO/T-HEHS-00-106). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/GAOREPORTS-T-HEHS-00-106/pdf/GAOREPORTS-T-HEHS-00-106.pdf>

UnitedHealth Group. (2009, December 21). [Letter to Secretary Kathleen Sebelius, Re: HIPAA administrative simplification: Enforcement rule]. Retrieved from <https://www.regulations.gov/document?D=HHS-OCR-2009-0020-0012>

Who's who in privacy?: And who's doing what? (2008). *Privacy Journal*, 34(11), 1,3-4. Retrieved from <http://proxy-iup.klnpa.org/login?url=https://search-proquest-com.proxy-iup.klnpa.org/docview/215231863?accountid=11652>

Your health and your privacy: Protecting health information in a digital world: Hearing before the Subcommittee on Privacy, Technology and the Law of the Committee on the Judiciary, United States Senate, 112<sup>th</sup> Cong. (S. Hrg. 112-867). (2011). Retrieved from GPO's Federal Digital System: <https://www.govinfo.gov/content/pkg/CHRG-112shrg87166/pdf/CHRG-112shrg87166.pdf>

## Appendix G

### Audit Trail

I used a paper notebook as a journal to maintain a written record and audit trail, and the record is lengthy. Therefore, the following audit trail contains the entries that highlight decisions, observations, and reflections.

8-28-17

I began data collection after receiving an email from Dr. Shinberg in which she approved me to start research. I will use the tables from Chapter 3 to guide the searches.

9-23-17

I tried the Newsstand database, but it forwarded to Newsstream.

10-1-17

I searched the Newspaper Source database, but it did not yield much other than seminar or software promotions.

10-2-17

WestLawNext appears to be malfunctioning. I am able to type search terms but when I click search nothing happens. This has happened on different days and attempts. I am removing the database from my list.

10-7-17

I found the Access Newspaper Archive database not to be useful and removed it from my list. It pulls entire newspapers when locating a search term.

11-2-17

As I am going through testimony, I am recognizing names after repeated appearances. Lawmakers also appear to know people who are testifying.

11-12-17

I continued to do coding via colors. I am still deciding whether or not to use the colors (for groups) as my initial codes.

12-22-17

I started to set up an Access database with a primary key (article #) as a record keeping tool. It will also serve as a relationship link to the forthcoming coding database.

1-20 and 1-21-18

I noticed that in document # 8 that people who testified appeared to be invited and/or had ties to the politicians. The tone of the hearing was friendly but pointed with repeat guests (witnesses).

1-27 and 1-28-18

In terms of stakeholders, privacy advocates seem to cycle through a particular organization and move to other organizations or law schools.

2-12 through 2-15-18

I made another attempt at reviewing stakeholder blogs for usable information or data. Again, the blogs had generic entries without opinions, or they were started after the timeframe of interest.

2-19-18

I reflected on the subquestions. The response for Subquestion 1 is likely to involve testimony, use of press, and comment submission. For Subquestion 2, collaboration may be difficult to address. Direct collaboration is really not mentioned. For Subquestion 3, it looks like lack of civil monetary penalties did contribute to the shift, a private right of action is also a topic.

2-24-18 and 2-25-18

I started focused coding and assigned a color code to each subquestion. I also wrote down overall ideas and thoughts.

2-26 and 2-27-18

I am recognizing information is not what I originally thought would appear. For example, there are numerous references to consequences other than fines.

3-2-18

I decided to create an extra coding table for Subquestion 3 so that I can investigate/explore penalty options not dealing with fines.

3-11-18

I rediscovered an article that I forgot about in the back of a binder. The article listed HIPAA's influential people. I went back and coded the article since I found it during my article searches. Some names were very familiar then I remembered I had put the article aside to read last, because I was cognizant of potential bias. I also have two additional news articles supporting a point/theme under Subquestion 1.

4-4 through 4-6-18

I worked through the subquestions by completing a "thought" page for each. The pages are for reflection, tracking, and clarity. The pages also layout how the themes will be presented with special attention paid to Subquestion 1 since I will not include names.

4-14 and 4-15-18

I made decisions regarding the presentation of theme pairings.

4-19-18

I continued to place extracts into the Chapter 4 outline. I also reflected on the writing process especially how to integrate the novel narrative. I realized that the original enforcement approach was not “killed” but hidden/disguised behind HITECH. So was the hearing/testimony merely “theatrics” to divert attention for voluntary compliance could be placed in “witness protection”.

4-20-18

I finished placement of the extracts in the Chapter 4 outline. I want to have three to five extracts per point/theme/finding to help with conciseness.

5-2-18

I completed chapter 4 and wrote Chapter 5.

## Appendix H

### Possible Inspiration for the Privacy Rule

This supplemental information originally was part of the historical background, but the section contains information that some readers may find interesting.

Concrete connections are present between the contents of Privacy and Freedom and the HIPAA Privacy Rule. The proposed Privacy Rule contains direct references to Westin and his book. One statement refers to how Westin (1967) examined the history of privacy. The writers of the proposed Privacy Rule stated that “(t)he multiple historical sources for legal rights to privacy are traced in many places, including Chapter 13 of Alan Westin’s “Privacy and Freedom” (Standards for Privacy, 1999, p. 60008). Another statement refers to Westin as a proponent of using good judgment regarding privacy protections. The writers of the proposed Privacy Rule also named Westin as a writer who “urged a philosophical or common-sense right to privacy in one’s personal information” (Standards for Privacy, 1999, p. 60008).

Parallels also exist in concepts that Westin (1967) presented and descriptions appearing in the HIPAA Privacy Rule. The first pairing concerns access to data in records. A person would be allowed to review the data in their file and question the correctness via a procedure along with offering a response that would be placed in their file (Westin, 1967). The text of the proposed Privacy Rule (1999) contains a similar description of a right to review documentation. The HHS secretary submitted recommendations to Congress regarding the protecting health information including the creation of procedures that permit people to access their records and ask for flawed information to be corrected (Standards for Privacy, 1999).

The second pairing pertains to a worker managing or mismanaging private information. Westin (1967, p. 325) advocated for the concept that the handling of private information “creates

special duties and liabilities on the information utility or government system handling it.” The HHS secretary’s recommendations addressed guarding data against misuse. Individuals possessing private information be mandated to protect the material against improper use or release (Standards for Privacy, 1999). The recommendations also addressed responsibility and handling violations. Individuals who utilize protected information should be made responsible for their management of the data, and individuals affected by mismanagement should have legal remedies available (Standards for Privacy, 1999).

The final pairing concerns designating an authorized agency and how that agency approaches privacy infractions, Westin (1967, p. 325) suggested that the “review of these information systems should be set up in an independent regulatory agency with an ombudsman-type character: a watchdog agency.” Even though OCR focuses on reviewing the activities of covered entities rather than information systems, the functions are the same: “The Office of Civil Rights (OCR), located at the Department of Health and Human Services, has the primary responsibility to monitor and audit covered entities” (Standards for Privacy, 1999, p. 60018). Once the agency receives the authority to enforce the established protections, the agency must implement enforcement procedures including punitive options. Westin (1967, p. 325) also suggested that penalties for infractions should consist of “the usual criminal penalties, damage actions, and injunctions.” The writers of the proposed Privacy Rule outlined the enforcement duties that OCR will have: “OCR will be required to recommend penalties and other remedies as part of their enforcement activities” (Standards for Privacy, 1999, p. 60018).