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HEALTH CARE QUALITY REPORTING: A FAILED FORM OF MANDATED DISCLOSURE?

Kristin Madison*

When I received an invitation to participate in a symposium sponsored by the Hall Center for Law and Health and the *Indiana Health Law Review*, I was delighted to discover that it would include a decision-making and transparency panel. Having written numerous articles discussing law and policy issues related to health care quality reporting,[1] it seemed obvious that my role on the panel

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[1] *See, e.g.,* Kristin Madison, *Regulating Health Care Quality in an Information Age*, 40 U.C. DAVIS L. REV. 1577 (2007); Kristin Madison, *The Law and Policy of Health Care Quality Reporting*, 31 CAMPBELL L. REV. 215 (2009) [hereinafter, *Quality Reporting*]; Kristin Madison, *Legal &*

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should be to comment on the influence of quality metrics on patient decision-making. Just two years before, I had published an article that discussed recent trends in health care quality measurement and reporting and offered an optimistic view of how these trends might benefit patients in the future.[2] The symposium would offer an opportunity to further expand on these thoughts. But the official symposium topic, "medical myths," seemed to point in a different direction. If the goal of the symposium was to encourage challenges to commonly held beliefs, then perhaps I should re-examine my own.

A critical examination of quality reporting as a policy tool seemed particularly appropriate in light of a provocative article[3] and related recently-published book[4] proclaiming the failure of mandated disclosure. Surveying the vast landscape of mandated disclosure policies, Professors Omri Ben-Shahar and Carl E. Schneider acknowledge that "mandated disclosure addresses a real problem and rests on a plausible assumption," but argue that "it chronically fails to accomplish its purpose" and that "[e]ven where it seems to succeed, its costs in money, effort, and time generally swamp its benefits."[5] Quality reporting is one of the many types of disclosure mandates the authors scrutinize. Consumer-directed health care, for example, is a "bounteous fount of mandated disclosure" because it depends on access to reliable information about cost and quality.[6] Provider report cards are discussed in an article section entitled "The Failures of Other Mandated Disclosures."[7]

The claim that mandated disclosure is a failure calls into question policy makers' long-standing commitment to public

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Policy Issues in Measuring and Improving Quality, in THE OXFORD HANDBOOK OF U.S. HEALTHCARE LAW (I. Glenn Cohen, Allison K. Hoffman & William M. Sage eds., March 2016).

[2] Kristin Madison, *Donabedian's Legacy: The Future of Health Care Quality Law & Policy*, 10 IND. HEALTH L. REV. 325 (2013).

[3] Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PA. L. REV. 647 (2011).

[4] OMRI BEN-SHAHAR & CARL E. SCHNEIDER, MORE THAN YOU WANTED TO KNOW: THE FAILURE OF MANDATED DISCLOSURE (2014).

[5] Ben-Shahar & Schneider *supra* note 3, at 651.

[6] *Id.* at 661.

[7] *Id.* at 672-74.

reporting of provider quality. Was Pennsylvania's 1986 legislation mandating extensive quality reporting pointless or even harmful?[8] Was the federal government's 2005 release of hospital quality ratings a waste of time?[9] Was a 2015 Center for Medicare and Medicaid Services press release announcing an expansion of quality reporting initiatives clearly mistaken when it stated "[t]his large release of quality measures for hospitals and physicians empowers consumers with information to make more informed health care decisions, encourages health care professionals to strive for higher levels of quality, and drives overall health system improvement?"[10] Should we abandon the federal website that reveals how often hospital nurses communicated well[11] and how often surgery patients were given antibiotics at the right time?[12] Should the federal government decline to publish information about hospital heart attack patient mortality,[13] nursing home deficiencies,[14] and nursing home staffing?[15]

It is not entirely clear how Ben-Shahar and Schneider would answer these questions. On one hand, their analysis leaves room for the possibility that quality reporting yields benefits. While emphasizing that mandated disclosure

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[8] Kristin M. Madison, *From HCQIA to the ACA: The Evolution of Reporting as a Quality Improvement Tool*, 33 J. LEGAL MED. 63, 73-74 (2012).

[9] *Id.* at 79.

[10] Press Release, Ctrs. for Medicare & Medicaid Servs., CMS Expands Quality Data on Physician Compare and Hospital Compare to Help Consumers Choose Health Care Providers (Dec. 10, 2015) *available at* https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-12-10.html [https://perma.cc/7GGU-2KL7].

[11] *What Information Can I Get About Hospitals?,* MEDICARE.GOV, https://www.medicare.gov/hospitalcompare/About/Hospital-Info.html [https://perma.cc/H93E-K8JK] (last visited May 26, 2016).

[12] *Id.*

[13] *Id. Readmissions and Deaths*, MEDICARE.GOV https://www.medicare.gov/hospitalcompare/About/RCD.html [https://perma.cc/55UM-XBN8] (last visited May 26, 2016).

[14] *What Information Can I Get About Nursing Homes?,* MEDICARE.GOV, https://www.medicare.gov/NursingHomeCompare/About/Nursing-Home-Info.html. [https://perma.cc/5RNW-PYL4] (last visited Mar. 3, 2016).

[15] *Id.*

"routinely fails," they say that it is not doomed to do so,[16] that "*[m]any* studies show some improvements" in disclosees' understanding, and that they have "never argued . . . that all disclosures fail."[17] In the context of report cards, Ben-Shahar and Schneider acknowledge the existence of "evidence of some success in using disclosures to help people identify superior hospital care."[18] On the other hand, frequent health care examples illustrate the many limitations and pitfalls of quality reporting as a policy tool. The authors note that many people do not use report card information.[19] They reference studies that suggest that quality report cards may produce harmful gaming and ultimately reduce welfare.[20] The skepticism inherent in their thesis could easily extend to quality reporting.

So should I temper my past optimism about reporting's potential effects? At the risk of being called a "disclosurite," a label Ben-Shahar and Schneider apply to commentators who favor disclosure,[21] I remain guardedly optimistic. Their work imparts valuable lessons and certainly offers food for thought for disclosurites of all sorts. The book's sensible arguments and voluminous evidence cutting across a broad range of regulatory areas should lead readers to question the advisability of mandated disclosure as a regulatory strategy. At the same time, however, the broad sweep of their work constrains their ability to offer comprehensive assessments of the advisability of particular disclosure policies, leaving readers to wonder whether there are exceptions to the authors' general claim, and if so, what form they might take.

In this essay, I explore the possibility that quality reporting might be just such an exception. I find cause for optimism, in that evidence suggests quality reporting can make a difference. At the same time, however, the exercise reveals just how difficult assessing the success of a particular mandate can be.

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[16] BEN-SHAHAR & SCHNEIDER, *supra* note 4, at 6.

[17] *Id.* at 47, 118.

[18] *Id.* at 52. They are also mindful of the possibility that health plans could make good use of report cards; they characterize disclosure to intermediaries as "more sensible than the present system." *Id.* at 188.

[19] *Id.* at 64-65.

[20] *Id.* at 52-53.

[21] *Id.* at 6.

Part I of this essay explains why Ben-Shahar and Schneider believe that mandated disclosure fails. After conceding that health care quality reporting suffers from many of the problems they have identified, Part I explains why a closer look at the potential impact of health care quality reporting is nonetheless required.

Part II considers the purposes and potential benefits of mandated disclosure. At various points in their book, Ben-Shahar and Schneider offer a quite narrow view of the objectives that disclosure mandates are intended to achieve. In some cases, this view may accurately capture regulators' goals. Part II argues, however, that the policy objectives of governmental quality reporting initiatives are significantly broader than the goal at the heart of Ben-Shahar's and Schneider's analysis. As Professor Richard Craswell has pointed out,[22] a multiplicity of goals will inevitably complicate efforts to assess whether a disclosure mandate has succeeded or failed.[23]

Part III examines the costs of mandated disclosure, including both the financial costs of complying with mandates and the costs associated with mandates' unintended effects. It finds that the costs of quality reporting are conceptually challenging to assess because these costs also support other benefit-producing activities. Part III therefore emphasizes the importance of thinking about costs and benefits of disclosure mandates against the backdrop of a broader and ever-changing group of policy interventions.

Part IV briefly considers the question that Ben-Shahar and Schneider leave for the last chapter of their book: what should replace mandated disclosure? They describe ways in which information could reach marketplaces even in the absence of disclosure mandates. They also contemplate the possibility of command-and-control forms of regulation. The points they make are good ones. However, an attempt to apply their analysis to the context of quality reporting shows that the issues involved may be more complex than they first appear.

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[22] Richard Craswell, *Static Versus Dynamic Disclosures, and How Not to Judge Their Success or Failure*, 88 WASH. L. REV. 333, 337-40 (2013).

[23] *Id.*

Part V concludes by calling for the development of a framework that lays out key characteristics of disclosure mandates and the environments in which they operate, so that we can develop a better understanding of the characteristics associated with mandate success.

I. THE FAILURES OF MANDATED DISCLOSURE

In their book, *More Than You Wanted to Know: The Failure of Mandated Disclosure*, Professors Omri Ben-Shahar and Carl E. Schneider describe many situations in which individuals or entities are legally obligated to disclose some kind of information.[24] Lenders must provide information about their loans to prospective borrowers; physicians must provide information about treatments to patients; food manufacturers must provide nutrition information; and the list goes on.[25] Policy makers clearly believe that disclosure mandates can provide *some* kind of benefit (more on this in Part II). The book's title suggests, however, that mandated disclosure fails. In this Part, I describe the reasoning underlying this claim, and show that many of the troubles that Ben-Shahar and Schneider identify do indeed plague health care quality reporting mandates. I nevertheless argue that it may not be appropriate to classify quality reporting mandates as a "failure," and explain why further analysis is required.

A. The Troubles of Mandated Disclosure

Ben-Shahar and Schneider lay out their basic claim in the introduction to their book. It is not a claim based on their own empirical research on the effects of the myriad mandates they describe. Instead, they present an argument based on their conception of how disclosure requirements are created and implemented and how the information that flows from requirements is used (or not used): "[m]andated disclosure fails because it depends on a long chain of fragile links. It works only if three actors – lawmakers, disclosers, and

[24] *See* BEN-SHAHAR & SCHNEIDER, *supra* note 4.

[25] *See id.* at 3-32 (discussing many types of disclosures).

disclosees – play demanding parts deftly."[26] Disclosure requirements must be well-crafted to solve problems that policy makers have accurately diagnosed.[27] In disclosing data, disclosers must act in ways fully consistent with the well-crafted requirements.[28] And disclosees must review and fully understand the information provided in order to act appropriately in response to it.[29] The argument is essentially that broken links lead to failed disclosure. Ultimately, "mandated disclosure seems plausible only on logically reasonable but humanly false assumptions."[30]

Ben-Shahar and Schneider support their argument with citations to many studies that provide empirical evidence of broken links.[31] The authors argue, for example, that individuals are often reluctant to make their own decisions, and may see little value in an extended deliberative process.[32] Studies show that consumers may devote little time to making a decision, and may reach a decision without making use of available information.[33] Studies documenting limited levels of literacy and numeracy give reason to doubt that people will understand disclosures. Studies of particular forms of disclosure confirm that such doubts are justified;[34] people may "misperceive, misinterpret, and misuse" disclosures.[35] Information overload may undermine decision-making.[36] Furthermore, putting information to good use may require background information that people lack.[37] Studies provide many examples of ways that bounded rationality can lead to poor decision-making.[38]

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[26] *Id.* at 7.

[27] *Id.*

[28] *Id.*

[29] *Id.* at 8-11.

[30] *Id.* at 10.

[31] *See* Craswell, *supra* note 22, at 351-54 for a description and critique of Ben-Shahar's and Schneider's analytical approach.

[32] BEN-SHAHAR & SCHNEIDER, *supra* note 4, at 62-64 (reluctance to make decisions); 70-77 (reasons people may choose not to make use of disclosures).

[33] *Id.* at 64-70.

[34] *Id.* at 80-86.

[35] *Id.* at 112.

[36] *Id.* at 104-106.

[37] *Id.* at 86-91.

[38] *Id.* at 110-12.

Moreover, disclosures may unduly focus attention in one area, leading disclosees to neglect other areas that may also be important to their decision.[39] And disclosers may respond in kind, acting in ways that make their mandated disclosures look good, but allowing their performance to deteriorate in areas that are not subject to reporting.[40] Reporting can lead to changes in behavior that make some intended beneficiaries of the disclosure mandate worse off.[41]

B. The Troubles of Quality Reporting

Many of the troubles that Ben-Shahar and Schneider aptly describe regularly arise in the world of quality reporting. Indeed, the authors use a number of report card-related studies to support their analysis. For example, they cite a study for its finding that relatively few patients sought out comparative information or even considered alternative providers of surgical services.[42] They cite a study that found that nursing homes improved in areas documented by report cards, but performed less well in other areas.[43] They cite a classic study showing that when hospital cardiac care report cards were implemented, sicker patients ended up worse off.[44] This study points to the possibility that entities seeking high scores may alter their conduct in ways that ultimately worsen patient care.

These are just a few of many studies of health care quality reporting that should caution any policy maker or policy analyst who favors quality reporting as a policy strategy. Many patients remain unaware of quality differentials or believe that their current provider is of high quality, so are

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[39] *Id.* at 175.

[40] *Id.* at 176.

[41] *Id.* at 179-80; *id.* at 52-53.

[42] *Id.* at 65, citing Lisa M. Schwartz et al., *How Do Elderly Patients Decide Where to Go for Major Surgery?*, 331 BMJ 821 (2005).

[43] *Id.* at 176, citing Susan Feng Lu, *Multitasking, Information Disclosures and Product Quality: Evidence from Nursing Homes*, 21 J. ECON. MGMT. STRATEGY 673 (2012).

[44] *Id.* at 179-80 (citing David Dranove et al., *Is More Information Better? The Effects of "Report Cards" on Health Care Providers*, 111 J. POL. ECON. 555 (2003)).

not motivated to seek out quality report cards.[45] Recent studies show that relatively few patients consult ratings. A 2012 survey of internet users found that about 17% had consulted online rankings or reviews of doctors or other providers, while about 14% had consulted rankings or reviews of hospitals or medical facilities.[46] A 2015 poll found that 10% of respondents had seen comparative quality information about doctors in the past year, and about 61% of those individuals had used it. About 13% had seen such information about hospitals, and about 35% of those individuals had used it.[47] There are also studies showing that individuals may misinterpret information on report cards.[48] The federal websites' move toward using quality "stars" and other simplified presentations of data is an acknowledgment of the overly complex nature of previous presentation formats.[49] And information overload continues to be a problem, although it is not necessarily inherent to government quality reporting mandates. The main problem instead arises from the many competing and sometimes conflicting sources of quality information available through many different websites.[50]

As I have discussed elsewhere, there are also plenty of troubles associated with the content of report cards.[51]

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[45] *See Quality Reporting*, *supra* note 1, at 227.

[46] Susannah Fox & Maeve Duggan, Health Online (2013), *available at* http://www.pewinternet.org/~/media//Files/Reports/PIP_HealthOnline.pdf [https://perma.cc/9C8L-PRXJ].

[47] *Kaiser Health Tracking Poll: April 2015,* KAISER FAMILY FOUND. 12-13 (Apr. 2015), http://files.kff.org/attachment/topline-methodology-kaiser-health-policy-news-index-april-2015 [https://perma.cc/6FYT-47D9].

[48] *See Quality Reporting*, *supra* note 1, at 227, and sources cited therein (exploring difficulties in report card interpretation).

[49] *See Home Health Star Ratings*, CMS.GOV, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-instruments/HomeHealthQualityInits/HHQIHomeHealthStarRatings.html [https://perma.cc/F5AV-PUDQ] (last visited May 26, 2016) (explaining reasons for addition of star ratings).

[50] *See, e.g.,* Michael B. Rothberg et al., *Choosing the Best Hospital: The Limitations of Public Quality Reporting*, 27 HEALTH AFF. 1680 (2008), *available at* http://content.healthaffairs.org/content/27/6/1680.full.pdf+html [https://perma.cc/EM3R-7YS5].

[51] *See Quality Reporting*, *supra* note 1, at 227-36.

Measure selection is often driven by data availability and other practical considerations, which means that the quality measures reported may not provide the information that consumers care about most. Problems with measure design and data collection can mean that measures fail to reflect true quality. While consumers may be interested in data about individual physicians, the relatively limited number of patients each physician sees presents significant statistical challenges for quality measurement.. Commentators regularly highlight the difficulties in providing accurate information about provider quality.[52]

C. The Need to Look Beyond the Troubles

Commentators have pointed out the numerous flaws in quality reporting for many years,[53] and calls to improve upon quality measurement and reporting initiatives are frequent.[54] Despite all of these shortcomings, however, I still cling to the possibility that mandated quality reporting might not be a failure.

I confess that my optimism is driven in part by an intuition that Ben-Shahar and Schneider contest: that the somewhat flawed data produced through mandates is better than no data or the bad data that might otherwise fill the information void. It is mostly driven, however, by the belief that some users value the data, coupled with the knowledge

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[52] *See, e.g.*, Steven Findlay, *Health Policy Brief: Physician Compare*, HEALTH AFF. (Oct. 29, 2015), *available at* http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_146.pdf [https://perma.cc/C3X9-N5NL] (describing the challenges in developing the federal physician rating website); Lisa Rosenbaum, *Scoring No Goal – Further Adventures in Transparency*, 373 NEW ENG. J. MED. 1385 (2015), *available at* http://www.nejm.org/doi/pdf/10.1056/NEJMp1510094 [https://perma.cc/48YW-2Z49] (describing statistical limitations involved in assessing physician quality).

[53] *See, e.g.*, Timothy Stoltzfus Jost, *Oversight of the Quality of Medical Care: Regulation, Management, or the Market?,* 37 ARIZ. L. REV. 825, 851-55 (1995) (discussing challenges of creating well-structured report cards).

[54] *See, e.g.*, Elizabeth A. McGlynn & John L. Adams, *What Makes a Good Quality Measure?*, 312 JAMA 1517 (2014) (calling for creation of "a clear framework and expectations for the intended goals of quality measures").

that quality reporting can sometimes make a difference. More than half of the respondents to a 2015 survey indicated that "[m]aking information comparing the quality of health care provided by doctors and hospitals more available to patients" was a "top priority."[55] *Health Affairs* articles that have caught my eye include *Public Reporting Drove Quality Gains at Nursing Homes*[56] and *Public Reporting Helped Drive Quality Improvement in Outpatient Diabetes Care Among Wisconsin Physician Groups.*[57] Other articles with less descriptive titles also suggest that report cards may influence health care delivery.[58]

Perhaps I am overly optimistic about reporting's potential. Given my previous work in this area, I may suffer from confirmation bias. I may accord too much weight to studies finding that report cards have an effect, particularly if journals are more inclined to publish studies showing statistically significant results. But studies like these do give me reason to believe that mandated reporting could at least potentially benefit patients, which raises the question: does it? Or, to be more precise, do the benefits associated with mandated quality reporting exceed its costs?

In their book, Ben-Shahar and Schneider seem to call for investigation of this very question: "[t]he harmlessness hypothesis needs to go; the cost-benefit analysis that has become a norm for regulation should come."[59] They do not undertake such an analysis in their book, however. Perhaps they decline to follow through on their suggestion because the broad scope of the book does not allow for detailed

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[55] *Kaiser Health Tracking Poll Topline: April 2015*, KAISER FAMILY FOUND. 6 (Apr. 2015), http://files.kff.org/attachment/topline-methodology-kaiser-health-policy-news-index-april-2015. [https://perma.cc/NF55-7X2Z].

[56] Rachel Werner et al., *Public Reporting Drove Quality Gains at Nursing Homes*, 29 HEALTH AFF. 1706 (2010).

[57] Maureen A. Smith et al., *Public Reporting Helped Drive Quality Improvement in Outpatient Diabetes Care Among Wisconsin Physician Groups*, 31 HEALTH AFF. 570 (2012).

[58] *See, e.g.,* M. Kate Bundorf et al., *Do Markets Respond to Quality Information? The Case of Fertility Clinics*, 28 J. HEALTH ECON. 718 (2009); Justin Wang et al., *Do Bad Report Cards Have Consequences? Impacts of Publicly Reported Provider Quality Information on the CABG Market in Pennsylvania*, 30 J. HEALTH ECON. 392 (2011).

[59] BEN-SHAHAR & SCHNEIDER, *supra* note 4, at 182.

examinations of particular areas of disclosure. Or perhaps they believe that the gains from disclosure are so low, and the costs so high, that careful analysis is not needed to conclude that mandated disclosure is a failure. Or perhaps a full cost-benefit analysis is just not feasible, given the current state of the data.

But even if the data proves to be lacking, a preliminary investigation could help clarify the issues to be addressed in a fuller analysis. In the remainder of this essay, I will describe key benefits and costs of mandated reporting, and explain why I am not yet convinced that mandated quality reporting is a failure, despite all of its troubles.

II. THE GOALS OF MANDATED DISCLOSURE

To determine whether any mandate has succeeded or failed, it is important to first clarify what the mandate intended to achieve. In the words of Professor Craswell, "we cannot evaluate the success or failure of any disclosure law without considering the possible goals that law might have had."[60] While Professors Ben-Shahar and Schneider acknowledge many potential benefits of properly functioning disclosure laws, much of their analysis implies that policy makers' typical goal in enacting disclosure laws is fully informed decision-making by disclosees. This Part argues that while informed decision-making is surely one goal of quality reporting mandates, it is not the only one, and that any assessment of the impact of quality reporting should take this reality into account.

A. Failure to Do What, Exactly?: The Goals of Mandated Disclosure

At one level, the goal of mandated disclosure laws is obvious: it is to ensure the availability of the mandated information. But to what end?

Professors Ben-Shahar and Schneider offer one possible answer in the introduction to their book: mandated disclosure "aspires to help people making unfamiliar and complex decisions while dealing with specialists by requiring

[60] Craswell, *supra* note 22, at 334.

the latter (disclosers) to give the former (disclosees) information so that disclosees choose sensibly and disclosers do not abuse their position."[61] This framing of the issues focuses on the informational advantage that disclosers possess, the possibility that disclosers might exploit this advantage, and the desire to ensure that disclosees make decisions that make sense. Other comments in the book focus more on informing choice than on forestalling exploitation, although clearly the concepts are related. In describing how the success of a disclosure mandate might be assessed, Ben-Shahar and Schneider provide a number of citations that support a view that the "conventional disclosurite understanding" is that a successful mandate will "provid[e] information that equips disclosees to understand their choice well enough that they analyze it and make a well-informed, well-considered decision."[62] They suggest that disclosurites often look for "full disclosure."[63]

Passages scattered throughout the book provide a more nuanced look at the goals of mandated disclosure laws, as illustrated by the writings of a variety of authors. These alternative descriptions of the functions and aims of disclosure mandates are not necessarily inconsistent with an overarching goal of well-considered decisions (or sensible choices). They do, however, focus on different ways that information may be relevant to the decision-making process. For example, in describing the goals of informed consent, Ben-Shahar and Schneider mention the ideas of sovereignty, patient control, and autonomy, in addition to rationality.[64] They subsequently make a connection between the "autonomy rationale" for disclosure and "dignity," and note that "[s]ome disclosurites believe that giving people disclosures honors disclosees' autonomy whatever its effect on their decisions."[65] In describing the varied functions of different types of mandates, they suggest that "[d]isclosures seek to facilitate, to persuade, and to educate," and that

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[61] BEN-SHAHAR & SCHNEIDER, *supra* note 4, at 3.
[62] *Id.* at 34.
[63] *Id.* at 35.
[64] *Id.* at 34-35.
[65] *Id.* at 36.

"[s]ome disclosures seek more to persuade than inform."[66] Later, in discussing requirements that drug companies disclose payments to physicians, they mention an aim of "accountability."[67]

This short list of brief passages gives a sense of the considerable challenges of attempting to provide a global assessment of the impact of mandated disclosure laws. If the goal of mandated disclosure is ensuring autonomy, then the question is how much disclosure is necessary to ensure autonomy. If the goal is instead persuasion, then providing full information may not be necessary and may indeed be counterproductive. If the goal is accountability of the discloser, then the question becomes accountability to whom for what, and the focus of the analysis may begin to shift away from the details of the disclosee's decision-making process.

The difficulties of assessing success become even clearer when examining particular mandates. Everyone may agree that the point of nutrition labeling is to provide the information necessary for consumers to choose wisely. But what does this mean? Choosing wisely could mean that consumers weigh the nutritional information along with the price of the food, the taste of the food, and a host of other characteristics in deciding what to eat. This would certainly be consistent with the authors' "well-considered" decision-making frame, an orientation toward full disclosure, and the views of many commentators. But the quote the book supplies suggests a different end goal: a reduction in mortality.[68]

Full disclosure might be consistent with a mortality reduction goal, and well-considered decisions may help achieve the goal. An evaluation of whether labeling succeeds in reducing mortality might look quite different, however, from an evaluation of the impact labeling has on fully-informed decision-making. For one thing, if the goals of policy makers and individual consumers do not align, then fully-informed decision-making will not yield the desired results. If consumers place a high value on a tasty diet, a

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[66] *Id.* at 28, 30.

[67] *Id.* at 147.

[68] *See id.* at 39 (quoting from another author's discussion of nutrition labeling).

study could show that consumers are perfectly informed but that the disclosure mandate is a "failure" from a policy perspective. More importantly, disclosure might reduce mortality even if it falls short of ensuring fully informed decision-making. Labeling might lead to fully informed, well-considered decisions that alter consumption patterns and reduce mortality. But it might instead lead to more consumer focus on nutritional quality and somewhat more informed decision-making, which together prod manufacturers to reformulate their products, reducing mortality.

In his essay, Professor Craswell highlights the importance of distinguishing between "static" and "dynamic" disclosures in assessing the success of disclosure mandates. The goal of a static disclosure is to "improve a consumer's choice from among the existing choice set," while the goal of dynamic disclosures "is to improve the existing choice set by creating incentives for sellers to improve the quality of offerings."[69] Craswell's analysis makes clear that the proper approach to assessment will depend on the nature and purpose of the disclosure. To evaluate the success of static disclosures, Craswell suggests examining consumer beliefs; to evaluate the success of dynamic disclosures, Craswell suggests a focus on the average quality of the product in the marketplace.[70] It may be that one reasonable way of

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[69] Craswell, *supra* note 22, at 334. Under Craswell's model, the goal of static disclosure is to bring the consumer's assessment of quality closer to the true quality, *id.* at 342, which in turn will ensure that the consumer purchases the right quantity of a particular brand. By contrast, the goal of dynamic disclosure is to "improve the mix of products that is available on the market." Sellers have a proper incentive to improve their product only if changes in consumers' assessment in quality are commensurate with sellers' actual improvement; the goal of dynamic disclosures is thus basically to ensure that sellers get full credit, nothing more, and nothing less, for their improvements. *Id.* at 343-44. If disclosures achieve perfect information in the marketplace, they will serve both functions, *id.* at 344, but reality falls short of perfection.

[70] Craswell, *supra* note 22, at 345-350 (assessing static disclosures); *id.* at 354-72 (assessing dynamic disclosures). As an example of an assessment of dynamic disclosures, Craswell suggests an examination of changes in the relative market shares of high-fat salad dressings and low-fat dressings. *Id.* at 358-59. Such changes in market share, however, could result from multiple phenomena. First, if most consumers would

evaluating the success of the informed consent process is by assessing patients' understanding of available treatment options; an evaluation of nutrition labeling may benefit from a different focus.

In sum, Professors Ben-Shahar and Schneider highlight a view that the core goal of mandated disclosure is well-informed, well-considered decisions, and demonstrate that

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prefer to avoid fat but cannot estimate fat content, leading them to buy too many high-fat dressings, ratings that correct misperceptions will increase their purchases of low-fat dressings, while higher-fat dressings remain on the shelf. Second, if consumers accurately estimate fat content but usually ignore it, labeling could draw their attention to this attribute, a phenomenon that would also lead to more purchases of low-fat dressings. In both cases, product mix will change without any manufacturer intervention, although presumably lower levels of consumer demand would eventually lead them to shut down their high-fat production lines. Third, in anticipation of increased demand for low-fat products from better-informed or more motivated consumers, producers might reformulate all of their products to be lower in fat, thus increasing market share for low-fat products. Even consumers who pay no attention to fat levels would end up buying low-fat dressings, further boosting low-fat market shares. A fourth possibility is that manufacturers will try to take advantage of consumer attention to salad dressings and their fat content by introducing new products in a way that both expands consumer choice sets and shifts market share toward low-fat products.

I would argue that the first phenomenon seems consistent with Craswell's static disclosure model, while the third is the closest match to the dynamic disclosure model; the second phenomenon seems outside both models, and I am not sure how the fourth is best conceptualized. The effects of all four phenomena, however, are dynamic in nature, since they will ultimately alter product mix in the marketplace.

The difficulty of developing cleanly-defined categorizations of disclosure mechanisms and their effects is apparent in quality reporting as well. The theoretical literature on quality reporting talks about "selection" pathways, where quality increases because patients abandon low-quality providers in favor of higher quality providers, and "change" mechanisms, where quality increases because existing providers improve their own quality. *See* Damien Contandriopoulos, Francois Champagne & Jean-Louis Denis, *The Multiple Causal Pathways Between Performance Measures' Use and Effects*, 71 MED. CARE RES. AND REV. 3, 7 (2013) (discussing causal pathways). These scholars observe that "[f]rom a systemic perspective," these two pathways are not always cleanly distinguishable: "the reallocation of resources toward high performers and the eventual closure of underperforming units would probably be construed as change, while, from the perspective of individual units, it amounts to selection." *Id.* at 8.

many commentators see full disclosure as ideal. Their book also makes clear, however, that mandated disclosures vary quite widely in nature and content, and can encompass a broader set of functions and goals. In evaluating the success or failure of a disclosure mandate, it is important to consider the benefits that policy makers hope to achieve.

B. The Goals of Quality Reporting

So what goals might a policy maker who mandates quality reporting seek to achieve, and what are the mechanisms by which reporting may achieve its goals?

In a 2015 press release announcing an update to its health care quality report cards, the Centers for Medicare and Medicaid Services (CMS) explicitly lays out multiple aims: "[t]his large release of quality measures for hospitals and physicians empowers consumers with information to make more informed health care decisions, encourages health care professionals to strive for higher levels of quality, and drives overall health system improvement."[71] The first aim, informed decision making, nicely illustrates the theme that Professors Ben-Shahar and Schneider emphasize. It is consistent with a general goal of ensuring patient autonomy. Patients will be able to understand the choices facing them more clearly, and so may be able to make decisions consistent with their own goals. The CMS formulation does not declare a goal of fully informed decisions, just more informed decisions, which perhaps serves as an implicit acknowledgment of the costs and/or impossibility of achieving a full information ideal.

The second and third aim seem more in line with the dynamic effects that Professor Craswell emphasizes. CMS asserts that quality reporting will alter the effort that providers devote to achieving health care quality; this could be described as an instrumental aim intended to achieve an ultimate goal of boosting quality. And "driv[ing] overall health system improvement" could be described as CMS' overall objective in implementing the quality reporting program.[72]

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[71] Press Release, Ctrs. for Medicare & Medicaid Servs, *supra* note 10.
[72] *Id.*

In theory, quality reporting programs could generate a number of desired effects that would culminate in "overall health system improvement." First, the very existence of quality reporting could bring quality issues to consumers' attention. Quality expert David Eddy has suggested that historically, it was assumed that "through the rigors of medical education, followed by continuing education, journals, individual experiences, and exposure to colleagues, each physician always thought the right thoughts and did the right things."[73] If consumers believe that providers think the right thoughts and do the right things, there is little reason for them to seek quality-related information, even if they value quality highly. A survey suggests that many consumers do not believe there are "big differences" in quality across providers.[74] If consumers believe that "big differences" are the only ones worth looking into, and if in fact there are differences that meet consumers' definitions of "big," then the policy argument for focusing consumers' attention on quality is stronger. In such cases, quality reporting could result in more fully informed decision making that allows consumers to pursue their own quality-related aims.

Second, quality reporting could improve average levels of quality by redirecting the flow of patients to higher quality providers. Patients could visit quality reporting websites and use the available information to select high-quality providers, a mechanism consistent with the basic model that Ben-Shahar and Schneider present. For this mechanism to work, measures must be accurate and consumers must understand and appropriately act on them.

Alternatively, other entities could use the data provided in public quality reports to direct patients to higher-quality providers. For example, an insurer might exclude a poorly-rated provider from a network or provide a financial incentive to the patient to choose a more highly-rated provider. Ben-Shahar and Schneider highlight the potential role that intermediaries might play in ensuring that

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[73] David M. Eddy, *Evidence-Based Medicine: A Unified Approach*, 24 HEALTH AFF. 9, 9 (2005).

[74] *Quality Reporting*, *supra* note 1, at 227 n.61.

consumers reap the benefit of disclosures, even in the absence of full information.[75]

Third, quality reporting could improve average levels of quality by altering provider behavior. Again, there are several possible mechanisms through which this effect could occur. One is competition: if patients seek matches to more highly-rated providers, and treating patients is profitable, then profit-seeking providers have reason to try to obtain higher ratings. Note that this effect does not depend on the reason for which patients end up at the doorstep of more highly-related providers; all that matters is that they do (or, more precisely, that providers believe they will).

Another possible mechanism through which reporting could alter provider practices is reputation; physicians and hospitals may seek to be recognized for providing higher quality care.[76] Public reporting could potentially motivate such providers to do better, regardless of the financial consequences that follow from any changes they make. This mechanism requires that public reporting channel information to individuals or entities whose views providers care about; providers might worry about the views of their own patients, but they could also be motivated by information that flows to other providers or to the general public through reporting processes.[77]

Some of these mechanisms require that patients review and understand data, but others do not. Studying whether patients acquire, understand, and use data makes sense if

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[75] BEN-SHAHAR & SCHNEIDER, *supra* note 4, at 188 (discussing intermediaries).

[76] Public reporting could also alter provider practice by supplying information about each provider's own performance as well as the performance of top providers. Providers could use this information to identify areas in need of improvement, to identify other providers potentially worthy of emulation, and to track improvement in the aftermath of efforts to improve quality. I relegate these quality improvement mechanisms to the footnotes because it is mostly quality measurement and private reporting that are important for taking these steps, not public reporting.

[77] A third, perhaps less likely mechanism, is that patients may place direct pressure on providers to improve quality. A patient aware of a provider's high infection rates might become especially vigilant about provider handwashing practices, for example. Patients could also become more vigilant about their own handwashing practices, which could also result in better health outcomes.

one of the goals of information provision is patient autonomy; it also makes sense as an assessment of whether patient-based quality improvement mechanisms have any hope of succeeding. But other tests are also available to determine whether reporting mandates at least have the potential to succeed in improving quality; for example, studies could examine whether providers undertake efforts to improve quality in response to quality rating. And then there is the most direct route to studying whether reporting succeeds in driving improvement: examining the empirical relationship between reporting and quality.

C. The Benefits of Quality Reporting

There are actually quite a few studies that have examined quality reporting. They vary considerably in the type of reporting examined, the time period considered, the methodology used, and the overall quality of the analysis. My goal in examining a few of these studies is not to provide a comprehensive review, but instead to convey a sense of the data on which an evaluation of the success or failure of reporting could be based.

As discussed in Part I.B, surveys suggest that some patients use quality data. These same surveys demonstrate, however, that many patients do not. According to the previously mentioned 2015 survey, about six percent of respondents used comparative quality data about physicians.[78] If the goal is to improve patient autonomy or ensure well-informed decisions, is this finding an indication of success or failure? It's actually hard to say. Some survey respondents might not have had a need for physician care, and so were never faced with a decision about the identity of their provider. Such individuals should surely be excluded from an analysis of whether patients use quality information. Others might have seen a provider, but never even considered the possibility of an alternative provider. It might be argued that these patients should be excluded too, since they did not view themselves as making a decision; alternatively, it might be argued that they should be included, on the grounds that it is important to consider

[78] KAISER FAMILY FOUNDATION, *supra* note 46, at 13.

provider quality whenever an individual seeks treatment. Furthermore, even if all individuals are included in the analysis, it could be argued that physician report cards succeeded because they were used by the six percent. There is no obvious place to draw a line between "success" and "failure" when examining a metric like this in isolation;[79] what matters most is whether a reporting initiative achieves its ultimate goals.

In short, a few patients actively use report cards, but only a few. If the expectation is that autonomy requires every patient to be fully informed about physician quality at every patient encounter, then reporting could be deemed a failure in this respect. In my view, however, this is not a reasonable standard, and, more importantly, quality improvement, not autonomy, is the primary goal of reporting. From a quality improvement perspective, data suggesting low report card use rates should temper expectations about the impact report cards can have through patient choice-based mechanisms. It is important to look beyond patient survey data, however, to assess the aggregate effect of report cards on care delivery.

Many studies have done just that.[80] Studies examining whether report cards channel patients to higher-quality providers have found mixed results with respect to a variety

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[79] *See* Craswell, *supra* note 22, at 339, 348 (pointing out the indeterminacy of the line between success and failure).

[80] *See* David Dranove, *Health Care Markets, Regulators, and Certifiers*, *in* 2 HANDBOOK OF HEALTH ECON. 639, 681 (Mark V. Pauly, Thomas G. McGuire, & Pedro Pita Barros eds., 2012) (summarizing empirical studies of report cards effects); Constance H. Fung et al., *Systematic Review: The Evidence That Publishing Patient Care Performance Data Improves Quality of Care*, 148 ANNALS INTERNAL MED. 111 (2008) (providing a systematic review of quality report card studies); Dana B. Mukamel et al., *Top-Down and Bottom-Up Approaches to Health Care Quality: The Impacts of Regulation and Report Cards*, 35 ANN. REV. PUB. HEALTH 477, 486 (2014) (reviewing empirical studies of report cards from 2006 or later); Agency for Healthcare Research and Quality, *Executive Summary, Public Reporting as a Quality Improvement Strategy, Closing the Quality Gap: Revisiting the State of the Science*, Evidence Report No. 208 (2012), *available at* https://effectivehealthcare.ahrq.gov/ehc/products/343/1198/Evidencereport208_CQG-PublicReporting_ExecutiveSummary_20120724.pdf [https://perma.cc/4T8L-NH2R] (summarizing results of multiple report card studies).

of providers, including hospitals, physicians, and nursing homes. Most of these studies do not examine the specific mechanisms for this selection effect, but instead the relationship between reporting and treatment by providers with high quality ratings. For example, one study found that voluntary California bypass surgery report cards increased volume at hospitals with low mortality,[81] while another found that Pennsylvania's mandated bypass surgery report cards reduced the patient volume of poorly rated surgeons.[82] A study of report cards on fertility clinics found that clinics with higher birth rates obtained larger market shares after report card adoption.[83] A study examining patient nursing home choice before and after the release of federal nursing home report cards found a statistically significant relationship between reported quality and nursing home choice, but the effect was quite small.[84] A few studies looking at a variety of service types, report cards, and time periods failed to find an effect.[85] Given the quantity and quality of the studies that do find an effect, however, my conclusion is that it is likely that at least under some conditions, report cards can influence patients' choice of providers.

Recent hospital survey data suggests that providers respond to quality reporting initiatives. One study reports that "[f]or each of the mortality, readmission, process, and patient experience measures, more than 70% of hospitals agreed with the statement that 'public reporting stimulates quality improvement activity at my institution.'"[86] Furthermore, "87.1% of hospitals reported incorporating performance on publicly reported measures into their hospital's annual goals, whereas 90.2% reported regularly

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[81] Patrick S. Romano et.al., *Impact of Public Reporting of Coronary Artery Bypass Graft Surgery Performance Data on Market Share, Mortality, and Patient Selection*, 49 MED. CARE 1118 (2011).

[82] Justin Wang et al., *supra* note 58, at 392.

[83] M. Kate Bundorf et al., *supra* note 58.

[84] Rachel M Werner et al., *Do Consumers Respond to Publicly Reported Quality Information? Evidence form Nursing Homes*, 31 J. HEALTH ECON. 50, 59 (2012).

[85] *See* Mukamel et al., *supra* note 81 at 486 (documenting studies).

[86] Peter K. Lindenauer et al., *Attitudes of Hospital Leaders Toward Publicly Reported Measures of Health Care Quality,* 174 JAMA INTERNAL MED. 1904, 1907 (2014).

reviewing the results with the hospital's board of trustees and 94.3% with senior clinical and administrative leaders."[87] The evidence that public reporting alters hospital behavior is quite robust; this recent evidence adds to a number of other studies that have documented hospitals' responses to quality reporting.[88] Stimulating quality improvement activity, however, is only an intermediate goal of quality reporting; what matters is whether this activity translates into quality improvement.

Studies examining the relationship between report cards and quality have begun to accumulate. As is the case with provider selection studies, these studies do not generally try to isolate the mechanism by which reporting might have an effect, if indeed it does. Findings of these quality studies are mixed, but many studies have found a relationship between reporting and quality, and recent studies seem to have been more likely to find an effect.[89] For example, one empirical study used a differences-in-differences approach to compare treatment outcomes for Pennsylvania hospital patients with those of patients treated at hospitals subject to less intensive or no public reporting; the authors concluded that reductions in mortality were associated with intensive public reporting.[90] A very recent study using detailed clinical registry data to control for patient risk found that patients who underwent percutaneous coronary interventions (angioplasties) in states with mandated public reporting had lower mortality rates than patients in other states.[91] Another study found that for "two of three reported. . .

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[87] *Id.*

[88] *See, e.g.,* Mark R. Chassin, *Achieving and Sustaining Improved Quality: Lessons from New York State and Cardiac Surgery*, 21 HEALTH AFF. 40 (2002); Joanne M. Hafner et al., *The Perceived Impact of Public Reporting Hospital Performance Data: Interviews with Hospital Staff*, 23 INT'L J. FOR QUALITY IN HEALTH CARE 697 (2011); Mukamel et al., *supra* note 81, at 487 (discussing recent quality improvement studies).

[89] *See* Mukamel et al., *supra* note 81, at 488 (providing broad overview of recent studies).

[90] Christopher S. Hollenbeak et al., *Reductions in Mortality Associated with Intensive Public Reporting of Hospital Outcomes*, 23 AM. J. MED. QUALITY 279 (2008).

[91] Matthew A. Cavender et al., *State Mandated Public Reporting and Outcomes of Percutaneous Coronary Intervention in the United States*, 115 AM. J. CARDIOLOGY 1494, 1499 (2015).

measures," postacute care quality rose after the initiation of federal quality reporting.[92]

These studies do not establish that mandated quality reporting is the key to health care system improvement. Relatively few studies have examined physician quality reporting. Some studies, such as the postacute care study just described, find a relationship between reporting and some quality metrics, but not others. When studies do find an impact, its magnitude may be relatively small. For example, a study of federal hospital reporting found no reductions in mortality for heart attack and pneumonia, and only a "modest reduction" for heart failure.[93]

As with the empirical evidence on provider selection, the prevalence of studies finding a connection between reporting and quality metrics suggests that reporting can make a difference, and so mandated quality reporting is not a failure in that sense. The universe of studies leaves open questions about how much of a difference, and the conditions under which report cards are most likely to succeed. Understanding the magnitude of quality benefits (as well as any benefits associated with autonomy or other aims) is important, given the costs associated with reporting.

III. THE COSTS OF MANDATED DISCLOSURE

As Part II makes clear, there has been significant effort devoted to thinking about the potential benefits of mandated disclosure, including in the context of quality reporting. This focus makes sense; there is no reason to pursue any regulatory initiative, including reporting mandates, if it yields no cognizable benefits. But if reporting initiatives plausibly meet that threshold, then the next question must be whether the benefits exceed the costs. There seem to be many fewer studies focusing on the costs of disclosure. Some kinds of costs are difficult to calculate for conceptual reasons;

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[92] Rachel M. Werner et al., *Impact of Public Reporting on Quality of Postacute Care*, 44 HEALTH SERVS. RES. 1169, 1169 (2009).

[93] Andrew M. Ryan et. al., *Medicare's Public Reporting Initiative on Hospital Quality Had Modest or No Impact on Mortality from Three Key Conditions*, 31 HEALTH AFF. 585, 588-90 (2012) (finding in an analysis adjusted for patient characteristics and time trends, a .97 relative risk ratio for heart failure-related mortality).

other kinds of costs are more straightforward, but are not as accessible to researchers as the kinds of data used for Part II's studies. Nevertheless, it is important to at least acknowledge the costs associated with disclosure mandates, including quality reporting.

A. The Many Costs of Mandated Disclosure

In a chapter entitled, "At Worst, Harmless?," Professors Ben-Shahar and Schneider describe harms that could arise from mandated disclosure. There are many, and they are right to remind disclosure advocates that the costs of disclosure mandates are real, just as they are for other types of mandates. For the regulated entity, costs include those associated with collecting data, preparing disclosure content, disseminating information, and possibly documenting the provision and receipt of the disclosure.[94] Disclosees' costs include the costs associated with reading disclosures.[95] I would add that the regulators who design and enforce disclosure mandates may also devote considerable resources to this effort.

But Ben-Shahar and Schneider also recognize that costs extend far beyond those associated with creating and implementing a mandate. They explain that "mandates can undercut other regulation, deter lawmakers from adopting better regulation, impair decisions, injure markets, exacerbate inequality, and in some important cases, cripple valuable enterprises."[96] While all of these effects are illustrated with examples, some seem more broadly applicable than others; I will focus on a few potential costs that seem to have special relevance to quality reporting.

One such cost is "impair[ed] decisions." Ben-Shahar and Schneider note that information supplied could be wrong or direct disclosees' attention away from other things that matter; an overabundance of information could obscure the points that matter most and undermine the value of reporting.[97] Another cost is directing *disclosers'* attention

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[94] BEN-SHAHAR & SCHNEIDER, *supra* note 4, at 169-70.
[95] *Id.* at 170.
[96] *Id.* at 169.
[97] *Id.* at 175-76.

away from other things that might matter, but are not subject to reporting. Ben-Shahar and Schneider classify this cost as "making markets worse."[98] A third cost is "exacerbating inequality," which can occur if the costs of disclosure mandates are borne by all, but it is the best-educated and, in some cases, the most economically advantaged, who are best positioned to make full use of them.[99]

B. The Costs of Quality Reporting

The costs associated with mandated health care quality reporting are significant. While the costs of disclosing relevant data are not likely to be especially high in this age of web-based data dissemination, the costs of collecting and reporting the required data can be large. To get a sense of these costs, consider a recent study of cardiology, orthopedics, primary care, and multispecialty practices that concluded that United States physician practices collectively spend more than $15.4 billion per year on quality reporting.[100] Or consider the 2015 final rule addressing Medicare's Hospital Inpatient Quality Reporting program.[101] The regulatory impact analysis indicates that by removing certain measures from the previous reporting program, the final rule will reduce the "burden associated with the collection of chart-abstracted data."[102] How much? It estimates that removing nine measures will reduce the total burden across all hospitals by 741,000 hours.[103] The analysis also estimates that for each of the 3,300 hospitals impacted, the "burden per hospital for previously finalized requirements" was 1,135 hours for "chart-abstracted and

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[98] *Id.* at 176.

[99] *Id.* at 178-80.

[100] Lawrence P. Casalino et al., *U.S. Physician Practices Spend More Than $15.4 Billion Annually to Report Quality Measures*, 35 HEALTH AFF. 401, 401 (2016) (summarizing results), *id.* at 402 (describing groups surveyed).

[101] Medicare Program, 80 Fed. Reg. 49,326 (Aug. 17, 2015) (to be codified at 42 C.F.R. pt. 412).

[102] *Id.* at 49,837.

[103] *Id.*

structural measures, forms" and "review[ing] reports for claims-based measures."[104]

Quality reporting also implicates many of the other kinds of costs on the list offered by Ben-Shahar and Schneider. The risk that poorly-executed report cards could mislead users is real. The data underlying report card metrics could be incorrect, or the metrics themselves could be poor reflections of true quality. Correct metrics could be misinterpreted or misused; for example, findings of one study suggested that giving patients information about provider cost in the hope of promoting high-value care could yield unexpected results, because some patients equate higher cost with higher quality.[105] The provision of ratings related to some dimensions of quality, but not others, could lead patients to unduly focus on those dimensions in making their decisions. Patients checking out Medicare's hospital comparison site by clicking through the tabs presenting different types of quality ratings will first see ratings based on patients' experiences; if they do not click through the rest of the tabs, they may not take into account clinical quality measures such as complication rates or mortality in making their decisions.[106]

Even if patients make good use of report cards, the incentive effects associated with quality reporting could make care worse. Ben-Shahar and Schneider cite research suggesting that nursing homes performed better on measures captured in public reporting, but did worse on others;[107] if providers neglect unmeasured areas, average quality may go down, and quality metrics could mislead report card users. Poorly-constructed measures can have unintended consequences; a metric designed to capture the prompt administration of antibiotics for pneumonia was

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[104] *Id.* at 49,838.

[105] Judith H. Hibbard et al., *An Experiment Shows That a Well-Designed Report on Costs and Quality Can Help Consumers Choose High-Value Health Care,* 31 HEALTH AFF. 560, 565-66 (2012), *available at* http://content.healthaffairs.org/content/31/3/560.full.pdf+html [https://perma.cc/FL3J-74HE] (showing also that altering presentation format and the quality signal provided could help address this problem).

[106] *Hospital Compare*, MEDICARE.GOV, https://www.medicare.gov/hospitalcompare/search.html [https://perma.cc/U88C-3N2V] (last visited May 26, 2016).

[107] BEN-SHAHAR & SCHNEIDER, *supra* note 4, at 176.

revised after its time constraints put pressure on providers to supply antibiotics to patients whose diagnosis was not yet confirmed.[108]

Quality reporting can also lead to gaming that can lower quality for patients and potentially exacerbate inequalities. One study found that when New York and Pennsylvania implemented their cardiac surgery reporting systems, the average severity of illness of patients receiving bypass surgery went down, suggesting that physicians were turning away sicker patients. [109] While the results indicated that sicker patients were more likely to be matched with teaching hospitals, the adoption of report cards was associated with poorer outcomes overall, including for sicker patients.[110] Another study found that the release of New York's bypass surgery report card was associated with increased racial and ethnic disparities in the receipt of cardiac care.[111] This could occur if physicians are concerned that members of racial or ethnic minority populations might be at a "higher risk for poor outcomes" in ways that quality metrics fail to capture, thus inappropriately worsening outcomes measures.[112]

Quality ratings could also increase disparities if one group is more likely to see, understand, and properly use quality ratings than another. For example, if more educated individuals have both better underlying health and a stronger tendency to use report cards well, then education-based disparities may begin to increase. Note, however, that this kind of effect depends on both treatment patterns in the absence of report cards and on the identity of report card users. If the most educated patients already acquire quality information through other sources, then it may be less educated patients whose behavior is most impacted by report cards.

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[108] *See* Robert M. Wachter et al., *Public Reporting of Antibiotic Timing in Patients with Pneumonia: Lessons from a Flawed Performance Measure*, 149 ANNALS INTERNAL MED. 29, 29 (2008).

[109] Dranove et al., *supra* note 43, at 570, 582-84.

[110] *Id.*

[111] Rachel M. Werner, David A. Asch & Daniel Polsky, *Racial Profiling: The Unintended Consequences of Coronary Artery Bypass Graft Report Cards*, 111 CIRCULATION 1257, 1257 (2005).

[112] *Id.*

There are plenty of reasons to believe that the costs discussed in this section are "real," and evidence points to the existence of some types of costs. Evidence is sparser for other types, however, and many of the costs are difficult to quantify, increasing the challenges of a full analysis of the net impact of reporting.

Note that even if studies show that these costs exist, there are ways to limit them. As electronic health records spread and improve, data collection costs should go down. Reporting refinements and other interventions can also reduce the costs of reporting. Researchers have identified ways to increase the likelihood that users understand the information presented.[113] Gaming is always a possibility, but revising outcomes metrics to capture the risks that most concern physicians may reduce the opportunity for gaming. Thus, while using current evidence to assess costs is an important first step in analyzing the impact of reporting initiatives, it is also important to consider the likelihood of future changes that might affect those costs. The same observation could be made about an analysis of reporting's benefits.

C. The Marginal Costs of Quality Reporting

One other complication in evaluating the impact of quality reporting is that the infrastructure necessary to comply with government reporting mandates may yield other benefits. Many of the financial costs associated with reporting are not actually the costs of reporting; they are the costs of data collection and measurement. These costs could be viewed as an investment supporting a range of provider activities.

For example, a health care provider may want to track a variety of quality metrics in an effort to improve its own health care quality, without regard to the existence of any mandated reporting program. Third parties with an interest in monitoring quality may seek access to quality metrics, regardless of whether the metrics are also publicly reported. Private and public payers may choose to incorporate quality

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[113] *See* Hibbard, *supra* note 105 (discussing effects of changing report card and format).

metrics into their payment formulas.[114] If an accountable care organization must report a series of quality metrics in order to receive payments under the federal shared savings program, then the marginal financial costs associated with public reporting of the same metrics will be small.[115] In the current environment, many provider organizations would face significant data collection and measurement costs even in the absence of a public reporting program. The marginal costs of a disclosure mandate would therefore be quite low, strengthening the justification for quality reporting requirements.

At the same time, however, the existence of these other uses of quality data might also affect the marginal benefits of a reporting mandate. If pay-for-performance payment regimes are effective mechanisms for ensuring quality,[116] then public reporting may not have much effect. Ultimately, in a world in which quality measurement is already underway, assessing whether a disclosure mandate is a "success" or "failure" requires a comparison between the marginal costs and the marginal benefits associated with adding a reporting requirement. The gains from reporting may be small, but if the marginal costs are smaller still, implementing the reporting mandate will have a positive net impact. If quality measurement is not yet underway, then the costs of implementing a measurement-based reporting regime should be compared not just to the benefits associated with reporting, but also to other benefits arising from the development of the underlying measurement infrastructure.

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[114] *See* Julia James, *Health Policy Brief: Pay-for-Performance*, HEALTH AFF. 1 (Oct. 11, 2012) (describing pay-for-performance programs).

[115] *See* Dep't of Health & Human Servs., *Improving Quality of Care for Medicare Patients: Accountable Care Organizations* (April 2014), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Quality_Factsheet_ICN907407.pdf [https://perma.cc/6AUS-YR62] (describing quality metrics used as the basis for rewards in Medicare's Shared Savings Program and noting the alignment between the program and other quality reporting metrics).

[116] *See* BEN-SHAHAR & SCHNEIDER *supra* note 4 at 176 (describing results of studies of pay-for-performance programs). Like the studies on quality reporting, studies on the impact of pay-for-performance are mixed.

The costs will almost certainly be large, but the gains may be as well. In short, an assessment of the net impact of reporting will depend not just on the attributes of the reporting mandate in question, but also on the nature of other quality-related initiatives already underway or soon to be adopted. These assessments will be challenging in an environment characterized by continuous reform; in such circumstances, longer-term gains will be much more difficult to evaluate than short-term costs.

IV. ALTERNATIVES TO MANDATED DISCLOSURE

Given the prevalence of mandated disclosure as a regulatory mechanism, it is natural to respond to a call to abandon the mechanism with a question about how best to replace it. Professors Ben-Shahar and Schneider dismiss the question, and with good reason, if their premise is correct. If mandated disclosure does nothing, or makes things worse, then nothing is lost if it is abandoned. [117] The only question to be asked in such a case is whether there is some other sort of regulation or other initiative that would actually achieve the goals of the mandated disclosure, at a reasonable cost. Ben-Shahar and Schneider do not explore this question in detail, as it is beyond the scope of their book, but they do discuss a few possibilities.[118] This Part explores two possible alternatives to reporting mandates: voluntary reporting and direct regulation.

A. Voluntary Reporting as an Alternative to Mandatory Quality Reporting

Ben-Shahar and Schneider point out that there are often alternative sources of the kinds of information that reporting provides. Many organizations provide consumer information, including ratings, reviews and other much-wanted forms of advice that mandated disclosures may lack.[119] Organizations that collect and disseminate

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[117] BEN-SHAHAR & SCHNEIDER, *supra* note 4, at 183.

[118] *See id.* at 183-95 (discussing alternatives to disclosure).

[119] *Id.* at 185.

information abound, and they do not necessarily need to obtain information through mandates.[120]

As Ben-Shahar and Schneider suggest, it is true that private entities do not need publicly-reported health care quality data to create their own ratings. Consumers can obtain advice similar to what they would get from government report cards through a number of private organizations that supply quality information drawn directly from providers, from public claims databases, or from third parties.[121] This reality, though, creates problems of its own. To the extent that organizations' measures are derived from data supplied directly by providers, private reporting programs have the potential to add to the burden faced by providers that might already be reporting on hundreds of measures for public reporting or payment purposes.[122] Furthermore, a proliferation of quality metrics can also create considerable confusion for patients, who are confronted with many competing and sometimes contradictory quality metrics.[123] In other words, a proliferation of voluntary reporting programs can create a sort of overload, just as an overly complex mandated disclosure can.

Professor Craswell notes the problems of inconsistent measurement systems, and suggests that mandatory disclosures might benefit users by making direct comparisons easier and reducing the burden consumers would otherwise face in trying to understand multiple

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[120] *Id.* at 187-88, 190.

[121] *See, e.g., 2015 Leapfrog Hospital Survey Results Now Available*, THE LEAPFROG GROUP http://www.leapfroggroup.org/cp [https://perma.cc/2YYX-YHNN] (last visited May 26, 2016) (reporting based on data supplied by hospitals); *FAQ: How and Why We Rate Hospitals,* U.S. NEWS & WORLD REPORT (July 21, 2015, 12:01 AM), http://health.usnews.com/health-news/best-hospitals/articles/2015/05/20/faq-how-and-why-we-rate-and-rank-hospitals?int=ab2909&int=ad4609 [https://perma.cc/PE4N-34LJ] (describing hospital rating methodology involving physician surveys).

[122] *See, e.g.,* MASSACHUSETTS HEALTH POLICY COMMISSION, 2014 COST TRENDS REPORT 59 (2014) (finding that Massachusetts providers reported more than 400 quality measures to different entities).

[123] Michael B. Rothberg et al., *Choosing the Best Hospital: The Limitations of Public Quality Reporting*, 27 HEALTH AFF. 1680, 1686 (2008).

metrics.[124] Federal reporting websites do this to at least to some extent by providing information on a very large number of providers for a very broad range of services, and ensuring at least some consistency in the presentation of information. The federal government's purchasing power ensures that it has access to a broad range of provider data. By contrast, other quality-related websites may include only a subset of providers, or exist for only a particular type of care.

It may be possible to achieve consistency in reporting through collaboration across entities, rather than by governmental mandate. Recently, the Center for Medicare and Medicaid Services worked with major commercial health plans and others to increase the alignment across measures used for a variety of quality programs.[125] However, even if such multistakeholder groups exist, the government's leadership role in reporting initiatives may help to accelerate the process of reaching a voluntary agreement.

Craswell highlights one more important effect of a governmental mandate: he suggests that "when the government requires the disclosure of information, that decision itself signals to (some) consumers that the issue is important enough to worry about, thus making sellers' later voluntary disclosures more salient to consumers."[126] It is possible that this is the case for health care quality. By making data available to the public for free and publicizing its availability, policy makers may increase the public's focus on health care quality.

For all of these reasons, mandatory reporting may yield gains that purely voluntary reporting programs might struggle to achieve. It is also the case that existing mandatory reporting regimes possess some of the attributes

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[124] Craswell, *supra* note 22, at 368.

[125] Press Release, CMS and Major Commercial Health Plans, in Concert with Physician Groups and Other Stakeholders, Announce Alignment and Simplification of Quality Measures (Feb. 16, 2016), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-02-16.html [https://perma.cc/M7TK-PDUE]; Patrick H. Conway and the Core Quality Measures Collaborative Workgroup, *The Core Quality Measures Collaborative: A Rationale and Framework for Public-Private Quality Measure Alignment,* HEALTH AFF. BLOG (June 23, 2015).

[126] Craswell, *supra* note 22, at 368.

that Ben-Shahar and Schneider look for in alternative reporting mechanisms. For example, publicly-produced quality reporting would seem to fall in the category of "advice" that Ben-Shahar and Schneider describe. Furthermore, while other types of mandated disclosure may "rarely teach" "how businesses actually behave," [127] quality report cards attempt to characterize actual behavior. In short, while a variety of information provision mechanisms might perform some key functions of reporting mandates, today's quality reporting mechanisms offer important benefits for information users.

B. Direct Regulation as an Alternative to Mandatory Quality Reporting

Ben-Shahar and Schneider also note that in some cases, more paternalistic forms of regulation might be a viable alternative to reporting mandates.[128] If policy makers believe that having more nurses may help achieve higher quality of care, but are convinced by Ben-Shahar and Schneider that a nurse staffing ratio report card will fail as a policy intervention, then perhaps they could regulate directly by mandating staffing ratios. The translation of some quality metrics, such as mortality rates, to command-and-control regulations is more challenging than the staffing ratio example implies, but in theory government regulators could become more active in mandating practices that have been found to reduce mortality.

Many people would view this kind of intervention as problematic on the grounds that it involves too much interference with the ever-changing practice of medicine. Command-and-control regulation can forestall innovation and impose inappropriate or unnecessarily costly practices on providers. Structural and process-based quality reporting measures allow for variation, even while pushing providers toward a particular standard; outcome-based metrics such as adjusted mortality rates provide flexibility to providers in how they seek to achieve better outcomes. A desire for flexibility is no reason to advocate for reporting that does not

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[127] *Id.* at 188.
[128] *Id.* at 194.

work, but flexibility can help avoid some of the risks of command-and-control regulation.

Note too that command-and-control regulations are subject to many of the criticisms lodged against mandated disclosure, a point emphasized by Professor Craswell.[129] Nurse staffing mandates, like nurse staffing reporting requirements, could undermine quality if the metrics used are not actually associated with quality. A nurse staffing mandate pulls resources away from other areas in need of attention, possibly including areas that matter more for quality. A requirement for nurse staffing levels may lead to gaming that helps providers meet the requirement without improving outcomes.

Authors of a recent article that compares evidence on quality reporting with evidence on direct quality regulation argue that both approaches can "induce teaching to the test" and "be subject to cream skimming," and then state that "[a]lthough very few efforts have been made to measure the costs of these approaches, regulation, when enforced, is almost certainly more costly."[130] This conclusion points to the advantages of reporting, but the authors' ultimate conclusion points in a different direction. While one of the authors' objectives was "to compare the effectiveness and cost-effectiveness of regulation and report cards in improving quality," they conclude that "such a comparison is not yet feasible," partly because studies evaluating the policy tools "use different metrics to measure their effects," partly because they address different sectors, and partly "because of the dearth of cost studies."[131]

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[129] *See* Craswell, *supra* note 22, at 367. At the same time, disclosure mandates can share some of the shortcomings of command-and-control regulation. Professor Ryan Bubb suggests that some disclosure mandates may be intended to manipulate consumer choice, rather than merely attempting to debias faulty consumer decision making, and "should be subjected to cost-benefit analysis in much the same way as are more transparently coercive tools like product regulation." Ryan Bubb, *TMI? Why the Optimal Architecture of Disclosure Remains TBD*, 113 MICH. L. REV. 1021, 1039 (2015).

[130] *See* Mukamel et al., *supra* note 81, at 492.

[131] *See id.*

V. CONCLUSION

The challenges of comprehensively evaluating the effects of policy interventions give room both to claims that disclosure mandates have failed, and to claims that they might succeed. While the evidence discussed in Part II.C makes clear that mandated quality reporting has the potential to succeed, Part III's evidence on costs is much sparser. It is certainly possible that reporting's costs exceed its benefits. On the other hand, it is also possible that gains exceed costs for at least some subset of current quality reporting initiatives. I lean toward this latter conclusion, in part because I believe that quality reporting has done a lot to focus providers' attention on quality issues, and in part because of the long-term benefits that investments in the infrastructure supporting quality reporting can yield. Whatever may be true right now, I believe that it is likely that future versions of today's mandates will fare better in a cost-benefit analysis, both because I anticipate that reporting systems will be revised in light of emerging research about what works and what does not, and because I believe that the marginal costs of quality reporting will decline over time.

I suspect that similar observations could be made for other forms of mandated disclosure, but I am not sure how much can be extrapolated from this essay's analysis of quality reporting. It would not be unreasonable to view quality reporting as a sui generis form of disclosure mandate. It differs from other disclosure mechanisms in multiple ways. For example, the primary end goal of quality reporting does not seem to be fully informed consumers, but instead higher quality care; in other words, the ultimate aim is not to support patient (consumer) choice in a world with diverse products, but instead to ensure that the product delivered has a particular attribute. While many of the mandates Professors Ben-Shahar and Schneider consider involve the direct provision of information from a business to a consumer, health care quality reporting typically involves health care providers' provision of information to a government entity, which then makes information available to consumers. For many people, health care quality likely matters more than the specific details of privacy policies, or boilerplate contract terms that govern disputes that rarely

arise. Quality report cards seem much more straightforward to understand than a mortgage. The fact that providers may find quality measurement useful for multiple purposes means that quality reporting processes may be intertwined with provider operations in ways that other kinds of disclosures meant to clarify product characteristics, such as term sheets, are not.[132]

This brief list of some of the ways that health care quality reporting differs from other mandates makes clear that there are many dimensions along which disclosure mandates may differ. They differ in their goals and the mechanisms by which they seek to achieve them.[133] They differ in their degree of salience to their audiences.[134] They differ in complexity. They differ in costs, financial and otherwise, and they may differ in who bears these costs. They may also differ in the extent to which alternative regulatory mechanisms could achieve their goals.[135] The sheer diversity of disclosure mandates raises the possibility that some disclosures will succeed while others fail; even Ben-Shahar and Schneider leave open the possibility that at least some mandates succeed. If we could develop a framework that systematically lays out the key characteristics of disclosure mandates and the environments in which they operate, then

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[132] Provider quality reporting mandates may also differ from other disclosure regimes in that they often take the form of "pay for reporting" initiatives, rather than statutory or regulatory requirements to report. *See, e.g.*, *Home Health Quality Reporting Requirements*, CMS.GOV, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html [http://perma.cc/PQM6-9G5F] (last modified 10/29/2015 3:25 PM) (noting that federal statute requires home health agencies to submit data, describing the financial consequences if home health agencies do not submit data, and describing the requirement as a "pay-for-reporting" requirement).

[133] Professor Bubb offers a thoughtful discussion of the implications of disclosure mandates that seek to debias versus mandates that seek to manipulate behavior. Bubb, *supra* note 129, at 1028-1039.

[134] *See* Mukamel et al., *supra* note 81, at 492 (noting that the risk of delayed treatment for pneumonia "may not be significant to enough potential patients to make report card effective; therefore, direct regulation may be a more appropriate approach than a report card").

[135] *Cf. id.* (Observing that reporting "is considered an attractive policy instrument in an area where surgeon skill is very important and probably difficult to regulate").

we may be able to better predict disclosure mandate success — and increase it.

The utility of such a framework will necessarily depend on the quality of data that underlies it. Evaluating the success of existing mandates requires careful consideration of both benefits and costs. As Professor Bubb has observed, "[t]he right response to the important critiques of mandatory disclosure that Ben-Shahar and Schneider raise is . . . rigorous empirical assessment of which disclosures work and which do not, with an eye toward the pitfalls the authors document."[136] Moreover, as Professor Craswell emphasizes, it will be important to define criteria for success, which will in turn depend on the nature of the goals policy makers seek to achieve.[137]

More Than You Wanted to Know conveys an important warning: disclosure mandates rarely fulfill their advocates' hopes, and the reasons that disclosure mandates disappoint are not easily addressed. This essay demonstrates, however, that some disclosure-based policy strategies have a reasonable chance of succeeding. With more data, more analysis, and a clear articulation of policy goals, we can determine whether they actually do.

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[136] Bubb, *supra* note 127, at 1023.

[137] *See* Craswell, *supra* note 22, at 337-40 (on goals); *see also id.* at 380 (calling for development of criteria for success).

CONTROLLING HEALTH CARE SPENDING: MORE PATIENT "SKIN IN THE GAME?"

David Orentlicher[1]

I. INTRODUCTION

While health care cost inflation slowed during the past few years, it has started to pick up again,[2] and policy makers have good cause for concern about future increases in health care spending. Moreover, even if future increases moderate, policy makers rightly worry about the already high levels of U.S. spending. The need for effective cost containment strategies in health care persists, even though the Affordable Care Act appears to have had some success at containing health care costs.

Health care spending reforms can focus on physician and hospital practices or on patient behavior, and popular reform

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[1] Samuel R. Rosen Professor and Co-Director, Hall Center for Law and Health, Indiana University Robert H. McKinney School of Law. MD, JD, Harvard University. I am grateful for the excellent editing of the *Indiana Health Law Review*.

[2] Drew Altman, *New Evidence Health Spending Is Growing Faster Again*, WALL ST. J. (June 11, 2015, 3:14 PM), http://blogs.wsj.com/washwire/2015/06/11/new-evidence-health-spending-is-growing-faster-again/ [perma.cc/D2YC-YBNQ].

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proposals include both approaches. For example, rather than paying physicians and hospitals in terms of the *quantity* of care that they provide and encouraging the provision of too much care, private insurers and government programs are turning more and more to forms of reimbursement that are based on the *quality* of care delivered. Insurers often adjust physicians' compensation based on whether they screen their patients for cancer or high cholesterol, administer recommended immunizations, or achieve good control of blood sugar levels for their patients with diabetes.[3] The Affordable Care Act addresses patient behavior by requiring insurers to cover important kinds of preventive care for free.[4] That way, people will not be discouraged for financial reasons from seeking early care that can keep them healthier and avoid the need for hospitalizations and other expensive treatments.

In this article, I consider an increasingly common strategy that insurers use to influence patient behavior—giving people more "skin in the game." When medical treatment can be obtained at very low cost, people may be too quick to seek it when they feel sick, visiting their physicians when they would do just as well by staying home. Hence, insurers have raised deductibles[5] and co-payments[6] and shifted the costs of care to patients in other ways[7] in the hope that people will

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[3] Aparna Higgins, German Veselovskiy & Lauren McKown, *Provider Performance Measures in Private and Public Programs: Achieving Meaningful Alignment with Flexibility to Innovate*, 32 HEALTH AFF. 1453, 1456-57 (2013).

[4] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended at 42 U.S.C. § 18001 et. seq. (2010)).

[5] A deductible refers to the costs of care that the patient pays before insurance kicks in. If the deductible is $500, the patient pays the first $500 in health care costs for the year.

[6] A co-payment refers to the patient's share of costs when care is provided. For example, a visit to the doctor's office may come with a co-pay of $25, with the insurance company picking up the remainder of the physician's fees for the visit. Co-payments are similar to co-insurance, under which patients pay a percentage of the costs of care, say twenty percent of the costs of a hospitalization.

[7] Insurers also shift more costs to patients by raising the annual cap on the patient's share of their health care costs from deductibles, co-payments, and co-insurance (the cap on total out-of-pocket spending), as

become more conscious of the costs of their care. Although concerns about patients seeking too much care are important, common strategies for giving patients more skin in the game have been poorly conceived. There is room for skin-in-the-game strategies to contain high health care spending, but only when they are properly designed.

II. THE HIGH COSTS OF HEALTH CARE

Health care spending in the United States is approaching 18% of Gross Domestic Product ("GDP"), a level well above other economically-advanced democracies.[8] Countries such as Canada, Germany, Switzerland, and Japan spend only about 10 to 11% of GDP on health care.[9] And current U.S. spending is very high when compared with past U.S. expenditures. In 1980, health care spending accounted for only 9% of GDP.[10]

To some extent, higher spending makes sense. The United States is a rich country and therefore can afford to spend more on health care than many other countries. It is probably better for a country to spend its plentiful resources on health care than on yachts or tickets to professional football games.

But do Americans get enough bang for their extra health care bucks? Concerns about health care spending are focused not only on the amount of spending but also on the fact that the United States does not appear to get sufficient benefit for all of its extra spending. On many health status metrics, the United States lags other countries. For example, life expectancy in the United States trails that of a wide range of countries, not only including Canada, Germany, Switzerland,

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well as by providing less coverage for care received from physicians or hospitals that are not in the insurance company's network ("out-of-network" care).

[8] OECD, HEALTH AT A GLANCE 2013: OECD INDICATORS 157 (OECD Publishing, 2013), *available at* http://www.oecd.org/els/health-systems/Health-at-a-Glance-2013.pdf [https://perma.cc/KAF2-GPE7].

[9] *Id.*

[10] *Snapshots: Health Care Spending in the United States & Selected OECD Countries*, KAISER FAMILY FOUND. (April 12, 2011), http://kff.org/health-costs/issue-brief/snapshots-health-care-spending-in-the-united-states-selected-oecd-countries/ [https://perma.cc/A4KL-GTXA].

and Japan, but also Italy, Spain, Greece, and the United Kingdom.[11]

Of course, many factors other than health care affect life expectancy and other measures of health. People in Italy, Spain, and Greece may live longer because they consume a Mediterranean diet.[12] Perhaps our higher health care spending helps narrow the gap between the United States and other countries even if it does not eliminate the gap. Indeed, some data suggest that Americans do get value for their health care dollar. For example, five-year breast cancer survival rates are higher in the United States than in Canada, Germany, Japan, and the United Kingdom.[13] Similarly, five-year colon cancer survival rates are higher in the United States than in Canada, Germany, and the United Kingdom, though lower than in Japan.[14] And empirical data indicate that greater spending on cancer care contributes to the higher survival rates. In a study that considered the benefits and costs of cancer care in the United States and Europe, researchers found that the survival gains from the extra spending on cancer in the United States exceeded the costs of the care.[15] In another study, researchers found that reductions in deaths from cancer were greatest in countries where cancer care spending rose the most between 1995 and 2007.[16]

But other data indicate that we spend our health care dollars inefficiently. For example, asthma hospitalization rates are much higher in the United States than in Canada,

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[11] OECD, *supra* note 8, at 25. Infant mortality rates also are better in many other countries, including Japan, Portugal, Spain, Greece, France, Poland, and the United Kingdom. *Id.* at 37.

[12] Francesco Sofi et al., *Accruing Evidence on Benefits of Adherence to the Mediterranean Diet on Health: An Updated Systematic Review and Meta-Analysis*, 92 AM. J. CLINICAL NUTRITION 1189 (2010).

[13] OECD, *supra* note 8, at 127.

[14] *Id.* at 129.

[15] Tomas Philipson et al., *An Analysis of Whether Higher Health Care Spending in the United States Versus Europe Is 'Worth It' in the Case Of Cancer*, 31 HEALTH AFF. 667, 670-71 (2012) (assuming that an extra year of life has an economic value of $150,000 and comparing the economic value from the increased life expectancy to the costs of care).

[16] Warren Stevens et al., *Cancer Mortality Reductions were Greatest Among Countries Where Cancer Care Spending Rose the Most, 1995–2007*, 34 HEALTH AFF. 562 (2015).

France, Japan, and the United Kingdom, and hospitalization rates for diabetes are much higher than in Canada, Spain, Italy, and the United Kingdom.[17] If health care did more in the United States to maintain the health of people with asthma or diabetes, hospitalization rates would look more like those in other countries. And a study that estimated the efficiency of health care systems by comparing health care spending with health status of a country's residents found that the United States trailed a wide range of countries, from Canada, France, Germany, Italy, and the United Kingdom to Mexico, Colombia, Venezuela, and China.[18]

There also are domestic data suggesting that much health care spending is wasted. U.S. patients treated in high-cost communities are no healthier than patients treated in low-cost communities.[19] Indeed, patients actually might fare better in lower-spending areas.[20]

III. IMPROVING THE RETURN ON OUR HEALTH CARE DOLLAR

There are many ways to improve the efficiency of health care spending. If fee-for-service reimbursement encourages physicians to perform too many surgical procedures, it makes sense to rely more on salary-based compensation. Or a percentage of physicians' compensation could be based on the extent to which they meet quality-related targets for the health care they provide. For example, physicians would be paid more if more of their patients receive an annual influenza vaccine.

A. Increasing Patient "Skin in the Game"

Should we also try to improve the efficiency of health care spending by giving patients more "skin in the game?" If patients had to pay a higher percentage of their health care

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[17] OECD, supra note 8, at 109.

[18] David B. Evans et al., *Comparative Efficiency of National Health Systems: Cross National Econometric Analysis*, 323 BMJ 307, 308-09 (2001).

[19] Elliott S. Fisher, Julie P. Bynum & Jonathan S. Skinner, *Slowing the Growth of Health Care Costs—Lessons from Regional Variation*, 360 NEW ENG. J. MED. 849, 850 (2009).

[20] *Id.*

costs, would people be more likely to refrain from seeking care when they really do not need a doctor's attention? More importantly, would people take better care of themselves if they had to pay more for their medical treatments? Perhaps, Americans would be healthier, and health costs would be lower, if people were more sensitive to the costs of the care that they receive.

By its very nature, health care insurance dulls patient sensitivity to the costs of care. Assume, for example, that a particular treatment costs $100 and provides a value to the patient worth only $75. If the patient were paying the full cost of care, the treatment would be declined. But if insurance covers most of the costs of the care, so the patient would face a co-payment of only $25, the patient would likely choose the care. Getting $75 of value for $25 is a good deal.[21]

As long as we have health care insurance, patients will not be fully sensitive to the costs of their health care. But cost sensitivity is not an all-or-nothing phenomenon. Even if we cannot make patients fully sensitive to the costs of their care,[22] we have to decide on the level of sensitivity. If health care coverage is too generous, people may seek too much care, wasting health care resources. If health care coverage is not generous enough, people may not seek enough care, to the detriment of their health.

Many employers, insurers, and analysts think that patients have been insufficiently sensitive to the costs of their care.[23] Hence, in recent years, we have seen marked increases in the size of deductibles and co-payments to make patients more sensitive to health care costs.[24] Indeed, among employee health care plans, the average deductible for individual coverage more than doubled between 2006 and

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[21] *See* David Orentlicher, *Cost Containment and the Patient Protection and Affordable Care Act*, 6 FLA. INT'L U. L. REV. 67, 71 (2010).

[22] Nor would we want them to be. An important reason for having health care coverage is to ensure that people can have good access to health care even when they have limited financial resources.

[23] *See, e.g.,* JAMES W. HENDERSON, HEALTH ECONOMICS AND POLICY 8 (6th ed. 2014) ("Fully-insured patients have no incentive to limit their utilization [of health care].").

[24] Higher deductibles and co-payments also offer a way to limit increases in health care insurance premiums.

2014, and the percentage of individual plans with deductibles of $1,000 or more nearly quadrupled.[25] Is this a good trend?

If the goal is simply containing costs, then giving patients more skin in the game may be useful. Raising the patient's share of health care costs through deductibles, co-payments and other out-of-pocket costs reduces patient demand for care. In the RAND Health Insurance Experiment, in which participants were randomly assigned to health care plans with different levels of cost-sharing, researchers found that higher cost-sharing led to fewer physician visits, fewer prescriptions, and fewer hospitalizations.[26]

But the reductions in financial costs may come with increases in non-financial costs. In particular, when patients refrain from seeking care because of the costs of care, their health may suffer. Several studies indicate that when patients reduce their demand for care because of costs, they many not distinguish between needed and unneeded care. In the RAND study, for example, there was no adverse impact on health for the average person.[27] However, for poor individuals with medical problems, those with free care had better health measures and lower predicted mortality rates than their counterparts who were discouraged from seeking care by their deductibles or co-payments.[28]

In another study, which involved emergency department care, researchers again found that increased cost-sharing had an adverse effect on health for the poor.[29] Higher-income individuals in high-deductible plans reduced their emergency department visits only for "low-severity" services—services that were not urgent and could be provided at a clinic or doctor's office at a later date.[30] But, low-income persons

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[25] KAISER FAMILY FOUND. & HEALTH RESEARCH & EDUC. TRUST, EMPLOYER HEALTH BENEFITS: 2014 ANNUAL SURVEY 125-26 (2014), *available at* http://files.kff.org/attachment/2014-employer-health-benefits-survey-full-report [https://perma.cc/HD8U-Y8GS].

[26] JOSEPH P. NEWHOUSE & THE INS. EXPERIMENT GRP., FREE FOR ALL?: LESSONS FROM THE RAND HEALTH INSURANCE EXPERIMENT 338 (1993).

[27] *Id.* at 338-39.

[28] *Id.* at 339.

[29] J. Frank Wharam et al., *Low-Socioeconomic-Status Enrollees in High-Deductible Plans Reduced High-Severity Emergency Care*, 32 HEALTH AFF. 1398 (2013).

[30] *Id* at 1399.

reduced visits for both "low-severity" services and the kinds of "high-severity" services that should be treated urgently in an emergency department.[31]

Or consider a study that analyzed the impact of a new deductible and co-payments for prescription drugs.[32] The increases in out-of-pocket costs led low-income persons to reduce their use of both low-value and high-value drugs, and accompanying the reduction in drug use, there was an increase in "serious adverse events" (hospitalizations, nursing home admissions, and deaths).[33]

While broad increases in patient cost-sharing seem ill-advised because of their adverse effects on patient health, might more targeted increases be useful? Recall in this regard that in the RAND study, greater cost-sharing for the average person led to a reduction in health care spending with no harm to health.[34] A few possibilities for targeted cost-sharing come to mind.

1. Higher Cost-Sharing for Lower-Value Care

If the goal of patient skin in the game is to discourage unnecessary care while preserving desirable care, then it makes sense to reserve higher cost-sharing for lower-value care. The Affordable Care Act's requirement of free preventive care is a good model for this approach.[35] We want people to receive effective preventive care—a high value kind of care—so the Affordable Care Act prohibits the imposition of any fees on people when they obtain the care. Similarly, to encourage the use of generic rather than more expensive brand-name versions of the same drug, insurers often require higher co-payments for brand-name drugs. As a general matter, heath care policy should remove obstacles to desired behavior while erecting obstacles to undesired behavior.

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[31] *Id* at 1403.

[32] Robyn Tamblyn et al., *Adverse Events Associated with Prescription Drug Cost-Sharing among Elderly and Poor Persons*, 285 JAMA 421, 421 (2001).

[33] *Id.*

[34] JOSEPH P. NEWHOUSE & THE INS. EXPERIMENT GRP., *supra* note 26.

[35] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended at 42 U.S.C. § 18001 et. seq. (2010)).

2. "Reference pricing"

The high cost problem is not only a problem of patients receiving unnecessary care; it also is a problem of patients receiving necessary care at excessive prices. Hip replacement surgery might cost $40,000 at one hospital and $80,000 at another hospital with no difference in quality (or possibly lower quality at the higher price). Accordingly, some insurers will reimburse for surgical procedures only at a fixed "reference" price that reflects the fees charged by low-cost, high-quality physicians and hospitals.[36] If a patient chooses a more expensive provider of care, the patient is responsible for the difference between the provider's fees and the reference price. Data on reference-pricing indicate that it leads patients to switch to lower-cost providers.[37] It also causes higher-cost providers to lower their fees.[38]

3. "Scaled Cost-Sharing"

The degree to which patients are sensitive to the costs of their care depends on their income and wealth.[39] A deductible of $1,000 represents 5% of income for a family earning $20,000, but only 0.5% of income for a family earning $200,000. Or when annual caps on out-of-pocket spending are set at $6,000, they represent 30% of income for a family earning $20,000 but only 3% of income for a family earning $200,000. Hence, standard policies for out-of-pocket costs will likely have a bigger impact on the care-seeking behavior of lower income persons. And as suggested by the previously-discussed studies on the health effects of cost-sharing, lower-income persons may be overly discouraged from seeking care by standard cost-sharing policies. Accordingly, rather than

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[36] James C. Robinson & Timothy T. Brown, *Increases in Consumer Cost Sharing Redirect Patient Volumes and Reduce Hospital Prices for Orthopedic Surgery*, 32 HEALTH AFF. 1392, 1392-93 (2013).

[37] *Id.* at 1394-95.

[38] *Id.*

[39] Christopher T. Robertson, *Scaling Cost-Sharing to Wages: How Employers Can Reduce Health Spending and Provide Greater Economic Security*, 14 YALE J. HEALTH POL'Y L. & ETHICS 239, 244 (2014).

setting cost-sharing levels at fixed dollar amounts, insurers could calculate deductibles, annual caps, and other forms of cost-sharing as a percentage of income.[40] Deductibles could be set at 1% of income, and annual caps could be set at 5% of income.

B. Limits of Cost Containment

While carefully-designed health insurance reforms can play a significant role in making patients more conscious of costs, these reforms can play only a limited role in cost containment. The impact of cost-sharing strategies dissipates when patients hit their annual cost-sharing maximums. Once a deductible is satisfied, for example, it no longer can have any influence, and once annual caps on total out-of-pocket expenses are exceeded, patients no longer need to worry about other cost-sharing policies such as copayments. Reference pricing would still matter even after annual caps on out-of-pocket spending are satisfied, but estimates indicate that reference pricing would reduce overall spending by less than two percent.[41] In sum, it is useful to consider health insurance reforms that encourage greater cost-consciousness among patients, but policy makers will have to look elsewhere for major savings in health care spending.

Might other patient-directed policies be useful? This article has focused so far on insurance plan design, but there are ways to influence patient behavior. The next section considers the potential role of employer wellness programs in containing health care costs.

IV. EMPLOYER WELLNESS PROGRAMS

In addition to lowering health care spending by sending patients higher bills for their visits to the doctor or the

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[40] *Id.*

[41] PAUL FRONSTIN & M. CHRISTOPHER ROEBUCK, REFERENCE PRICING FOR HEALTH CARE SERVICES: A NEW TWIST ON THE DEFINED CONTRIBUTION CONCEPT IN EMPLOYMENT-BASED HEALTH BENEFITS 10 (Employee Benefit Research Institute 2014), *available at* http://www.ebri.org/pdf/briefspdf/ebri_ib_398_apr14.refprcng.pdf [https://perma.cc/26PW-Y3UA].

hospital, we might lower spending by encouraging patients to take better care of themselves. If people are healthier, they will not need as many appointments with their doctors or admissions to the hospital. Employers are increasingly using the skin-in-the-game approach to promote healthier behavior. Through financial incentives tied to "wellness programs," the hope is that employees will eat more nutritiously, exercise more regularly, and require less health care.[42]

Wellness programs typically are divided into (1) screening initiatives and (2) intervention activities.[43] Screening initiatives include questionnaires that ask individuals about their diet, exercise, and other health-related matters.[44] Screening also can include clinical measurements such as a person's weight, blood sugar, cholesterol, and blood pressure.[45] If people realize that their weight, blood pressure, or other measurements are too high, they can follow up with a physician to see what kinds of action would be helpful.

Or they might follow up with the wellness program's intervention activities. These can include counseling about exercise and diet, smoking cessation programs, gym memberships, and healthy food offerings in cafeterias or vending machines.[46]

While many employers simply offer their wellness programs alone, other employers combine the programs with financial incentives, sometimes rewarding employees for participation in the programs, at other times rewarding employees for improvement in their weight, blood pressure,

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[42] Wellness programs can be implemented outside of the workplace. Governments, insurers, and individuals for themselves also can design wellness programs. Kristin M. Madison, Kevin G. Volpp & Scott D. Halpern, *The Law, Policy & Ethics of Employers' Use of Financial Incentives to Improve Health*, 39 J.L. MED. & ETHICS 450, 450-51 (2011). But there are important advantages to employment-based programs, in large part because people spend much of their waking time at their workplace. *Id.* at 455.

[43] David Orentlicher, *Health Care Reform and Efforts to Encourage Healthy Choices by Individuals*, 92 N.C. L. REV. 1637, 1648 (2014).

[44] *Id.*

[45] *Id.*

[46] *Id.*

or other measures of health.[47] Under federal law, there is no limit on the magnitude of incentives that can be used to encourage employees to participate in wellness programs.[48] While a typical incentive might provide employees with a rebate on their health insurance premiums of $100 or $200 for checks of weight, blood pressure, blood sugar, and cholesterol, an employer could offer much higher rebates for participation—or impose surcharges of any amount for non-participation.[49]

Employers also might want to link their financial rewards or penalties to results. For example, a rebate or surcharge on insurance premiums might be tied to the losing of weight, the reduction of blood pressure, or the achievement of other health targets. For incentives tied to the satisfaction of health targets, the incentive may not be any higher than 30% of the cost of the employee's health insurance coverage (with a 50% maximum for meeting smoking cessation targets).[50]

While wellness programs are sound in principle—an ounce of prevention is worth a pound of cure—there are significant problems with these programs in practice. For example, employers often do not choose effective programs.[51] And even when wellness programs are successful, their results are modest. In one study, only one-third of employees lost at least five percent of weight.[52] In another study,

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[47] *Id. at 1648-49.*

[48] *Id.* (provisions regarding financial incentives for wellness programs are included in HIPAA and ACA.).

[49] *Id.*

[50] *Id.* at 1649. To protect employees from unfair discrimination, employers must offer reasonable alternative standards. For example, if the incentive is tied to weight loss, and a worker has a genetic disease that makes it very difficult to lose weight, the employer would have to revise the target for the employee. *See id.*

[51] Karen Chan Osilla et al., *Systematic Review of the Impact of Worksite Wellness Programs*, 18 AM. J. MANAGED CARE e68, e78 (2012) (finding positive outcomes only one half of the time for wellness programs that were studied with a randomized controlled trial).

[52] Caryn Zinn et al., *A "Small-Changes" Workplace Weight Loss and Maintenance Program: Examination of Weight and Health Outcomes*, 54 J. OCCUPATIONAL & ENVTL. MED. 1230, 1234-35 (2012).

participants lost less than one percent of weight on average.[53] And these modest results may be exaggerated. When programs are voluntary, "selection bias" may exaggerate their effectiveness.[54] Hence, randomized controlled studies of wellness programs find smaller impacts than do non-randomized studies. In one review of wellness program studies, researchers found that exercise programs generated positive results 62% of the time, but only 43% of the time when the studies involved a randomized control group for comparison.[55] Unfortunately, experts have not yet figured out how to design wellness programs that reliably deliver a high level of effectiveness.

Ineffective programs are not only wasteful, they also can be harmful. In one of its most important provisions, the ACA promotes access to health care coverage by eliminating insurance premium surcharges for people with cancer, diabetes, heart disease, or other "pre-existing" medical conditions.[56] No longer does a person's health status affect the ability to afford health care coverage. But financial incentives tied to losing weight, lowering blood pressure, reducing blood sugar, or meeting other health targets will impose greater costs on persons with health problems, thereby undermining ACA's protection of persons with pre-existing medical conditions. Indeed, an analysis of employer wellness programs suggests that savings on health care spending from the programs may simply reflect the shifting of costs to employees with higher risks of illness.[57] ACA's goal of affordable health care is further undermined by the fact that when person with health problems bear greater costs, the greater costs fall disproportionately on persons who are poor.

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[53] Susan B. Racette et al., *Worksite Opportunities for Wellness (WOW): Effects on Cardiovascular Disease Risk Factors after 1 Year*, 49 PREVENTIVE MED. 108, 110 tbl. 2 (2009).

[54] Selection bias refers to the possibility that a voluntary program will attract especially motivated participants whose experiences will be different from the people who choose not to participate in the program.

[55] Osilla et al., *supra* note 51, at e69.

[56] *See* 42 U.S.C. § 300gg–4(a) (2016).

[57] Jill R. Horwitz, Brenna D. Kelly & John E. DiNardo, *Wellness Incentives in the Workplace: Cost Savings through Cost Shifting to Unhealthy Workers*, 32 HEALTH AFF. 468, 469 (2013).

While financial incentives tied to wellness programs often are ineffective and even harmful, there are some wellness incentives that can be useful. A number of features are important:

When incentives are tied to short-term progress, they seem to work better than incentives calculated on an annual basis. People respond more readily to immediate rewards and penalties than to delayed rewards and penalties.[58] Thus, in one study of financial incentives for weight loss, participants received lottery tickets or accumulated "deposit contract" rewards on a daily basis if they met their weight loss goals,[59] and the incentives were effective at encouraging weight loss during the four months of the study.[60]

As this study also suggested, incentives may need to be maintained indefinitely. Within several months after the study ended, there was no significant difference in weight loss between the participants and a control group of people who had not received the financial incentives.[61] Of course, this may simply reflect the fact that any strategies for weight loss need to be continued indefinitely, just as treatments for high blood pressure, diabetes, and other chronic medical conditions need to be continued indefinitely.

Finally, program designers need to consider whether their incentives should be implemented as penalties for failure or rewards for success. Penalties often are more effective than rewards at eliciting changes in behavior. People worry more about losing something they already have than about gaining something they do not have.[62] On the other hand, people

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[58] Orentlicher, *supra* note 43, at 1643, 1652.

[59] Kevin G. Volpp et al., *Financial Incentive-Based Approaches for Weight Loss: A Randomized Trial*, 300 JAMA 2631, 2632-33 (2008) (describing a study with deposit contracts where participants committed a small amount of money each day that was matched at a higher amount by the study, with the total dollars paid to participants who achieved their weight loss goals). While deposit contract awards could be earned on a daily basis, the awards were actually paid out on a monthly basis. *Id.* at 2632.

[60] *Id.* at 2634-35.

[61] *Id.* at 2635.

[62] Scott D. Halpern et al., *Randomized Trial of Four Financial-Incentive Programs for Smoking Cessation*, 372 NEW ENG. J. MED. 2108, 2109 (2015).

prefer to be rewarded for success than penalized for failure, so reward-based incentives may be a more effective strategy overall.[63]

V. CONCLUSION

In recent years, concerns about health care cost containment have led employers, insurers, and governments to give individuals more skin in their health care game. But the interest in patient incentives for cost consciousness has exceeded the benefits that these incentives can deliver. When used in a limited and properly designed fashion, the incentives can achieve some cost savings. But the overall savings will be small, and they can easily be offset by their own costs if the incentives are not well-designed.

[63] *Id.* at 2114.

SIXTEEN MYTHS OF MEDICINE AND MEDICAL MALPRACTICE

Norman G. Tabler, Jr.*

http://dx.doi.org/10.18060/3911.0020

Good morning. I was delighted and flattered to receive Professor Terry's invitation to speak this morning. I was even more delighted when he told me the topic: myths of medicine and medical malpractice. I was delighted because this gives me a rare opportunity to vent in public—to complain about the misconceptions and erroneous beliefs that I have encountered on a daily basis in my forty plus years of representing clients in the health care industry.

With your indulgence, I want to start from a thirty-thousand-foot view of American health care in general and gradually narrow our focus to the tort system of addressing claims of professional liability. If time allows, I would like to devote a few minutes to a special interest of mine: the role of apologies in resolving professional liability issues.

MYTH I: AMERICA HAS THE BEST HEALTH CARE IN THE WORLD

Here is the first myth—one that survives despite mountains of evidence to the contrary. The myth is that the Americans have the best health care in the world. You hear and read this myth every day of the week, from the sophisticated and unsophisticated alike.

Here is the Speaker of the United States House of Representatives, John Boehner, on the July 1, 2012, edition of the CBS Sunday morning staple *Face the Nation*: "Governor Romney understands that Obamacare will bankrupt our country and ruin *the best health care delivery system in the world*."[1]

And on the Senate side of Congress, here's then-Senate Minority (now Majority) Leader Mitch McConnell's take on the matter: the United States has "the finest health care system in the world."

When Speaker Boehner's office was asked for evidence to back up the claim, a spokesman observed that "there is no

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*Counsel, Faegre Baker Daniels LLP; former Senior Vice President & General Counsel, Indiana University Health.

[1] Louis Jacobsen, *'Best Health Care Delivery System in the World'? John Boehner Thinks So,* POLITIFACT.COM (Jul. 5, 2012, 10:30 AM), http://www.politifact.com/truth-o-meter/article/2012/jul/05/best-health-care-delivery-system-world-john-boehne/ [https://perma.cc/EC66-HRZX] (Italics added).

generally accepted measure for quality of care," but said that there are several measures by which the United States fares well. For example, in 2004 The Commonwealth Fund rated the United States the best in four out of five preventive-care categories when compared to four other advanced industrialized countries. And, he went on, the United States has strong survival rates for patients with cancer.[2]

Finally, the Speaker's spokesman invoked the old saw: wealthy foreigners flock to the United States for their care. To me, that's like saying we know the Dominican Republic has the best housing in the world because rich people have winter homes there.

But let's pause to analyze this evidence offered on behalf of the Speaker. We'll start with the statement that "there's no generally accepted measure for quality of care." There are two glaring problems with that statement. First, it was the Speaker who claimed that there *is* a generally accepted measure: he said that the United States ranks number one by that measure.

Second, with the apparent exception of the Speaker, everyone knows that generally accepted measures of quality do, in fact, exist. And, again with the apparent exception of the Speaker, everyone knows what some of the measures are and where to find them. I suggest that the Speaker google this phrase: "Medicare AND quality measures." He'll find a lifetime of reading material, all of it focused on generally accepted quality measures.

And notice the hasty retreat by the spokesman from the Speaker's sweeping claim to *overall* superiority to the infinitely narrower and more modest claim of best in four out of five preventive-care categories when compared to four other countries and "strong survival rates" for patients with cancer. Those are admirable rankings, if accurate, but they are nowhere near to proving the unqualified overall superiority the Speaker claimed.

The spokesman cited a 2004 survey by The Commonwealth Fund. However, the Speaker might be interested in a study released by the same organization just last summer. The headline of the press release accompanying sums up the findings nicely: "U.S. Health

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[2] *See id.*

System Ranks Last Among Eleven Countries on Measures of Access, Equity, Quality, Efficiency, and Healthy Lives."[3] Not best: *worst*. Not first: *last*.

MYTH II: YOU GET WHAT YOU PAY FOR (IN HEALTH CARE)

The Commonwealth Fund study provides a great segue to the next myth: that you get what you pay for in health care. That study, while ranking the United States eleventh out of eleven in quality, also ranked us as the most expensive of the eleven countries. And the contest was by no means close. The average annual cost in the United States was over *twice* the cost in the United Kingdom, which, incidentally, ranked first in quality: $8,500 in the United States versus $3,400 in the United Kingdom.

The study puts the lie to the you-get-what-you-pay-for myth in two different ways. The more obvious of the two is that the worst health care has the highest cost, and the best health care has the lowest cost. The second of the two ways deserves its own section. Here it is.

MYTH III: THE BEST HEALTH CARE IS THE MOST EXPENSIVE HEALTH CARE

To the surprise of no one, with the possible exceptions of Speaker Boehner and Senator McConnell, the 2014 study by The Commonwealth Fund revealed that the factor that most significantly dragged the United States down in the rankings was a wide-spread lack of access to primary care, especially access by the poor.

Primary care—almost by definition—is the least expensive care. It is much less expensive than specialty care and, of course, vastly less expensive than hospital care. But the unavailability of that inexpensive primary care has the inevitable result of increasing the need for, and consumption

[3] Press Release, The Commonwealth Fund, U.S. Health System Ranks Last Among Eleven Countries on Measures of Access, Equity, Quality, Efficiency, and Healthy Lives, (Jun. 16, 2014), *available at* http://www.commonwealthfund.org/publications/pressreleases/2014/jun/us-health-system-ranks-last [https://perma.cc/ZXF5-33CV].

of, more expensive specialty and hospital care. So the best quality care is the least expensive care. It is primary care.

If you ask experts in the relevant fields—say, population management and disease prevention and control—to name the best investments for improving health, they do not cite multi-million dollar robotic equipment or subspecialist physicians in exotic fields. They cite investments that are very—even shockingly—inexpensive. They suggest sending social workers and dental hygienists into the inner city. They suggest sending drivers to assure that people have transportation to their doctors' offices and clinics.

So the best care is not the most expensive. The best care is, relatively speaking, dirt cheap. The myth is not just wrong. It is the precise opposite of the truth. What is more, the myth is harmful because it is so misleading.

MYTH IV: MORE HOSPITAL CARE IS BETTER CARE

Somehow this myth survives—the myth that more hospital care is better care. Think how often you read about a celebrity who has checked into a hospital because he "needs the rest." Rest? In a hospital? With all the busy nurses and aides working around the clock? With the sounds of carts wheeling through the halls twenty-four hours a day? Not to mention the comings and goings of people who are really sick—the ones who are in the hospital because they are sick rather than because they want to rest.

If the celebrity wants rest, he would be better off in a Ritz-Carlton Hotel. It would be a lot quieter—a lot more restful. And it would cost only a fraction of a hospital stay.

And the Ritz-Carlton would be *safer* than a hospital. Those of us in the industry or who serve the industry don't like to acknowledge it in public, but a hospital is not a particularly safe place to be. Why? Because it is full of sick people. And the acuity—the degree of sickness—increases every year. There is a reason we have a term called "hospital-acquired infections" but not a term called "hotel-acquired infections." It is because people regularly get sick, or sicker, from exposure to infections present in hospitals. That does not happen in hotels to any significant degree.

Federal law and some state laws do not seem to take this factor into consideration when they impose mandatory

minimums on length-of-stay benefits in health insurance plans. The best known of such laws is the Newborns' and Mothers' Health Protection Act of 1996 (the Newborns' Act),[4] enacted as an amendment to the Employee Retirement Income Security Act of 1974 (ERISA),[5] which generally mandates coverage of a minimum of forty-eight and ninety-six hours, respectively, for vaginal and cesarean births, and prohibits incentives that would encourage earlier discharges.

There is no doubt that the intentions behind the Newborns' Act were entirely benign. (Besides, given the name of the act, who would dare oppose it?) But if the mother and child do not *need* forty-eight or ninety-six hours, is it always a great idea to keep them in the hospital? Might it not be better, cheaper, and safer to allow them to spend the last night in the Ritz-Carlton? Or, more realistically, how about providing a home care nurse for a day or two?

MYTH V: WE DON'T RATION HEALTH CARE

This is the most fascinating of all the myths: that in America we do not *ration* health care. It is as though, at birth, every American swears an oath to deny that we ration health care and to agree that rationing health care would be a mortal sin.

So, whenever anyone opposes a health care program, he condemns it as a plan to *ration* health care. It happened with the Affordable Care Act, and it happened with various state Medicaid programs, most notable Governor John Kitzhaber's Oregon Health Plan.[6]

But what is even more fascinating is the response of program proponents to the accusation. They do not say, "Of course, it's rationing health care. There's a limit on how

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[4] Newborns' and Mothers' Health Protection Act of 1996, Pub. L. No. aw104-204 (1996).

[5] Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406 (1974).

[6] For a discussion, *see* Jonathan Oberlander, *Health Reform Interrupted: The Unraveling of the Oregon Health Plan,* HEALTH AFF., (Dec. 2006), *available at* http://content.healthaffairs.org/content/26/1/w96.full?sid=5e5f6332-5a32-41a8-adbb-d376bde2b65d [https://perma.cc/H9XK-AY6P].

much we'll spend on health care. So we ration it. And we try to do it rationally."

Instead, they tacitly agree with the premise that rationing health care would be unthinkable. So they defend the program by denying that it involves rationing health care.

America has always rationed health care. Before the inception of Medicare in the mid-sixties, we rationed it primarily through the free market system. Providers decided where to locate and not locate and how much to charge. Members of the public who had geographic access and financial capability got health care; those without access and capability went without. That's how we rationed it.

Of course, even before Medicare, there were various governmental assistance programs for the needy. They *rationed* health care in an even more explicit way than through the free market system. They set budgets and eligibility requirements. Then they rationed available health care, within the limits imposed by those budgets and eligibility requirements. Medicaid now plays that role, and in a big way. Medicaid is the largest health insurance program in the United States.

But let's stick with health care as it applies to those who don't qualify for Medicaid or other programs for the needy. For those tens of millions, Medicare is without a doubt *the* primary force in American health care. Interestingly, though, Medicare exerts all its power *indirectly*.

How? By setting reimbursement rates and policies that then determine how health care providers (most of them private) deliver (or don't deliver) care. If Medicare rates are high in certain specialties and low in others, the result is an overall increase in the availability of the former specialty care and decrease in the latter. The chronic shortage in primary care is a conspicuous example.

Remember The Commonwealth Fund study finding that Americans have less access to health care than any other industrialized nation?[7] It showed that about 40% of

[7] Press Release, The Commonwealth Fund, U.S. Health System Ranks Last Among Eleven Countries on Measures of Access, Equity, Quality, Efficiency, and Healthy Lives (June 16, 2014), *available at* http://www.commonwealthfund.org/publications/press-

respondents with below-average income reported that during the previous twelve month they had foregone health care due to cost.[8] Try telling them that we do not ration health care.

Let's be clear, though: this may (and probably does) mean that we do a poor job of rationing. But it doesn't mean that rationing is in itself bad.

MYTH VI: THE TORT SYSTEM SHOULD WEED OUT BAD DOCTORS

Now let's narrow our focus to the tort claim system for resolving professional negligence disputes in the medical area. In this context, we often hear the complaint that the tort system is ineffective in weeding out incompetent physicians. And Professor Hyman has very persuasively demonstrated that the system is, indeed, ineffective in doing that.[9] The tort system does *not* weed out bad doctors.

But I'd like to go one step deeper in the analysis and ask, "Why *should* the tort system weed out bad doctors. Why should we have that expectation?"

I can think of three different ways to address the question, and by all three of them, the answer is the same: we should *not* rely on the tort system for that purpose. The first of the three comes from Professor Hyman's study: such reliance is misplaced because the system is unreliable for that purpose.

The second way is by analogy to other industries and other walks of life. Imagine that you ask the Federal Aviation Authority how it weeds out bad pilots. The FAA responds that if there is a crash and someone sues and proves the cause was pilot negligence, the pilot gets fired. How would you feel about that as a method for weeding out bad pilots?

Or say you ask a local hospital executive about medical staff credentialing, and he says, "Oh, we rely on malpractice

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releases/2014/jun/us-health-system-ranks-last [https://perma.cc/GP4Y-H47J].

[8] *Id.*

[9] *See* David A. Hyman & Charles Silver, *Five Myths of Medical Malpractice*, 143 CHEST J. 222 (Jan. 2013), *available at* http://www.americanbar.org/content/dam/aba/administrative/medical_liability/five_myths_of_medical_malpractice.authcheckdam.pdf [https://perma.cc/FRS4-4RVL].

case outcomes to weed out the bad doctors." I assume you would not be checking into that hospital any time soon.

Or think about your own experience and observations when it comes to driving. We have a tort system for resolving negligence issues arising out of driving automobiles and trucks. Does it weed out bad drivers?

The third way is by taking a hard look at the reality of the tort system as it applies to medical negligence. The myth appears to envision something like this: doctor commits malpractice, gets sued, loses, makes malpractice insurer pay, becomes uninsurable, and has to leave practice— all in short order.

Contrast that with reality. If there is any hope for a financial recovery by the patient, *all* of the following factors must be present: negligence is provable; damage to the patient is provable; the patient has the knowledge and the will to pursue the matter; the patient has a lawyer willing and able to pursue the case; the doctor has insurance; the patient and lawyer have the patience *and the financial resources* to pursue the matter for what may well be many years; a judge or jury finds negligence and awards damages; and the doctor becomes uninsurable and therefore retires from practice.

How likely is all of that?

MYTH VII: WHEN A CASE GOES TO TRIAL, THERE IS A WINNER (OTHER THAN THE ATTORNEYS)

That parenthetical is not meant to demean the role of attorneys in professional negligence cases. I put it in because I want to focus on the plaintiffs and defendants.

We typically talk as though there is a winner and a loser in a negligence trial. Even we lawyers use those terms. But I contend that, in practical terms, there generally *are not* any true winners.

Let's start with a plaintiff's Platonic ideal. Assume that a patient is damaged by a doctor's professional negligence, that $1 million is an accurate measure of the damage, that the judge or jury finds liability and awards precisely that amount, that the doctor has insurance or resources to cover the award, and that the plaintiff is promptly paid in full.

The next morning's newspaper would report that the patient had "won" the case and was $1 million richer. But is that really the case? Let's look a little deeper. We know that his damage was $1 million, and so was the award. Chances are overwhelming that the patient owes his lawyer anywhere from $300,000 to $400,000, plus expenses in the five figures. And the process has likely taken years—maybe as many as ten.

So in this best (for the plaintiff) case scenario, the plaintiff has debits of at least $300,000 in legal fees, say $25,000 in costs, and say $60,000 in loss of use of the money (at 6% a year). In other words, in the best case scenario, the so-called winner receives $615,000 in return for a $1 million loss. He can't afford many more such "wins."

Now let's look at the best case scenario for a doctor. He wasn't negligent and a judge or jury says so after years of effort, distraction, embarrassment, and anxiety. What does he get at the end of the ordeal other than an end to it?

It is true, I will acknowledge, that if a patient takes home more of a damage award than the combined value of his actual damage and the cost of pursuing the matter, he is in a sense a "winner." Conversely, the doctor who is vindicated, regardless of his negligence actually harming a patient, may have won something. Although the tort process is in itself a heavy price for a defendant.

But the reality is that these extremes rarely occur. The hurdles for plaintiffs are simply too numerous and too high to allow very many instances when they truly come out ahead of the game.

And the doctor whose malpractice seriously harms a patient? If the patient pursues a civil action, chances are small that the doctor will survive the ordeal without *some* finding of liability. If the doctor avoids liability, it's probably because the patient didn't—or couldn't— pursue the matter. If the patient sticks with it, the doctor will in all likelihood be held to *some* degree of liability.

MYTH VIII: JURIES AWARD MORE MONEY THAN JUDGES

I have to start discussion of this myth with the acknowledgment that I have no experience and little

information about medical malpractice awards outside the state of Indiana. All I have to say is based on Indiana.

Let's start by stating the myth. The myth persists that juries generally award more than judges—that juries become enflamed by emotion and outrage and award enormous, jaw-dropping sums. Remember the climactic scene in *The Verdict*, starring Paul Newman? So enflamed was the jury by the perfidy of the defendant hospital (represented by a sneering James Mason) that they asked the judge, "Are we allowed to award more than the plaintiff asked for?"

That happens in Hollywood. It doesn't happen in Indiana. In Indiana juries tend to be very conservative—even stingy—in calculating awards. And that's when they find the malpractice defendant liable. I know of cases where the jury found the doctor or hospital liable and then awarded damages equal to the patient's medical bill—not a penny more.

In cases like that no judge would have awarded less that the jury. That's why in certain kinds of medical malpractice cases, experienced plaintiffs' lawyers prefer that a judge rather than a jury calculate the damages.

MYTH IX: A HOSPITAL-ACQUIRED INFECTION MUST BE THE HOSPITAL'S FAULT

As we've discussed, the term "hospital-acquired infection" is well accepted and well-known. But the term isn't always well *understood*.

The definition of the term is self-evident. A hospital-acquired infection is an infection that the patient acquired in the hospital. It is distinguished from a community-acquired infection, which is acquired somewhere outside the hospital. Hospitals are required to track and report their hospital-acquired infection rates. The rates are published and hospitals are punished financially for high rates.

But are hospital-acquired infections always the hospital's fault? Not necessarily. First, let us look at the distinction between hospital- and community-acquired infections. Most Indiana counties have only one hospital, and that hospital may be among the largest employers in the county. It is not unusual for a hospital cafeteria to be a popular community gathering place at mealtime, especially lunch. When the

cafeteria is full of local residents at lunchtime, is there a clear difference between the hospital and the community? I am not sure there is.

Now let us turn to fault. And let us exclude the lunchtime crowd from the calculus. A typical patient has visitors, generally relatives and sometimes others. In pediatric area, it is almost a given that family members will visit a patient, frequently staying around the clock. And especially with the youngest children, the family has a significant role in caring for the child, providing comfort and assisting with eating and toilet needs.

If a patient acquires an infection from contact with a family member or other visitor, is it always the hospital's fault? Doesn't the family member or other visitor share at least some part of the responsibility?

MYTH X: UNEXPECTED READMISSION IS EVIDENCE OF POOR TREATMENT

This myth not only persists, but gains momentum every day: the myth that the unexpected readmission of a patient to the hospital is proof that the care during his earlier stay must have been inadequate. So in recent years insurance programs, led by Medicare, have begun to refuse to pay for the readmission stay. The theory is that the readmission would have been unnecessary if the treatment had been adequate first time around.

A hospital suffers from readmissions in two different ways. First, as noted above, it may not get paid for the second stay. Second, its readmission rate is published online, and it suffers from the adverse publicity.

But let's examine the myth. It is based on the premise that no factor other than poor hospital treatment could possibly contribute to the need for readmission. That premise defies common sense and general experience. What if the patient did not take the medicine prescribed by the doctor? What if he could not afford it? What if he could not get to the pharmacy? What if he did not keep his incision wound clean? What if he ate or drank things his doctor warned him against? In short, are there not countless factors outside the hospital's control that might have contributed to the need for readmission?

You have probably noted that many of these factors outside the hospital's control are related to a patient's financial resources—or, more precisely, a patient's *lack* of financial resources. So you will not be surprised to learn that studies of the issue invariably reveal that the unexpected readmission rates for hospitals in low-income areas is higher than the rates in high-income areas.[10]

You might say that in certain areas and with certain population groups, unexpected readmissions are not unexpected.

Yet the myth persists that an unexpected readmission is proof of poor hospital care. It is a little like saying that an undernourished child is proof of a poor school cafeteria.

MYTH XI: A LOW CAP ON DAMAGES REDUCES PLAINTIFF RECOVERIES

When we talk about tort reform, we generally make the uncritical assumption that a cap on damages—that is, a legal limitation on the amount—will necessarily result in lower recoveries by plaintiffs. And, of course, it is undeniably true that a cap will result in lower recoveries in *some* cases. What is a myth, though, is the belief that a cap will result in lower recoveries in *all* cases. In fact, as we shall see, there is evidence that a cap will actually result in *higher* recoveries in some cases—and higher *average* recoveries overall.

Let's take a look at Indiana's cap. Indiana has long had the lowest cap of all states. That's what happens when a state elects a physician as its governor, as Indiana did in 1972 with the election of Dr. Otis Bowen, later United States Secretary of Health & Human Services.

Indiana's cap currently limits a health care provider's liability for an incident of medical malpractice to $250,000; and it limits a plaintiff's recovery to $1,250,000.[11] You are wondering, "If the doctor's liability is limited to $250,000, how can the plaintiff receive $1,250,000?" The explanation

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[10] *See, e.g.*, Joel S. Weissman et al., *The Impact of Patient Socioeconomic Status & Other Social Factors on Readmission: A Prospective Study in Four Massachusetts Hospitals*, 31 JSTOR 163, 169 (1994).

[11] Ind. Code § 34-18-14-3 (2016).

lies in the Indiana Patient Compensation Fund ("the Fund"): a state-run insurance program that can pay the difference between the defendant's obligation and the $1,250,000 limit.

In 1991 Professors Eleanor Kinney and William Gronfein published the results of an exhaustive study of the first ten years of experience under the Indiana cap on malpractice liability. The results were eye-opening. Indiana plaintiff recoveries in large-claims cases (defined back then as $100,000 or more) actually *exceeded* large-claim recoveries in neighboring Ohio and Michigan—larger states with no caps.[12]

What is the explanation? How can a damage cap cause recoveries to go *up*? The answer appears to be that in large-claim cases the limit on a provider's liability (currently $250,000, but only $75,000 at the time of the Kinney-Gronfein study) encourages an insurer to effectively concede liability for an amount up to, or exceeding the limit on, the insured's liability, leaving the excess for the Fund to pay and saving the insurer from further costs of defense.

So, paradoxically, a cap can—and does—often *increase* plaintiff recoveries.

MYTH XII: THERE IS SUCH A THING AS A NEVER EVENT

Most of the myths we are discussing are old. They have been around as long as anyone can remember. This is a new one. It sprang up almost overnight, and it spread like wildfire. In fact, it is still spreading, with more and more events classified as "never events."

The term was introduced in 2001 by Ken Kizer, M.D., former chief executive officer of the National Quality Forum.[13] The term was meant for truly shocking events—*e.g.*, surgery on the wrong patient—that should never occur. Over time, the list of events has expanded. Medicare now lists 29 "never events" and often declines to pay for care that

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[12] Eleanor D. Kinney & William P. Gronfein, *Indiana's Malpractice System: No-Fault by Accident?,* 54 LAW & CONTEMP. PROBS. 169, 182 (1991).

[13] *See, e.g.*, *Never Events*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY (Dec. 2014), http://psnet.ahrq.gov/primer.aspx?primerID=3 [https://perma.cc/E72T-ARAH].

involves such events.[14] Other insurance carriers have joined in, also declining to pay for never events. Many states have adopted requirements that hospitals report events of the sort that appear on never event lists.

There is no doubt that every event on the list is unfortunate and regrettable. None of them *should* occur, and hospitals should do their utmost to prevent them. But I maintain that it is wrong to claim that all of them are always avoidable or that a good hospital—even an excellent hospital—can always avoid all of them.

Let us consider a few examples: physical assault of a patient or staff member in the hospital or on the hospital grounds, serious injury of a patient from a fall, certain pressure ulcers acquired in the hospital, and serious injury from a medication error.

All of these are regrettable. But can a good hospital *always* avoid them? Let us start with physical assault. If a hospital is open to the public for 24 hours a day, how can it assure that no patient or staff member will ever be physically assaulted in the hospital or on the hospital grounds? If it can, why have all institutions in all industries not taken the same steps?

Or patient falls. People fall down. Old, sick, and medicated people are particularly susceptible to falls. Hospitals are forbidden to apply physical restraints to patients. How, then, can *all* falls be prevented?

Or pressure ulcers bed sores in common parlance. Some studies show that when a mature adult lies motionless for two hours or more skin breakdown starts to occur.[15] So what happens when a seventy-year-old lies motionless on an operating table for four or more hours? You guessed it.

Take a look at the Mayo Clinic's published list of factors contributing to bed sores. It describes a large proportion of Medicaid and Medicare patients who find themselves in the

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[14] *Id.*

[15] *See Factsheet: Skin Breakdown and Pressure Ulcer Prevention in Persons with SCI*, REHABILITATION RESEARCH AND TRAINING CENTER ON SECONDARY CONDITIONS IN THE REHABILITATION OF INDIVIDUALS WITH SPINAL CORD INJURY (2012), http://sci-health.org/RRTC/publications/PDF/Skincare-Factsheet.pdf [https://perma.cc/ZEP6-FKDV].

hospital: old age, weight loss, poor nutrition, incontinence, smoking, and dry skin.[16]

Let's complete our review with medication errors. Two primary factors assure that even excellent hospitals will experience medication errors. One is the emergency, not-a-moment-to-spare, nature of some hospital work. That kind of situation is most likely to occur in the emergency department. It also occurs, however, in inpatient areas when emergencies arise. Sometimes hospital personnel need to act first and carefully consider the matter later. That may be unfortunate, but it is reality in a hospital.

The other factor contributing to medication errors is the *sheer number* of times medications are administered. It may simply be impossible for humans to do anything a million times without an error. Does a million sound like too high a number? Just consider a hospital with 200 beds. Assume each of the 200 patients needs medications five times a day. That's 200 X 365 X 5, or 365,000 doses a year.

But that is not the total number. Each medication has been prescribed by a doctor, prepared or sent by the pharmacy, delivered from the pharmacy area to the nurses' station, and administered by a nurse. That is four separate stepswith each involving four or more separate people. If it is four, then we can multiply our initial 365,000 by that number, for a total of nearly 1,500,000. It is hard for human beings to do anything 1,500,000 times a year without a single error. Even with 99.9% accuracy, there would still be 1,500 errors.

So these events cannot really be *never* events. They are unfortunate and hospitals should do all they can to avoid them. But they will continue to occur.

MYTH XIII: AN INSURER SHOULD HAVE LOW ADMINISTRATIVE COSTS

I apologize in advance for this one. It's inside baseball. If you look at a performance report on a liability insurance carrier, one of the factors you always see is a comparison of

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[16] *See Bedsores (pressure sores)*, MAYO CLINIC (DEC. 13, 2014), http://www.mayoclinic.org/diseases-conditions/bedsores/basics/risk-factors/con-20030848 [https://perma.cc/3KRP-UHLF].

the amount it pays to resolve liability claims—judgment and settlement payments—to all other expenses, *i.e.*, administrative costs. And the prevailing wisdom is that a high proportion of administrative costs is a bad thing—an indicator of inefficiency.

At first glance, this conventional wisdom sounds right. Let's take a closer look. What if a health system operates its own captive insurance program, spends a high amount on risk management and risk reduction strategies, and as a result pays only a very modest amount in claims settlements? The arithmetic would show a high proportion of administrative costs. But would that be a bad thing? I don't think so.

MYTH XIV: THERE'S AN ANSWER TO, "SHOULD PHYSICIANS APOLOGIZE FOR MEDICAL ERRORS?"

I have spoken and published articles on the subject of the role of physician apologies in resolving cases professional negligence. Often, in discussions of the subject, people ask me the question posed on the screen: "Should physicians apologize for medical errors?" To me, that's a little like asking, "Should parents send a child to a private school?" The only accurate answer is, "It depends."

Let's first discuss why there is not one answer to the question. Later I'll give you my own general view on a matter that is hard to generalize about. Why is there not a one, one-size-fits-all answer? First, consider the most basic variables in any one case. Was there an error? That is harder to answer than you might think. It's common for experts to disagree on that fundamental matter when, say, a case is reviewed by a medical review panel. That is, of course, why in Indiana we use a panel rather than a single expert.

Next, does the error really reflect fault? Or did the error occur despite the provider's adherence to the standard of care appropriate to the circumstances?

Next, was there damage to the patient? It is a fact—fortunately—that most errors in a hospital do not cause any significant harm or any harm at all. Most are never even detected. In my earlier hypothetical about the 200-bed hospital, we found 1,500,000 separate actors annually in

medication administration alone: opportunity for more than a few errors. Most of those errors are never discovered.

Finally, if there *was* damage, what was the extent of it? Did the damage leave the patient disabled for life? Dead? Or was it a bedsore that healed in two weeks?

Now, one more difficult and sensitive question: assuming we can answer all the previous questions the way the plaintiff wants them answered, who was responsible? Was it really the defendant? Remember that in the context of hospital care, medicine is a *team* sport. If, for example, the incident occurred in surgery, team members might have included one or more surgeons, two or more nurses, an anesthesiologist, maybe one or more residents or fellows, one or more technicians, and that always-present team member, the facility itself.

So whose fault was it? Or, in terms of the question on the screen, who should do the apologizing? Do we really want the surgeon to say to the plaintiff, "I want to apologize for the incompetence of the circulating nurse?"

MYTH XV: AN APOLOGY NECESSARILY INVOLVES ADMISSION OF LIABILITY

According to conventional wisdom, a physician can't apologize for a medical error without admitting responsibility for it. Therefore, a physician shouldn't apologize for an error because doing so would make him liable for the damage to the patient.

But, as a linguistic matter, an apology *can* be separated from an acceptance of responsibility. And interestingly, some states have adopted rules of evidence that turn on that separation.

Since 2006 our own state, Indiana, has distinguished between a "communication of sympathy" and a "statement of fault." The former is inadmissible in evidence. The latter is not.[17] Assume, for example, that a surgeon said to a plaintiff, "I am very sorry your husband died on the operating table; I was at fault." The first independent clause would not be admissible in evidence, but the second one would be admissible.

[17] Ind. Code § 34-43.5-2-4 (2016).

In contrast to Indiana, Colorado would make the surgeon's entire statement inadmissible.

The Colorado statute says that in a civil action arising out of an "unanticipated outcome of medical care," all of the following are inadmissible: all statements made by a health care provider "expressing apology, fault, sympathy, commiseration, compassion, or a general sense of benevolence."[18]

So in terms of the words on the screen, both states make a distinction between an apology—or at least, an expression of sympathy—and an admission of liability. Indiana makes one inadmissible and the other admissible. Colorado distinguishes between the two but makes both inadmissible.

MYTH XVI: APOLOGIZING FOR MEDICAL ERRORS IS ALWAYS A MISTAKE

You have probably guessed from my last couple of points how I feel about the issue on the screen. Let me start with my conclusion and then explain how I got there. My conclusion is that there's no single, one-size-fits-all answer; but sometimes—even often—an apology can actually be a *good* idea for the physician or the hospital.

There is by no means a wealth of evidence on the effects of disclosure and apology for medical errors. But the evidence that exists points to the conclusion that physician apologies decrease both the incidence of lawsuits and size of awards to patients. In 1987, the Veterans Administration (VA) Hospital of Lexington, Kentucky, instituted one of the earliest formal disclosure policies. A study over a seven-year period (1990—96) revealed that, compared to the other 35 VA hospitals in the eastern United States, the Lexington VA hospital was in the top quartile in the number of claims filed but the bottom quartile in the amount of payments.[19]

In 2002 the University of Michigan Health System launched a program that, among other things, called for

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[18] Col. Rev. Stat. § 13-25-135 (2016).

[19] Steve S. Kramer & Ginny Hamm, *Risk Management: Extreme Honesty May Be the Best Policy*, 131 ANN. INTERN. MED. 963, 963 (1999); *See also* Albert W. Wu, *Handling Hospital Errors: Is Disclosure the Best Defense?* 131 ANN. INTERN. MED. 960 (1999).

prompt acknowledgement of errors and prompt compensation to patients. From August 2001 through August 2005, the average number of open cases declined from 260 to 114. Annual litigation costs dropped from approximately three million dollars to one million dollars.[20]

We generally assume that the victim of negligence is motivated primarily—even exclusively—by the desire for money. But that's not what the research shows.

According to Lucian L. Leape, M.D., of the Harvard School of Public Health, what the typical patient most wants—more than money—is that the physician (a) acknowledge the error and explain it, (b) take responsibility and apologize, and (c) discover the underlying cause and take steps to prevent recurrence.[21] Similarly, Professor Carol B. Liebman of Columbia Law School, and Chris Hyman, of the Medical Mediation Group in New York City, report that what patients most want—more than money—are (a) basic information about the incident, (b) an apology, and (c) prevention of recurrence of similar incidents.[22]

These two studies are consistent with studies of why patients sue their physicians. The primary reasons are (a) the perception that the physician wasn't honest in addressing the incident, (b) the perception that no one would explain what happened, and (c) the receipt of advice from someone (often another health care provider) to sue.[23]

Now consider the several disclosure requirements that already obligate a physician and a hospital to disclose a medical error to the patient. The American Medical Association has long held that a physician has an ethical duty to disclose a harmful error to the patient.[24] And The Joint

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[20] Hillary R. Clinton & Barack Obama, *Making Patient Safety the Centerpiece of Medical Liability Reform*, 354 NEW ENG. J. MED 2205 (2006).

[21] Lucian L. Leape, *Understanding the Power of Apology: How Saying 'I'm Sorry' Helps Heal Patients and Caregivers*, 8 FOCUS ON PATIENT SAFETY FOUND. 1 (2005).

[22] Carol B. Liebman & Chris S. Hyman, *A Mediation Model to Manage Disclosure of Errors and Adverse Events*, 23 HEALTH AFF. 22, 24 (2004).

[23] *Id. See also id.* at 23 n. 9, where Liebman & Hyman identify multiple studies on physician mistakes and subsequent behavior that prompt malpractice claims.

[24] AM. MED. ASS'N, PRINCIPLES OF MEDICAL ETHICS I-IV (2001); AM. MED. ASS'N, CODE OF MEDICAL ETHICS, OPINION 8.12 (2007).

Commission, the major hospital accreditation authority in the United States, has for years required hospitals to disclose harmful medical errors, including the requirement that the disclosure be made by the "responsible physician (or a designee . . .)."[25]

So I ask you, in light of the apology statutes, results of these studies, and the disclosure requirements that the AMA and The Joint Commission already impose, isn't it reasonable to conclude that in many cases an apology is the best course of action?

CONCLUSION

Thank you for giving me the opportunity to identify what I regard as medical myths. I've been waiting my entire professional life for the chance to complain about them. You've given me that chance.

[25] *See, e.g.*, THE JOINT COMM'N, HOSPITAL ACCREDITATION STANDARDS, ETHICS, RIGHTS, AND RESPONSIBILITIES.

mHEALTH AND UNREGULATED DATA: IS THIS FAREWELL TO PATIENT PRIVACY?

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I. INTRODUCTION

Mobile health, or mHealth is a rapidly expanding industry. Globally, the total number of mHealth applications ("mHealth apps") on iOS and Android systems surpassed 100,000 in Q1 of 2014.[1] Market revenue for this industry is projected to reach $26 billion by 2018[2] and the number of mHealth users is projected to reach 1.7 billion worldwide by 2018.[3] mHealth is defined as "medical and public health practice supported by mobile devices," and it is quickly becoming a defining feature of popular technologies such as "mobile phones,… personal digital assistants,… and other wireless devices."[4] Users of mHealth apps produce volumes of data about their health, and this data is highly revealing. Several commentators note that the health data produced by patients' use of mHealth is more revealing than their Electronic Health Record (EHR).[5] Despite this reality, the vast majority of mHealth apps are not subject to significant regulation. The current regulatory scheme governing mHealth is narrow and only concerns a small fraction of the mHealth market, even including those apps covered by the

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[1] RESEARCH2GUIDANCE, mHEALTH APP DEVELOPER ECONOMICS 2014: THE STATE OF THE ART OF mHEALTH APP PUBLISHING 16 (2014) *available at* http://www.research2guidance.com/r2g/research2guidance-mHealth-App-Developer-Economics-2014.pdf [https://perma.cc/GFV4-2J5X].

[2] *Id.* at 7.

[3] *Id.*

[4] WHO GLOBAL OBSERVATORY FOR eHEALTH, mHEALTH: NEW HORIZONS FOR HEALTH THROUGH MOBILE TECHNOLOGIES, 6 (2011), *available at* http://www.who.int/goe/publications/goe_mhealth_web.pdf [https://perma.cc/PR83-JRNQ] (defining mHealth as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices.").

[5] *See* JANE SARASOHN-KAHN, HERE'S LOOKING AT YOU: HOW PERSONAL HEALTH INFORMATION IS BEING TRACKED AND USED 5 CA Healthcare Found. (2014).

Health Insurance Portability and Accountability Act (HIPAA)[6]. This paper investigates mHealth apps that are not subject to FDA oversight or HIPAA and the privacy issues involved, and ultimately proposes a United States labeling system intended to ensure consumer confidence and stimulate growth in the mHealth market.

II. THE CURRENT REGULATORY SCHEME

There are two significant regulatory questions for any mHealth app: (1) whether the app will be subject to agency regulation; and (2) whether the app will be subject to HIPAA. Beyond this, no federal laws specifically regulate mHealth applications.[7]

A. Agency Regulation

Multiple agencies share regulatory jurisdiction over the mHealth industry, including: the Food and Drug Administration (FDA), the Office of the National Coordinator for Health Information Technology (ONC),[8] and the Federal Communications Commission (FCC) (hereinafter referred to collectively as "the agencies"). In 2012, Congress directed the agencies, in Section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112-144, to collaborate and issue a report

> that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation,

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[6] Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, 110 Stat. 1936 (codified as amended in scattered sections of 29 and 42 U.S.C.) 104th Cong. (1996).

[7] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-13-663, INFORMATION RESELLERS: CONSUMER PRIVACY FRAMEWORK NEEDS TO REFLECT CHANGES IN TECHNOLOGY AND THE MARKETPLACE 19 (2013) [hereinafter INFORMATION RESELLERS] *available at* http://www.gao.gov/assets/660/658151.pdf [https://perma.cc/BA2T-PWLZ].

[8] The ONC is an office within the Department of Health and Human Services and is not an independent agency.

> protects patient safety, and avoids regulatory duplication.[9]

In fulfilling this charge, the agencies issued the "FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework," which explains, in part, that the FDA will primarily regulate health IT with medical device functionality.[10] Health IT with medical device functionality is used to diagnose and treat illnesses, as opposed to software that supports administrative functions like scheduling and documentation.[11]

With respect to mHealth applications, the FDA explained its regulatory approach in a guidance document entitled "Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff."[12] The current approach is for the FDA to focus on a subset of mHealth apps that the agency refers to as "\mobile medical applications" or "mobile medical apps."[13] An app is determined to be a "mobile medical app" based on two criteria: the app must transform a mobile device into a medical device within the meaning of section 201(h) of the Food, Drug, and Cosmetic Act ("FD&C Act"),[14] and the app must be intended for use as

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[9] U.S. FOOD & DRUG ADMIN., FDASIA HEALTH IT REPORT: PROPOSED STRATEGY AND RECOMMENDATIONS FOR A RISK-BASED FRAMEWORK 3 (2014) [hereinafter FDASIA REPORT], *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf [https://perma.cc/9ZPN-GG3V].

[10] *Id.* at 12.

[11] *Id.* at 11-12.

[12] U.S. FOOD AND DRUG ADMIN., MOBILE MEDICAL APPLICATIONS, GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2015) [hereinafter FDA MEDICAL APPLICATION GUIDANCE], *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf [https://perma.cc/2L65-4NPF].

[13] *Id.* at 7 ("…a 'mobile medical app' is a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); and either is intended: to be used as an accessory to a regulated medical device; or to transform a mobile platform into a regulated medical device.").

[14] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(h) (2016). Section 201 (h) of the Food, Drug, and Cosmetics Act defines device as

a regulated medical device or as an accessory to a regulated medical device.[15] If an app qualifies as a mobile medical app, it will be subject to certain regulatory controls, depending on its risk classification.[16]

There are three device classes.[17] Class I devices are generally considered low risk. These devices are usually exempt from premarket approval, although they must adhere to "general controls."[18] Class II devices are considered moderate risk or present well-understood risks. These devices are generally required to submit 510(k) premarket notification.[19] They are also subject to general controls, as

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> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is… intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

[15] FDA MEDICAL APPLICATION GUIDANCE, *supra* note 12.

[16] *Id.* at 30.

[17] Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539. (1976).

[18] 21 CFR §§ 800-98 (1999); FDA MEDICAL APPLICATION GUIDANCE, *supra* note 12, at 19, General controls include: Establishment registration, and Medical Device listing (21 CFR Part 807); Quality System (QS) regulation (21 CFR Part 820); Labeling requirements (21 CFR Part 801); Medical Device Reporting (21 CFR Part 803); Premarket notification (21 CFR Part 807); Reporting Corrections and Removals (21 CFR Part 806); and Investigational Device Exemption (IDE) requirements for clinical studies of investigational devices (21 CFR Part 812).

[19] U.S. Food & Drug Admin., *FDA Premarket Notification 510(k)*, FDA.GOV (Sept. 16, 2015), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm [https://perma.cc/7TUS-KEG9] (device manufacturers are required to prove that the device to be marketed is "substantially equivalent" to another legally marketed device–meaning the new device is as safe as another device with similar functionality that is already on the market).

well as "special controls,"[20] based on the particular device type. Class III devices are high risk or present risks that are poorly understood. These devices are also subject to general and special controls, as well as premarket approval,[21] and certain other regulatory controls.

Mobile medical apps are a small fraction of the overall mHealth market and the vast majority are Class I or Class II devices.[22] The FDA lists 191 medical mobile apps that have cleared the 510(k) approval process as of February 11, 2016.[23] The agency claims that this is not a comprehensive list; however, it exceeds the total listed in a comprehensive analysis compiled at the end of 2013 by the industry research group MobiHealthNews, which listed the total of approved mobile medical apps at 103. [24] The FDA maintains a database that lists approved mobile medical apps, however these apps are listed alongside other devices that have received 510(k) approval and are not uniquely identified as

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[20] 21 U.S.C. § 360c(a)(1)(B). The Secretary of Health and Human Services promulgates special controls when determined to be necessary for the assurance of safety and effectiveness. Special controls include: Performance standards; Post-market surveillance; Patient registries, Special labeling requirements; Premarket data requirements; and Guidelines.

[21] FDA Premarket Approval (PMA) http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/default.htm [https://perma.cc/73ZD-THLV]. *See* U.S. Food and Drug Admin., *supra* note 19 (Premarket approval uses scientific evidence to ensure the safety and effectiveness of devices that are particularly risky or present poorly understood risks).

[22] Christy Foreman, Dir. Office of Device Evaluation, Ctr. for Devices and Radiological Health, Health Information Technologies: Administration Perspectives on Innovation and Regulation (Mar. 21, 2013), http://energycommerce.house.gov/hearing/health-information-technologies-administration-perspectives-innovation-and-regulation#video (Director Foreman testified that there had not been a Class III mobile medical application to date).

[23] U.S. FOOD AND DRUG ADMIN., *Examples of Pre-Market Submissions that Include MMAs Cleared or Approved by FDA*, FDA (Feb. 11, 2016) http://www.fda.gov/medicaldevices/digitalhealth/mobilemedicalapplications/ucm368784.htm [https:// perma.cc/E3LF-2DLN] [hereinafter *Pre-Market MMAs*] (last updated Feb. 11, 2016).

[24] *103 FDA Regulated Mobile Medical Apps*, MOBIHEALTHNEWS (Nov. 25, 2013), *available at* http://mobihealthnews.com/research/103-fda-regulated-mobile-medical-apps/ [https://perma.cc/W2MM-QN8A].

apps.[25] As a result, approved apps are not easily searchable and may be difficult to identify as apps rather than any other medical device. Given the pace of the FDA's approval of mobile medical apps, it is reasonable to assume that the total number of approved apps is near the listed 191,[26]a small fraction of the more than 100,000 mHealth apps on the market.[27]

The FDA is pursuing this narrow regulatory framework for a variety of reasons. First, the FDA is following a risk-based approach,[28] with its primary focus on those apps that pose significant risk to patient safety.[29] Using the risk-based framework laid out by the Medical Device Amendments of 1976,[30] the agency categorizes mobile medical apps by class. Apps presenting significant risks are sent to market after obtaining the proper approval. Second, Congress directed the FDA to promote innovation in the mHealth industry[31] and

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[25] *Pre-Market MMAs*, *supra* note 23.

[26] *Id.*

[27] RESEARCH2GUIDANCE, *supra* note 1 at 7.

[28] FDA MEDICAL APPLICATION GUIDANCE, *supra* note 12 at 3.

[29] *Id.* at 8 (2015), ("…we intend to apply this oversight authority only to those mobile apps whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended.").

[30] FDASIA REPORT, *supra* note 9 at 5 n.7.

> The Medical Device Amendments of 1976 created three device classes. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. Class I devices are generally low risk. Such devices are for the most part exempt from premarket review and are subject–unless exempt–to the requirements for reporting of adverse events, manufacturing and design controls, registration and listing, and other "general" controls. Class II devices generally present moderate or well-understood risks. Such devices are subject to general controls and are usually subject to premarket review. Class II devices are also subject to "special controls" that are closely tailored to the risks of the particular device type. Class III devices generally present high or poorly understood risks. In addition to general controls, Class III devices are subject to premarket approval and certain other regulatory controls.

[31] *Id.* at 3.

has expressed concern that regulation could stifle the industry in its infancy. Several bills have been proposed to restrict or limit FDA regulation over the mHealth industry, including: The Medical Electronic Data Technology Enhancement for Consumers' Health Act of 2015 ("MEDTECH Act"),[32] the Preventing Regulatory Overreach to Enhance Care Technology Act of 2014 ("PROTECT Act"),[33] and the Sensible Oversight for Technology which Advances Regulatory Efficiency Act of 2015 ("SOFTWARE Act");[34] none have been passed by Congress. Third, stakeholder comments have emphasized that a flexible regulatory scheme is necessary to allow for the development of new technologies.[35]

With limited resources and significant pushback from both Congress and stakeholders, it is not surprising that the FDA is conducting a narrow regulatory framework. However, commentators have expressed concern over the FDA's light touch on the industry,[36] citing potential danger to patients, or claiming that unreliable technology will inhibit adoption of mHealth by medical professionals, while others assert that more stringent regulation could provide economic benefit to stakeholders.[37]

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[32] Medical Electronic Data Technology Enhancement for Consumers' Health (MEDTECH) Act, S. 1101, 114th Cong. (2015).

[33] Preventing Regulatory Overreach To Enhance Care Technology Act of 2014, S. 2007, 113th Cong. (2014).

[34] Sensible Oversight for Technology Which Advances Regulatory Efficiency Act of 2013, H.R. 2396, 114th Cong. (2015).

[35] FDASIA REPORT, *supra* note 9, at 9.

[36] *See generally* Natalie R. Bilbrough, *The FDA, Congress, and Mobile Health Apps: Lessons from DSHEA and the Regulation of Dietary Supplements*, 74 MD. L. REV. 921 (2015) (proposing an "Office of mHealth" within the FDA to provide greater expertise and further regulate the industry); Alex Krouse, *iPads, iPhones, Androids, and Smartphones: FDA Regulation of Mobile Phone Applications as Medical Devices*, 9 IND. HEALTH L. REV. 731 (2012) (suggesting a decentralized approval process for mHealth devices); Daniel F. Schulke, *The Regulatory Arms Race: Mobile-Health Applications and Agency Posturing*, 93 B.U. L. REV. 1699 (2013) (analyzing various regulatory models and ultimately suggesting a meta-regulatory approach).

[37] MOBIHEALTHNEWS RESEARCH, FDA REGULATION OF MOBILE HEALTH 47 (2nd ed.) (on file with the *Indiana Health Law Review*).

B. HIPAA and mHealth

The regulatory efforts of the FDA are an important first step for ensuring patient safety and promoting the adoption of mHealth in the healthcare industry. However, the majority of mHealth apps operate unencumbered by significant regulation. Beyond the FDA's regulation of mobile medical apps, mHealth apps face one significant regulatory question: when is an mHealth app subject to HIPAA?[38] HIPAA rules only apply to "covered entities" and their "business associates."[39] A covered entity is defined as a health plan, healthcare clearinghouse, or healthcare provider.[40] A business associate is a person, subcontractor, or organization that receives or transmits "protected health information" on behalf of a covered entity or the business associate.[41] Protected health information (PHI) means individually identifiable health information.[42] An mHealth app is subject to HIPAA if it receives or transmits a patient's PHI or is used by a covered entity or business associate.[43] PHI is created in the context of patient care and apps that store or transmit that information are subject to HIPAA. On the other hand, apps that are consumer oriented manage user-generated information that is not HIPAA protected, such as the calories in one's meal or the amount of steps one has taken on a given day. As long as an mHealth app does not deal in PHI or communicate with a covered entity or business associate it is not subject to HIPAA. Additionally, de-identified information is not subject to HIPAA protection.[44]

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[38] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 104th Cong. (1996).

[39] 45 C.F.R. § 160.103 (2016).

[40] *Id.*

[41] *Id.*

[42] *Id.*

[43] Adam H. Greene, *When HIPAA Applies to Mobile Applications,* MOBIHEALTHNEWS (June 16, 2011), http://mobihealthnews.com/11261/when-hipaa-applies-to-mobile-applications/ [https://perma.cc/Z2K5-5DR9].

[44] Dept. Health & Human Svcs., *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy*

For example, "Bob" is concerned that he might be an alcoholic and has been clinically diagnosed with depression. Bob uses a blood alcohol content calculator on his smart phone to help moderate his drinking and a mood-tracking app that allows him to enter his mood at a given time and track fluctuations. Two recently launched startup companies produced these apps and neither shares information with covered entities. The data collected by these companies is not subject to HIPAA, even though both of the companies' databases identify Bob by name and include a listing of his unique mobile identification number. Bob's self-regulation is not going well, so he goes to visit a physician at a nearby clinic. The physician prescribes Bob with anti-depression medication. At the physician's recommendation, Bob downloads a HIPAA compliant telehealth application that allows Bob to video chat with his physician rather than drive in to the clinic on a regular basis. Bob consults with his physician using the telehealth app once a month until his condition improves and his treatment ends a year later. The data collected by the telehealth app is subject to HIPAA regulation because Bob uses the app to consult with a healthcare provider (i.e. a covered entity).

Bob's communications with his physician are protected by the HIPAA Privacy and Security Rules.[45] However, Bob's entries in his smartphone using the blood alcohol content calculator and mood-tracking apps are not protected by such rules. Both apps were free to download and Bob agreed to their terms and conditions without reading their privacy policies, a common consumer practice.[46] The privacy policies for both apps state that data collected will be sold to third parties for marketing purposes. While Bob views his past

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Rule (2012), [hereinafter *De-identification Guidance*] http://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/#rationale [https://perma.cc/8HTW-J9LY].

[45] *See* 45 C.F.R. Part 160 and Part 164, Subparts A and 45 C.F.R. §§ 160.101-160.552, 164.102-164.534 (2013).

[46] SDL, MARKETING DATA AND CONSUMER PRIVACY: WHAT YOUR CUSTOMERS REALLY THINK 3 (Feb. 26, 2014), *available at* http://www.scribd.com/doc/214108509/SDL-Marketing-Data-and-Consumer-Privacy-What-Your-Customers-REALLY-Think [https://perma.cc/J3EX-MF73]. In a survey of more than 4,000 individuals, 65% of respondents reported that they rarely or never read privacy policies before making online purchases.

year as a success, he considers both his struggle with alcohol and depression deeply personal. Unbeknownst to Bob, he has documented both in great detail and his user generated health data can now be sold as a commodity on the open market through a system of data brokers.

III. USER GENERATED HEALTH INFORMATION

Like Bob in the above hypothetical, real-world persons are generating volumes of sensitive health data and signing it away as a commodity without fully understanding the implications. While mHealth apps and the services they provide can help users manage personal health, third party exploitation of that data may violate patient privacy and cause a chilling effect on the adoption of this useful technology.

A. How Consumer Data is Collected

A study by Evidon, an analytics firm (now restructured as Ghostery, Inc.), found that the top twenty mHealth apps sold "information to up to [seventy] third party companies."[47] Another study, conducted by Privacy Rights Clearinghouse, analyzed forty-three popular wellness apps for technical security risk and found that twenty of these apps transferred individually identifiable information about its users to third parties.[48] The study also found that approximately half of the apps analyzed published a privacy policy and complied

[47] Emily Steel & April Dembosky, *Worried- Well Online Have New Symptom to Fear*, CNBC: FIN. TIMES, (Sept. 1, 2013), *available at* http://www.cnbc.com/id/101002123 [https://perma.cc/22GD-5W9M].

[48] Craig Michael Lie Njie, *Technical Analysis of the Data Practices and Privacy Risks of 43 Popular Mobile Health and Fitness Applications*, PRIVACY RIGHTS CLEARINGHOUSE 7 (July 15, 2013) *available at* https://www.privacyrights.org/sites/privacyrights.org/files/CCPF-SmartphoneHealthApps-TechnicalReport-Final-July15-2013%281%29_0.pdf [https://perma.cc/3YGY-Q2GC]. The study ranked apps by risk level, indicating that apps with a risk level of 5 or higher transferred individually identifiable information to third parties. The study lists twenty apps at risk level 5 or higher. Therefore twenty of the apps studied transferred individually identifiable information to third parties.

with it.[49] In light of these two studies, the Federal Trade Commission (FTC) decided to run a similar experiment. Analyzing twelve mHealth apps, the team found a number of personal details were being transmitted to third parties.[50] For example, "22 third parties received additional information about our consumers such as exercise information, meal and diet information, medical symptom search information, zip code, gender, geo-location."[51] These studies point to a broad trend of data sharing, with few limitations on what type of data service providers are willing to sell or share with third parties.

A 2015 study mirroring the techniques used by Privacy Rights Clearinghouse and the FTC analyzed several categories of apps and similarly found mHealth apps sharing information with third parties[52]. However the researchers observed only three of the thirty mHealth apps tested sent medical information to third parties.[53] While this finding is significantly lower than the FTC report and Privacy Rights Clearinghouse Study, it is unclear why this difference exists.[54] Alongside this observation, the study notes that on the Android platform "Health & Fitness and Communication apps sent sensitive data, mostly [personally identifiable information] data, to more third-party domains than apps in other categories," while iOS apps did not similarly stand out

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[49] *Id.* at 20.

[50] SPRING PRIVACY SERIES: CONSUMER GENERATED AND CONTROLLED HEALTH DATA, FED. TRADE COMM'N 26 (2014), *available at* https://www.ftc.gov/system/files/documents/public_events/195411/2014_05_07_consumer-generated-controlled-health-data-final-transcript.pdf [https://perma.cc/3YH5-BPDN].

[51] *Id.* at 27.

[52] Jinyan Zang et al., *Who Knows What About Me? A Survey of Behind the Scenes Personal Data Sharing to Third Parties by Mobile Apps,* TECH. SCIENCE (Oct. 30, 2015), http://techscience.org/a/2015103001 [https://perma.cc/6YHF-BFN8].

[53] *Id.*

[54] This anomalous finding may be due to the sample size, the research methods (this research group did not use WireShark or tcpdump to monitor non-TCP traffic, while Privacy Rights Clearinghouse did), or changing attitudes among app developers toward privacy implications. There is no clear explanation for the difference in this study and others that indicate broad sharing of behavioral data.

by category.[55] Among the mHealth apps tested, nearly all shared information with third parties that the researchers deemed sensitive, including personally identifiable information, behavioral data, and location data.[56]

Several commentators note that the data revealed by patients' digital footprint is more revealing than their EHR.[57] A physician is only able to test a finite number of variables during a patient visit, whereas mHealth apps continuously monitor patients' habits. Furthermore, much of the data collected occurs without the user being involved or aware that a data transmission has taken place.[58]

A qualitative study conducted by the International Institute of Communications looked into users' perceptions of data management and found "limited awareness" of the techniques by which user data was collected.[59] The study identified two types of data collection: actively collected data and passively collected data. Actively collected data is information that is voluntarily revealed to the service provider by the user–for example, entering what one ate that day into a diet tracking app.[60] And passively collected data[61] is information that is automatically revealed to the service provider and does not require active participation by the user–for example, location metadata[62] being sent to the service provider along with one's diet entry. The study also distinguishes a subset of passively collected data called inferred data. Inferred data is information that is inferred from existing data through analytic models–for example, analyzing a user's dietary patterns to predict that this

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[55] Jinyan Zang et al. *supra* at note 52.

[56] *Id.*

[57] JANE SARASOHN-KAHN, HERE'S LOOKING AT YOU: HOW PERSONAL HEALTH INFORMATION IS BEING TRACKED AND USED 5 (2014).

[58] *Personal Data Management: The User's Perspective*, International Institute of Communications, 12 (2012) (on file with the *Indiana Health Law Review*).

[59] *See id* at 14.

[60] *Id* at 12.

[61] *Id.*

[62] Metadata is data that describes other data. For instance, an app may store calorie counts as a series of numbers. Metadata could help make sense of this raw data by labeling the numbers as "calorie counts."

particular user will likely develop type 2 diabetes.[63] Users are aware of actively collected data, because it requires their active participation; but users generally are not aware of passively collected data or inferred data because it occurs without their participation.[64]

B. How Consumer Data is Used

The data produced by mHealth users is stored in a number of places. Some information is stored locally on the user's mobile device, however the bulk of user data is stored on servers. These servers may belong to the company that developed the mHealth app, or, as is more often the case, to a contracted third party that offers server storage as a service. For many users, the chain of storage and data sharing should ideally end here, so that only the key service providers have access to user data. But rarely does the chain of data sharing end here. Often, data is shared with or sold to a number of third parties. The primary buyers in the consumer information data market are called data brokers.[65] Additionally, other entities purchase consumer data for a variety of purposes.

1. Use by Data Brokers

In 2014, the FTC released a report titled "Data Brokers: A Call for Transparency and Accountability."[66] The report examines the products offered by nine prominent data brokers and the types of data they collect, as well as common industry practices.[67] The FTC found that these companies collect a great deal of information about consumers–one company, Acxiom, reported to have "over 3000 data segments

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[63] *Personal Data Management: The User's Perspective*, *supra* note 58 at 13.

[64] *Id.* at 40.

[65] FED. TRADE COMM'N, DATA BROKERS: A CALL FOR TRANSPARENCY AND ACCOUNTABILITY, i (2014) (defining data brokers as "companies that collect consumers' personal information and resell or share that information with others.").

[66] *Id.*

[67] *Id.* at i.

for nearly every U.S. consumer."[68] While some of the data collected by data brokers is publicly available or seemingly benign, the FTC notes that other information is sensitive, specifically citing health data.[69]

The report identifies mobile devices as a new source of consumer data that "has dramatically increased the availability, variety, and volume of consumer data."[70] Data that is collected is used to create descriptive profiles about consumers, and these profiles include consumers' health information. For example, a consumer profile may include descriptive elements such as: "Ailment and Prescription Online Search Propensity", "Buy Disability Insurance", "Geriatric Supplies", "Allergy Sufferer", "Tobacco Usage", "Purchase History or Reported Interest in Health Topics including: Allergies, Arthritis, Medicine Preferences, Cholesterol, Diabetes, Dieting, Body Shaping, Alternative Medicine, Beauty/Physical Enhancement, Disabilities, Homeopathic Remedies, Organic Focus, Orthopedics, and Senior Needs", among other information.[71] Additionally, consumers are categorized more generally with labels "such as 'Expectant Parent,' 'Diabetes Interest,' [or] 'Cholesterol Focus.'"[72] To some degree, such labels provide benefits to consumers. On the other hand, these labels can be used in ways that are adverse to consumer interests. For instance, the report states, "while data brokers have a data category for 'Diabetes Interest' that a manufacturer of sugar-free products could use to offer product discounts, an insurance company could use that same category to classify a consumer as higher risk."[73]

Consumers are often unaware that data brokers even exist because data brokers do not interact directly with consumers.[74] Only two of the nine data brokers studied by the FTC required the data sources they contracted with to provide notice to consumers that their information will be

[68] *Id.* at 8.
[69] *Id.* at v.
[70] *Id.* at 5.
[71] *Id.* at B-6.
[72] *Id.* at 47.
[73] *Id.* at vi.
[74] *Id.* at i.

shared with third parties.[75] Additionally, "seven of the nine data brokers buy from or sell information to each other."[76]

The findings of the FTC reiterated those of a separate report issued by the Government Accountability Office (GAO) in 2013.[77] The GAO similarly identifies the collection of health data as a cause for concern and notes that "mobile devices have enabled even cheaper, faster, and more detailed data collection and sharing among resellers and private-sector companies."[78] Additionally, the GAO report explains that there is no federal privacy law that specifically addresses mobile applications and technologies,[79] nor does federal law generally restrict the methods for data collection or the sources of collection.[80] Ultimately, the statutory landscape leaves consumers with "limited legal rights to control what personal information is collected, maintained, used, and shared and how."[81]

2. Use by Other Entities

New uses for data are being discovered, and while less is known about these practices, it is important to note that health data extends beyond the context of data brokers and the products they offer. On June 26, 2014, Bloomberg reported that the largest hospital chains in the Carolinas and Pennsylvania were using consumer data to identify high-risk patients.[82] The chains reportedly use this data to predict when patients might fall ill due to unhealthy habits and intervene before reaching a point that would require more costly care. Similarly, a study conducted by a student at the Carolina Health Informatics Program of the University of

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[75] *Id.* at 16.

[76] *Id.* at 14.

[77] INFORMATION RESELLERS, *supra* note 7.

[78] *Id.* at 19.

[79] *Id.* at 24.

[80] *Id.* at 18.

[81] *Id.* at 17.

[82] Shannon Pettypiece & Jordan Robertson, *Hospitals Soon See Donuts-to-Cigarette Charges for Health*, BLOOMBERG TECH. (June 26, 2014, 12:35 PM), http://www.bloomberg.com/news/articles/2014-06-26/hospitals-soon-see-donuts-to-cigarette-charges-for-health [https://perma.cc/ZD6K-WJMG].

North Carolina at Chapel Hill reveals that mHealth data can be used to improve risk profiling in the insurance industry and track users' engagement with health and wellness activities.[83]

While evidence of such use is scant, it is clear that providers and insurers could use mHealth data to monitor and profile patients' behaviors. Used in this manner, mHealth data could provide increased understanding of patient populations, but such use may simultaneously motivate paternalistic practices. In a system where global payments to providers are based on population health, direct intervention may be a more common interaction with patients. For instance, a patient with diabetes mellitus who is not physically active as recommended will have higher blood glucose and increased risk for infections. That patient may receive a phone call or home visit from a care coordinator to motivate them to get into an exercise program as a result. Ultimately, patients may be unwilling to use mHealth tools if doing so means that their behaviors will be monitored and judged by providers and insurance companies.

IV. EXISTING POLICY IS INADEQUATE IN THE MHEALTH CONTEXT

Data collection, analysis, and use have been a subject of concern for quite some time. A common reference point for policies governing data practices is the Fair Information Practice Principles (FIPPs).[84] These guidelines were initially created by an advisory committee to the Secretary of Health, Education, and Welfare and were the basis of the Privacy Act of 1974,[85] which governs federal agencies' collection and use

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[83] Dave Barrett, *mHealth at BCBSNC–An Evaluation of the Collection and Usage of Mobile Health Data through Existing BCBSNC Resources,* UNC CAROLINA HEALTH INFORMATICS PROGRAM, http://miksa2.ils.unc.edu/chip/practicum/files/posters/pdf/dave_barrett.pdf [perma.cc/JKW7-SDLC].

[84] U.S. DEP'T OF HEALTH, EDUC. & WELFARE, DHEW PUB. NO. (OS)73-94, RECORDS, COMPUTER, AND THE RIGHTS OF CITIZENS: REPORT OF THE SECRETARY'S ADVISORY COMMITTEE ON AUTOMATED PERSONAL DATA SYSTEMS (1973), *available at* https://www.justice.gov/opcl/docs/rec-com-rights.pdf [https://perma.cc/929M-5XJH].

[85] 5 U.S.C. § 552a (1974).

of personal information. In 1980 the FIPPs were revised by the Organisation for Economic Co-operation and Development (OECD) and became an internationally recognized set of privacy principles.[86] The FIPPs are principles and while they have been used as a reference point for the creation of laws at home and abroad, they do not carry any legal authority themselves. These principles are admirable (e.g., collection limitation, data quality, purpose specification, use limitation, security safeguards, openness, individual participation, accountability[87]), but they are broad and do not adequately address consumer concerns regarding mHealth privacy on their own. Additionally, there are a limited number of torts associated with privacy harms, and those that do exist are ill suited to address the privacy issues involved in large-scale, systematic data collection.[88] Furthermore, statutory protections, implemented before the age of cloud computing, are insufficient and broadly permit third party access.[89]

A. The Fair Information Practice Principles Were Drafted Before Big Data

The FIPPs were created over four decades ago and rest on certain assumptions about data and its usage that must be reevaluated in a new age of computing. These principles continue to serve as meaningful guidelines, but forward thinking policies will require more nuanced considerations.

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[86] OECD, OECD Guidelines on the Protection of Privacy and Transborder FlowS of Personal Data (1980), *available at* http://www.oecd.org/internet/ieconomy/oecdguidelinesontheprotectionofprivacyandtransborderflowsofpersonaldata.htm [http://perma.cc/P4XF-PGQH]. (These guidelines were recently updated in 2013 with additional enforcement and privacy protections).

[87] *Id.*

[88] President's Council of Advisors on Science and Technology, Big Data and Privacy: A Technological Perspective 6-7 (2014), *available at* https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_big_data_and_privacy_-_may_2014.pdf [https://perma.cc/W79K-PK3G].

[89] *See* Electronic Communications Privacy Act, 18 U.S.C. § 2702 (1986) (allowing third party access to customer communications or records with legal consent).

In short, "big data" has changed the game.[90] While big data encompasses much more than mHealth, it is necessary to understand the tools and economic forces of big data to see why the FIPPs are no longer adequate. Put simply, exponential growth in computing power is continuously occurring and this growth has altered the ground rules upon which the FIPPs were built.

1. Big Data and Emerging Analytical Techniques

In January of 2014, President Barack Obama ordered a comprehensive review of big data technologies by counselor John Podesta and the President's Council of Advisers on Science and Technology.[91] Two workgroups executed this order in a 90-day, simultaneous effort, and produced insightful reports on the technologies and policy implications of big data.[92] These reports (hereinafter referred to as the "Big Data Report" and the "PCAST Report") supplement one another to explain what big data is, what its benefits and pitfalls may be, and how current and future policy will be affected by big data.

Big data is commonly thought of as the "3 Vs": Volume, Variety, and Velocity.[93] Volume refers to the sheer amount,

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[90] Jonathan Stuart Ward & Adam Barker, *Undefined By Data: A Survey of Big Data Definitions*, ARXIV.ORG (Sept. 20, 2013, 1:51:18 PM), COMPUTER SCIENCE DATABASES *available at* arXiv:1309.5821, http://arxiv.org/abs/1309.5821/ [http://perma.cc/M53M-MWZ2] (defining big data as "a term describing the storage and analysis of large and or complex data sets using a series of techniques including, but not limited to: NoSQL, MapReduce and machine learning.")

[91] *Transcript of President Obama's Jan. 17 Speech on NSA Reforms*, WASHINGTON POST (Jan. 17, 2014), http://www.washingtonpost.com/politics/full-text-of-president-obamas-jan-17-speech-on-nsa-reforms/2014/01/17/fa33590a-7f8c-11e3-9556-4a4bf7bcbd84_story.html/ [http://perma.cc/HKC4-VCHE].

[92] JOHN PODESTA ET AL., BIG DATA: SEIZING OPPORTUNITIES, PRESERVING VALUES 3-4 (2014), *available at* https://www.whitehouse.gov/sites/default/files/docs/big_data_privacy_report_may_1_2014.pdf.

[93] *IT Glossary*, GARTNER, INC., https://www.gartner.com/it-glossary/big-data/ [http://perma.cc/K8QD-6JQ9] (last visited Feb. 17, 2016). Gartner's *IT Glossary* defines big data as "high-volume, high-velocity and/or high–variety information assets that demand cost-

variety refers to the different types, and velocity refers to how quickly it is produced.[94] It is "big" because the amount of data sources has grown exponentially in recent years. As stated in the Big Data Report, "[t]he declining cost of collection, storage, and processing of data, combined with new sources of data like sensors, cameras, geospatial and other observational technologies, means that we live in a world of near-ubiquitous data collection."[95] Data can be "born digital"[96] or "born analog."[97] Data that is born digital is created by users or automated computer proxies for use by a computer system (e.g. entering food one has eaten into a diet tracking application, posting a review of the app, or metadata that is passively collected with a given transaction).[98] Data that is born analog comes from the physical world (e.g. a photo of a wound, one's heartbeat measured by a sensor, or the video content of a sonogram).[99] All of this seemingly disparate data can be assembled and analyzed together to reveal unexpected insights about a specified group or individual, a technique known as "data fusion."[100] The results of such assembly and analysis can be useful in healthcare research.

For example, one study used data taken from neonatal monitors to find early warning signs of infection that were unobservable to attending physicians.[101] Similarly, the hospital systems in the Carolinas and Pennsylvania, mentioned above, were able to use consumers' purchase history information to identify patients at risk of hospital

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effective, innovative forms of information processing for enhanced insight, decision making, and process automation."

[94] PODESTA ET AL., *supra* note 92, at 4.

[95] *Id.* at 4. (explaining just how big "big data is," the report indicates that in 2013 an estimated four zetabytes were produced worldwide–a zetabyte equals 1,000,000,000,000,000,000,000 bytes, or units of information.").

[96] *Id.* at 4.

[97] *Id.*

[98] *Id.* at 19.

[99] *Id.* at 22.

[100] *Id.* at 4.

[101] IBM, SMARTER HEALTHCARE IN CANADA: REDEFINING VALUE AND SUCCESS 5 (2012) *available at* https://www.ibm.com/smarterplanet/global/files/ca__en_us__healthcare__ca_brochure.pdf [https://perma.cc/ZKZ8-CN2F].

admission due to unhealthy habits.[102] While both of these uses of big data analytics provide a benefit, namely fighting infections in premature infants and reducing healthcare costs through early intervention, the second example poses a privacy issue that the first does not. It seems unlikely that parents would object to improved care for their infants. But are patients comfortable with the notion that insurers are monitoring their daily habits? This type of monitoring practice may lower treatment costs and assist behavioral change, but it may also do harm to patients' perceptions of healthcare institutions and violate basic notions of privacy that people hold.[103]

Such considerations are particularly important in the context of mHealth. Users' data can be combined and analyzed to determine a number of piercing insights. Consider the variety of information that mHealth apps collect about a given user. Sleep monitoring apps track sleep schedules, motion during sleep, and so-called "sleep debt"; diet tracking apps record what foods the user ate and for which meal, their calorie count, a user's weight, and nutritional information; fitness apps record calories burned, whether a user does aerobic or anaerobic activities, and the frequency with which one exercises; alcohol tracking apps log how many drinks the user consumes, how frequently, and blood alcohol content; smoking cessation apps record the number and frequency of cigarettes consumed; pregnancy tracking apps record likely conception dates, due dates, and symptoms; mood tracking apps record emotional and psychological information; period trackers record menstruation dates, chart ovulation and fertility, and duration of menstruation and symptom searching apps record symptoms searched.[104] This snapshot of mHealth apps

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[102] See discussion *infra* Part III.B.2.

[103] PODESTA ET AL., *supra* note 92, at 79. Professional practices are currently one of the few sectors that enjoy a great deal of public trust with personal data–a finding that may change as public awareness of health surveillance grows.

[104] This general list of apps and the types of data they collect was compiled through a search of the iOS App Store and Google Play Store. It is a small sample of the types of apps offered in mobile app markets and the information they collect.

and the information they record is far from a complete picture of what is available, but the variety of information is extraordinary. This variety, in and of itself, poses a difficult problem for the protection of individual privacy.

2. Big Data Weakens De-identification

Under the HIPAA Privacy Rule, patient data may be shared broadly so long as it is de-identified.[105] De-identification works by stripping identifying information about persons from a data set.[106] The Safe Harbor Method of the Privacy Rule requires the removal of eighteen specific fields of information.[107] Some privacy conscious companies similarly de-identify data they collect before selling or sharing that data with third parties.[108] But PCAST warns that de-identification as a method of protecting privacy has limited value moving forward, because re-identification methods are becoming highly sophisticated.[109] In fact, the Big Data Report states, "[c]ollective investment in the capability to fuse data is many times greater than investment in technologies that will enhance privacy."[110] Data fusion allows seemingly anonymous data to be re-

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[105] *De-identification Guidance, supra* note 44.

[106] *Id.* Covered entities can satisfy the de-identification standards of the Privacy Rule by two methods: "1) a formal determination by a qualified expert; or 2) the removal of specified individual identifiers as well as absence of actual knowledge by the covered entity that the remaining information could be used alone or in combination with other information to identify the individual."

[107] *Id.*

[108] *See, e.g., Privacy Policy,* N. Y. TIMES http://www.nytimes.com/content/help/rights/privacy/policy/privacy-policy.html#e [https://perma.cc/W7P5-JH8G] (last updated June 10, 2015) (discussing that they "share information about our audience in aggregate or de-identified form. Nothing in this Privacy Policy is intended to restrict our use or sharing of aggregated or de-identified information in any way."); *see also* PODESTA ET AL, *supra* note 92, at 8.

[109] PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY, EXEC. OFFICE OF THE PRESIDENT: Big Data and Privacy: A Technological Perspective 44 (2014) [hereinafter *Big Data Report*] *available at* https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_big_data_and_privacy_-_may_2014.pdf [https://perma.cc/F3RB-SC5Q].

[110] PODESTA ET AL., *supra* note 92, at 54.

identified.[111] Efforts to protect the privacy of users through de-identification are increasingly futile as this technique is becoming obsolete.[112]

Additionally, prohibitions on re-identification would be difficult. It is not always obvious which data elements will identify an individual. With a large enough data set, individuals can be identified through the "mosaic effect", whereby seemingly anonymous and unrelated data create patterns from which identifying information can be inferred. [113] While data fusion paints a seemingly bleak picture for the privacy of health information, the problem is one that can be compartmentalized.

B. Compartmentalizing Health Data

Re-identification poses a real problem for the privacy of health data. But solving the problem for PHI is different from

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[111] K. El Emam et al., *Evaluating the Risk of Re-identification of Patients From Hospital Prescription Records* 62 CANADIAN J. OF HOSPITAL PHARMACY 307, 307-319; (2009); G. Loukides et al., *Symposium, The Disclosure of Diagnosis Codes Can Breach Research Participants Privacy*, 17 J. AM. MED. INFORMATICS ASSOCIATION 322-327 (2010); B. Malin & L. Sweeney, *How (Not) to Protect Genomic Data Privacy in a Distributed Network: Using Trail Re-identification to Evaluate and Design Anonymity Protection Systems*, 37 J. OF BIOMEDICAL INFORMATICS, 179-192 (2004); L. Sweeney, *A Presentation at the Workshop on the HIPAA Privacy Rule's De-Identification Standard, Data Sharing Under HIPAA: 12 Years Later*, Washington, DC. March 8-9 (2010).

[112] *Big Data Report, supra* note 111, at 38-39. Programming languages used by those who manage data typically have commands like "join" that connect data sets based on common data points. To illustrate how easy it is to re-identify data, suppose a company has matrix A with five columns of data and matrix B with five columns of data. Suppose matrix A and B overlap on one common data point. A programmer can write a command that "joins" matrix A and B based on their common data point, creating one matrix with 9 columns of data. Given the sheer amount of data being produced by users and stored by data brokers, it does not take long to find a consistently unique data point to merge data sets with–like a cell phone's IMEI or any other device-specific number.

[113] OFFICE OF MGMT. AND BUDGET, EXEC. OFFICE OF THE PRESIDENT: Open Data Policy—Managing Information as an Asset Memorandum for the Heads of Executive Departments and Agencies (2013), *available at* https://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-13.pdf [https://perma.cc/D73R-XKU3].

solving the problem for mHealth data. When PHI is de-identified, it is no longer PHI and its disclosure is not restricted.[114] If that data is re-identified, then it is once again PHI and receives all of the legal protections originally prescribed to PHI.[115] On the other hand, mHealth data, as discussed above, typically does not fall under the auspices of HIPAA.[116] There are no requirements to de-identify data from non-HIPAA apps (though doing so is encouraged[117]), and it is often sold to or shared with third parties.

Currently the only protections afforded to users of mHealth apps not covered by HIPAA are those detailed in the privacy policy of the app. Privacy policies evolved from the "notice and consent" model prescribed by the FIPPs.[118] But consumers struggle to understand privacy policies, and many do not bother reading them before agreeing to their terms.[119] Additionally, the technical nature of *how* data is collected, secured, and shared is difficult to understand as a consumer–particularly when it is embedded in the legal language of a privacy policy. Even if consumers do choose to read privacy policies, doing so is not particularly enlightening. Privacy policies are written primarily to cover the developing company's legal notice requirements and not to accurately inform the consumer.[120] One study came to the conclusion that, "[t]he only way for a user to know how great a privacy risk an app may be posing is by doing a technical evaluation–something beyond the ability of almost all users."[121] PCAST similarly observed, "Only in some fantasy

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[114] *De-identification Guidance, supra* note 44.

[115] *Id.* at 9.

[116] *See infra* Part II.B.

[117] *Using Consumer Health Data: Some Considerations for Companies,* FED. TRADE COMM'N: BUSINESS BLOG (Apr. 28, 2015, 9:52 AM), https://www.ftc.gov/news-events/blogs/business-blog/2015/04/using-consumer-health-data-some-considerations-companies [https://perma.cc/7RXU-ZYEQ].

[118] U.S. DEP'T OF HEALTH, EDUC. & WELFARE, *supra* note 86, at xxvi; *see also Big Data Report, supra* note 109, at 38.

[119] SDL, *supra* note 46 (finding in a survey of more than 4,000 individuals, 65% of respondents reported that they rarely or never read privacy policies before making online purchases).

[120] Craig Michael Lie Njie, *supra* note 48, at 20-21.

[121] *Id* at 21. The technical evaluation techniques described in this study require users to intercept the internet traffic of their mobile devices

world do users actually read these notices and understand their implications before clicking to indicate their consent." [122] Under the "notice and consent" model, the consumer is incapable of modifying the privacy policy and is left with a binary choice: agree to the terms or stop participating in digital society. A new system is needed to restore meaningful choices to consumers.

V. REMOVING UNCERTAINTY WILL PROVIDE MEANINGFUL CHOICES IN THE MHEALTH MARKET

Congress deemed health information uniquely private and worth protecting when it passed HIPAA's stringent Privacy and Security Rules. One would expect that user generated data should receive the same protections, but such data presents a unique problem. As noted in the Big Data Report, "[t]he powerful connection between lifestyle and health outcomes means the distinction between personal data and health care data has begun to blur."[123] Data one may never think of as health information can be extrapolated and cross-referenced to produce deep insights into an individual's health. For instance, by cross-referencing purchasing information with additionally purchased consumer data, Target was able to identify customers who were in their second trimester of pregnancy. [124] However mHealth applications are uniquely revealing. Such apps produce detailed logs of a user's health information, and do not require costly or difficult analysis. While it is true that data fusion allows some health information to be inferred, inferred data does not provide the level of detail and granularity that mHealth apps effortlessly expose. In particular, devices that measure biometric information through sensors provide data that cannot be inferred to the same level of accuracy. If the unfettered trade of detailed

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by connecting a "man-in-the-middle, SSL-enabled proxy server", and decoding their internet traffic through a series of software tools that go far beyond the average user's understanding of computers. *Id.* at 11.

[122] *Big Data Report, supra* note 109, at xi.

[123] *Id.* at 23.

[124] Charles Duhigg, *How Companies Learn Your Secrets*, N. Y. TIMES MAGAZINE (Feb. 16, 2012), http://www.nytimes.com/2012/02/19/magazine/shopping-habits.html?_r=0 [http://perma.cc/LGG3-NGAT].

biometric and behavioral data is allowed, HIPAA's privacy protections will become obsolete.

Additional government intervention is needed, but given the inherent problem in defining or regulating "health data" the government cannot realistically ban the sale of health data. Instead, Congress should create a simple labeling system. In particular, there is a need for two labels: (1) a label that reads "HIPAA Compliant", and (2) a label that reads "Confidential." Apps marked HIPAA Compliant would be just that, compliant with the regulations of HIPAA and suitable for use by covered entities and their business associates.[125] Apps marked Confidential would guarantee that user data is not sold to or shared with third parties. Apps with no label will continue under the current notice and consent regulatory scheme.

A. "Confidential" Label Provides a Meaningful Consumer Choice

The current notice and consent framework of the FIPPs does not provide consumers with meaningful choices. Rather, an unregulated data market incentivizes companies to pursue a single business model: collect and sell as much data as possible.[126] As a result, there is little incentive to provide consumers with tools to restrict data collection. Industry representatives argue that ubiquitous collection actually provides a benefit to consumers, because the data market subsidizes the true cost of software and provides consumers with free services.[127] The premise of this argument is that personal data is a commodity and consumers are trading this commodity in exchange for digital services. If one accepts

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[125] Letter from Tom Marino & Peter DeFazio, Members of Congress, (Sept. 18, 2014), *available at* http://actonline.org/wp-content/uploads/2014/09/Letter-to-Secretary-Burwell-September-18-2014.pdf [http://perma.cc/KN7R-9BC6] (Representatives Marino and DeFazio have already suggested a "voluntary badge program" to indicate HIPAA compliance).

[126] *Big Data Report, supra* note 111, at 54 (referring to this phenomena as a "digital land grab" that has resulted in "structural over-collection").

[127] GOV'T ACCOUNTABILITY OFFICE, *supra* note 7, at 40.

that personal data is a commodity, then the currencies of the data market become clear. Consumers that wish to have their personal data kept from third parties will have to pay the full cost of the software. Many consumers already believe that if they pay for the software they are using, then only the service provider will use their data,[128] but there is no guarantee that this is the case. In fact, paid mHealth apps have been found to collect and share data only marginally less than free apps. [129] The "Confidential" label would unambiguously provide that guarantee.

The current "notice and consent" system relies on contractual agreements. Consumers are responsible for reading, and accepting or denying, the terms of each service contract. The Confidential label is meant to simplify the most important privacy component of the contractual agreement - data sharing with third parties. It is intended to bind companies to certain terms. The essential terms of the Confidential label are: (1) Products with confidentiality labels cannot sell or share consumer data with third parties; (2) Products with confidentiality labels cannot revoke the label once it has been adopted;[130] (3) If a company offering products with a Confidential label goes bankrupt or is sold to a third party, it can only transmit consumer data to the new parent company and cannot sell data to additional third parties.[131] The Confidential label would serve as a condensed privacy policy that is actually intelligible, with terms enshrined in law and not up to the whims of changing contracts.

Creating such a label would standardize the terms of data use in the user and service provider relationship. Consumers interested in keeping their mHealth data from third parties would not have to wade through extensive privacy policies,

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[128] INTERNATIONAL INSTITUTE OF COMMUNICATIONS, *supra* note 58, at 12.

[129] Craig Michael Lie Njie, *supra* note 48, at 15.

[130] This term aims at preventing mid-service changes in privacy policies, so that a service provider cannot simply reorder the terms of their agreement and have users unwittingly agree to retroactive third party access to data.

[131] Natasha Singer & Jeremy B. Merrill, *When a Company Is Put Up for Sale, in Many Cases, Your Personal Data Is, Too,* N. Y. TIMES, http://www.nytimes.com/2015/06/29/technology/when-a-company-goes-up-for-sale-in-many-cases-so-does-your-personal-data.html.

but instead could look for a product that is marked Confidential. For privacy conscious consumers, this label would provide a meaningful choice in a marketplace where currently the only choice is to broadcast health data or live without mHealth tools.

B. Voluntary Labeling

These labels should be adopted voluntarily by companies rather than mandated. It is unrealistic, and unwieldy to have an agency determine each and every app that needs to be labeled HIPAA Compliant or Confidential before the app goes to market. There are more than 100,000 apps in the mHealth market,[132] but only a fraction of this total enjoys a wide user base. Diverting agency resources to regulate unused or underused apps does not address the heart of the problem.

Mandating that mHealth developers not sell or share data would likely require most companies to restructure code–because data sharing is often automated–contracts, and business models. A number of stakeholders have voiced concerns to Congress and Federal agencies that costly economic impact will accompany mandatory regulatory compliance.[133] Allowing voluntary adoption rather than mandating increased privacy protections would still allow companies to provide free options to consumers while providing privacy conscious consumers with a meaningful choice. This would increase the range of products available to the consumer. Furthermore, voluntary adoption allows companies to decide whether their company is compliant with the label's standards before labeling their product.

Adopting a HIPAA Compliant label would not result in any increased regulatory burden to developers–those who are subject to HIPAA must be compliant whether they are labeled or not. The benefit of the label is that it would clarify product availability for covered entities and business associates. Adopting a Confidential label, however, would result in an increased regulatory burden, because the

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[132] *Infra* Part I; Jen Miller, *The Future of mHealth Goes Well Beyond Fitness Apps*, CIO, (Dec. 4, 2014 4:09 AM PT) http://www.cio.com/article/2855047/healthcare/the-future-of-mhealth-goes-well-beyond-fitness-apps.html [http://perma.cc/KA3C-2Z2E].

[133] *See* INFORMATION RESELLERS, *supra* note 7, at 29-30, 33, 37, 42-43.

developer would voluntarily revoke the right to sell consumer data.

The benefit of doing so rests on the assumption that consumers value their privacy enough to pay a higher cost upfront to offset developers' loss in revenue from data sales. Personal data has been estimated to be worth as little as $0.0005 per person for general information, such as age, gender, and location, to $0.26 per person for medical information, such as listed conditions like arthritis, high blood pressure, and diabetes.[134] Developers could calculate the estimated value of the data they collect and charge this cost upfront. It is conceivable that the first Confidential products could be marketed for the highest price, while competition would, over time, drive down prices to the benefit of consumers.

C. Labels Create Legally Enforceable Standards

These labels could be achieved by amending two existing pieces of legislation. The HIPAA Compliance label could be added to the HIPAA Privacy Rule, and the Confidentiality label could be added to the Federal Trade Commission Act (FTC Act). [135] The Department of Health and Human Services enforces HIPAA through the Office for Civil Rights, while the FTC has carried out enforcement actions against non-HIPAA mHealth developers for unfair or deceptive practices related to privacy policies.[136] Similarly, the FTC

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[134] Emily Steel et al., *How Much is Your Personal Data Worth?,* FINANCIAL TIMES, (Jun. 13, 2013, 8:11 PM), http://www.ft.com/cms/s/2/927ca86e-d29b-11e2-88ed-00144feab7de.html [http://perma.cc/4GC5-2VQG] (select "Family & Health" tab).

[135] The HIPAA Privacy Rule is codified at 45 CFR Parts 160 and 164, Subparts A and E; the FTC Act can be found at 15 U.S.C. §§ 41-58 (2016).

[136] U.S. DEP'T OF HEALTH AND HUMAN SERVICES, *HIPAA Enforcement*, *available at* http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/; Payments MD, LLC, No. C-4505, F.T.C. (Jan. 27, 2015); Payments MD, LLC, No. C-4505. 2015 FTC LEXIS 24 (F.T.C., Jan. 27, 2015); GMR Transcription Services, Inc., No. C-4482, F.T.C. (Aug. 14, 2014); GMR Transcription Services, Inc., No. C-4482, 2014 FTC LEXIS 199 (F.T.C., Aug. 14, 2014); Accretive Health Inc., No. C4432, (Feb. 5, 2014); Accretive Health Inc., No. C4432, 2014 FTC LEXIS 30 (F.T.C., Feb. 14, 2014).

has hosted industry workshops that urge mHealth companies to protect user data,[137] and is the agency charged with consumer protection.

1. Enforcement

Enforcement mechanisms are already part of HIPAA and the FTC Act.[138] The Health and Human Services' Office of Civil Rights (OCR) is charged with enforcement of the Privacy Rule.[139] In the FTC Act, the FTC is charged with enforcement of consumer protection.[140] By piggybacking off of these existing resources and procedures, the labels could be created and enforced at a relatively low cost.

2. Compliance

Companies that choose to adopt a Confidential or HIPAA Compliant label would be responsible for assessing the company's ability to comply. Once a company adopts a label, the OCR and FTC should monitor company actions and receive patient and consumer complaints reporting misuse of data.

3. Exceptions

In order for the Confidentiality label to be technically feasible, a few exceptions to the ban on sharing data would be necessary. mHealth developers must be able to contract for server storage and cloud services. Additionally, mHealth developers must be able to analyze user data in order to improve technical performance and offer new services to their customers. It is common to have third parties perform such analysis and provide developers with relevant findings.

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[137] *See Spring Privacy Series: Consumer Generated and Controlled Health Data*, FED. TRADE COMM'N, https://www.ftc.gov/news-events/events-calendar/2014/05/spring-privacy-series-consumer-generated-controlled-health-data [http://perma.cc/UVX2-ZU74].

[138] The HIPAA Enforcement Rule is codified at 45 CFR Part 160, Subparts C, D, and E; the FTC Act can be found at 15 U.S.C. §§ 41-58 (2016).

[139] U.S. DEP'T OF HEALTH AND HUMAN SERVICES, *supra* note 136.

[140] The FTC's enforcement powers are granted in 15 U.S.C. § 57b (2016).

Much like the "business associates" referred to in HIPAA, which are granted certain access rights to PHI, the business associates of mHealth developers should be granted the ability to access and analyze user data.

VI. CONCLUSION

While the FDA has taken a meaningful first step in regulating mobile medical devices through the FD&C Act, apps not currently covered by HIPAA are producing volumes of patient data. This user-generated data is being commoditized and sold, and consumers are often unaware of the ramifications. This problem is significant, as data produced by mHealth users can be even more revealing than the person's medical record. A voluntary labeling system should be put in place that would provide meaningful choices for consumers and protect their data. By focusing on HIPAA compliance and standardizing data confidentiality, this labeling system could demystify much of the confusion and ignorance that currently exists for companies and consumers alike. The time has come to address the unregulated data market that silently exists in the U.S. today.

IDENTIFYING SCHRÖDINGER'S CAT: *EX REL. KANE* AND THE FUTURE OF THE SIXTY DAY REPORT AND RETURN RULE

David A. Mata*

On August 3, 2015, the Southern District of New York ("S.D.N.Y.") issued its long-awaited Opinion and Order denying the defendants' motion to dismiss the case *Ex Rel. Kane v. Healthfirst, Inc., et al.*[1] Healthcare providers have waited with baited breath for a court's first impression of the Sixty Day Report and Return Rule (the "Rule"). The Rule is part of the Affordable Care Act's ("ACA") Medicare and Medicaid Program Integrity Provisions which requires providers to report and return overpayments within sixty days of identification.[2] Issues with the law's statutory construction have frustrated its interpretation and implementation. Glaringly, the law does not define when an overpayment is "identified" yet provides definitions for the words "knowing" and "knowingly" without using them

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[1] Kane *ex rel.* U.S. v. Healthfirst, Inc., 120 F. Supp. 3d 370 (S.D.N.Y. 2015).

[2] 42 U.S.C. § 1320a-7k(d) (2016).

http://dx.doi.org/10.18060/3911.0022

elsewhere in the statute.[3] The implementation of the Rule hinges on the definition of "identified," and the S.D.N.Y. took the statute beyond what its language may bear in order to provide what it feels is the proper reading.

I. BACKGROUND

Kane ex rel U.S. v. Healthfirst Inc. ultimately stems from a software problem.[4] Healthfirst, "a private non-profit health insurance program," administers a Medicaid managed care program whose beneficiaries receive services at three New York hospitals operated by Continuum Health Partners.[5] This managed care program operates on what is called a capitation model, where the New York State Department of Health ("DOH") provides a monthly payment for the beneficiaries as opposed to the fee-for-service model.[6] Normally, when Healthfirst sends payments to hospitals on behalf of these beneficiaries, a code is included which tells providers they may not seek out secondary payment for the services beyond co-payments from certain patients.[7] Continuum's billing software erroneously translated the code as one permitting secondary payors.[8] The hospitals automatically generated bills to entities such as the DOH, which mistakenly paid some of these improper claims.[9]

In September 2010, the New York State Comptroller's office questioned Continuum about the incorrect billing.[10] After discovering the problem's cause, Continuum tasked Relator Kane with determining "which claims had been improperly billed."[11] In early February 2011, Kane emailed a spreadsheet containing more than 900 claims with the erroneous code to several members of Continuum's

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[3] *Id.* CMS recently issued a Final Rule defining "identified," discussed *infra* section V.

[4] *Kane,* 120 F. Supp. 3d 370 at 375.

[5] *Id.* at 376.

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *Id.*

[11] *Id.* at 377.

management.[12] He indicated that further analysis was needed and that the spreadsheet gave "some insight to the magnitude of the issue."[13]

Continuum terminated Kane's employment four days later and allegedly "did nothing further" with Kane's analysis.[14] It reimbursed the DOH "for only five improperly [paid] claims."[15] The Comptroller identified several further "tranches of wrongful claims, which it brought to Continuum's attention" through most of 2011 and early 2012.[16] The government issued a Civil Investigative Demand in June 2012 seeking more information on the overpayments, and Continuum never shared Kane's email with the Comptroller.[17] Continuum did not fully reimburse the DOH until March 2013, a little over two years from Kane's email.[18] Ultimately, roughly half of Kane's listed claims resulted in overpayments.[19]

The government alleges that Kane's email "identified" overpayments under the Rule, thus triggering the countdown back in February 2011.[20] The defendants filed a motion to dismiss the case on the grounds that the email did not identify overpayments, amongst other reasons.[21] The court denied the motion and provided insight for its agreement that the clock began with the email.[22] This article will focus on the issue of "identified" and not other portions of the order such as pleading requirements under Rule 9(b).

The Rule provides in relevant part:

> **(2) Deadline for reporting and returning overpayments**
> An overpayment must be reported and returned under paragraph (1) by the later of—

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[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.* at 377-78.
[17] *Id.* at 378.
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*

> (A) the date which is 60 days after the date on which the overpayment was identified…
> (3) Enforcement
> Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729 (b)(3) of title 31) for purposes of section 3729 of such title.
> (4) Definitions
> In this subsection:
> (A) Knowing and knowingly
> The terms "knowing" and "knowingly" have the meaning given those terms in section 3729 (b) of title 31.
> (B) Overpayment
> The term "overpayment" means any funds that a person receives or retains under subchapter XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such subchapter.[23]

II. THE RULE'S INTERPLAY WITH THE FALSE CLAIMS ACT

A threshold question to ask when reviewing this law is what exactly does it add to the statutory lexicon? The False Claims Act ("FCA") already prohibits holding on to money owed to the government.[24] What this law provides is a "clock." It tells providers how long they have to report and return an overpayment before potential "reverse FCA" liability attaches, where an entity is liable for failing to return money to which it is not entitled. But when does the clock start? Unfortunately, a definition of "identified" was not provided.

Guidance on this issue is of the utmost importance for healthcare providers given the Rule's FCA enforcement provision. The FCA permits the government to impose hefty penalties ranging from $5,500 to $11,000 per false claim and

[23] 42 U.S.C. § 1320a-7k(d) (2016).
[24] 31 U.S.C. § 3729(a)(1)(D) (2016).

up to treble total damages.[25] The FCA is invoked here through its "reverse" provision, which Congress introduced in 1986 with amendments to the FCA.[26]

Reverse false claims occur when a person knowingly avoids, conceals, or decreases an obligation to pay the government.[27] Courts struggled with how to define "obligation," with some circuits holding that an obligation could only exist through an independent legal duty to pay the government, and that simply making a false claim which *could* result in a penalty was not sufficient.[28] These decisions frustrated the FCA's enforcement, and in early 2009 the Department of Justice wrote Congress a letter stating that the courts "unduly narrowed the reverse false claim provision by holding or suggesting that the term obligation encompasses only a duty to pay that is fixed in all particulars, including the specific amount owed."[29]

Congress listened, and in April 2009 it passed the Fraud Enforcement and Recovery Act ("FERA") to combat fraud experienced during the housing crisis of 2008 and to

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[25] Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L .No. 101-410, § 5(a)(3), 104 Stat 890 (Jan. 5, 1990).

[26] James B. Helmer, Jr., *False Claims Act: Incentivizing Integrity for 150 Years for Rogues, Privateers, Parasites, and Patriots,* 81 U. Cin. L. Rev. 1261, 1272 (2013).

[27] 31 U.S.C. § 3729(a)(1)(G) (2009).

[28] *See* United States *ex rel.* Bahrani v. Conagra, Inc., 465 F.3d 1189, 1195 (10th Cir. 2006) (Tenth Circuit holding that an obligation arises from an independent legal duty and not from simply using or making a false record or statement that could result in a potential penalty); United States *ex rel.* Bain v. Ga. Gulf Corp., 386 F.3d 648, 658 (5th Cir. 2004) (Fifth Circuit holding that a chemical plant did not create a reverse false claim obligation when it falsified environmental emission reports because "the mere contingent potential that such fines or penalties might be… sought and imposed does not constitute an obligation…"); United States v. Q Int'l Courier, Inc., 131 F.3d 770, 774 (8th Cir. 1997) (Eighth Circuit holding that a courier service did not have a reverse false claims obligation for taking mail to Barbados and sending it back to the United States to save on postage costs because the penalties were potential and not "a fixed sum that is immediately due.").

[29] Letter from M. Faith Burton, Acting Assistant Att'y Gen., U.S. Dep't of Justice, to Sen. Patrick Leahy, Chairman, Senate Comm. on the Judiciary, (Feb. 24, 2009) *available at* http://www.friedfrank.com/files/QTam/DoJ%20Views%20on%20Section%204%20of%20FERA%20(2).pdf [perma.cc/VAJ6-Z668].

strengthen the FCA.[30] Senator Patrick Leahy, one of the bill's sponsors, declared that FERA "will rebuild the nation's capacity to investigate and prosecute the mortgage and corporate frauds that have so severely undermined the economy and hurt so many working people."[31] On the Senate floor, Senator Leahy spoke of the importance of updating the FCA and called it "one of the most potent civil tools we have for rooting out waste and fraud in government."[32] Reiterating the law's focus on the housing crisis, he said the "the False Claims Act must quickly be corrected and clarified in order to protect from fraud the Federal assistance and relief funds expended in response to our current economic crisis."[33]

In the House of Representatives, Dan Maffei of New York voiced prophetic concerns on the new reverse false claim provision's application to the medical field.[34] His speech shows that Congress contemplated the provision's effect on hospitals before deciding the changes would not unduly burden healthcare providers. His speech shows that Congress contemplated the provision's effect on hospitals before deciding the changes would not unduly burden healthcare providers. He stated,

> Drafting language to pursue unlawful retention of an overpayment proved difficult... When we considered similar legislation in committee, I learned that hospitals, universities, and other research institutions are among various entities that function in government programs where

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[30] Tyler Robinson & Roger R. Clayton, *Rise of the "Reverse" False Claim & Proposed Rules from CMS on Reporting & Returning Overpayments*, ILL. ASS'N DEF. OF COUNSEL QUARTERLY, (Jan. 9, 2014), http://www.iadtc.org/news/152147/Rise-of-the-Reverse-False-Claim--Proposed-Rules-from-CMS-on-Reporting--Returning-Overpayments.htm [perma.cc/LG6Q-EBPT].

[31] *Senate To Consider Leahy-Grassley Anti-Fraud Measure During Wednesday's Session*, OFF. OF SEN. PATRICK LEAHY (Apr. 22, 2009), http://www.leahy.senate.gov/press/senate-to-consider-leahy-grassley-anti-fraud-measure-during-wednesdays-session [perma.cc/NDA8-ZHPR].

[32] 111 Cong. Rec. S1682 (Feb. 5, 2009) (statement of Sen. Leahy).

[33] *Id.*

[34] 111 Cong. Rec. H5268 (May 6, 2009) (statement of H.R. Maffei).

> the program rules do require those entities to account for overpayments . . . .
> . . . A new subsection of the False Claims Act will not impose liability for the mere retention of an overpayment over the course of the reconciliation period. Rather, the new subsection would require proof of a knowing false record or statement, of knowing concealment, or of knowing and improper acts to avoid or decrease an obligation to pay money to the government.
> So, if a person or entity receives an overpayment from the United States and fails to return it immediately and instead takes steps to return the overpayment through an applicable reconciliation process, then liability would not attach. However, if a person falsifies information during a reconciliation period or otherwise acts knowingly and improperly to avoid the payment, liability would attach.
> So it's vitally important that we pass this legislation to fight financial fraud. But it's also important that we not punish universities, hospitals, and other important research institutions when they're doing everything that they are supposed to do. We must have enforcement and also fairness.[35]

Congress tailored the reverse false claim provision to healthcare institutions using the Rule. The Rule's addition of the sixty day clock shows Congress's intent to spur providers into action to repay obligations in a timely fashion. But Congress failed to shed adequate light on *when* a healthcare provider "identifies" an overpayment, and the S.D.N.Y. has adopted the government's position, which manifests Representative Maffei's warnings of the reverse false claims provision unduly burdening healthcare providers.

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[35] *Id.*

III. THE S.D.N.Y.'S FAULTY ANALYSIS

A. Plain Language Meaning

The S.D.N.Y. begins its analysis with the law's plain language, arguing that dictionaries do not resolve the questions of the meaning of "identified."[36] The court cites Black's Law Dictionary, which defines "identify" as "to prove the identity of."[37] Merriam-Webster's Dictionary defines "identify" as "to know and say who someone is or what something is," "to find out who someone is or what something is," and "to show who someone is or what something is."[38] The Oxford Dictionary offers, "to establish or indicate who or what someone or something is."[39] The court then turns to the "less prominent" Collins Dictionary which lists synonyms for "identify" as " 'recognize,' 'name,' 'pinpoint,' 'point out,' and 'spot.'"[40]

After listing these definitions, the court conclusorily states that "while Kane did not purport to conclusively prove the identity of any overpayments – and hundreds of the claims he listed had not actually been overpaid – he did 'recognize' nearly five hundred claims that did in fact turn out to have been overpaid as worthy of attention."[41] This conclusion appears to be derived from the list of synonyms in the Collins dictionary, conveniently ignoring the long list of definitions which give the real meaning of the word "identify." Looking through these definitions, the common thread is that something is not "identified" until someone can prove or show or what that thing is.

The analysis should have ended here, and the court should have determined that Kane's email did not identify any overpayments because the email did not prove or show funds received in error. Instead, the court moves on to an analysis of the Rule's legislative history to support its

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[36] Kane ex rel. U.S. v. Healthfirst, Inc., 120 F. Supp. 3d 370 (S.D.N.Y. 2015).

[37] *Id.* at 384.

[38] *Id.* at 384-85.

[39] *Id.* at 385.

[40] *Id.*

[41] *Id.*

position.[42] An overview of the Rule's development runs counter to the government and court's interpretation.

B. The Rule's Legislative Development

The Senate and House both worked on separate versions of the ACA for most of 2009.[43] The House chairmen working together on the ACA released the first House version of the health care legislation, called a "discussion draft," on June 19, 2009.[44] The purpose of this draft was to spur conversation to begin the legislative process in the House.[45] The Rule first appears here with the basic elements – reporting and returning overpayments – in place.[46]

However, this version of the Rule differs from the final one in several ways. The final Rule applies if "a person has received an overpayment," whereas the discussion draft version applies if "a person knows of an overpayment."[47] The discussion draft version's sixty day clock begins when an overpayment is "identified," much like the final Rule.[48] The two versions also state that overpayments kept beyond the sixty days become obligations under the FCA.[49] Absent from the discussion draft version is the clause tying the use of "knowing" or "knowingly" to the FCA definition (the "Definition Clause").[50]

After more hearings, the House Committee leaders introduced House Bill 3200, America's Affordable Health Choice Act of 2009, on July 14, 2009.[51] Traditionally House

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[42] *Id.* at 386.

[43] John Cannan, *A Legislative History of the Affordable Care Act: How Legislative Procedure Shapes Legislative History*, 105 LAW LIBR. J. 131, 145 (2013).

[44] *Id.* at 137.

[45] *Id.*

[46] *Id.*

[47] H.R. 3200, 111th Cong. at 725 (2009), *available at* https://www.gpo.gov/fdsys/pkg/BILLS-111hr3200ih/pdf/BILLS-111hr3200ih.pdf [perma.cc/2BLM-MM8E].

[48] *Compare* H.R. 3200 *with* 42 U.S.C. § 1320a-7k(d)(1) (2010).

[49] *Compare* H.R. 3200 *and* 42 U.S.C. § 1320a-7k(d)(1) (2010) *with* 31 U.S.C. § 3729 (2016).

[50] *Compare* H.R. 3200 *and* 42 U.S.C. § 1320a-7k(d)(1) (2010) *with* 31 U.S.C. § 3729 (2016).

[51] Cannan, *supra* note 43, at 137-38.

bills are crafted through a process where the Committee debates, amends, and then votes on whether or not to report out the bill.[52] Each amended version of the bill is known as a "markup" and is invaluable to a legal researcher for shedding light on amendments that were considered, debated, and discarded.[53] In the case of House Bill 3200, committee leadership instead drafted the bill behind closed doors and outside the markup process, leaving only its plain text as a guide.[54]

The House Bill 3200 version of the Rule altered the discussion draft version.[55] It kept the opening clause that the Rule applies if "a person knows of an overpayment," but changed the sixty day countdown's start from when the overpayment is "identified" to when "the person knows of the overpayment."[56] Along with this change, the House Bill 3200 version also introduced the Definition Clause defining "knows" as having the same meaning as "knowing and knowingly" from the FCA.[57]

The Senate Finance Committee also worked on a draft of the ACA during this time.[58] On September 16, 2009, Senator Baucus released his Chairman's mark of bill, called America's Healthy Future Act.[59] Undoubtedly the Finance Committee reviewed House Bill 3200, which was released two months before their version. This Senate version is written in a colloquial style, detailing the current status of the law and the proposed changes.[60] It states that the

> 60 days providers and suppliers have to repay Medicare overpayments would be modified to either 60 days after the date on which the

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[52] *Id.* at 138.

[53] *Id.*

[54] *Id.*

[55] America's Affordable Health Choices Act of 2009, 111th Cong., H.R.B 3200 (July 14, 2009), *available at* http://www.jeffhead.com/HC-HouseII.pdf [perma.cc/YTX8-N2HT].

[56] *Id.*

[57] *Id.* at 727.

[58] Cannan, *supra* note 43, at 147.

[59] *Id.*

[60] U.S. SENATE, COMMITTEE ON FINANCE, AMERICA'S HEALTHY FUTURE ACT OF 2009, S. DOC. NO. 111-89 (1st Sess. 2009).

> overpayment was made or the date the corresponding cost report is due. Providers and suppliers would be required to repay any Medicare or Medicaid overpayment identified through an internal compliance audit.[61]

Although it implies that the clock starts when an overpayment is made, much less identified or known, this mark was likely intended to foster discussion in anticipation of a heated legislative session and is not written in a legal manner.[62]

Back in the House, the Ways and Means Committee, the Committee on Education and Labor, and the Committee on Energy and Commerce conducted markups of House Bill 3200 in July 2009 and reported them to the House floor on October 14, 2009.[63] None of these markups changed the Rule's text.[64] House Bill 3200 ended with these three versions.[65]

Meanwhile, the Senate Finance Committee's markup sessions produced Senate Bill 1796, reported out on October 19, 2009.[66] Senate Bill 1796 contains the Rule in essentially its final form.[67] The only difference between the Senate Bill 1796 version and the final version, are clean-ups involving updating or clarifying internal citations such as changing a reference to "title XVIII" to "subchapter XVIII."[68]

The Senate made several changes to the House version of the Rule. First, the Senate changed the opening language from "if a person *knows* of an overpayment" to "if a person

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[61] *Id.*

[62] Cannan, *supra* note 43, at 147.

[63] *Id.* at 140.

[64] H.R. 3200, 111th Cong. at 725 (2009), *available at* https://www.gpo.gov/fdsys/pkg/BILLS-111hr3200ih/pdf/BILLS-111hr3200ih.pdf [perma.cc/2BLM-MM8E]; H.R. REP. NO. 111-299, pt. 1 (2009); H.R. REP. NO. 111-299, pt. 2 (2009) (note that the markup does not explicitly list the Rule but encompasses it because it says to keep Division B, which contained the Rule).

[65] Canaan, *supra* note 43, at 140.

[66] 111th CONG. SEN. FIN. COMM, S. 1796, Oct. 19, 2009.

[67] *Id.* at 1355-57.

[68] 42 U.S.C. § 1320a-7k(d) (2010).

has *received* an overpayment."[69] Importantly, it changed the clock's start to "the date on which the overpayment was identified" instead of "the date the person knows of the overpayment."[70] The most striking and confounding change that this Senate version produced from House Bill 3200 is that it removed all forms of the word "know" from the statute's text. However, it kept the Definition Clause and *even updated it* to now read "The terms 'knowing' and 'knowingly'" instead of "The term 'knows.'"[71]

A summary of the Rule's development is as follows:

[69] *Compare* 111th Cong. House Ways and Means Comm., H.R. 3200, (July 19, 2009), *with* 111th CONG. SEN. FIN. COMM., S. 1796, (Oct. 19, 2009).

[70] *Compare* 111th Cong. House Ways and Means Comm., H.R. 3200, (July 19, 2009), *with* 111th CONG. SEN. FIN. COMM., S. 1796, (Oct. 19, 2009).

[71] *Compare* 111th Cong. House Ways and Means Comm., H.R. 3200, (July 19, 2009), *with* 111th CONG. SEN. FIN. COMM., S. 1796, (Oct. 19, 2009).

	Discussion Draft	House Bill 3200	Senate Bill 1796
Opening	If a person knows of an overpayment	If a person knows of an overpayment	If a person has received an overpayment
Start of Clock	The date that is 60 days from the date the overpayment is identified	The date that is 60 days after the date the person knows of the overpayment	The date which is 60 days after the date on which the overpayment was identified
Definition Clause	N/A	The term 'knows' has the meaning given the terms 'knowing' and 'knowingly' in section 3729(b) of title 31 of the United States Code.	The terms 'knowing' and 'knowingly' have the meaning given those terms in section 3729(b) of title 31 of the United States Code.[72]

After a shorter review of the Rule's legislative history, the S.D.N.Y. acknowledged that Congress may have intended to impose a higher burden than the FCA knowing standard given its rejection of "knows" for "identified."[73] Yet the court also states that "it is equally plausible that Congress included the definitions of 'knowing' and 'knowingly' within the ACA's report and return provision in order to indicate

[72] *Compare* 111th Cong., *Discussion Draft*, (June 19, 2009), *available at* https://web.archive.org/web/20090624235405/http:/waysandmeans.house.gov/media/pdf/111/HRdraft1xml.pdf [perma.cc/MXM9-PQD2]; *with* H.R. 3200, 111th Cong. (Jul. 14, 2009); *as compared with* 1S. Res. 1796, (Oct. 19, 2009).

[73] Kane *ex rel.* U.S. v. Healthfirst, Inc., 120 F. Supp. 3d 370, 386 (S.D.N.Y. 2015).

that the FCA's knowledge standard should apply to the determination of when an overpayment is deemed 'identified.'"[74] The legislative history counters this assertion as it demonstrates that Congress is capable of providing definitions to words when it so intends.

C. The Rule's Plain Language Trumps the S.D.N.Y.'s Unsupported Policy Position

Admittedly, the court does not directly use the Definition Clause to provide its reasoning, although its conclusion comports with the FCA knowing standard. Instead, the court resorts to a general "policy" argument.[75] As recently seen in *King v. Burwell*, policy can play a strong role in the interpretation of the ACA.[76] The court harkens back to the reasoning behind FERA's passage. Congress updated the term "obligation" to include "an established duty, *whether or not fixed*, arising… from the retention of an overpayment."[77] Therefore, "Congress intended for FCA liability to attach in circumstances where, as here, there is an established duty to pay money to the government, even if the precise amount due has yet to be determined."[78] This logic ignores the fact that "overpayment" and "obligation" are not used synonymously in the Rule.

This nuance is crucial to understanding why the S.D.N.Y.'s position falls flat on its face, and why the definition of the word "overpayment" is just as critical as the word "identified." The clock starts with the identification of an "overpayment."[79] An overpayment is defined as "any funds that a person receives or retains … to which the person,

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[74] *Id.* at 387.

[75] *Id.* at 23.

[76] King v. Burwell, 135 S. Ct. 2480, 2496 (U.S. 2015) (stating that a policy goal of the Affordable Care Act is "to improve health insurance markets," therefore "[i]f at all possible, we must interpret the Act in a way that is consistent" with this goal). Notably, this case cited numerous examples of policy positions to support its claim, whereas here the record of policy statements on the Rule is barren.

[77] *Kane ex rel. U.S.,* 120 F. Supp. 3d 370, 388 (S.D.N.Y. 2015) (emphasis in original).

[78] *Id.* at 388.

[79] 42 U.S.C. § 1320a-7k(d) (2016).

after applicable reconciliation, is not entitled."[80] An overpayment becomes a reverse false claims obligation after sixty days.[81] Therefore, an overpayment cannot exist unless funds have been received and retained, and an obligation cannot exist without an overpayment. How, then, can Kane's spreadsheet identify any overpayments when the list does not state the corresponding funds received for each claim?

The clear answer is that it cannot. By the court's own admission, "approximately half of the claims listed therein were never actually overpaid."[82] If no excess funds were received, there was no overpayment, and no overpayment means no obligation. There is no dispute that an exact dollar amount need not be pre-determined for an obligation to exist. But by the same token, an obligation under the Rule cannot exist when the existence of an overpayment is unknown.

D. Creating Absurdity Where None Exists

The court makes the case that its interpretation avoids the "absurdity" that comes with the plain language meaning of the Rule.[83] This reading, the court argues, "would make it all but impossible to enforce the reverse false claims provision of the FCA in the arena of healthcare fraud" because providers would intentionally bury their heads in the sand.[84] Without holding that Kane's email identified overpayments, "there will be no recourse for the Government when providers behave as Continuum allegedly behaved here."[85] One would be hard pressed to find a provider that argues that it is allowed to hold onto overpayments, given that the Rule did not replace the FCA. Retaining funds to which the person is not entitled is still an illegal act.

When viewed with the realities of a provider's internal Medicare and Medicaid audit process, the Rule is not absurd. The defense described the process to the court's deaf ears, noting that once a provider is made aware of a potential

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[80] *Id.* at § 1320a-7k(d)(4)(B).
[81] *See id.* at § 1320a-7k(d)(2).
[82] *Kane ex rel. U.S.*, 120 F. Supp. 3d 370, 388 (S.D.N.Y. 2015).
[83] *Id.* at 389.
[84] *Id.* at 390.
[85] *Id.*

overpayment it must pull and review the relevant medical records, discuss the cases with the physicians, consult with coding staff and possibly counsel, and then expand the scope of the audit if the initial sample reveals overpayments.[86] The provider then makes arrangements to return the overpayments which may involve identifying every specific claim that resulted in an overpayment.[87]

Applied as written, the Rule gives providers a hard deadline of sixty days to return the overpayments that are identified once funds are matched to claims in the audit process. This would ensure that overpayments continuously and timely roll to Medicare Administrative Contractors while the provider conducts the audit. This standard would establish a level of predictability for providers and their Medicare Administrative Contractors for the backwards flow of money. The "absurdity" the court warns will consume the industry is not apparent.

IV. CONCLUSION

The court stretches the language of the statute beyond what it can bear in order to satisfy the government's hindsight-driven argument. It is disheartening that the court did not take the opportunity to interpret the law as it is written. Such a holding, if not what the legislature intended, would spur Congress to reexamine the poorly-written statute. Hearings on the Rule attended by compliance officers and other deep in the trenches would teach Congress the operations of a provider's reimbursement process.

Returning Medicare and Medicaid overpayments is an extremely important policy goal for the Office of Inspector General and the Department of Justice. Those charged with protecting the Medicare Trust Fund must have the proper tools to fulfill their mission, and conscripting providers to timely return overpayments will free the government's already thin resources. But the enforcers must stay within the law. The government rightfully argues that failing to

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[86] *Id.* at 388-389 (quoting Mem. of Law in Support of Defendant's Mot. to Dismiss Gov't. Compl. at 10–11, Kane v. Healthfirst, Inc., No. 11 Civ. 2325 (ER) (S.D.N.Y. Sept. 22, 2014)).

[87] *Id.* at 389.

return the overpayment by day sixty-one does not automatically mean that the provider will be hauled to court, stating at a pre-motion conference that if "the hospital is diligently working on the claims and it's on the sixty-first day . . . the government wouldn't be bringing that kind of a claim."[88]

As shown above, it is questionable if the government could even bring a claim if no overpayment exists. But assuming the government's position prevails, is constantly hanging the Sword of Damocles over the heads of the nation's hospitals a good policy goal? By ensuring that healthcare providers will be in an eternal state of panic, the S.D.N.Y. is securing employment for audit consulting firms for years to come. Hospitals that do not have the finances to hire a legion of CPAs or consultants must either fold or rely on the mercy of government attorneys such as the one who promised they "wouldn't be bringing that kind of a claim."[89]

On February 12, 2016, the Centers for Medicare & Medicaid Services (CMS) released its final rule on the 60 Day Report and Return Rule's applicability to Medicare Parts A and B.[90] Relevant to this discussion, the final rule states that an overpayment is "identified" when the person "has, or should have through the exercise of reasonable diligence, determined that the person received an overpayment and quantified the amount of the overpayment." [91] This is a welcome departure from using the False Claims Act knowing standard. However, only through future enforcement will we have a clearer picture of what this test means. The *Kane* statutory analysis remains relevant in the event that the CMS Final Rule fails to withstand judicial scrutiny.

Going forward, providers will operate under the "reasonable diligence" test. CMS states that "reasonable diligence" captures both proactive and reactive solutions including timely investigations in response to credible

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[88] *Id.* at 389-90 (quoting Transcript of Record at 22:8-12, Kane v. Healthfirst, Inc., No. 11 Civ. 2325 (ER) (S.D.N.Y. Sept. 5, 2014).

[89] *Id.*

[90] Medicare Program; Reporting and Returning of Overpayments, 81 Fed. Reg. 7654 (Feb. 12, 2016) (to be codified at 42 C.F.R. pts. 401 and 405).

[91] 42 C.F.R. § 401.305 (2016).

information of a potential overpayment.[92] Applied to *Ex Rel Kane*, the defendants would likely run afoul of exercising "reasonable diligence" given that it took more than two years to repay the full amount and only after repeated requests for information.

Despite CMS's improvements, the statute's sixty day time limit will continue to weigh on the nation's healthcare providers. The law will likely produce its intended effect to spur proactive compliance departments, but the price may outweigh its benefits. Perhaps instead of the "report *and* return rule," the Rule should be the "report *then* return rule" with the clock's length determined by the scope of the potential overpayment. Were this the Rule when Continuum received Kane's email, Continuum could have reported the potential overpayment to the government. The government would have then determined the amount of time to return any identified overpayments based on the number of questionable claims and possible dollar amount.

The final rule allows for extended repayments under the existing Extended Repayment Schedule program, but a provider must show financial hardship in terms of repaying an identified overpayment and not because of the demands of internal investigations.[93] With the hard wall of sixty days, compliance departments will need to hire and train enough employees to respond in full force to even the slightest scent of smoke. These costs will be passed on to taxpayers and patients through increased hospital charges until Congress takes the initiative to amend the Rule to reflect reality.

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[92] Medicare Program; Reporting and Returning of Overpayments, 81 Fed. Reg. 7661.

[93] Medicare Program; Reporting and Returning of Overpayments, 81 Fed. Reg. at 7679, 7684.

HELP THAT HURTS: HOW DOL'S HOME CARE RULE HARMS PEOPLE WITH DISABILITIES AND CAREGIVERS

Emily Munson, JD, MA*

People with disabilities and their caregivers work together every day. In addition to the obvious—caregivers assisting clients with disabilities in performing activities of daily living—the two groups have frequently come together in support of a cohesive policy agenda.[1] In 2011, when the Department of Labor (DOL) issued a notice of proposed

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[1] *ADAPT Disability Rights Activists and SEIU Home Care Attendants Tell Congress: Community Choice is a Right*, PR NEWSWIRE (Apr. 29, 2009), http://www.prnewswire.com/news-releases/adapt-disability-rights-activists-and-seiu-home-care-attendants-tell-congress-community-choice-is-a-right-62029822.html [http://perma.cc/G5QP-XQLU]; Edgar Walters, *Conservatives Join Push to Pay Care Workers More*, TEX. TRIB. (Mar. 3, 2015), http://www.texastribune.org/2015/03/03/among-conservatives-push-pay-attendants-more/ [http://perma.cc/VGQ7-AWFM].

http://dx.doi.org/10.18060/3911.0023

rulemaking to limit the companionship exemption to the Fair Labor Standards Act (FLSA), the two groups' interests diverged.

Advocacy groups for home care workers, as well as lobbying groups for the minorities that comprise a significant portion of the home care worker pool, had been clamoring for minimum wage and overtime protections for years. To these groups, the denial of FLSA protections to workers constituted an injustice.[2] However, disability rights groups were concerned that the recipients of care–also historically marginalized–lacked the resources, both individually and governmentally, to cover the benefits home care workers desired, as Congress itself recognized when debating the companionship exemption.[3] The disability community argued that the DOL's failure to first ensure adequate infrastructure to support FLSA protections for workers jeopardized those receiving care.[4]

Part I of this paper begins by exploring how the federal government has classified domestic workers since the inception of the FLSA. Part II explores the genesis of the companionship exemption, as well as the challenges it has faced from the legislative, judicial, and administrative branches of government. Finally, the most recent challenge to the DOL's interpretation of the home care rule, *Home Care Ass'n of America v. Weil*,[5] is discussed.

Subsequent parts of the paper focus on the harm that will result from implementation of the new home care rule. Part III describes why the well-being of people with disabilities is jeopardized by implementation of the rule, and details how states are grappling with the new regulatory requirements.

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[2] *NELP Applauds Historic Decision to Uphold Minimum Wage and Overtime Rights for Home Care Workers*, NELP (Aug. 21, 2015), http://www.nelp.org/news-releases/nelp-applauds-historic-decision-to-uphold-minimum-wage-overtime-rights-for-home-care-workers/ [http://perma.cc/8TV7-DVGT].

[3] *See* 119 CONG. REC. 24,797 (1973) (statement of Sen. Dominick); *id.* at 24,789 (statement of Sen. Johnston).

[4] *DOL Proposes Changes to Companionship Exemption HURT People with Disabilities!*, ADAPT, http://www.adapt.org/main/dol [http://perma.cc/M2A3-3ZCH] (last visited Apr. 11, 2016).

[5] Home Care Ass'n. of Am. v. Weil, 78 F. Supp. 3d 123, 128 (D.D.C.), *rev'd sub nom.*, 799 F.3d 1084 (D.C. Cir. 2015).

Part IV explains why the rule will not actually benefit home care workers, and even may leave some worse off than before.

I. HOME CARE WORKERS AND THE FLSA

In 1938, Congress enacted the FLSA.[6] The FLSA was deemed necessary to address "labor conditions detrimental to the maintenance of the minimum standard of living necessary for health, efficiency, and general well-being of workers."[7] Its protections included minimum wage and overtime standards.[8]

However, not all employees benefited.[9] FLSA excluded from its minimum wage and overtime protections certain classes of worker, including domestics and other workers traditionally performing services in the home.[10] As such, those workers providing care for the elderly and disabled were not protected by the FLSA at its inception.

In 1961 and 1966, the FLSA was amended to provide coverage to certain additional employees through "enterprise coverage."[11] For the first time, workers would receive minimum wage and overtime protections based on the size of their employer, as opposed to the specific nature of their individual work. Thus, if a domestic worker was employed by an agency (or other enterprise) with gross annual sales of $250,000 or more, she was entitled to receive the minimum wage and additional compensation for overtime.[12] However, these protections were short-lived.

Less than a decade later, in 1974, Congress explicitly exempted several categories of domestic employees from

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[6] Codified as amended at 29 U.S.C. § 201 *et seq.* (2016).

[7] Codified at 29 U.S.C. § 202(a) (2016).

[8] 29 U.S.C. §§ 206-207 (2016).

[9] In fact, only about one-fifth of the American labor force was covered by FLSA. Jonathan Grossman, *Fair Labor Standards Act of 1938: Maximum Struggle for a Minimum Wage*, U.S. DEP'T LAB., http://www.dol.gov/oasam/programs/history/flsa1938.htm [http://perma.cc/A5D3-QCMJ] (last visited Apr. 11, 2016).

[10] *See* 29 U.S.C. §§ 201-219 (2016).

[11] *See* 29 U.S.C. § 203(r)–(s) (2016).

[12] *See* Fair Labor Standards Amendments of 1966, Pub. L. No. 89-601, 80 Stat. 830, 836 (1966) (current version at 29 U.S.C. § 203(s)(1) (2016) (current limit is $500,000)).

FLSA coverage by implementing the "companionship exemption." Exempted companions included "any employee employed on a casual basis . . . to provide babysitting services,"[13] as well as those "employed . . . to provide companionship services for individuals who (because of age or infirmity) are unable to care for themselves."[14] The Secretary of Labor was left to define the specifics.[15]

In 1975, the DOL reported receiving a variety of comments in response to its proposed implementing regulations, from groups as diverse as law firms to working mothers.[16] Based on these comments, the DOL amended the final rule to: clarify that individuals engaged in a home business are not domestic service employees, simplify record-keeping mandates for live-in caregivers, and describe timekeeping methods.[17] Perhaps most controversial, Wage and Hour Division Administrator Betty Murphy determined that third parties could avail themselves of the companionship exemption since the exemption applies to "any employee."[18] This meant that domestic service workers affiliated with agencies constituting enterprises under the FLSA would no longer be entitled to overtime and minimum wage protections.

II. CHALLENGES TO THE COMPANIONSHIP EXEMPTION

The companionship exemption has subsequently been challenged through multiple channels. While no Congressional proposals have yet been successful in amending the exemption, that has not stopped senators and representatives from offering proposed amendments. Other challenges have come from home care workers seeking FLSA protection through litigation, as well as through administrative rulemaking efforts. This section provides a brief summary of how the exemption has been challenged since 1975.

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[13] 29 U.S.C. § 213(a)(15) (2016).

[14] *Id.*

[15] *Id.*

[16] Extension to Domestic Service Employees, 40 Fed. Reg. 7404 (Feb. 20, 1975) (codified at 29 C.F.R. pts. 516, 552).

[17] *Id.* at 7405.

[18] *Id.*

A. Legislative Challenges

Most recently, efforts to amend the FLSA to cover home care workers have come in the form of proposed legislative amendments. In 2007, Representative Lynn Woolsey introduced the Fair Home Health Care Act in the House (House Bill 3582).[19] The short bill defined "casual basis" domestic service employment as "irregular or intermittent" and provided that it is neither performed by an individual whose vocation is the provision of companionship services, nor may it exceed an aggregate twenty hours per week.[20] Senator Tom Harkin introduced a similar bill in the Senate.[21] Both bills were referred to committees, where they remained.[22]

Senator Robert Casey and Representative Linda Sanchez introduced the Direct Care Workforce Empowerment Act in 2010 where, again, the bills' primary purpose was limiting the companionship exemption by narrowing the scope of casual basis employment. [23] Specifically, the bills would require casual employment to be "irregular or intermittent," and disallowed such employment from being performed by an individual in a vocational capacity.[24] The bills further provided that "[e]mployment is not on a casual basis, whether performed for one or more family or household employers, if such employment for all such employers exceeds [twenty] hours per week in the aggregate."[25] The bills also directed the Secretary of Health and Human Services to create a data

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[19] H.R. 3582, 110th Cong. § 2 (2007).

[20] *Id.* § 2.

[21] S. 2061, 110th Cong. (2007). Notably, cosponsors of this bill included Senators Clinton and Obama. As will be discussed, the Clinton and Obama Administrations also attempted to limit the companionship exemption through administrative action.

[22] *H.R. 3582- Fair Home Health Care Act,* CONGRESS.GOV, https://www.congress.gov/bill/110th-congress/house-bill/3582 (last visited Feb. 27, 2016); *S.2061 -Fair Home Health Care Act of 2007* , CONGRESS.GOV, https://www.congress.gov/bill/110th-congress/senate-bill/2061 (last visited Feb. 27, 2016).

[23] S. 3696, 111th Cong. (2010); H.R. 5902, 111th Cong. (2010).

[24] S. 3696, 111th Cong. (2010); H.R. 5902, 111th Cong. (2010).

[25] S. 3696, 111th Cong. (2010); H.R. 5902, 111th Cong. (2010).

collection and monitoring program, National Advisory Council on the Direct Care Workforce, and three-year grant program designed to improve recruitment, retention, and education of the direct care workforce.[26] Neither bill made it out of committee.[27]

The following June, Senator Casey and Representative Sanchez tried again, introducing the Direct Care Job Quality Improvement Act of 2011 into their respective houses.[28] These bills sought to clarify that the term "casual basis in domestic service employment to provide companionship services" means intermittent employment that is "not performed by an individual – (1) whose vocation is the provision of companionship services; or (2) who is employed by an employer or agency other than the family or household using their services."[29] In the event that a caregiver works for a family or individual more than five hours per week or for more than twelve weeks per year, the caregiver would not be considered to be working on a casual basis.[30] In addition to FLSA amendments, the bills also called for the creation of a workforce monitoring program, a data sharing program, reports on the adequacy of long-term care support for Medicaid purposes, and multiple grant programs.[31] Again, the bills were stuck after being referred to committee.[32]

In response to DOL's proposed narrowing of the companionship exemption, Representative Lee Terry introduced the Companionship Exemption Protection Act.[33]

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[26] S. 3696, 111th Cong. (2010) §§ 4-5; H.R. 5902, 111th Cong. (2010) §§ 4-5.

[27] *H.R. 5902- Direct Care Workforce Empowerment Act*, CONGRESS.GOV, https://www.congress.gov/bill/111th-congress/house-bill/5902 (last visited Feb. 27, 2016); *S.3969 -Direct Care Workforce Empowerment Act*, CONGRESS.GOV, https://www.congress.gov/bill/111th-congress/senate-bill/3696/text (last visited Feb. 27, 2016).

[28] H.R. 2341, 112th Cong. (2011); S. 1273, 112th Cong. (2011).

[29] H.R. 2341, § 3.

[30] *Id.*; S. 1273, § 3.

[31] *Id.* §§ 4-6; *Id.* §§ 4-6.

[32] *H.R. 2341-Direct Care Job Quality Improvement Act of 2011*, CONGRESS.GOV, https://www.congress.gov/bill/112th-congress/house-bill/2341/text (last visited Feb. 27, 2016); *S.1273 -Direct Care Job Quality Improvement Act of 2011*, CONGRESS.GOV, https://www.congress.gov/bill/112th-congress/senate-bill/1273/related-bills (last visited Feb. 27, 2016).

[33] H.R. 3066, 112th Cong. (2011).

The Act proposed stripping the Secretary of Labor of the authority to define and delimit the exemption.[34] A similar bill was introduced in the Senate by Senator Mike Johanns.[35] Ultimately, neither was successful.

B. Challenges through Litigation

As individuals with disabilities began leaving institutions for group homes, ambiguity remained as to whether the companionship exemption applied to community-based settings that were not necessarily private homes (e.g., group homes owned by a provider and largely funded by the state). Even before the Supreme Court's seminal *Olmstead* decision,[36] courts had begun providing greater clarity regarding the companionship exemption's applicability. One of the first cases to address the issue was *Lott v. Rigby*.[37] There, house parents at Stephens County Independent Group Residence for the Mentally Retarded petitioned the court for overtime compensation. However, the court determined that the companionship exemption only applied to those services provided in a private home.[38] Because the Residence was publicly funded, the house parents could not be domestic service employees.[39]

Numerous cases followed. In *Linn v. Developmental Services of Tulsa, Inc.*, the court held that to determine whether a home was private, the court should focus on the elements of control, such as whether the service provider furnished the residence, maintained a set of keys, and paid rent, as well as whether residents were related and were offered a setting similar to an institution.[40] In *Madison v. Resources for Human Development, Inc.*, the court deemed the fact that clients did not live in the home prior to becoming clients of the service provider a significant factor in

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[34] *Id.*

[35] S. 3280, 112th Cong. (2012).

[36] Olmstead v. L. C. *ex rel.* Zimring, 527 U.S. 581 (1999).

[37] Lott v. Rigby, 746 F. Supp. 1084 (N.D. Ga. 1990).

[38] *Id.* at 1088.

[39] *Id.*

[40] *See* Linn v. Developmental Servs. of Tulsa, Inc., 891 F. Supp. 574 (N.D. Okla. 1995).

determining whether the home was private.[41] In *Johnston v. Volunteers of America, Inc.*, the Tenth Circuit ruled that the employer bears the burden of proving that its employees meet the exemption.[42]

In 2004, the Tenth Circuit revisited the issue in *Welding v. Bios Corp.*[43] There, a group of caregivers for individuals with developmental disabilities in multiple homes alleged that their employer violated FLSA by improperly availing itself of the companionship exemption. The court determined that housing units are part of a "continuum," and "key inquiries" in determining where on that continuum the unit lies "are who has ultimate management control of the living unit and whether the living unit is maintained primarily to facilitate the provision of assistive services."[44] Factors to be addressed are: whether the recipient of care lived in the home prior to becoming a client of the provider; who owns the home, which "is significant because it evidences control"; who maintains the home by paying the mortgage, utilities, and food; whether the recipients of care would continue living in the home if you no longer received services from the provider; the difference in the relative values of services provided and the total cost of the living unit; and whether the provider uses any part of the home for business purposes.[45] "[N]o single factor is dispositive, [though] some may be more important than others."[46] Two years later, the DOL adopted the *Welding* factors as its own.[47]

A second area of litigation involving the companionship exemption challenged the notion that certain home care workers were untrained personnel. In *McCune v. Oregon Senior Services Division*, a group of live-in caregivers alleged that, as certified nursing assistants (CNAs), they met the

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[41] *See* Madison v. Res. for Human Dev., Inc., 39 F. Supp.2d 542 (E.D. Pa. 1999).

[42] *See* Johnston v. Volunteers of Am., Inc., 213 F.3d. 559 (10th Cir. 2000).

[43] Welding v. Bios Corp., 353 F.3d. 1214 (10th Cir. 2004).

[44] *Id.* at 1219.

[45] *Id.* at 1219-20.

[46] *Id.* at 1219.

[47] Rebecca M. Fowler, *Home Healthcare Workers and the Fair Labor Standards Act*, 1 J. HEALTH & LIFE SCI. L. 107, 122 (2008).

companionship exemption exception for trained personnel.[48] The appellants had received 60 hours of training in order to achieve CNA certification.[49] Appellants further requested that the court consider crediting them with additional training that had been received directly from the physicians of those receiving care.[50] Like the district court, the Ninth Circuit rejected this argument because, under Oregon law, the tasks that physicians trained the CNAs in were outside the scope of CNA competence and were instead the duties of a licensed nurse.[51] The Court determined that it would be inappropriate to reward appellants for acting outside the scope of their authority.[52] Moreover, it recognized that asking the State to account for on-the-job training and constantly reassess their employees for development would be "an administrative nightmare."[53]

The Seventh Circuit faced a similar challenge from a home health aide in *Cox v. Acme Health Services, Inc.*[54] The appellant had received 105 hours of training to become certified as a CNA, and completed additional training to achieve certification as a home health aide.[55] Maintaining home health aide certification required a minimum of 12 hours continuing training each year.[56] In bringing her claim for unpaid overtime wages, Cox argued "her training and duties as a home health aide were akin to the training and duties of a registered or practical nurse within the meaning of the exception to the FLSA's exemption for 'companionship services.'"[57] The Court opined that Cox had "received only a fraction of the training received by registered or practical

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[48] McCune v. Or. Senior Servs. Div., 894 F.2d 1107 (9th Cir. 1989). The group also alleged that because they provide general housekeeping services to clients, essentially performing the collective duties of cooks, maids, nurses, and other workers entitled to FLSA coverage, they, too, should be covered by the FLSA. *Id.* at 1109.

[49] *Id.* at 1113.

[50] *Id.* at 1111.

[51] *Id.*

[52] *Id.*

[53] *Id.*

[54] Cox v. Acme Health Servs. Inc., 55 F.3d 1304 (7th Cir. 1995).

[55] *Id.* at 1307.

[56] *Id.* at 1306.

[57] *Id.* at 1308.

nurses."[58] Additionally, the requirements for becoming a registered or practical nurse were more stringent, and included statutorily-mandated training in areas from biological sciences to nursing theory.[59] Although Cox had obtained training beyond the mandatory seventy-five hours necessary to be a home health aide in Indiana, it was "of no consequence" because the tasks she was performing did not require the additional training.[60] The court held that to avail oneself of the trained personnel exception, "a domestic service employee must not only perform services requiring the training of a registered or practical nurse, but must in fact have obtained training comparable in scope and duration to that of a registered or practical nurse."[61]

Only one case involving the companionship exemption made its way to the Supreme Court, *Long Island Care at Home, Ltd. v. Coke*.[62] At issue was whether the DOL's regulation permitting third-party employers to avail themselves of the companionship exemption was valid.[63] Coke was a caregiver that regularly worked seventy hours per week,[64] and she sought minimum wages and overtime pay from her employer, a home care agency, and its owner.[65] Coke argued that third-party employers should not benefit from the companionship exemption for three reasons.

First, Coke claimed that domestic service employment is an activity limited to those employed by the recipients of care. In support of her argument, Coke argued that the Social Security Act defines "domestic service employment" as activity conducted in the home of the employer.[66] She further argued that domestic service workers used to be covered through enterprise coverage.[67] The Court deemed this

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[58] *Id.* at 1309.

[59] *Id.* at 1310.

[60] *Id.*

[61] *Id.* (emphasis omitted).

[62] Long Island Care at Home, Ltd. v. Coke, 551 U.S. 158 (2007).

[63] *Id.* at 162.

[64] Elizabeth Riordan, *Where the Heart Is: Amending the Fair Labor Standards Act to Provide Wage and Overtime Pay Protection to Agency-Employed Home Health Aides*, 85 ST. JOHN'S L. REV. 837 (2011).

[65] *Long Island Care at Home, Ltd.*, 551 U.S. at 164.

[66] *Id.* at 166.

[67] *Id.* at 165.

argument unconvincing, noting that FLSA "expressly instructs the agency to work out the details of those broad definitions [of 'domestic service employment' and 'companionship services']. . . . [W]hether to include workers paid by third parties within the scope of the definitions is one of those details."[68]

Next, Coke argued that the plain language of the third-party regulation conflicts with the definition of "domestic service employment," in that the latter requires the worker to be in the home of the person by whom he or she is employed.[69] The Court agreed that conflict exists, but determined that the third-party regulation governs.[70] From a practical perspective, the Court did not believe it made sense for the exemption to hinge on whether the payor resided in the same household as the individual receiving care. If the conflict was resolved as Coke desired, then family members would not be able to avail themselves of the exemption if they lived in a different household than the individual receiving care. Such was not the intent of Congress.[71] From a legal perspective, "normally the specific governs the general," meaning that the third-party regulation, the sole purpose of which is to address the issue of third-party payors, should trump the more general definitional regulation.[72]

Finally, Coke took issue with the way the regulation was promulgated.[73] She argued that the third-party regulation was interpretive, and interpretive regulations cannot be used to bindingly fill a statutory gap, but are more appropriately deemed persuasive materials.[74] However, the Court found this reasoning unconvincing.[75] The DOL used formal notice and comment procedures, suggesting the regulation was meant to be as binding as any other.[76] Moreover, the regulation was within the scope of the DOL's authority and

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[68] *Id.* at 167.
[69] *Id.* at 168.
[70] *Id.* at 169.
[71] *Id.* at 170.
[72] *Id.*
[73] *Id.* at 171-72.
[74] *Id.* at 172.
[75] *Id.*
[76] *Id.* at 173.

was reasonable.[77] Coke argued that promulgation procedures were defective because notice and explanation of the regulation were inadequate.[78] The Court found that DOL complied with its legal promulgation duties.[79] Therefore, the new law of the land permitted third parties to avail themselves of the companionship exemption.

C. Administrative Challenges

In 1993, the first attempt to limit use of the companionship exemption was attempted by the Clinton Administration.[80] Specifically, the DOL published its intent to forbid third-party employers from using the companionship and live-in exemption, except for those circumstances in which the employer had a joint employment relationship with the recipient of care.[81] The rule was proposed as a mere clarification, based on the DOL's belief that the issue "may be susceptible of misinterpretation."[82]

In 1995, the DOL reopened the comment period for those rules proposed in 1993.[83] Although only seven comments were received in response to the 1993 notice of proposed rulemaking, they caused the DOL to consider the potential effect the proposed rule would have on state and local governments responsible for funding companionship services.[84] Thus, the DOL specifically sought comments on permitting government entities, along with recipients of care and their family members, to avail themselves of the companionship exemption.[85]

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[77] *Id.*

[78] *Id.* at 174.

[79] *Id.* at 175.

[80] Application of the Fair Labor Standards Act to Domestic Service, 58 Fed. Reg. 69,310 (Dec. 30, 1993) (to be codified at 29 C.F.R. pt. 552).

[81] *Id.*

[82] *Id.* at 69,311.

[83] Application of the Fair Labor Standards Act to Domestic Service, 60 Fed. Reg. 46,797 (Sept. 8, 1995) (to be codified at 29 C.F.R. pt. 552).

[84] *Id.* at 46,797-98.

[85] *Id.* at 46,798.

A second, more comprehensive effort to amend the companionship exemption occurred in 2001.[86] The notice of proposed rulemaking stated that the home care industry had experienced "significant changes" since 1975, such that home care workers were "performing types of duties and working in situations that were not envisioned when the companionship services regulations were promulgated."[87] Finding that the exemption no longer matched Congress's intent, the DOL again proposed excluding third-party employers from utilizing the companionship and live-in exemption.[88] The DOL also proposed redefining "companionship services" and amending qualification criteria for "trained personnel."[89]

The Bush Administration withdrew the proposed rule in 2002.[90] The DOL under President Clinton stated that the proposed rule would not have a significant economic impact.[91] However, this assertion was "seriously called into question" by commenters, including the Small Business Administration and the Department of Health and Human Services.[92]

The companionship exemption remained untouched until 2011, when the Obama Administration decided to revive the Clinton proposals and introduce further amendments. As in 1993, the DOL cited changes in the home care industry, including "growing demand for long-term in-home care," the "rising cost of traditional institutional care," the "availability of funding assistance for in-home care under Medicare and Medicaid," and a "significant increase in our aging

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[86] Application of the Fair Labor Standards Act to Domestic Service, 66 Fed. Reg. 5481 (Jan. 19, 2001) (to be codified at 29 C.F.R. pt. 552).

[87] *Id.* at 5482.

[88] *Id.* at 5485.

[89] *Id.* at 5483-84.

[90] Application of the Fair Labor Standards Act to Domestic Service, 67 Fed. Reg. 16,668 (Apr. 8, 2002) (to be codified at 29 C.F.R. pt. 552).

[91] Application of the Fair Labor Standards Act to Domestic Service, 58 Fed. Reg. 69,310, 69,311 (Dec. 30, 1993) (to be codified at 29 C.F.R. pt. 552).

[92] Application of the Fair Labor Standards Act to Domestic Service, 67 Fed. Reg. at 16,668.

population."[93] According to the DOL, these factors contribute to a different workforce then that intended by Congress.[94] Today's companions are often employed by third-party agencies rather than directly by the recipient of care,[95] and many of the companions rely on the job as their primary source of income.[96] The DOL asserted that narrowing the companionship exemption would more accurately reflect congressional intent.[97]

First, the DOL proposed broadening section 552.6, defining "companionship services," into four paragraphs.[98] Paragraph (a) defines "companionship services" as "the provision of fellowship and protection for a person who, because of advanced age or physical or mental infirmity, is unable to care for themselves," and goes on to define "fellowship" and "protection."[99]

Paragraph (b) provides that "companionship" includes the provision of care, so long as that care is incidental in nature.[100] Incidental services constituting companionship, per the DOL, include using public transportation, going to appointments, and attending social events.[101] Other services may be deemed incidental only after a fact-intensive inquiry. For example, the DOL expects that recipients of care can schedule their bathing routines to be outside of a companion's hours.[102] Therefore, assisting a client with a bath or shower is outside the scope of companionship. However, if there is "an imminent need" for "cleansing," the DOL consider it "a reasonable but limited exception[]" and permit assistance from a companion.[103]

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[93] Application of the Fair Labor Standards Act to Domestic Service, 76 Fed. Reg. 81,190, 81,190-91 (Dec. 27, 2011) (to be codified at 29 C.F.R. pt. 552).

[94] *Id.* at 81,192.

[95] *Id.* at 81,193.

[96] *Id.* at 81,197.

[97] *Id.* at 81,192.

[98] *Id.*

[99] *Id.* at 81,193.

[100] *Id.* at 81,192.

[101] *Id.* at 81,193.

[102] *Id.*

[103] *Id.*

Paragraph (c) further limits the scope of incidental duties, excluding "[g]eneral household work . . . such as vacuuming, washing windows, and dusting" from the definition of companionship.[104] Because Congress offered FLSA protection to domestic service workers such as maids, the DOL believes tasks traditionally performed by these workers should not be included within a FLSA coverage exemption.[105] As such, companions can no longer assist their clients with light housework.

Paragraph (d) eliminates from companionship services "medical care that is typically provided by personnel with specialized training."[106] The list of excluded activities is broad. Some tasks, such as blood sugar screening and the provision of physical therapy, clearly require training or direction. Yet other activities, such as "routine foot, skin, and back care"[107] appear to be just that–routine activities that require nothing more than common sense and an able body. Nevertheless, companions may not provide such assistance.

Further, the DOL eradicated the third-party companionship exemption for all parties, except "for the individual, family, or household" receiving care.[108] This means that states and other government entities involved in funding homecare may be on the hook to pay minimum wage and overtime.

It is also important to note that individuals and families receiving care are not completely isolated from the rule's reach. Recall that the scope of "companionship services" was limited.[109] Thus, if a companion fails to qualify for the exemption and the individual or family receiving care can be considered a sole or joint employer, the individual or family will be required to pay minimum wage and overtime, regardless of any previously negotiated contract. If a recipient of care needs help going to the bathroom an extra time one day, this extra care could potentially trigger the 20 percent threshold and require that individual to pay

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[104] *Id.* at 81,195.
[105] *Id.*
[106] *Id.*
[107] *Id.*
[108] *Id.* at 81,198.
[109] *See supra* Section IC.

minimum wage and overtime. If a recipient of care eats with a feeding tube, that individual will automatically be liable for minimum wage and overtime, as assisting him triggers the medically related services provision.

Finally, the DOL withdrew permission for live-in aides and employers to negotiate an employment contract in lieu of keeping a log of hours worked.[110] In fact, the proposed regulation puts complete responsibility on the employer "for making, keeping, and preserving records of hours worked and ensuring the accuracy" thereof.[111]

D. Home Care Association Challenge

Despite the DOL "anticipat[ing] that the proposed rule will have relatively little effect on the provision of companionship services,"[112] concerns were immediately raised by home care agencies and recipients of home care services. The Home Care Association of America, the International Franchise Association, and National Association for Home Care and Hospice quickly brought an action under the Administrative Procedures Act, arguing that the proposed rules constituted an arbitrary and capricious endeavor, clearly contrary to congressional intent and delegated authority.[113] They requested an injunction, in order to continue utilizing the third-party provisions of the companionship exemption.[114]

The D.C. Circuit Court held that the regulations conflict with both the legislative history and plain language of the FLSA.[115] In Step I of the *Chevron* analysis, the court must address whether Congress directly spoke to the question at issue.[116] If the answer is "no", Chevron Step II requires the

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[110] Application of the Fair Labor Standards Act to Domestic Service, 76 Fed. Reg. at 81,198.

[111] *Id.* at 81,199.

[112] *Id.* at 81,223.

[113] Complaint for Declaratory and Injunctive Relief, Home Care Ass'n of Am. v. Weil, 76 F. Supp. 3d 138 (D.C. Cir. 2014) (No. 1:14-cv-00967).

[114] *Id.*

[115] Home Care Ass'n of Am. v. Weil, 76 F. Supp. 3d 138, 147-48 (D.D.C. 2014), *rev'd sub nom.*, 799 F.3d 1084 (D.C. Cir. 2015).

[116] *Id.* at 143.

court to determine whether Congress delegated authority to the executive agency to implement statute or fill a gap.[117]

Judge Leon found that "Congress surely did not delegate to the Department of Labor here the authority to issue a regulation that transforms defining statutory terms into drawing policy lines based on who cut the check rather than what work is being performed."[118] Although Congress did leave some gaps to be filled by the DOL, including the definition of companionship services, once the "gaps were filled. . . , the statutory loop was closed."[119] Ultimately, by implementing regulations that Congress declined to implement by statute, the DOL engaged in "yet another thinly-veiled effort to do through regulation what could not be done through legislation. Such conduct bespeaks an arrogance to not only disregard Congress's intent, but seize unprecedented authority to impose overtime and minimum wage obligations in defiance of the plain language of Section 213."[120]

Once Leon vacated the third-party employment regulation, the trade associations gained standing. The associations petitioned for emergency injunctive relief to prevent the enforcement of the proposed regulations. The petition resulted in a memorandum decision from the DC Circuit Court, again written by Judge Leon.

In this second decision, Judge Leon found that while Congress did explicitly delegate to the DOL the power to define "companionship services," that delegation did "not grant it a blank check to do so in a way that contradicts the Act itself."[121] More specifically, the FLSA references companionship services in a way that makes clear such services are to be provided to individuals that cannot care for themselves.[122] Yet, the DOL's proposed regulations remove that essential care from the definition.[123] Congress revisited

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[117] *Id.* at 143-44.

[118] *Id.* at 144.

[119] *Id.* at 145.

[120] *Id.* at 147-48.

[121] Home Care Ass'n. of Am. v. Weil, 78 F. Supp. 3d 123, 128 (D.D.C.), *rev'd sub nom.*, 799 F.3d 1084 (D.C. Cir. 2015).

[122] *Id.*

[123] *Id.*

the companionship provisions of the FLSA on numerous occasions since 1974, but never amended those provisions.[124] Therefore, the DOL, in offering regulations on a topic in which Congress has already spoken and made its intent clear, acted outside the scope of its authority.[125] The inquiry stops at Step I of the *Chevron* analysis.[126]

The DOL appealed, arguing that the Supreme Court's decision in *Coke* precludes the analysis ending at Step I.[127] The U.S. Court of Appeals agreed.[128] Judge Srinivasan opined that *Coke* placed within the DOL a "broad grant of authority" to decide whether companions employed by third parties fall within the scope of the companionship exemption.[129] While the D.C. Circuit Court was incorrect to look to unpassed legislation as evidence of congressional intent, the Supreme Court already determined that, when it comes to the inclusion of third-party employers, "the full range of potential outcomes lay within the agency's discretion."[130]

Home Care Association asserted that the DOL's interpretation was arbitrary, but the Court found that the proposed regulations were "entirely reasonable."[131] Particularly, the DOL was attempting to bring FLSA protections to those employees "whose *vocation* is domestic service."[132] Moreover, the court determined that the heightened standard Home Care Association wanted imposed with regard to a justification for reversing forty years of contrary interpretation was inappropriate.[133] The DOL provided "a reasoned explanation" for limiting the exemption, which meets its legal burden.[134]

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[124] *Id.* at 130.

[125] *Id.*

[126] *Id.* at 128.

[127] Corrected Reply Brief for Appellants, Home Care Ass'n of Am. v. Weil, 799 F.3d 1084 (D.C. Cir. 2015) (No. 15-5018), 2015 WL 1602118.

[128] Home Care Ass'n of Am. v. Weil, 799 F.3d 1084, 1087 (D.C. Cir. 2015).

[129] *Id.* at 1092 (internal quotation marks omitted).

[130] *Id.* (internal citation omitted).

[131] *Id.* at 1093.

[132] *Id.* at 1094 (internal citation omitted) (emphasis original).

[133] *Id.*

[134] *Id.* at 1094-95.

Ultimately, the court reversed and granted summary judgment to the DOL.[135] On September 24, 2015, the trade associations petitioned Supreme Court Chief Justice John Roberts to stay the rule, pending disposition of a petition for certiorari.[136] Justice Roberts denied the petition on October 6, 2015.

III. EFFECTS FOR RECIPIENTS OF CARE

The 2010 census revealed that 56.7 million, or about one in five, people have a disability.[137] More than half of them consider their disability to be severe.[138] Almost 10 million noninstitutionalized people indicated the need for assistance with one or more activities of daily living.[139] These activities include tasks like dressing, toileting, and preparing meals. Thus, there is a great need for the services of home care workers. Indeed, given the reliance of people with disabilities on their caregivers, the home care rule has the potential to negatively affect them.

A. Delivery of Services

In order to understand how the home care rule will affect the quality and amount of care received by people with disabilities, it is necessary to examine the methods through which these services are delivered. Home care is funded through a variety of sources, including private pay by individuals and families and via government insurance programs. Approximately three-quarters of home care expenditures are paid by Medicare and Medicaid.[140]

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[135] *Id.* at 1097.

[136] Application for a Stay of Mandate Pending the Timely Disposition of a Petition for a Writ of Certiorari, Home Care Ass'n of Am. v. Weil, 799 F.3d 1084 (D.C. Cir. 2015) (No. 15-A-326).

[137] *Nearly 1 in 5 People Have a Disability in the U.S.*, U.S. CENSUS BUREAU (July 25, 2012), https://www.census.gov/newsroom/releases/archives/miscellaneous/cb12-134.html [http://perma.cc/FJ79-TRJT].

[138] *Id.*

[139] *Id.*

[140] Application of the Fair Labor Standards Act to Domestic Service, 76 Fed. Reg. 81,190, 81,223 (Dec. 27, 2011) (to be codified at 29 C.F.R. pt. 552). Medicaid funds the bulk of home care, paying for approximately

Medicaid is not required to cover home health care,[141] though most states have chosen to fund home care through a variety of methods.[142]

Traditionally, Medicaid beneficiaries receiving personal care in community settings have received services from a third-party home health agency that manages their care.[143] Under this system, the agency is responsible for hiring and firing caregivers, seeking payment, and addressing any problems that arise.[144] The state provides payment to the agency for this service.

In self-directed care programs, also known as consumer-directed care, the recipient of care is responsible for taking on many of the tasks historically performed by home care agencies.[145] Payment of these caregivers depends on the type of system the state has adopted.[146] Sometimes, the recipient of care is responsible for paying their caregiver and completing taxes.[147] Other times, the state will contract with a fiscal intermediary that handles payroll and taxes.[148] Regardless of the program's particulars, consumer-directed care is growing. Since 2001, almost all states have implemented at least one consumer-directed care program.[149]

41% of the yearly home care expenditures. Medicare pays approximately 35% of these expenditures.

[141] *Medicaid Long-Term Care Services*, U.S. DEP'T HEALTH & HUM. RESOURCES, http://longtermcare.gov/medicare-medicaid-more/medicaid/medicaid-long-term-care-services/ [http://perma.cc/64JJ-FD9N] (last visited Apr. 11, 2016). However, Medicaid is required to pay for care in institutional settings.

[142] *Id.*

[143] Robert Newcomer et al., *Consumer-Directed Personal Care: Comparing Aged and Non-Aged Adult Recipient Health-Related Outcomes Among Those With Paid Family Versus Non-Relative Providers*, 30 HOME HEALTH CARE SERVS. Q. 178, 179 (2011).

[144] *Id.*

[145] Teresa Scherzer et al., *Financial Management Services in Consumer-Directed Programs*, 26 HOME HEALTH CARE SERVS. Q. 29, 30 (2007).

[146] *Id.*

[147] *Id.*

[148] *Id.* at 33.

[149] *Id.* at 30.

B. State Implementation

Many states are unprepared to comply with the new home care rule. Fiscal year budgets are already in place for 2016, and 2017 budgets are already well-developed in many states.[150] This means that even if states were willing to bolster already-stretched Medicaid budgets, in order to cover the additional costs of minimum wage and overtime, it is too late. It is unlikely that agencies will be reimbursed beyond current Medicaid reimbursement rates for the foreseeable future. This means home health agencies will be required to eat the cost of the rule's new burdens or cease Medicaid participation.

The situation is even more complex for states offering Medicaid beneficiaries the opportunity to participate in consumer-directed services. States will be required to conduct an analysis to determine whether managed care organizations and fiscal intermediaries participating in these programs constitute a joint employment relationship. The DOL issued guidance on joint employment relationships, indicating that an economic realities analysis must be conducted.[151] Elements of this analysis include "whether the potential employer has the power to hire and fire the employees, supervise and control the employees' work, determine the rate of payment, maintain employment records, and control where the work is performed."[152]

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[150] BAZELON CENTER FOR MENTAL HEALTH LAW ET AL., ACTION STEPS FOR CONSUMERS AND ADVOCATES REGARDING THE DOL HOME CARE RULE: HOW TO PREVENT SERVICE CUTS AND PROTECT CONSUMER-DIRECTED PROGRAMS 4-5 (2015), *available at* http://www.bazelon.org/LinkClick.aspx?fileticket=u0RrEBo3adY%3d&tabid=40 [https://perma.cc/JAP3-9FXQ].

[151] Wage and Hour Division, *Fact Sheet #79E: Joint Employment in Domestic Service Employment Under the Fair Labor Standards Act (FLSA),* U.S. Dept. of Labor, (last updated June 2014) https://www.dol.gov/whd/regs/compliance/whdfs79e.htm [https://perma.cc/96ZT-8QKR].

[152] CINDY MANN, CMCS INFORMATIONAL BULLETIN: SELF-DIRECTION PROGRAM OPTIONS FOR MEDICAID PAYMENTS IN THE IMPLEMENTATION OF THE FAIR LABOR STANDARDS ACT REGULATION CHANGES 2 (2014), *available at* http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/CIB-07-03-2014.pdf.

In the event that the relationship constitutes joint employment, a state must be vigilant not only of how many hours an employee works for each Medicaid beneficiary, but also whether the cumulative hours of each Medicaid beneficiary served by the employee will trigger minimum wage and overtime protection. Even if an employee provides caregiving services for less than 40 hours per week to multiple Medicaid beneficiaries, States must also calculate travel time between beneficiaries' homes and include it in the worker's hours.[153]

Given the parameters of existing budgets, states are trying to develop creative solutions for implementing the Rule. Unfortunately, these solutions may come at the expense of the recipients of care, as discussed in the sections below. The Department of Health and Human Services (DHHS) has released documents "strongly urg[ing] states to ensure that overtime or travel costs beyond an individual's control not be deducted from the individual's self-directed budget."[154] That is, a recipient of care should not be forced to forgo services while a caregiver is driving to or from their home.

The DHHS and the Department of Justice also released a joint "Dear Colleague Letter" reminding states of their obligation under Title II of the Americans with Disabilities Act (ADA) to provide those services that permit individual with disabilities to live in the least restrictive environment.[155] In particular, the agencies recognized that states are planning to put a 40-hour cap on the amount of services that can be provided by any given worker. They warned that "implementation of across-the-board caps risks violating the ADA if the caps do not account for the needs of individuals with disabilities and consequently places them at serious risk of institutionalization or segregation."[156]

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[153] *See* Application of the Fair Labor Standards Act to Domestic Service, 76 Fed. Reg. 81,190, 81,219 (Dec. 27, 2011) (to be codified at 29 C.F.R. pt. 552).

[154] MANN, *supra* note 153, at 3.

[155] Vanita Gupta & Jocelyn Samuels, *Olmstead Dear Colleague Letter on FLSA Home Care Rule*, DEP'T HEALTH & HUM. SERVS. (Dec. 15, 2014), http://www.hhs.gov/sites/default/files/2014hhsdojdearcolleagueletter.pdf [http://perma.cc/MC2P-WG69].

[156] *Id.* at 3.

Nevertheless, states will be faced with difficult choices. Unfortunately, institutionalization, as well as increased safety risks, appear to be very real natural consequences of the rule's implementation at the state level.[157]

C. Harms to Recipients of Care

From the beginning, the DOL has failed to recognize the magnitude of the changes it has mandated. The notice of proposed rulemaking anticipated "that the proposed rule will have relatively little effect on the provision of companionship services."[158] Yet, it admits that there is "almost no data . . . that can directly be used to model the market for companionship services."[159] Additionally, "[d]ue to the sometimes informal nature of the consumer-directed employment arrangements, there are no data on the total number of customers under this model, and there is limited information on the total number of providers."[160]

Instead of conducting a thorough market analysis, the DOL concluded that, because 14 states currently provide some type of minimum wage or overtime protection to companions, "objections raised in the past regarding the feasibility and expense of prohibiting third parties from claiming the companionship and live-in worker exemptions" are negated.[161] This fact is misleading because not all fourteen states provide the complete protection mandated under the new rule.[162] It also ignores the fact that those

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[157] This is especially ironic considering that the expenses of *Olmstead* litigation, and even institutionalized care itself, are greater financial burdens for states than the provision of a good home- and community-based care system. *See* Charlene Harrington et al., *Do Medicaid Home and Community Based Service Waivers Save Money?*, 30 HOME HEALTH CARE SERVS. Q. 198, 210 (2011).

[158] Application of the Fair Labor Standards Act to Domestic Service, 76 Fed. Reg. at 81,223.

[159] *Id.*

[160] *Id.* at 81,208.

[161] *Id.* at 81,197. These states are: Colorado, Hawaii, Illinois, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New York, Pennsylvania, Washington, and Wisconsin.

[162] *Id.* at 81,204-06.

states chose to implement the protections, and consequently had the opportunity prepare for implementation.[163]

The DOL, while perhaps not aware of the severity of changes, was aware that home care agencies will need to make significant changes in order to comply with the new regulation. It offered three operational choices to these agencies:

> First, the agency might manage existing staff to reduce overtime hours while managing the same caseload and staffing levels. . . . Second, as suggested in the City of New York's amicus brief, agencies might choose not to allow staff to exceed 40 hours per week. . . . The third scenario comprises a mix of the first and second approach. Neither of those approaches is costless to agencies, therefore, agencies will weigh the costs of hiring additional workers with the cost of paying overtime to existing workers to determine the optimal mix of overtime a new hires approximate to their circumstances.[164]

Easier said than done.

In an *amici* brief, multiple States argued that "the operational viability" of the Medicaid program has been threatened, "both in letter and spirit."[165] How have states reacted thus far? By the time ADAPT and the National Council on Independent Living submitted their joint brief, Arkansas had proposed placing a forty-hour per week cap on

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[163] DOL did not release FACT SHEET #79E, regarding the homecare rule's effect on States, until June 2014. *See* U.S. DEP'T OF LABOR, FACT SHEET #79E: JOINT EMPLOYMENT IN DOMESTIC SERVICE EMPLOYMENT UNDER THE FAIR LABOR STANDARDS ACT (FLSA) (2014), *available at* http://www.dol.gov/whd/regs/compliance/whdfs79e.pdf.

[164] Application of the Fair Labor Standards Act to Domestic Service, 76 Fed. Reg. at 81,218.

[165] Brief of the States of Kansas, Arizona, Georgia, Michigan, Nevada, North Dakota, Tennessee, Texas and Wisconsin in Support of Affirming the District Court at 2, Home Care Ass'n of Am. v. Weil, 799 F.3d 1084 (D.C. Cir. 2015) (No. 15-5018), 2015 WL 1534373, at *2.

companionship hours.[166] Virginia proposed a fifty-six hour cap and requiring providers of companionship services to have a single employer.[167] Illinois, Massachusetts, New Mexico, and New York–a few of the states the DOL looks to as proof that the home care rule will be effective–openly acknowledge capping hours.[168]

Individuals receiving care will not simply stop needing to go to the bathroom after receiving 40 hours of care. Rather–and assuming they are provided the extra assistance–these individuals will have to invite more strangers into their homes. As disability rights activists maintain: "[p]ersonal autonomy and bodily integrity are fundamental human rights. Our courts have upheld these rights in a variety of situations where others have sought to regulate an individual's body."[169] Likewise, laws against assault and battery "protect individuals from experiencing unwanted touching from another person. However, under the new rule, disabled people will be forced to allow unwanted touching by new attendants if they want to live in the community."[170]

Legal scholars brush over this argument. Molly Biklen writes, "[t]he commodification of caregiving and the growth of the home healthcare industry suggest that there is no longer a core of intimate personal services to be protected by an exemption."[171] Tell that to the elderly woman who needs help cleaning up after she could not quite make it to the restroom on time. Tell the transgendered man who needs assistance changing his clothes that it is no big deal who sees his surgical scars.[172] Try keeping a straight face, knowing

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[166] Corrected Brief for ADAPT and the National Council on Independent Living as Amici Curiae Supporting Appellees at 10, Home Care Ass'n of Am. v. Weil, 799 F.3d 1084 (D.C. Cir. 2015) (No. 15-5018), 2015 WL 1534374, at *10.

[167] *Id.* at 11.

[168] *Id.*

[169] *Id.* at 22.

[170] *Id.* at 25.

[171] Molly Biklen, *Healthcare in the Home: Reexamining the Companionship Services Exemption to the Fair Labor Standards Act*, 35 COLUM. HUM. RTS. L. REV. 113, 150 (2003).

[172] *See* Corrected Brief for ADAPT and the National Council on Independent Living as Amici Curiae Supporting Appellees, *supra* note 162, at 23-24.

that individuals with disabilities have a dramatically higher rate of suffering violent crime than non-disabled individuals.[173]

Lack of respecting one's preference is a particularly salient issue for participants in consumer-directed care programs. People choose to participate in such programs for the very purpose of controlling their care. As New York's Consumer Directed Personal Assistance Program (CDPAP) attempted to persuade in its *amicus* brief:

> The CDPAP is the gem of the Medicaid program. It is quintessentially American. It is about liberty. In the CDPAP, the individual, not the agency, decides when to get up, when to take a bath, when to get dressed, and when to go to bed. The individual decides who to let into his or her own home. The individual decides how services are delivered. The individual decides who can touch his or her body. The individual is in charge of his or her own life.[174]

If a fiscal intermediary is forced to cap caregiver hours under the new rule, participants will lose vital autonomy.

In certain situations, individuals may lose caregivers altogether. Consider Arkansas again, which has considered forbidding caregivers from serving more than one client with a disability.[175] These caregivers, in order to make a living, are going to seek out those clients that need a number of

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[173] *Violent Crime Rate in 2013 Against Persons with Disabilities was More than Double the Age-Adjusted Rate for Persons without Disabilities,* BUREAU OF JUSTICE STATISTICS (May 21, 2015, 10:00 AM), http://ojp.gov/newsroom/pressreleases/2015/ojpapr05212015.pdf [http://perma.cc/7K5U-PFET].

[174] Amicus Curiae Brief of the Consumer Directed Personal Assistance Association of New York State Submitted in Support of the Plaintiffs/Appellees at 10, Home Care Ass'n of Am. v. Weil, 799 F.3d 1084 (D.C. Cir. 2015) (No. 15-5018), 2015 WL 1544793, at *10.

[175] Corrected Brief for ADAPT and the National Council on Independent Living as Amici Curiae Supporting Appellees, *supra* note 162, at 18.

hours of service as close to the maximum as possible.[176] Yet many people with disabilities only need–or have only been approved for–as few as two or three hours of service per day. Services received during these hours are often crucial, entailing, for example, getting out of bed in the morning or getting transported to work. But, unless these individuals find caregivers willing to earn minimum wage for fifteen hours per week, they may be stuck in bed.[177]

The DOL answered advocates' concerns by advancing the position that continuity of care is already diminished because "low wages, poor or nonexistent benefits, and erratic and unpredictable hours" result in high caregiver turnover.[178] It claims that, in some locations, the turnover rate is 100%.[179] These extreme statistics are questionable on their face. Disability advocacy groups furthermore recognize that, in gathering turnover rate data, the DOL combined post-acute, long-term, and consumer-directed care statistics.[180] This amalgam is improper because post-acute care is, by its nature, not designed to be sustained.[181]

Regardless of whether continuity of care is already poor, the home care rule threatens to exacerbate the problem. Kansas told the court that it has a shortage of home care workers available in its rural communities.[182] Other states lack a sufficient number of caregivers to assist recipients of care for whom spoken English is not the primary language.[183] Individuals requiring care in these situations are already at

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[176] Presumably, this maximum will be 40 hours per week.

[177] Or, of course, get forced into an institution.

[178] Application of the Fair Labor Standards Act to Domestic Service, 76 Fed. Reg. 81,190, 81,229 (Dec. 27, 2011) (to be codified at 29 C.F.R. pt. 552).

[179] *Id.*

[180] Corrected Brief for ADAPT and the National Council on Independent Living as Amici Curiae Supporting Appellees, *supra* note 162, at 17.

[181] *Id.*

[182] Brief for the States of Kansas, Arizona, Georgia, Michigan, Nevada, North Dakota, Tennessee, Texas and Wisconsin at 4, Home Care Association of Am. v. Weil, 799 F.3d 1084 23, (D.C. Cir. 2015) (No. 15-5018).

[183] Corrected Brief for ADAPT and the National Council on Independent Living as Amici Curiae Supporting Appellees, *supra* note 162, at 20.

extreme risk of being institutionalized. Limiting the pool of available care by placing a limit on the number of hours that each caregiver may work is dangerous for people who need the care and is also against the interests of the caregivers themselves.

IV. CONSEQUENCES FOR HOME CARE WORKERS

The home care rule was promulgated for the benefit of those who have devoted their career to caregiving. The DOL cited "significant changes in the home health care industry over the last 35 years" as justification for the amendments.[184] Advocates for the inclusion of domestic service workers into FLSA's protective fold argue that the work is "at the very least, thankless," and, at best, "despised and low class."[185] By offering caregivers FLSA protection, by recognizing their job duties as valuable, and by treating them like other professionals, advocates argue, caregiver status is improved. But is this actually the case?

Both the DOL and labor advocates fail to recognize the role of the caregiver as unique. Caregivers are valued by those for whom they care. Indeed, without assistance from a caregiver, many individuals with disabilities would not be able to get out of bed in the morning. That an individual with a disability is so dependent upon a caregiver to provide necessary assistance with intimate activities of daily living creates a relationship beyond the typical employer-employee exchange. Caregivers do more than assist their employers routine job duties; instead, they assist them in living life. It is crucial that any regulations affecting home care take this dynamic into account.

Moreover, although the home care rule may sound good to some labor advocates in theory, the regulations do not guarantee that caregivers will actually receive higher wages. As discussed in Part III, the DOL actually provides employers with workarounds to avoid paying caregivers

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[184] Application of the Fair Labor Standards Act to Domestic Service, 76 Fed. Reg. at 81,190.

[185] Lisa Diaz-Ordaz, *Real Work: Domestic Workers' Exclusion from the Protections of Labor Laws*, 19 BUFF. J. GENDER L. & SOC. POL'Y 107-08 (2001).

increased wages.[186] Lessons from states currently attempting to implement the home care rule demonstrate that caregivers may actually have decreased wages and autonomy, as explored in Section B.

A. Home Care Worker Representation

It is not evident why the Obama Administration believed amending the regulations was appropriate. Although it cited a growing demand for care, as well as increased government funding, the DOL failed to make a case that the actual nature of home care has changed. As Congress members opposing the changes noted,

> [w]e may have made many technological advances . . . but no one has yet found a viable everyday substitute for eating, dressing, or bathing. An elderly or infirm person incapable of caring for himself or herself in 1974 needed the same type of assistance that . . . person needs today.[187]

Instead, the motivation for the rule appears political; supporters have certainly cast it in such terms. Secretary Perez stated: "The pie is growing; American workers helped bake it, but most of them aren't getting a bigger slice."[188] Scholars refer to the companionship exemption as

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[186] Application of the Fair Labor Standards Act to Domestic Service, 76 Fed. Reg. at 81,218.

[187] Brief for Amici Curiae Members of Congress at 20, Home Care Ass'n of Am. v. Weil, 799 F.3d 1084 (D.C. Cir. 2015) (No. 15-5018). Those represented by the brief include Senators Mitch McConnell, Pat Roberts, Lamar Alexander, Roy Blunt, John Boozman, Mike Enzi, Johnny Isakson, and Marco Rubio, as well as Representatives Tim Walberg and Lynn Jenkins.

[188] Thomas E. Perez, *The Fair Labor Standards Act at Seventy-Seven: Still "Far-Reaching, Far-Sighted"*, 30 ABA J. LAB. & EMP. L. 299, 300 (2015).

"shortchanging workers,"[189] promoting "a legal fiction,"[190] or a codification of "the legacy of slavery."[191]

It is true that many home care workers fit within at least one category typically viewed as marginalized. Per DOL statistics, the average caregiver is a female in her mid-40s.[192] There is approximately a 40% chance that she is African-American or Hispanic, and, in some regions, a fair chance that she is foreign-born.[193] These statistics also mean there is a great chance that many of these caregivers voted for Obama.[194] Indeed, the Service Employees International Union (SEIU) was a top contributor to the Obama campaign, raising more money for Democratic candidates in 2012 then Obama's biggest political action committee.[195]

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[189] Julia Lippitt, *Protecting the Protectors: A Call for Fair Working Conditions for Home Health Care Workers*, 19 ELDER L.J. 219, 236 (2011).

[190] Biklen, *supra* note 167, at 146.

[191] Brief of Women's Rights, Civil Rights, and Human Rights Organizations and Scholars as Amici Curiae in Support of Defendants-Appellants Seeking Reversal at 5, Home Care Ass'n of Am. v. Weil, 799 F.3d 1084 (D.C. Cir. 2015) (No. 15-5018). Those represented by the brief include the American Civil Liberties Union, the Asian American Legal Defense and Education Fund, Eileen Boris, Jennifer Klein, Students in the Health and Human Rights Clinic at Indiana University McKinney School of Law, Latina/Latino Critical Legal Theory, Inc., National Law Center on Homelessness and Poverty, National Center for Law and Economic Justice, National Council of La Raza, National Hispanic Leadership Agenda, National Women's Law Center, Northwest Arkansas Workers' Justice Center, Santa Clara University School of Law International Human Rights Clinic, the U.S. Human Rights Network, Frank Askin, Karl Klare, William P. Quigley, and Deborah M. Weissman.

[192] Application of the Fair Labor Standards Act to Domestic Service, 76 Fed. Reg. 81,190, 81,211 (Dec. 27, 2011) (to be codified at 29 C.F.R. pt. 552).

[193] *Id.* at 81,212.

[194] *United States Elections: How Groups Voted in 2012*, ROPER CENTER., http://ropercenter.cornell.edu/polls/us-elections/how-groups-voted/how-groups-voted-2012/ [http://perma.cc/9TQQ-P5W9] (last visited Apr. 11, 2016).

[195] Melanie Trottman & Brody Mullins, *Union is Top Spender for Democrats*, WALL ST. J., http://www.wsj.com/articles/SB10001424052970204707104578091030386721670 [http://perma.cc/2FLZ-J9B5] (last updated Nov. 1, 2012).

Home care workers began organizing in the mid-1980s.[196] The first states to organize were Oregon, Washington, Illinois, and Massachusetts.[197] Maryland, Missouri, Connecticut, Vermont, and Minnesota were next.[198] Through collective bargaining, home care workers in these states were able to negotiate some combination of healthcare, training, paid time off, grievance procedures, transportation, and benefits.[199] For example, in some California counties, a home care worker receives healthcare, training, free use of public transportation, and the opportunity to grieve about adverse employment determinations.[200]

However, these benefits come with a cost, sometimes to the recipient of care. The demands of organized labor are often at odds with the consumer-directed care model. Not only does an individual receiving care need to work with strangers in completing activities of daily living, but, in organized states, they are forced to invite yet another strange party into their private sphere. Each additional group that receives a voice in the care delivery discussion diminishes autonomy available to the recipient of care.

Although the SEIU may believe caregivers should have the right to appeal terminations, that means individuals receiving care may be stuck working with a caregiver that was terminated for an egregious error. Perhaps an omission caused the caregiver to injure her client. Surely, the injured party should not be forced to maintain such a dangerous situation. Granted, a consumer-directed care employer may terminate a caregiver for reasons unrelated to poor conduct, and possibly even for reasons over which the caregiver has no fault. But, recall that the recipient of care needs to feel comfortable with the individual assisting him or her with the most personal of tasks.

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196 SEIU Local 503, *Overview of Homecare Collective Bargaining*, SEIU LOCAL 503.ORG (Dec. 13, 2013), http://www.seiu503.org/2013/12/overview-of-homecare-collective-bargaining/ [http://perma.cc/GM9W-NAWX].

197 *Id.*

198 *Id.*

199 *Id.*

200 *Id.*

Similarly, labor scholar Peggie Smith complains that the Occupational Safety and Health Act does not adequately protect employees engaged in the provision of consumer-directed care.[201] She argues that home care workers have "no protection from various hazards including dangerous household objects, exposure to blood or other infectious material, and injuries occasioned by lifting and moving clients."[202] Yet going into homes and touching disabled, elderly, and potentially ailing bodies are essential functions of home care work. Smith appears to prefer that homes be treated as office buildings, and that clients subscribe to a strict union-approved protocol. Whether or not a Hoyer lift is a pain in the butt–or literally causes pain–for recipients of care is inconsequential, as long as protocols are in place.

Union activity also has costs for employees. Part of this cost comes from the collection of dues. Until the Supreme Court issued its 2014 decision in *Harris v. Quinn*, unions were collecting fair share dues from caregivers that had no desire to join.[203] In less than 18 months, approximately 30,000 home care workers ended their membership in SEIU Healthcare Illinois, Indiana, Missouri, and Kansas.[204] This mass exodus from the union's rolls suggests that perhaps SEIU was not speaking for most home care workers.

Indeed, union contracts have cost some home care workers wage-earning hours. In early 2015, SEIU negotiated with the State of Minnesota to set a $10.75 minimum wage for personal care attendants.[205] Minnesota resident Scott Price explained that he would have to cut back hours of care

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[201] Peggie R. Smith, *Home Sweet Home? Workplace Casualties of Consumer-Directed Home Care for the Elderly*, 21 NOTRE DAME J.L. ETHICS & PUB. POL'Y 537, 549-50 (2007).

[202] *Id.* at 550.

[203] Harris v. Quinn, 134 S. Ct. 2618 (2014).

[204] Sean Higgins, *Caregivers Leave Midwest Union in Droves One Year After Harris v. Quinn*, WASH. EXAMINER (Nov. 1, 2015, 1:01 AM), http://www.washingtonexaminer.com/caregivers-leave-midwest-union-in-droves-one-year-after-harris-v.-quinn/article/2575406 [http://perma.cc/6TGY-2V77].

[205] J. Patrick Coolican, *SEIU Contract Kicks in for 27,000 Home Care Aides in Minnesota*, STAR TRIB. (June 30, 2015, 11:06 PM), http://www.startribune.com/seiu-contract-kicks-in-for-27-000-home-care-aides-in-state/311086561/ [http://perma.cc/XP24-G4SY].

received by his daughter, a 23-year-old with cerebral palsy, because he could not afford to pay the higher minimum wage for those hours she was asleep.[206] As he explained, "The burden falls back on the family in terms of caring for a child with a disability[.]"[207] The Prices are not alone; few families are in a position to afford the $94,170 price tag that now comes with a year of 24-hour care in Minnesota.

The situation in Minnesota is illuminating for two reasons. First, as Mr. Price states, despite claims about increased professionalization of the caregiving workforce, much of the responsibility for caregiving falls to family members.[208] Some of this care is unpaid. However, consumer-directed care provides a unique opportunity for family members to receive payment for caring for a loved one with a disability. The DOL, for example, notes that California "has a high percentage of caregivers who are paid family members."[209] In Michigan, approximately half of the independent providers are related to recipients of care.[210]

That many caregivers are related to their employer diminishes the validity of accusations that these workers are treated deplorably. It also means that many of these workers feel intruded upon by increased regulatory and professional oversight, just as their employers do. They do not want union members to come to their homes and conduct inspections.[211] Nor are such workers interested in being trained regarding the care of a loved one.[212] Additionally, many of these

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[206] *Id.*

[207] *Id.*

[208] *Id.*

[209] Application of the Fair Labor Standards Act to Domestic Service, 76 Fed. Reg. 81,190, 81,212 (Dec. 27, 2011) (to be codified at 29 C.F.R. pt. 552).

[210] Pamela Doty et al., *Consumer Choice and the Frontline Worker*, 18 GENERATIONS 65 (1994), *available* at http://aspe.hhs.gov/sites/default/files/pdf/73936/frntlnwk.pdf [http://perma.cc/L65E-CLL4].

[211] Sean Higgins, *Big Labor Trickery on Display in Effort to Unionize Home Care*, WASH. EXAMINER (Oct. 31, 2015, 12:01 AM), http://www.washingtonexaminer.com/big-labor-trickery-on-display-in-effort-to-unionize-home-care/article/2575302 [http://perma.cc/4B7E-CQFN].

[212] Paul Kersey, *Union Recruiters Have Been Relentless in Making Sure that Caregivers Get to Hear the Union Pitch*, ILL. POL'Y (Nov. 18,

workers are not interested in having their personal information divulged to third parties, per union directives.[213]

Second, as illustrated by the Prices, many employers lack the resources to continue paying caregivers for the same amount of hours if wages are increased. While the care that is received by people with disabilities is often essential, the realities of today's economy mean that demand is not unceasingly elastic. Sometimes families, like the Prices, will provide uncompensated care themselves. Others will not have this capacity, leaving the person in need of care to simply suffer without it. Either way, the home care worker loses the ability to earn a portion of income previously attained.

Thus, while unions have played an increasing role in home care over the preceding decades, this involvement has not been unanimously embraced. Union victories have sometimes been championed at the expense of workers. The home care rule, which can be construed as another union victory, similarly brings negative consequences for the workers who have been heralded as its beneficiaries.

B. Pragmatic Effects for Home Care Workers

Certainly, the DOL is correct to recognize that caregiving is an important job and caregivers deserve decent wages. As discussed, caregivers enable people with disabilities to perform activities of daily living. This, in turn, enables people with disabilities to contribute to their communities through community engagement, employment, and family life. Although this author is unwilling to describe home care work as necessarily "strenuous"[214] or "physically demanding

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2014), http://www.illinoispolicy.org/proposed-law-force-parents-attend-union-led-training/ [http://perma.cc/VDT4-SH54].

[213] Mike Dennison, *Governor, Union Want In-Home Health Worker Info Public; Bill Would Keep it Private*, MISSOULIAN (Apr. 9. 2015), http://missoulian.com/business/local/governor-union-want-in-home-health-worker-info-public-bill/article_d77a143a-d327-5b10-b9db-a749e3b25ecc.html [http://perma.cc/CY4Z-UQZK].

[214] Brief of Women's Rights, Civil Rights, and Human Rights Organizations and Scholars as Amici Curiae in Support of Defendants-Appellants Seeking Reversal *supra* note 187, at 22.

and emotionally draining,"[215] it does take patience, diligence, and compassion. Not everyone can succeed as a caregiver, but those that do should receive fair compensation.

Unfortunately, those providing home care services are often paid too little. In 2015, the median pay rate for a home health aide was $10.54.[216] A personal care aide could expect to receive even less, on average, with a 2015 median hourly pay rate of $10.09 per hour.[217] In promulgating the home care rule, the DOL specifically looked at these two occupational categories and stated that the low income associated with these jobs is problematic.[218] Nevertheless, it is not clear that the home care rule will actually benefit these employees.

However, the DOL recognizes "very few [home care workers] work overtime" when employed by agencies.[219] Thus, few stand to benefit from the new overtime provisions. Even so, the few workers who may be eligible for overtime under the new regulations are unlikely to receive it. The DOL actually notes: "there is no reason to believe the agencies will simply continue current staffing patterns and pay workers overtime for any hours exceeding 40 per week."[220] Instead, agencies will cut hours, potentially reducing the total income home care workers received under the previous regulations. In fact, in the notice of proposed rulemaking, the DOL offers agencies the option to "choose not to allow staff to exceed 40 work hours per week."[221]

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[215] Peggie R. Smith, *Aging and Caring in the Home: Regulating Paid Domesticity in the Twenty-First Century*, 92 Iowa L. Rev. 1835, 1849 (2007).

[216] *Occupational Outlook Handbook*, BUREAU OF LABOR STATISTICS (Dec. 17, 2015), http://www.bls.gov/ooh/healthcare/home-health-aides.htm [http://perma.cc/JXV3-FTT6].

[217] *Id.*

[218] Application of the Fair Labor Standards Act to Domestic Service, 76 Fed. Reg. 81,192, 81,212 (Dec. 27, 2011) (to be codified at 29 C.F.R. pt. 552).

[219] *Id.* at 81,213. The DOL further admits that it does not have particularly robust or reliable information regarding how employees provide services through consumer-directed care employment relationships. *Id.* at 81,208.

[220] *Id.* at 81,220.

[221] *Id.* at 81,218.

Trapped in pre-allocated budgets, and unwilling to take on the administrative burden of more closely managing the hours of each home care worker, states are planning to implement similar, and sometimes more draconian, measures. Arkansas not only proposed a forty-hour weekly cap on the number of hours an attendant care worker may work each week, but also proposed limiting workers to providing assistance for only one Medicaid beneficiary.[222] If a caregiver works forty hours a week with multiple clients (e.g., ten hours each week with John and thirty hours each week with Nancy), she will need to choose which client with which she wants to continue working. No matter her choice, she faces a reduction in total hours worked. Unless she can find a private pay client, she also likely faces a reduction in income.

Ohio proposed eliminating its independent provider program entirely.[223] The proposal would require over 13,000 home care workers to find work with a home care agency in order to continue providing services.[224] In addition to being detrimental to recipients of care, the elimination of the independent provider program is also injurious to providers. Caregivers would be required to find new jobs. Even if a caregiver manages to get hired by the agency that serves her current clients, she no longer works directly with them, but must be supervised by an agency middleman.

Indeed, serving as an independent provider offers caregivers the opportunity to partake in benefits that the traditional agency model does not offer. Consider that 85% of workers in consumer-directed care programs felt as though

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[222] Arkansas Department of Human Services Division of Medical Services, *Alternatives for Adults with Physical Disabilities Waiver* (Oct. 31, 2014), http://170.94.37.152/REGS/016.06.14-026P-14580.pdf [http://perma.cc/L63M-M4GS].

[223] *Governor Proposes Changes Affecting Independent Providers of Home Care*, DISABILITY RIGHTS OHIO (Mar. 5, 2015), http://www.disabilityrightsohio.org/news/governor-proposes-changes-affecting-independent-providers-home-care [http://perma.cc/3AAB-5235].

[224] *Gov. John Kasich's Budget to Phase Out Independent Health Worker Option*, OHIO.COM, http://www.ohio.com/news/break-news/gov-john-kasich-s-budget-to-phase-out-independent-health-worker-option-1.565510 [http://perma.cc/FY4A-53TZ] (last updated Feb. 10, 2015, 1:29 PM).

they had close relationships with their employers, while only 55% of caregivers from agencies felt close to the recipients of their care.[225] Additionally, despite the poor pay, "about 45% of directly hired workers reported being very satisfied with their wages and benefits. . . . In contrast, 22% of agency workers report being very satisfied . . . ."[226] As such, there is evidence that working outside of the agency model offers caregivers increased job satisfaction and overall well-being. The new regulations jeopardize the continuance of these agreeable conditions, and fail to recognize that a job is more than a mere paycheck.

Nonetheless, it is critical to note that the paychecks of some independent caregivers may also be completely at risk. Other states are exploring whether it is appropriate to maintain consumer-directed care programs in the wake of the new rule.[227] Over 800,000 participants may be affected.[228] Of the participating providers, many are family members of care recipients. When given the option, many receiving consumer-directed care prefer hiring relatives.[229] These caregivers are unlikely to work for other clients, and are more likely to continue caring for their relative without any compensation. After all, this is what many had done before becoming an independent provider was possible.[230] Therefore, if the rule forces states to eliminate or shrink jobs for independent providers, these providers may leave the labor force entirely.

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[225] Stacy Dale et al., *How Do Hired Workers Fare Under Consumer-Directed Personal Care?*, 45 THE GERONTOLOGIST 583, 588 (2005).

[226] *Id.*

[227] E-mail from Allison Barkoff, Dir. of Advocacy, Bazelon Ctr. for Mental Health Law, to Emily Munson (Oct. 8, 2015, 8:35 PM EST) (on file with author).

[228] *Medicaid Offering Participant-Directed Long-Term Care Services*, AHC MEDIA (Mar. 1, 2011) http://www.ahcmedia.com/articles/129911-medicaid-offering-participant-directed-long-term-care-services [http://perm.cc/8LBR-F9KY].

[229] Newcomer, *supra,* at 140.

[230] Kathryn G. Kietzman et al., *Whose choice? Self-Determination and the Motivations of Paid Family and Friend Caregivers*, 44 J. OF COMP. FAM. STUD. 519, 531 (2013).

V. CONCLUSION

Home care workers deserve wages that reflect the importance and value of their work. People with disabilities deserve choice in how their activities of daily living are conducted and who provides assistance, as well as possess the right to live in the community. Rather than working with both of these groups to develop a feasible solution honoring the interests of those directly involved in home-based caregiving, the DOL took it upon itself to act.[231]

Perhaps the DOL was acting with the best of intentions. Nevertheless, those within the Beltway especially should know where good intentions lead. People with disabilities are at risk of perishing in hell on earth[232]–nursing homes and other institutional placements. Even if they manage to stay in their homes, access to the community will be limited, continuity of care will be diminished, and respect for privacy and personal autonomy will fade away.

Those providing care will not fare better. As states experiment with home care methods, some will lose their jobs, others will merely lose the autonomy gained by serving as independent providers. Job satisfaction will diminish, as workers are torn away from their favorite clients and limited in the types of assistance they can provide, despite their own desires to help.

Disability advocates and home care workers must come together with a coherent strategy. First, and most quickly, Congress could once again attempt to remove regulatory power over domestic service provisions of the FLSA from the Executive Branch. This legislation would result in decision-makers being accountable to voters. Second, the DOJ must

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[231] Letter from Cathy Cranston and David Wittie to Senator Harry Reid, Senator Mitch McConnell, and Speaker John Boehner (Nov. 11, 2014), *available* at https://view.officeapps.live.com/op/view.aspx?src=http%3A%2F%2Fwww.ancor.org%2Fsites%2Fdefault%2Ffiles%2Fnews%2Fadapt_-_dol_congress_letter.doc [http://perma.cc/E5CT-B8QY]. Although the DOL spoke with union officials while developing the proposed regulations, people with disabilities were excluded from the discussion. *Id.*

[232] *Real Life Nursing Home Horror Stories*, ADAPT, http://www.adapt.org/cca.rlnhhs [http://perma.cc/3Q9R-4EWL] (last visited Apr. 11, 2016).

be vigilant of *Olmstead* violations and repeatedly remind states of their responsibility to place individuals with disabilities in the least restrictive environment.

Longer-term solutions must also be considered. Congress must develop a comprehensive strategy for the provision of long-term care. Although the Patient Protection and Affordable Care Act is a start, its more inclusive provisions were removed prior to passage.[233] The 2016 election will be a good opportunity for candidates to introduce and discuss their plans for amending the healthcare delivery system, including methods of delivering long-term care. Additionally, emphasis must also be placed on raising Medicare reimbursement rates, which may drive individual states to similarly raise Medicaid reimbursement rates. If advocates had started there, perhaps the home care rule would not be the threat that it is today.

[233] Associated Press, *House Votes to Repeal CLASS Act*, POLITICO (Feb. 1, 2012, 11:46 PM), http://www.politico.com/story/2012/02/house-votes-to-repeal-class-act-072353 [http://perma.cc/XVD5-DCH2]. The Community Living Assistance Services and Supports (CLASS) Act would have permitted individuals, including those with disabilities, to participate in a voluntary long-term care insurance program. In the event that a participant would become disabled and need long-term care, they would receive a daily cash allowance to pay for care. Thus, the individual would be free to make their own care arrangements, free from Medicaid or Medicare restrictions.

IT ISN'T CRAZY: WHY INDIANA SHOULD RE-EVALUATE ITS MENTAL HEALTH RELATED BAR EXAM APPLICATION QUESTIONS

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I. INTRODUCTION

Any aspiring law student that has asked practicing attorneys what he or she could expect from the practice of law has likely been met with many of the same answers: high stress, long hours, demanding work environments, and tedious work projects. However, despite being aware of some of the less than ideal demands of the legal profession, students continue to go to law school. Although law schools have seen a decline in admissions since the recession, as of April 2016, 51,000 students had applied to American law schools for fall 2016 admission.[1]

While the stressful and tedious aspects of the legal profession certainly do not apply to every attorney at every firm or in every organization, these generalizations are widespread enough, and perhaps for good reason. Attorneys "are 3.6 times more likely to suffer from depression than" non-attorneys.[2] However, this problem does not just affect practicing attorneys, nor are the terms "high stress," "demanding," and "tedious" ones that apply solely to the practice of law – they are prevalent in the law school culture as well.

The first year of law school is often a shock to students, because for many it is their first experience with the Socratic method of teaching. Rather than merely attending a lecture, students are expected to be prepared to be called upon to answer any number of questions about an assigned case or a tangential hypothetical.[3] While some professors are much more demanding than others, the adjustment to this method

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[1] Elizabeth Olson, *Minnesota Law School, Facing Waning Interest, Cuts Admissions,* N. Y. TIMES (May 12, 2016), *available at* http://www.nytimes.com/2016/05/13/business/dealbook/minnesota-law-school-facing-waning-interest-cuts-admissions.html [https://perma.cc/6E3R-MA2P].

[2] Rosa Flores & Rose Marie Arce, *Why are Lawyers Killing Themselves?*, CNN U.S. (Jan. 20, 2014, 2:42 PM), http://www.cnn.com/2014/01/19/us/lawyer-suicides/ [https://perma.cc/82F8-ZX4Q].

[3] *See generally* Robert J. Rhee, *The Socratic Method and the Mathematical Heuristic of George Pólya,* 81 ST. JOHN'S L. REV. 881 (2007) (discussing the Socratic method).

of teaching is one that is often met with sweaty palms and a nervous stomach.[4] Further, the realization that each fellow classmate is your competition – thanks to grading on a strict bell curve – can lead to tense academic environments, and in extreme situations, an unwillingness of students to help one another with coursework. Add to this adjustment the pressure of meeting expectations, staying on top of reading assignments, and landing internships that will ideally lead to gainful employment after graduation, it is unsurprising that by the time law students reach the end of their third – which for many is their final – year of law school, 40% of them suffer from signs and symptoms of depression.[5] These rates may be even higher at certain institutions, as a recent study conducted at Yale Law School revealed that 70% of students surveyed reported experiencing mental health challenges during law school.[6]

Unfortunately, students that feel depressed, anxiety ridden, or overly stressed by the pressures of law school may be inclined to think twice before seeking professional treatment for these symptoms.[7] In order to be admitted to the bar in any state, graduated law students must not only

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[4] CHRISTOPHER J. YIANILOS, THE LAW SCHOOL BREAKTHROUGH: GRADUATE IN THE TOP 10% OF YOUR CLASS, EVEN IF YOU'RE NOT A FIRST-RATE STUDENT 38 (Gina M. Cheselka, ed., 2005).

[5] G. Andrew H. Benjamin, *Reclaim Your Practice, Reclaim Your Life,* TRIAL, Dec. 2008, at 30, *available at* http://www.lawyerswithdepression.com/wp-content/uploads/2015/02/Trail.HowStressandAnxietyBeccomeDepression.December.2008-1.pdf [https://perma.cc/M6UP-Z9FZ]; *see also* G. Andrew H. Benjamin et al., *The Role of Legal Education in Producing Psychological Distress Amount Law Students and Lawyers,* 1986 AM. B. FOUND. RES. J. 225; Stephen B. Shanfield & G. Andrew H. Benjamin, *Psychiatric Distress in Law Students,* 35 J. LEGAL EDUC. 65 (1985); Kate Mayer Mangan, *Law School Quadruples the Chances of Depression for Tens of Thousands: Some Changes That Might Help,* HUFFINGTON POST (Aug. 8, 2014) www.huffingtonpost.com/kate-mayer-mangan/law-school-quadruples-dep_b_5713337.html [https://perma.cc/S5WE-4AGA].

[6] YALE LAW SCHOOL MENTAL HEALTH ALLIANCE, FALLING THROUGH THE CRACKS: A REPORT ON MENTAL HEALTH AT YALE LAW SCHOOL 3 (2014), *available at* www.scribd.com/doc/252727812/Falling-Through-the-Cracks#scribd [https://perma.cc/8DHC-6AFK].

[7] Laura Rothstein, *Law Students and Lawyers with Mental Health and Substance Abuse Problems: Protecting the Public and the Individual,* 69 U. PITT L. REV. 531, 533 (2008).

pass the state's bar exam,[8] but in order to sit for the examination, the student must also pass the state's character and fitness application.[9] The National Conference of Bar Examiners ("NCBE") provides a set of model character and fitness questions that many states use on their bar applications verbatim.[10]

Taking into account the heightened rate of attorneys who experience depression and the often high-stress nature of both law school and the practice of law, it is not surprising that a majority of states inquire into bar exam applicants' mental health histories. However, for the applicants that are required to disclose information regarding their mental health histories to the state's board of examiners, the outcomes that those applicants may face range greatly. In some instances, no additional actions are taken.[11] However, there is the possibility that the state bar will request additional information, such as medical records, from the applicant; that it will only allow the applicant to be admitted to the bar on a conditional basis; or the most extreme outcome: a complete denial of admission to the state's bar.[12]

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[8] There is one exception to the requirement that an individual must have successfully passed the bar exam in order to practice law within the state. In Wisconsin, students that graduate from the University of Wisconsin Law School and Marquette University Law School are admitted to the practice of law by having the school certify their legal compliance and having the Board of Examiners certify their character and fitness. Elizabeth Olson, *Bar Exam, the Standard to Become a Lawyer Comes Under Fire,* N. Y. TIMES (Mar. 19, 2015), *available at* http://www.nytimes.com/2015/03/20/business/dealbook/bar-exam-the-standard-to-become-a-lawyer-comes-under-fire.html?_r=0 [https://perma.cc/65KA-S4D9].

[9] Clark v. Va. Bd. of Bar Exam'rs*,* 880 F. Supp. 430, 438 (E.D. Va. 1995).

[10] NAT'L CONF.OF BAR EXAM'RS, REQUEST FOR PREPARATION OF A CHARACTER REPORT 13-14, *available at* www.ncbex.org/dmsdocument/134 [https://perma.cc/4KB3-YEBZ].

[11] Melody Moezzi, *Lawyers of Sound Mind?,* N.Y. TIMES (Aug. 5, 2013), *available at* http://www.nytimes.com/2013/08/06/opinion/lawyers-of-sound-mind.html?_r=0. [https://perma.cc/5LV4-5CME].

[12] *Id.*

A. The Issue

Because of the sensitive nature of questions regarding applicants' mental health histories, the way in which these inquiries take place has been, and continues to be, a subject of great debate. Many bar exam applicants and legal scholars believe that inquiring into bar exam applicants' mental health histories is not only an unnecessary invasion of an applicant's privacy, but also a violation of the Americans with Disabilities Act ("ADA").[13]

In 2011, the Southern District of Indiana found in the case of *ACLU of Indiana v. Individual Members of the Indiana State Board of Law Examiners* that out of the four Indiana bar exam application questions regarding applicants' mental health, only one question – which asked bar applicants to disclose any mental, emotional, or nervous disorders they may have had from age sixteen to present – was a violation of the ADA.[14] However, the three remaining questions, which also took a broad look into applicants' mental health histories, were allowed to stand.[15] While the court took a step in the right direction by eliminating one question that looked too expansively into applicants' mental health histories, it was not a big enough step to ensure Indiana's compliance with Title II of the ADA, and to ensure that such inquiries meet the intended goals.

In 2016, the Indiana Board of Law Examiners asked the following questions of Indiana bar exam applicants:

> 25. Within the past five (5) years have you been *diagnosed with or have you been treated* for bi-

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[13] *See, e.g.,* Marian Alikhan, *The ADA is Narrowing Mental Health Inquiries on Bar Applications: Looking to the Medical Profession to Decide Where to Go From Here*, 14 GEO. J. LEGAL ETHICS 159 (2000); Alex B. Long, *Reasonable Accommodations as Professional Responsibility, Reasonable Accommodation as Professionalism*, 47 U.C. DAVIS L. REV. 1753 (2014); Jon Bauer, *The Character of the Questions and the Fitness of the Process: Mental Health, Bar Admissions, and the Americans With Disabilities Act*, 49 UCLA L. REV. 93 (2001).

[14] ACLU of Ind. v. Individual Members of the Ind. State Bd. Of Law Exam'rs, No. 1:09-CV-824-TWP-MJD, 2011 WL 4387470, at *13 (S.D. Ind. Sept. 20, 2011).

[15] *Id.*

> polar disorder, depression, or other emotional disorder, schizophrenia, paranoia, or any other psychotic disorder?[16]
>
> 26A. Do you have any condition or impairment (including but not limited to, substance abuse, alcohol abuse, or a mental, emotional, or nervous disorder or condition) which in any way currently affects, or if untreated could affect, your ability to practice law in a competent manner?[17]
>
> 26B. Are the limitations or impairments caused by your mental health condition or substance abuse problem reduced or ameliorated because you receive ongoing treatment (with or without medication) or because you participate in a monitoring program?[18]
>
> 27. Have you ever raised the issue of consumption of drugs or alcohol or the issue of a mental, emotional, nervous, or behavioral disorder or condition as a defense, mitigation, or an explanation for your actions in the course of any administrative or judicial proceeding or investigation, any inquiry or other proceeding, or any proposed termination by any educational institution, employer, government agency, professional organization or licensing authority?[19]

As they stand, not all of the Indiana state bar exam application questions pertaining to applicants' mental health focus on the applicants' behavior or conduct that could impact their ability to practice law. Instead, the questions posed to bar exam applicants focus solely on their mental health conditions. The expansive scope of these questions may also

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[16] Ind. Supreme Court Bd. of Law Exam'rs, *Character & Fitness Questionnaire*, APPLICATION INFORMATION (2016), *available at* https://myble.courts.in.gov/browseapplication.action?id=9 (select "Browse Form" beside "Character and Fitness Questionnaire," then click "General Questions" in the dropdown bar) (last visited Apr. 20, 2016).

[17] *Id.*

[18] *Id.* (To see the text of this question, respond "Yes" to question 26A).

[19] *Id.*

serve as a deterrent for individuals with symptoms of mental illness to seek help during their law school years, or as a deterrent for those who have been diagnosed with mental illness from truthfully disclosing information related to their mental health histories. The negative ramifications of not having properly tailored questions regarding applicants' mental health histories not only have the potential to impact the applicants themselves, but also the applicants' coworkers, clients, and the Indiana legal community as a whole.

B. Roadmap

Although the questions posed to Indiana bar exam applicants regarding their mental health histories are far less intrusive than they were prior to the court's holding in *ACLU of Indiana,* as they are currently written, the questions are still too broad and risk infringing upon the privacy afforded to each applicant under Title II of the ADA. This Note will address the importance of the Indiana Board of Law Examiners re-evaluating the way in which Indiana looks into bar exam applicants' mental health histories, and shifting its inquiry to one that is more focused on the conduct of the applicants rather than solely on their conditions.

First, this Note will provide background on the character and fitness requirements that bar exam applicants must meet, Title II of the ADA, and why many character and fitness questions related to mental health are challenged as a violation of Title II of the ADA. The evolution of Indiana's character and fitness questions related to mental health will be reviewed, and a February 5, 2014 letter from the United States Department of Justice ("DOJ") in regard to its stance on states' inquiries into applicants' mental health histories will be discussed. Next, current questions that the Indiana Board of Law Examiners is posing to its applicants will be analyzed to determine how well applicants are being protected under the rights afforded to them by Title II of the ADA. Finally, this Note will focus on the ways in which the Indiana Bar and its applicants may benefit from a re-evaluation of the current character and fitness questions related to mental health.

II. BACKGROUND

A. Bar Exam Applications: Character and Fitness Requirement

While the academic requirements a bar exam applicant must meet to become licensed in any given state in America have evolved over the years, the prerequisite that an applicant be one of virtue has been a constant.[20] However in today's society, boards of law examiners are looking for far more than virtue alone in the applicants hoping to become licensed attorneys. Rather, these licensing boards are looking for a thorough assessment of an individual's character and fitness.[21]

The importance in ensuring that an attorney meets requisite character and fitness standards lies in both "protecting the public" and in "preserving professionalism."[22] If an attorney is affected by an untreated mental or emotional illness, he or she may pose a possible risk to clients, colleagues, and the public, because some mental illnesses, if not properly treated, can negatively impact an individual's ability to competently and skillfully practice law.[23] State bar authorities require applicants to meet certain character and fitness criteria in order to sit for the state's bar examination.[24] However, states' definitions of "fitness" are not unanimous, and the criteria upon which they use to

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[20] Deborah L. Rhode, *Moral Character as a Professional Credential*, 94 YALE L.J. 491, 496 (1985).

[21] Aaron M. Clemens, *Facing the Klieg Lights: Understanding the "Good Moral Character" Examination for Bar Applicants,* 40 AKRON L. REV. 255, 257 (2007) (discussing that state bar examiners often look into several aspects of an applicant's past to determine whether the applicant has good moral character, such as his or her "financial [responsibility], past criminal history, mental illness and treatment, substance abuse, lack of academic integrity, and failure to cooperate with bar examiners. . . .").

[22] Rhode, *supra* note 20, at 507-512.

[23] Jennifer McPherson Hughes, *Suffering in Silence: Questions Regarding an Applicant's Mental Health on Bar Applications and Their Effect on Law Students Needing Treatment*, 28 J. LEGAL PROF. 187, 188 (2004).

[24] Marcus Ratcliff, *The Good Character Requirement: A Proposal for a Uniform National Standard*, 36 TULSA L.J. 487, 492 (2000).

evaluate applicants to determine whether they meet the established definition vary widely on a state-by-state basis.[25] Although the criteria and questions posed to applicants may vary, the methods in which these questions are posed are relatively similar. In most states, the character investigation takes place through a questionnaire completed by each applicant; however, some states have an added step requiring each candidate to undergo an in-person interview.[26]

For an individual to be admitted to practice law in Indiana, the applicant has the "burden of proving that he or she possesses the requisite good moral character and fitness to practice law."[27] In Indiana, "[t]he term 'good moral character' includes, but is not limited to, the qualities of honesty, fairness, candor, trustworthiness, observance of fiduciary responsibility, and of the laws of this State and of the United States, and a respect for the rights of other persons and things, and the judicial process."[28] The term "fitness" relates to the "physical and mental suitability of the applicant to practice law. . . ."[29] In addition to completing the Character and Fitness Questionnaire, every Indiana bar exam applicant must undergo an in-person character interview by a member of the committee or a member designated by the Board of Law Examiners.[30]

In *Clark v. Virginia Board of Bar Examiners,* an action brought by a 1993 graduate of George Mason University Law School against the Virginia Board of Bar Examiners, the United States District Court in the Eastern District of Virginia examined how states asked bar exam applicants about their mental health histories.[31] The court explained that states handled mental health inquiries in the following ways: (1) not looking into applicants' mental health histories, (2) asking only about hospitalization or institutionalization

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[25] *Id.*

[26] *Id.*

[27] IN. ST. ADMIS. AND DISC. R. 12 § 2 (2014).

[28] *Id.*

[29] *Id.*

[30] *Id.* § 4.

[31] *Clark v. Va Bd. of Bar Exam'rs,* 880 F.Supp. 430, 438-440 (E.D. Va. 1995).

for mental illness, and (3) inquiring broadly into applicants' treatment and/or counseling for mental and emotional disorders or illnesses.[32]

Due to the vast differences in how states question applicants about their mental health histories, passing muster for one state's character and fitness examination does not mean that an applicant will subsequently be able to meet the standards of another state, even if he or she has been proven competent to practice. In one instance, a Harvard Law School graduate, who had been diagnosed with bipolar disorder as a law student, was admitted to practice in both New York and Massachusetts.[33] However, when she applied to the Connecticut bar in the mid-1990s, she disclosed her mental illness and was not recommended for admission.[34] It took a lengthy judicial process for her to gain conditional admission to the Connecticut bar.[35] In order to maintain her conditional admission status, she was required to provide the Connecticut Bar Examining Committee with a "doctor's report and affidavit" twice a year to affirm that she was fit for the practice of law in Connecticut.[36] The conditional admission status placed on this applicant, who had been previously admitted to bars in two different states, lasted for nine years.[37]

The individual that endured nine years of being only conditionally admitted to practice in the state of Connecticut is Kathleen Flaherty.[38] After the tragic shooting that took place at Sandy Hook Elementary School in Newton, Connecticut in 2013,[39] Ms. Flaherty was appointed to the

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[32] *Id.*

[33] Moezzi, *supra* note 11; Debra Cassens Weiss, *Lawyer Says Her Experience With Bipolar Disorder is Reason for Appointment to Sandy Hook Commission,* ABA J. (Jan. 15, 2013, 6:11 PM), http://www.abajournal.com/news/article/lawyer_says_her_experience_with_bipolar_disorder_is_reason_for_appointment_/ [http://perma.cc/SBL9-UR85].

[34] Moezzi, *supra* note 11.

[35] *Id.*

[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] On December 14, 2012, 20-year old Adam Lanza entered Sandy Hook Elementary School and killed 20 children and six adult school

Sandy Hook Advisory Commission by Connecticut's Governor, Dannel P. Malloy.[40] Ms. Flaherty credits her personal experience with bipolar disorder as to why she was personally asked to serve on the commission.[41]

Instances such as these raise the question as to whether there is a correct way to ask applicants about their mental health histories, or if they should be inquired into at all. Had Ms. Flaherty been deterred from seeking admission to Connecticut's bar based upon her history of mental health related issues, or had she been unwilling to meet the extra requirements placed upon her to maintain her conditional admittance status that lasted for almost a decade, the state of Connecticut likely would not have benefitted from her knowledge, experience, and expertise in the wake of an unspeakable tragedy that stemmed from one individual's struggle with mental illness.[42] The line between adequately screening for individuals that may be a harm to themselves or to others based upon their mental health histories and violating the rights afforded to applicants under Title II of the ADA is a fine one. Thus, it is of the utmost importance for Indiana to take an objective look at the impact that the mental health inquiries on the character and fitness portion of its application are having on the individuals seeking admittance to the Indiana bar.

B. The Americans with Disabilities Act

The ADA, enacted in 1990, was created "to provide a clear and comprehensive national mandate for the elimination of

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employees. *See* James Barron, *Nation Reels After Gunman Massacres 20 Children at School in Connecticut,* N.Y. TIMES (Dec. 14, 2012) http://www.nytimes.com/2012/12/15/nyregion/shooting-reported-at-connecticut-elementary-school.html [perma.cc/E5R4-H288].

[40] *Id.*

[41] Weiss, *supra* note 33.

[42] Alison Leigh Cowan, *Adam Lanza's Mental Problems 'Completely Untreated' Before Newton Shootings, Report Says,* N.Y. TIMES (Nov. 21, 2014), http://www.nytimes.com/2014/11/22/nyregion/before-newtown-shootings-adam-lanzas-mental-problems-completely-untreated-report-says.html [perma.cc/3M7V-Y6HU] (discussing that Adam Lanza went untreated for "psychiatric and physical ailments like anxiety and obsessive-compulsive disorder").

discrimination against individuals with disabilities."[43] Prior to its enactment, individuals that were discriminated against based upon their disabilities were not afforded the same federal protection against discrimination that individuals who experienced discrimination based upon their "race, sex, religion, national origin, and age had."[44] Since the ADA went into effect over twenty-five years ago, numerous federal and state court decisions have discussed the interplay between the ADA and state bar examiners' inquiries into applicants' mental health histories.[45]

The ADA serves to protect individuals with disabilities. The Act defines "disability," with respect to an individual, as (1) "a physical or mental impairment that substantially limits one or more major life activities of such individual;" (2) "a record of such an impairment;" or (3) "being regarded as having such an impairment."[46] Title II of the ADA was enacted to prohibit discrimination against individuals by public entities, as it states that "no qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected to discrimination by any such entity."[47] "Public entity" is defined as "any State or local government" or "any department, agency, special purpose district, or other instrumentality of a State or States or local government. . . ."[48]

Regulations, such as those discussed below, were put into place to "indicate that coverage extends to the activities of the state judicial branch and to state licensing programs."[49] State bar examiners are widely considered to act as an arm of the state judiciary, and thus are covered by the

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[43] 42 U.S.C. § 12101(b)(1) (2016).

[44] Cary LaCheen, *Using Title II of the Americans With Disabilities Act On Behalf of Clients in TANF Programs*, 8 GEO. J. ON POVERTY L. & POL'Y 1, 37 (2001).

[45] Bauer, *supra* note 13, at 125-126.

[46] 42 U.S.C. § 12102(1) (2016).

[47] *Id.* § 12132.

[48] *Id.* § 12131(1).

[49] Bauer, *supra* note 13, at 128.

requirements in Title II.[50] More specifically, the ADA has been held to apply to questions asked to applicants by legal licensing boards.[51]

The ADA clearly states that a public entity may not "directly or through contractual or other arrangements, utilize criteria or methods of administration . . . [t]hat have the effect of subjecting qualified individuals with disabilities to discrimination on the basis of disability."[52] In specific reference to licensing, "[a] public entity may not administer a licensing or certification program in a manner that subjects qualified individuals with disabilities to discrimination on the basis of a disability."[53]

Further, in the course of administering such licensing or certification programs, "a public entity shall not impose or apply eligibility criteria that screen out or tend to screen out an individual with a disability or any class of individuals with disabilities from fully and equally enjoying any service, program, or activity, unless such criteria can be shown to be necessary."[54]

Although a public entity is allowed to put in place certain safety requirements to ensure "safe operation of its services, programs, or activities," such requirements must be "based

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[50] *Id.; See also* ACLU of Ind. v. Individual Members of the Ind. State Bd. Of Law Exam'rs, No. 1:09-CV-824-TWP-MJD, 2011 WL 4387470, at *5 (S.D. Ind. Sept. 20, 2011); Ware v. Wyo. Bd. of Law Exam'rs, 973 F.Supp 1339, 1352 (D. Wyo. 1997); Ellen S. v. Fla. Bd. of Bar Exam'rs, 859 F. Supp. 1489, 1493 n. 4 (S.D. Fla. 1994).

[51] *See, e.g.*, Clark v. Va. Bd. of Law Exam'rs, 880 F. Supp. 430, 446 (E.D. Va. 1995) (holding that a question inquiring into applicants' mental health was too broadly worded and discriminated against disabled applicants); *Ellen S.,* 859 F. Supp. at 1493-94 (holding that Florida's bar exam application questions pertaining to mental health discriminate against Plaintiffs by placing additional burdens on them because of their disability); Application of Underwood, No. BAR-93-21, 1993 WL 649283, at *112 (Me. Dec. 7, 1993) (holding that requirement that Maine bar applicants answer mental health questions "discriminates on the basis of disability and imposes eligibility criteria that unnecessarily screen out individuals with disabilities.").

[52] 28 C.F.R. § 35.130(b)(3)–(b)(3)(i) (2016).

[53] *Id.* § 35.130(b)(6).

[54] *Id.* § 35.130(b)(8).

on actual risks, not on mere speculation, stereotypes, or generalizations about individuals with disabilities."[55]

If bar exam applicants feel that they have been discriminated against in violation of the ADA, there are several remedies available to them. First, the applicant may file an administrative complaint within 180 days of the discrimination occurring.[56] Such complaint may be filed with an agency enumerated within the Title II regulations or with the Department of Justice.[57] Alternatively, an applicant may file a lawsuit.[58] Thus, if states' board of law examiners do not take it upon themselves to ensure that the methods being used to inquire into applicants' mental health histories are compliant with Title II of the ADA, it will be left for a court of law to determine, such as it was in *ACLU of Indiana*, and in several other jurisdictions throughout the country.[59]

C. Public Policy

Because of the number of law students and attorneys that experience depressive symptoms and mental health related issues, the public policy reasons behind many states inquiring into applicants' mental health histories are well taken. Safeguards need to be put in place that will ensure Indiana bar applicants are mentally fit to practice law, both for their own safety and wellbeing, and for the protection of those that they represent and interact with in a professional capacity.

However, the way in which the Indiana Board of Law Examiners chooses to screen applicants is crucial, both to reduce the number of false positives – applicants that are incorrectly flagged as being potentially unfit to practice law – during an application cycle and to protect the rights afforded to each applicant through Title II of the ADA. This

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[55] *Id.* § 35.130(h).

[56] *Id.* § 35.170(b).

[57] *Id.* § 35.170(c).

[58] *Id.* § 35.172(d).

[59] *See, e.g.,* Clark v. Va. Bd. of Law Exam'rs, 880 F. Supp. 430, 446 (E.D. Va. 1995); Ellen S. v. Fla. Bd. of Bar Exam'rs, 859 F. Supp. 1489, 1493 n. 4 (S.D. Fla. 1994); Application of Underwood, No. BAR-93-21, 1993 WL 649283, at *1 (Me. Dec. 7, 1993).

will not only be beneficial for the applicants, but will also preserve the Board of Law Examiners' time and resources during the application cycle. If there is a more effective set of questions in place, the time and resources spent evaluating applicants that have been falsely identified as being unfit for the practice of law will be greatly reduced.

Additionally, apart from the benefits that the Indiana Board of Law Examiners will experience from Indiana revisiting its mental health related inquiries, there are also benefits for the applicants themselves. The broad nature of Indiana's current questions may deter individuals from attending law school out of fear of having to disclose their mental health status. It may deter law students who are experiencing mental health related symptoms from seeking treatment. Moreover, Indiana's current questions may cause students who have been diagnosed with or are being treated for mental illness from being truthful in their disclosures on the bar exam application.

D. Indiana: Then

In 2009, plaintiffs – students at what is now Robert H. McKinney School of Law in Indianapolis Indiana, and a 2007 Valparaiso University School of Law graduate – filed a complaint against the Indiana Board of Law Examiners over four bar exam questions that they believed were too broad.[60]

Amanda Perdue, the original sole Plaintiff to this case, was an Illinois attorney who hoped to sit for the bar exam in Indiana.[61] Perdue had been diagnosed with anxiety disorder and posttraumatic stress disorder and she had undergone professional treatment for these conditions.[62] Upon applying to sit for the Indiana bar exam in 2008, Perdue, like all applicants, completed the character and fitness portion of the application.[63] Because of her mental health history, Perdue

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[60] ACLU of Ind. v. Individual Members of the Ind. State Bd. Of Law Exam'rs, No. 1:09-CV-824-TWP-MJD, 2011 WL 4387470 (S.D. Ind. Sept. 20, 2011).

[61] Perdue v. Individual Members of Ind. State Bd. of Law Exam'rs, 266 F.R.D. 215, 217 (S.D. Ind. 2010).

[62] *Id.*

[63] *Id.*

responded "yes" to question 23, which inquired into whether she had been diagnosed or treated for any type of emotional, mental, or nervous disorder from the age of 16 to present.[64]

Perdue's affirmative response triggered the Indiana Board of Law Examiners to request additional information regarding her mental health conditions and to refer Perdue to the Judges and Lawyers Assistance Program ("JLAP").[65] JLAP is a program that was created in 1997 to provide help to judges, attorneys, and law students who experience physical or mental disabilities that result from disease, chemical dependency, mental health problems, or age, which may impair these individuals' ability to practice in a competent and professional manner.[66]

JLAP provides assistance to Indiana attorneys and law students in several ways, including providing them with information and connecting them to resources that can help organize an intervention.[67]

The Indiana Board of Law Examiners has the ability to refer any applicant to JLAP if it is concerned about the applicant's mental fitness.[68] In determining whether it will refer an applicant to the program, many factors are taken into consideration, including: "how recent the mental health issue was; whether it's episodic; whether it required continuing treatment; whether it resulted in hospitalization or arrest; and whether it resulted in loss of employment or licensing."[69]

However, while the Indiana Board of Law Examiners has the ability to refer any individual to JLAP that it deems in need of JLAP's services, the individuals are not required to oblige. Perdue declined to consent to the requests and referral to JLAP.[70] Instead, she subsequently withdrew her application and filed suit against the Indiana Board of Law

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[64] *ACLU of Ind.,* 2011 WL 4387470 at *4.

[65] *Perdue,* 266 F.R.D. at 217.

[66] *About JLAP,* COURTS.IN.GOV, https://secure.in.gov/judiciary/ijlap/2361.htm [perma.cc/UD77-JTKB] (last visited Apr. 20, 2016).

[67] *Id.*

[68] *ACLU of Ind.,* 2011 WL 4387470, at *3.

[69] *Id.*

[70] *Perdue*, 266 F.R.D. at 217.

Examiners.[71] The lawsuit, which was initially brought by Perdue, eventually became a class action with the American Civil Liberties Union ("ACLU") being appointed as the class representative.[72]

At the time Perdue filed her original complaint against the Indiana Board of Law Examiners, applicants applying for admission to the Indiana bar were asked the following four questions regarding their mental health histories:

> 22. Have you been diagnosed with or have you ever been treated for bi-polar disorder, schizophrenia, paranoia or any other psychotic disorder?
> 23. From the age of 16 years to the present, have you been diagnosed or treated for any mental, emotional, or nervous disorders?
> 24. Do you have any condition or impairment (including, but not limited to, substance abuse, alcohol abuse, or a mental, emotional, or nervous disorder or condition) which in any way currently affects, or if left untreated could affect, your ability to practice law in a competent and professional manner?
> 25. IF YOUR ANSWER TO QUESTION 24 IS AFFIRMATIVE, are the limitations or impairments caused by your mental health condition or substance abuse problem reduced or ameliorated because you receive ongoing treatment (with or without medication) or because you participate in a monitoring program?[73]

If an applicant answered affirmatively to questions 22-25, he or she was required to complete a B-1 form, which sought more information about the applicant's condition, diagnosis,

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[71] *Id.*
[72] *Id.*
[73] *ACLU of Ind.*, 2011 WL 4387470, at *2.

treatment, and providers.[74] These applicants were also required to sign a general release of information.[75]

The court summarized its duty in this case as "[resolving] whether the challenged questions are '*necessary*' to determine whether the bar applicant poses a '*direct threat*'" to the health and safety of themselves and of others.[76] Ultimately, the court held that only one of these questions was in violation of the ADA – question 23 – which the court called "possibly the most expansive bar application question in the country."[77] It was reasoned to be too broad, to lead to too many false positives, and to have chosen an arbitrary time frame that was not a good indicator of an individual's current mental fitness to practice law.[78]

The other three questions – question 22, which asked about applicants' histories of bi-polar disorder, schizophrenia, paranoia, or other psychotic disorders, and questions 24 and 25, which asked applicants about any condition or impairment that "currently affects," or if "left untreated could affect," his or her ability to practice law competently and professionally – however, were allowed to stand.[79] Question 22, although it had no temporal limitation, was reasoned to involve "serious" mental illnesses that could be recurring in nature.[80] Because of the likelihood that these enumerated conditions could reappear during an applicant's lifetime, its broad nature was not found to violate the ADA.[81] Questions 24 and 25 were not considered to violate the ADA because the court considered them "narrowly focused on the *current* time period" and focused on "the applicant's *current* ability to practice law."[82]

However, in its opinion, the court looked at each question and considered its compliance with the ADA in depth. Ultimately, although it only struck down one question as

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[74] *Id.* at *3.
[75] *Id.*
[76] *Id.*at *8.
[77] *Id.* at *9.
[78] *Id.* at *9.
[79] *Id.* at *8-13.
[80] *Id.* at *7.
[81] *Id.* at *9.
[82] *Id.* at *10.

being too broad to comply with the ADA and allowed the remaining three questions to stand, the court did note that possibly no set of bar exam questions could perfectly meet both the need to screen problematic bar applicants and to "[respect] applicants' privacy."[83] The court is likely correct in its stance that there may never be a perfectly tailored set of questions that precisely meets each need that the character and fitness portion of states' bar exam applications are intended to serve. Even the most compliant set of questions will not perfectly screen all applicants, nor will all applicants necessarily respond truthfully to each question. Even so, this should not serve as a rationale for states to rest on their laurels and not re-evaluate the mental health related questions posed to bar exam applicants on a consistent basis. Thus, although the court struck one extremely broad question, Indiana should continually evaluate the questions it asks its bar exam applicants, as such re-evaluation is beneficial for the state, applicants themselves, and the clients and colleagues the applicants will work with.

E. Indiana: Now

As discussed *supra*, the Indiana Board of Law Examiners currently asks Indiana bar exam applicants the following questions, which have slightly changed since the court's decision in *ACLU of Indiana*:

> 25. Within the past five (5) years have you been *diagnosed with or have you been treated* for bi-polar disorder, depression, or other emotional disorder, schizophrenia, paranoia, or any other psychotic disorder?[84]
> 26A. Do you have any condition or impairment (including but not limited to, substance abuse, alcohol abuse, or a mental, emotional, or nervous disorder or condition) which in any way currently affects, or if untreated could affect,

[83] *Id.* at *13.
[84] Ind. Supreme Court Bd. of Law Exam'rs, *supra* note 16.

> your ability to practice law in a competent and professional manner?[85]
>
> 26B. Are the limitations or impairments caused by your mental health condition or substance abuse problem reduced or ameliorated because you receive ongoing treatment (with or without medication) or because you participate in a monitoring program?[86]
>
> 27. Have you ever raised the issue of consumption of drugs or alcohol or the issue of a mental, emotional, nervous, or behavioral disorder or condition as a defense, mitigation, or an explanation for your actions in the course of any administrative or judicial proceeding or investigation, any inquiry or other proceeding, or any proposed termination by an educational institution, employer, government agency, professional organization or licensing authority?[87]

Comparing these questions to those that were challenged in *ACLU of Indiana,* it is clear that some adjustments have been made. Of course, former question 23, which asked whether an applicant had been diagnosed with or treated for any mental, emotional, or nervous disorders – which was ultimately struck down in *ACLU of Indiana* – is no longer posed to applicants.[88] Additionally, current question 25 places temporal limitations on former question 22 by only requiring applicants to disclose whether they have been diagnosed with or treated for the enumerated disorders within the past five years.[89] Question 26A remains substantively identical to former question 24. Further, Indiana has added question 27, which asks whether

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[85] *Id.*

[86] *Id.*

[87] *Id.*

[88] ACLU of Ind. v. Individual Members of the Ind. State Bd. Of Law Exam'rs, No. 1:09-CV-824-TWP-MJD, 2011 WL 4387470, at *13 (S.D. Ind. Sept. 20, 2011).

[89] Ind. Supreme Court Bd. of Law Exam'rs, *supra* note 16.

applicants have ever, among other things, used their mental, emotional, nervous, or behavioral disorders as an explanation or defense in one or more of several settings, such as judicial proceedings or investigations.[90]

As seen above, the Indiana Board of Law Examiners has amended its questions over and above the standard the court in *ACLU of Indiana* determined would bring the questions into compliance with the ADA. However, as they stand, Indiana's questions still place additional criteria upon applicants based on their mental health histories. While placing additional criteria upon applicants alone is not a violation of the ADA, it must be shown that such criteria are *necessary* to the Board of Law Examiners' licensing function and are not merely additional criteria placed on individuals based on "mere speculation, stereotypes, or generalizations."[91]

F. Department of Justice's Stance on Mental Health Inquiries

In 2011, the Bazelon Center for Mental Health Law[92] filed complaints against the Louisiana Bar Examiners.[93] These complaints were made on behalf of two Louisiana attorneys who applied for admission to the Louisiana bar; however, because of their mental health histories, diagnoses, and treatments, these individuals were not granted full access to the Louisiana Bar but instead were admitted only on a

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[90] *Id.*

[91] 28 C.F.R. § 35.130 (h) (2016).

[92] The Judge David L. Bazelon Center for Mental Health Law is a national legal-advocacy organization representing people with mental disabilities. *Who We Are,* JUDGE DAVID L. BAZELON CENTER FOR MENTAL HEALTH, http://www.bazelon.org/Who-We-Are.aspx [https://perma.cc/P5F2-WRTA] (last visited Apr. 20, 2016).

[93] Letter from Jocelyn Samuels, Acting Assistant Attorney General, to Bernette J. Johnson, Louisiana Supreme Court Chief Justice, Elizabeth S. Schell, Executive Director of Louisiana Supreme Court Committee on Bar Admissions, and Charles B. Plattsmier, Chief Disciplinary Counsel of the Louisiana Attorney Disciplinary Board (Feb. 5, 2014) [hereinafter Letter from Jocelyn Samuels], *available at* http://www.bazelon.org/LinkClick.aspx?fileticket=7fvtHYXZawM%3d&tabid=698 [https:// perma.cc/DW6Z-YUYN].

"conditional" basis.[94] In response to the complaints filed on behalf of these individuals, the DOJ launched an investigation of Louisiana's attorney licensure system to determine whether it was compliant with Title II of the ADA.[95]

At the time of this investigation, the Louisiana Bar Examiners required each prospective applicant to request that the NCBE prepare a character report.[96] To obtain an NCBE character report, a prospective applicant must, among other things, answer twenty-eight questions – four of which deal with an applicant's mental health.[97] At the time, the NCBE posed the following questions to each applicant regarding his or her mental health histories:

> 25. Within the past five years, have you been diagnosed with or have you been treated for bipolar disorder, schizophrenia, paranoia, or any other psychotic disorder?
> 26A. Do you currently have any condition or impairment (including, but not limited to, substance abuse, alcohol abuse, or a mental, emotional, or nervous disorder or condition) which in any way currently affects, or if untreated could affect, your ability to practice law in a competent and professional manner?
> 26B. If your answer to Question 26(A) is yes, are the limitations caused by your mental health condition. . . reduced or ameliorated because you receive ongoing treatment (with or without medication) or because you participate in a monitoring program?
> 27. Within the past five years, have you ever raised the issue of consumption of drugs or alcohol or the issue of a mental, emotional, nervous, or behavioral disorder or condition as a defense, mitigation, or explanation for your actions in the course of any administrative or

[94] *Id.* at 3.
[95] *Id.*
[96] *Id.*
[97] *Id.* at 4-5.

> judicial proceeding or investigation; any inquiry or other proceeding; or any proposed termination by an educational institution, employer, government agency, professional organization, or licensing authority?[98]

When applicants responded affirmatively to questions 25 or 26 of the NCBE character report, they were required to complete a form authorizing each of their treatment providers to release information relating to their mental illness, including copies of medical records.[99] Additionally, the applicants that responded affirmatively to these questions were required to provide detailed information about the condition and any treatment they had received for it.[100] Applicants that responded affirmatively to question 27 were required to thoroughly explain the situation through a supplement to the application; however, an affirmative response to question 27 did not result in additional forms requiring treating professionals' authorizations or a description of the condition.[101]

At the conclusion of its investigation into the Louisiana Bar Examiners' methods for inquiring into applicants' mental health histories, the DOJ concluded that the four questions asked by the Louisiana Bar Examiners via the NCBE questions were in violation of Title II of the ADA.[102] The DOJ deemed questions 25, 26A, 26B and 27 of the NCBE Request for Preparation of a Character Report to be a violation of the ADA because they did not serve the purported goal of screening out applicants that may not be mentally fit for the practice of law.[103] Instead, the DOJ stated that these questions served as "eligibility criteria that screen out or tend to screen out individuals with disabilities based on stereotypes and assumptions about their disabilities and are not necessary to assess the applicants' fitness to practice

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[98] *Id.* at 5.
[99] *Id.* at 6.
[100] *Id.*
[101] *Id.*
[102] *Id.* at 18.
[103] *Id.*

law."[104] It also found that the following additional "forms of discrimination flow from the use of [these questions]":

> 1) imposing additional burdens on applicants with disabilities who were required to provide additional reports and/or medical records; 2) making admissions recommendations on the existence of a mental health disability as opposed to conduct; 3) placing burdensome condition upon an applicants' legal licenses because of a mental health diagnosis and/or treatment; 4) imposing additional financial burdens on applicants and attorneys with disabilities, and 5) failing to protect the conditional medical information of applicants with disabilities.[105]

In recommending ways to move forward and bring its questions regarding applicants' mental health histories into compliance with Title II of the ADA, the DOJ, among other things, urged Louisiana to discontinue its use of "[q]uestions 25 – 27 of the NCBE Request for Preparation of a Character Report as the questions were currently written."[106] The DOJ also called for a modification of the Louisiana Supreme Court Rules to allow for the Louisiana Bar Examiners to screen applicants using conduct-based methods.[107] The DOJ reasoned that a conduct-based method of inquiry, which would focus on specific behaviors that applicants had exhibited, would more successfully ensure that an individual's mental health diagnosis or treatment was not the basis for being referred for an additional evaluation during the application process.[108]

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[104] *Id.*
[105] *Id.*
[106] *Id.* at 31.
[107] *Id.* at 22.
[108] *Id.*

The Louisiana Supreme Court and the DOJ entered into a settlement agreement in August 2014.[109] The settlement agreement clearly stated that the Louisiana Supreme Court disagreed with the conclusions reached by the DOJ in its letter.[110] The Louisiana Supreme Court also denied that any applicants for licensure or conditionally admitted attorneys were discriminated against.[111] However, the statement affirmed that the Louisiana Supreme Court was willing to work with the DOJ to ensure that its questions were in complete compliance and to ensure a fair application process for applicants.[112] Despite its explicit disagreement with the DOJ's stance on its questions, Louisiana agreed to cease using the standard NCBE questions 25 – 27 as they were written at the time that the questions were challenged.[113] Additionally, it was agreed that individuals involved in admissions to the Louisiana Bar will "[n]ot recommend or impose conditional admission solely on the basis of mental health diagnosis or treatment."[114]

However, it is important to note that the DOJ is an executive department of the United States Government.[115] While it has power over all criminal prosecutions and civil suits in which the United States has an interest,[116] its opinion on Louisiana's bar exam questions does not bind state supreme courts or state agencies that choose character and fitness questions. Although the DOJ deemed the NCBE questions, as they were written at the time, a violation of Title II of the ADA, and an agreement was entered to cease use of those questions, states that continue to use them are not in violation of the law. For the questions to be deemed a violation of the ADA in a particular state, it will take an

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[109] Press Release, Settlement Agreement between the United States of America and the Louisiana Supreme Court Under the Americans With Disabilities Act (Aug. 15, 2014), *available at* http:// www.ada.gov/louisiana-supreme-court_sa.htm [perma.cc/UN6N-P4TB].

[110] *Id.*

[111] *Id.*

[112] *Id.*

[113] *Id.*

[114] *Id.*

[115] *About DOJ,* U. S. DEP'T. OF JUST.; *available at* https:// www.justice.gov/about [https://perma.cc/5LZK-YD8T] (last visited Apr. 20, 2016).

[116] *Id.*

applicant to that state's bar who feels he or she has been discriminated against to bring action in court, and for the court to hold that the questions run afoul of the law.

Therefore, because states vary greatly in how they inquire into applicants' mental health histories, even if an applicant challenges a state's questions in a court of law, the decisions rendered by that jurisdiction regarding whether the questions are compliant with Title II of the ADA may differ between jurisdictions, even if the two states use essentially the same questions. Because of this, it is unlikely that there will be a uniform standard of questions on a state-by-state basis related to applicants' mental health histories until such case reaches the U.S. Supreme Court.

G. The National Conference of Bar Examiners' Response

The NCBE amended questions 25 – 27 to the following:

> 25. Within the past five years, have you exhibited any conduct or behavior that could call into question your ability to practice law in a competent, ethical, and professional manner?
> 26A. Do you currently have any condition or impairment (including, but not limited to, substance abuse, alcohol abuse, or a mental, emotional, or nervous disorder or condition) that in any way affects your ability to practice law in a competent, ethical, and professional manner?
> 26B. If your answer to 26(A) is yes, are the limitations caused by your condition or impairment reduced or ameliorated because you receive ongoing treatment or because you participate in a monitoring or support program?
> 27. Within the past five years, have you asserted any condition or impairment as a defense, in mitigation, or as an explanation for your conduct in the course of any inquiry, any investigation, or any administrative or judicial proceeding by an educational institution, government agency, professional organization, or licensing authority, or in connection with an

> employment disciplinary or termination procedure?[117]

If an applicant answers "yes" to either questions 26(A) or (B), the applicant must also complete a separate Form 7 and 8 for each service provider who has treated the applicant.[118] Form 7 is an authorization to release medical information – without limitation – in relation to mental illness and the use of drugs and alcohol to the NCBE.[119] Form 8 requires a description of the condition or impairment, any treatment "program that includes monitoring or support," and contact information for attending physicians, counselors, and hospitals or institutions.[120]

The NCBE altered questions 25 and 26 to a conduct-based inquiry. Instead of asking whether the applicant has been diagnosed with or treated for bipolar disorder, schizophrenia, paranoia, or another psychotic disorder within the past five years,[121] question 25 now asks whether any such diagnosis affects the applicant's ability to competently, ethically, and responsibly practice law.[122] Additionally, the NCBE removed the "or if left untreated" language from question 26, which allows the question to now focus solely on the current impact that an applicant's mental, emotional, or nervous disorder or condition is having on his or her ability to practice law competently and professionally.[123]

It is clear, as question 27 remains unchanged, that the NCBE did not fully amend its questions to follow the DOJ's opinions. The DOJ considers question 27 to be unnecessary and in violation of the ADA. However, because the DOJ's opinions in the Louisiana matter are not binding authority, there was no duty for the NCBE to do so.

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[117] NAT'L CONF. OF BAR EXAM'RS, *supra* note 10.
[118] *Id.* at 14.
[119] *Id.* at 28.
[120] *Id.* at 29.
[121] Letter from Jocelyn Samuels, *supra* note 93.
[122] NAT'L CONF. OF BAR EXAM'RS, *supra* note 10.
[123] *Id.*

III. ANALYSIS

Although as a whole Indiana's bar exam application questions related to applicants' mental health histories are not as broad as they were prior to the *ACLU of Indiana* decision, they are still too broad to afford applicants the protections they are provided under Title II of the ADA. While the DOJ has made its stance clear and the NCBE has amended its own questions to be more conduct-focused, it is up to each state to decide whether or not to adopt these questions and how to interpret them.

Ultimately, it is the Indiana Supreme Court that is responsible for ensuring the state's licensing practices do not violate the ADA. However, for a court of law to intervene and scrutinize a state's licensing practices, it first takes an individual with the belief that he or she has suffered discrimination by the state bar examiner on the basis of disability to bring suit. It is likely that this decision is not one that will be made lightly by such applicant, as it takes an extreme determination and in some instances, such as in the case of Kathleen Flaherty, a willingness to allow an in depth look into the applicant's mental health records, to challenge the way in which a state is screening its bar exam applicants.

A prudent state should constantly review its own questions and procedures to determine if it is best meeting its own needs and the needs of applicants rather than waiting for a discriminated individual to bring suit in a court of law. However, unfortunately, it does not seem that this is the approach that Indiana has taken. The NCBE amended its model questions to be more conduct-focused; however, as discussed *supra*, although these questions do not necessarily fully comply with the stance taken by the DOJ, it shows progress. Indiana, however, continues to use the former NCBE model questions – those which the DOJ has opined are a violation of the ADA – to screen its applicants.

A. A Look at Indiana's Current Questions

1. Question 25

Indiana's current question 25 – which is similar in wording to the former question 22 – now requires individuals

who have been diagnosed with or have been treated for what the court in *ACLU of Indiana* deemed a "serious condition" to only disclose that information if such diagnosis or treatment has occurred within the past five years. The court in *ACLU of Indiana* allowed former question 22 to stand as it was written, despite the fact that it had no temporal limit because the types of conditions being asked about were those that were likely to recur throughout an applicant's lifetime.[124] Placing a temporal limit on the question makes it seem that the Indiana Board of Law Examiners has taken it upon itself to further limit its inquiries into applicants' mental health histories; however, this is not necessarily so.

Although there is now a five-year limit within which an applicant must disclose whether he or she has been diagnosed or treated for a "serious condition," current question 25 now includes language requiring an applicant to disclose any "other emotional disorder" or "any other psychotic disorder."[125] No definition is provided for what constitutes an emotional disorder or a psychotic disorder, so these categories have the potential to serve as a catchall, encompassing almost an endless number of conditions that an applicant would be required to disclose on his or her character and fitness application.

The "emotional" or "psychotic" disorder language of question 25 is also similar to the language of a question posed by the Virginia bar that was ultimately held to be a violation of Title II of the ADA.[126] In *Clark v. Virginia Board of Bar Examiners,* an applicant seeking admission to the Virginia bar challenged the application questions asked regarding her mental health as being in violation of the ADA.[127] The applicant, Julie Ann Clark, was a graduate of George Mason University Law School and "suffers from a condition that was previously diagnosed as 'major depression, recurrent.'"[128]

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[124] ACLU of Ind. v. Individual Members of the Ind. State Bd. Of Law Exam'rs, No. 1:09-CV-824-TWP-MJD, 2011 WL 4387470, at *2 (S.D. Ind. Sept. 20, 2011).

[125] Ind. Supreme Court Bd. Of Law Exam'rs, *supra* note 16.

[126] *See* Clark v. Va. Bd. Of Bar Exam'rs, 880 F. Supp 430, 437-438 (E.D. Va. 1995).

[127] *Id.* at 433.

[128] *Id.* at 432.

On her bar application, Ms. Clark was asked to answer a question that stated, "[h]ave you within the past five (5) years, been treated or counseled for a mental, emotional, or nervous disorders?"[129] She declined to answer this question, which if responded to in the affirmative would have required her to provide the "dates of treatment or counseling," contact information for her health care provider, hospital, or institution, and a complete description of the diagnosis and treatment.[130] Although "pursuant to agreement of counsel," the Virginia Board of Bar Examiners allowed Ms. Clark to sit for the Virginia bar exam without answering the question and providing the requisite information, it would not grant her a license until she did so.[131]

Ultimately, the court found that the question subjected applicants to discrimination based on their disability, as additional eligibility criteria was imposed on individuals with disabilities.[132] Thus, in order for the question at issue to comply with Title II of the ADA, it would have to be necessary to the performance of the Virginia Board of Bar Examiners' licensing function. However, the court did not find that the question was necessary.[133] Instead, it found that the question was not a strong indicator of identifying unfit applicants and that it had a strong deterrent effect on applicants.[134]

This same logic and reasoning can be applied to Indiana's question 25. The question places additional eligibility criteria on Indiana bar exam applicants without being necessary to the Indiana Board of Law Examiners' licensing function – the power it has to grant licenses to individuals to practice law within the state. The extremely broad scope of the listed conditions in which an individual is required to disclose a diagnosis or treatment is likely to have a deterrent effect on applicants from either seeking treatment or from being forthcoming on the application, which is completely adverse to the aim that the question is intended to serve.

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[129] *Id.* at 433.
[130] *Id.*
[131] *Id.*
[132] *Id.* at 442.
[133] *Id.* at 446.
[134] *Id.* at 446.

These concerns are of the utmost importance, as "[a]pproximately 1 in 4 people have a mental health problem."[135] However, in the United States and Europe, up to 75% of these people will not receive treatment, in part because of the stigma associated with receiving treatment for mental health related issues, which perpetuates individuals' fear of having to disclose a mental health condition.[136]

Although the scope of Indiana's question 25 is limited to five years, there remains no focus on an applicant's behavior or specific conduct that he or she has exhibited within the past five years. Instead, the question solely focuses on an applicant's diagnosis and/or treatment. This type of inquiry is likely to result in false positives, as "there is simply no empirical evidence that applicants' mental health histories are significantly predictive of future misconduct or malpractice as an attorney."[137]

Apart from question 25 being in violation of Title II of the ADA because of the additional eligibility criteria that it places on applicants that respond affirmatively, and because it is not necessary to the Indiana Board of Law Examiners' licensing function, it also raises valid public policy concerns. One of the main issues surrounding the states' inquiries into applicants' mental health histories is whether or not such inquiries will deter individuals who wish to seek treatment or speak with a counselor because individuals fear receiving a diagnosis they must disclose on the character and fitness application.

Additional concerns arise when applicants decide to get treatment, but are not fully forthcoming about their symptoms with their physicians out of fear that they will be required to disclose any diagnosis they receive.[138] Because

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[135] *Stigma 'Key Deterrent' in Accessing Mental Health Care,* KINGS C. LONDON NEWS (Feb. 26, 2014), http://www.kcl.ac.uk/ioppn/news/records/2014/February/Stigma-key-deterrent-in-accessing-mental-health-care.aspx/[https://perma.cc/2LXK-W8MX].

[136] *Id.*

[137] Bauer, *supra* note 13, at 141.

[138] *See, e.g.,* Clark v. Va. Bd. Of Bar Exam'rs, 880 F. Supp 430, 445-46 (E.D. Va. 1995);
Hughes, *supra* note 23, at 189-190. *See also* Chris Iliades, *Are You Telling Your Doctor the Truth About Your Depression?,* EVERYDAY HEALTH (Jan.

any successful patient-physician relationship rests on full disclosure from the patient, any treating physician with less than complete understanding of a patient's condition will not be able to provide the best care for the patient.[139] Patients' ability to feel comfortable with their physician often is synonymous with them being candid with their treating physicians. This candidness is especially imperative in instances of mental illness. Providing an abridged version of symptoms and feelings may result in a misdiagnosis, which may result in the prescription of medication when medication is not needed, a wrong dosage of a medication, or a prescription for the wrong type of medication. One or a combination of these events could worsen an individual's symptoms or not help at all, which could further inhibit his or her desire to seek help.

2. Question 26

Question 26A, which asks whether an applicant has a condition or impairment that in any way currently affects, or if untreated could affect, his or her ability to practice law is seemingly identical to former question 24, which the court in *ACLU of Indiana* allowed to stand because of its focus on the current time period and of an individual's current ability to practice law.[140] However, it does not appear that the entire question is truly focused on an individual's current ability to practice law and therefore, it may be considered to run afoul of Title II of the ADA.

The first portion of the question is focused on whether an applicant has a condition or impairment that is *currently* affecting him or her in a way that would impede upon the applicant's ability to practice law. Because this focuses on an applicant's current behavior as a result of his or her mental fitness, it is likely suitable under the ADA. By inquiring into the conduct of the applicant, this question is not stereotyping based upon the applicant's disability, which is what Title II

23, 2013), http://www.everydayhealth.com/health-report/ major-depression/telling-psychiatrist-the-truth.aspx [perma.cc/X4DY-8WHK].

[139] *Clark*, 880 F. Supp. at 438-440.

[140] ACLU of Ind. v. Individual Members of the Ind. State Bd. Of Law Exam'rs, No. 1:09-CV-824-TWP-MJD, 2011 WL 4387470, at *13 (S.D. Ind. Sept. 20, 2011).

of the ADA seeks to prohibit. Although – to an extent – question 26A does impose additional eligibility criteria on an applicant based upon his or her disability, for it to be considered a violation of Title II of the ADA, it would have to be shown that the question was unnecessary to the Indiana Board of Law Examiners' licensing function.

This question has a more direct relation to the Board's goals of inquiring into an applicant's mental health history – to screen out applicants that may pose a risk to themselves or others in the course of the practice of law. It requires applicants to disclose a condition only if it is currently affecting them in a way that may conflict with their ability to practice law in a competent manner, not solely because an applicant has been diagnosed with a certain disorder or is receiving treatment for a disorder. Thus, the burden it places on applicants is not an undue burden, but it is rather seeking to inquire into specific conduct and behaviors that may pose an actual risk to the applicant's ability to effectively engage in the practice of law.

Although there are certainly valid arguments as to why the first part of question 26A is necessary to the Indiana Board of Law Examiners' licensing function, the question as a whole is overly broad, which may have negative implications. Because of the question's broad nature, it may deter applicants from applying to the bar, or deter those who do apply from responding truthfully to the question. Additionally, applicants may not consider the type of behavior they are exhibiting to be the type of condition or impairment that needs to be disclosed. In sum, the first portion of question 26A makes a more conduct-focused inquiry, which is the type of question that the DOJ opines is compliant with Title II of the ADA. As such, it is much more suitable to providing applicants' the rights they are afforded under the ADA. However, because of the broad nature of the question, it is possible that this question will not truly assist the Indiana Board of Law Examiners in screening out the applicants that may pose a threat.

Apart from the public policy concerns that the question may deter applicants from applying to the bar, or if they do apply, from providing full disclosure, question 26A seems to be a well-suited question both to protect the rights and privacy of applicants afforded to them under Title II of the

ADA. However, the 'if untreated could affect' language bears no connection to an applicant's current mental fitness. Rather, it is solely hypothetical in nature. By including this portion of the question, far more applicants will be required to respond affirmatively and will be required to complete a Form B-1. Form B-1 requires the applicant to list dates of treatment, the name and contact information of his or her provider(s), and a detailed description of the "type of problem, condition, impairment, diagnosis, treatment, and/or monitoring program."[141]

Additionally, if an applicant responds in the affirmative to question 26A, he or she must answer 26B, which asks whether the limitations or impairments resulting from the applicant's mental health condition are reduced or improved because of treatment. If an applicant is undergoing treatment that improves the condition, and thus answers question 26B affirmatively, the applicant is required to fill out another Form B-1 detailing information about that treatment and the contact information for his or her provider.

Overall, the second prong of question 26A weakens the arguments that asking applicants this question is necessary to the Indiana Board of Law Examiners' licensing function. As a whole, question 26A places additional eligibility criteria upon applicants regarding their mental health status and requires them to opine on the types of behavior that they would exhibit if their conditions were left untreated. This forces applicants who are, and have always been, treated for their condition to determine whether they would behave in a way that was not competent or ethical in the practice of law if they were not being treated.

Further, the "if left untreated" language of question 26A requires a greater number of individuals to respond affirmatively to this question. As it is asked, individuals who have a condition or impairment that is under control and would not affect their ability to practice law in a competent manner would not be required to respond affirmatively.

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[141] Ind. Supreme Court Bd. Of Law Exam'rs, *Character & Fitness Questionnaire Form B-1*, APPLICATION INFORMATION (2016), *available at* https://myble.courts.in.gov/browseapplication.action?id=9 (last visited Apr. 20, 2016) (select "Browse Form" beside "Character and Fitness Questionnaire," click "General Questions" in the dropdown bar, select "yes" under question 26A).

However, the second prong of the question may require such individuals to have to disclose their condition anyway if the untreated condition would affect their behavior. Like the "other emotional" or "psychotic" disorder language in question 25, inquiring into the hypothetical behavior of an applicant is too broad of a reach, and does not effectively protect the rights and privacy of applicants.

3. Question 27

Indiana's question 27, which seeks information regarding whether a mental health condition has been used as a defense, mitigating factor, or explanation for an applicant's actions, once again fails to focus on the current conduct or behavior of an applicant. This question is extremely similar to the NCBE's question 27 both prior to and after the changes it made to questions 25 and 26.

The Indiana bar exam application thoroughly investigates applicants' experiences with civil and criminal litigation, employment history and educational history by asking specific, direct questions. Therefore, there is ample opportunity to question applicants on such events, including any such defenses, which if answered affirmatively, will allow for the applicant to be further questioned or for additional information to be obtained. Thus, it may be argued, as it was by the DOJ, that such question is unnecessary.[142]

Because many of the types of behavior and conduct that this question asks about are thoroughly covered by other sections of the Indiana bar exam, there is a chance that this may be considered placing additional criteria upon applicants based upon their disability. However, if whether a question focuses on an applicants' current conduct and/or behavior is used as the sole yardstick to determine compliance with Title II of the ADA, question 27, to the extent it reveals such current conduct or behavior, may be considered compliant.

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[142] Letter from Jocelyn Samuels, *supra* note 93, at 23.

B. Summary

The similarities between Indiana's current questions relating to mental health and the former NCBE questions, which the DOJ opined are in violation of Title II of the ADA, should not be ignored. For these mental health related inquiries to comply with Title II of the ADA, it must be shown that despite the additional eligibility criteria that the questions place on applicants based on their mental health status, the questions are necessary to the Indiana Board of Law Examiners' licensing function. However, as it has been demonstrated, it is unlikely that Indiana's questions, as currently written, are truly necessary. Thus, the questions should be re-evaluated to ensure that applicants are being afforded the full protections provided to them under Title II of the ADA.

While the simple solution may be to amend all mental health-related questions to conduct-based questions in order to comply with what the DOJ deems ADA appropriate questions, it may not truly remedy all of the issues associated with inquiring into applicants' mental health histories. Thus, although bringing Indiana's questions into full compliance with Title II of the ADA is surely a positive step to rectifying the issues posed by inquiring into applicants' mental health histories, the only way to truly remedy the deterrent effect caused by such inquiry is to begin to work toward removing the stigma surrounding mental illness.

IV. CONCLUSION

The high rates of depression and mental illness among both law students and practicing attorneys in the United States make states' interest in ensuring applicants' mental fitness one of high importance. By having a screening process in place to determine whether bar exam applicants are mentally fit to practice law, states are ensuring safety not only for the attorneys themselves, but also for the attorneys' colleagues and clients.

Indiana made adjustments to the ways in which it questions applicants regarding their mental health histories following the *ACLU of Indiana* decision. However, the measures taken were not enough to bring Indiana's mental

health related questions in compliance with Title II of the ADA. Indiana's current approach delves too deeply into the generalities of an applicant's mental health history instead of inquiring into how any such conditions have impacted the behavior and conduct of the applicant. This places additional eligibility criteria on these applicants based upon the stereotypes and generalizations associated with their mental health condition that are not necessary to the Board of Law Examiners' licensing function – a violation of Title II of the ADA.

Amending bar exam questions to be more behavior and conduct focused will bring Indiana's mental health related questions into compliance with Title II of the ADA. Inquiring into specific behaviors that may interfere with an applicant's ability to practice law would still place additional criteria upon those applicants with mental conditions who, based upon their responses to the questions, would be required to disclose additional information. However, these additional criteria are placed upon the applicants because they have exhibited behaviors that may impact their effectiveness to practice law, not solely because they have been diagnosed with or are receiving treatment for a mental health condition. Additionally, amending Indiana's mental health related questions to conduct-specific inquiries would likely lessen the number of false positives during an application cycle. This would reduce the extra attention required of the Indiana Board of Law Examiners during an application cycle, as it would no longer be expending time and resources to further inquire into perfectly fit applicants' character and fitness eligibility.

While designing questions that comply with Title II of the ADA is important to protect applicants' privacies and rights afforded to them by the law, there are far greater issues underlying how Indiana questions its applicants' mental health histories. Ultimately, the stigma surrounding mental health related issues is the main cause for concern. Until this stigma is removed, zealous advocates that are passionate about the law will be deterred from pursuing careers in law solely because of the fear of having to disclose their mental health status. Current law school students who are experiencing concerning symptoms will be hesitant to get help for fear of being flagged during the bar application

process, of conditional admission, or of being referred to JLAP. Students that have been diagnosed with and are being treated for mental health related issues may be hesitant to be fully candid with their treating physicians or to be truthful in their disclosures on the bar exam application, which only hinders those individuals themselves from getting the best care.

In both the law school and legal profession cultures, more discussion needs to be had regarding mental illness. The topic needs to be de-stigmatized and cease being considered taboo. It needs to be more than a pamphlet handed out at 1L orientation or a topic subtly mentioned at firm in-service meetings. Until the stigma surrounding mental illness is removed, any set of questions inquiring into bar exam applicants' mental health histories will not fully suffice, regardless of whether they are compliant with Title II of the ADA. Only by changing the way in which the legal profession views and discusses mental illness will it become possible to create the illusive set of questions that "[strikes] the perfect balance between detecting problematic bar applicants and respecting applicants' privacy" that the court in *ACLU of Indiana* alluded to.[143]

[143] *ACLU of Ind.*, 2011 WL 4387470, at *13.

THE RIGHT TO BE FORGOTTEN: APPLYING EUROPEAN PRIVACY LAW TO AMERICAN ELECTRONIC HEALTH RECORDS

Jordan D. Brougher*

I. INTRODUCTION

Imagine Jane Doe wakes up one morning and turns on the local news to find her health insurance provider, XYZ Insurance, is the victim of a cyberattack. A few days later she receives a letter informing her of the breach and that her data has been compromised. XYZ promises to provide identity theft protection for the next year. Jane places the letter in a folder containing three similar letters from other

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corporations which have suffered recent breaches. She feels helpless as cybercriminals now have access to her private medical information.

With the 2014 and 2015 data breaches at major corporations like Sony Pictures, Community Health Services, Target, and most recently Anthem, our individually identifiable medical information becomes increasingly at risk. Large corporations like Sony Pictures and Anthem store their employees' personal information through a system of electronic records.[1] The Sony cyberattack occurred during the build-up to the release of a comedy film depicting the attempted assassination of the North Korean Supreme leader, Kim Jong-un.[2] The attack illustrates a great cause of concern for employees across the United States. Employers hold valuable employee information such as Social Security numbers, salaries, performance reviews, and personal medical information.[3]

Additionally in February 2015, Anthem, one of the nation's largest health insurers, headquartered in Indianapolis, reported a breach that could affect up to 80 million customers and employees.[4] Anthem CEO, Joseph R. Swedish, believes the hack to be a "very sophisticated external cyberattack" with the cybercriminals accessing personal information like Social Security numbers and birthdates.[5] However, the Federal Bureau of Investigation is looking into whether health information was stolen or not.[6]

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[1] Cyberattacks are performed by groups targeting employee and customer stored information such as Social Security numbers, credit card information, and health information within the targeted companies' computer systems. Andrea Peterson, *Lawsuits against Sony Pictures Could Test Employer Responsibility for Data Breaches*, WASH. POST (Dec. 19, 2014), http://www.washingtonpost.com/blogs/the-switch/wp/2014/12/19/lawsuits-against-sony-pictures-could-test-employer-responsibility-for-data-breaches/ [http://perma.cc/U36E-U8BW].

[2] *See id.*

[3] *Id.*

[4] Reed Abelson & Matthew Goldstein, *Millions of Anthem Customers Targeted in Cyberattack*, NY TIMES (Feb. 5, 2015), http://www.nytimes.com/2015/02/05/business/hackers-breached-data-of-millions-insurer-says.html?_r=0 [http://perma.cc/7V4M-C739].

[5] *Id.*

[6] *Id.*

The most troubling part of the cyberattacks is the evidence showing that companies cut corners on data security to save money.[7] However, corporations that choose to cut corners ultimately pay a steeper price in the end, as do their employees. By failing to secure protected health information, data breaches can result in hefty fines from the Department of Health and Human Services (HHS) and monetary damages in the range of several million dollars.[8]

A major difference exists between the Sony attack and the Anthem attack. While Sony is a leader in the entertainment industry, Anthem is a leader within the health care industry. Yet, the Sony cyberattack allowed the cybercriminals to gain access to employee medical records including information on surgeries, therapies, and medical diagnoses such as cancer, kidney failure, and premature births.[9] Even though, cybercriminals mostly use the stolen information for identity theft purposes, there is a potential to use the information in the service of other crimes such as insurance and prescription fraud.[10] Meanwhile Sony will incur liability for the breach as

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[7] Peterson, *supra* note 1.

[8] Annually, data breaches cost the health care industry around $5.6 billion, and as more health care providers go to the electronic health record "cloud" this number is expected to continue to increase. Jason Millman, *Health Care Data Breaches Have Hit 30M Patients and Counting*, WASH. POST (Aug. 19, 2014), http://www.washingtonpost.com/blogs/wonkblog/wp/2014/08/19/health-care-data-breaches-have-hit-30m-patients-and-counting/ [http://perma.cc/B89L-7X8B] (citing Chris Burt, *Data Breaches Cost Healthcare Firms $5.6 Billion Annually: Ponemon Institute*, WHIR (Mar. 19, 2014), http://www.thewhir.com/web-hosting-news/data-breaches-cost-healthhealthhealth care-firms-5-6-billion-annuallay-ponemon-institute [http://perma.cc/92VJ-2C4U].

[9] Peterson, *supra* note 1.

[10] Pragati Verma, *Why Medical Data is Vulnerable—And Valuable—To Cybercriminals*, FORBES (Mar. 12, 2015, 4:59 PM), http://www.forbes.com/sites/teradata/2015/03/12/why-medical-data-is-vulnerable-and-valuable-to-cybercriminals/ [http://perma.cc/UM46-73LM]; *see also* Caroline Humer & Jim Finkle, *Your Medical Record is Worth More to Hackers Than Your Credit Card*, REUTERS (Sept. 24, 2014), http://www.reuters.com/article/2014/09/24/us-cybersecurity-hospitals-idUSKCN0HJ21I20140924 [http://perma.cc/H9YG-MXF8] ("Fraudsters use [health] data to create fake IDs to buy medical equipment or drugs that can be resold, or they combine a patient number

it is required by California law to keep medical information separate from other employee information in a different security system.[11]

The Sony and Anthem cyberattacks show the rapidly increasing inability of the United States' Health Information Portability and Accountability Act (HIPAA) and subsequent state law to properly motivate companies to protect patient data. The Act fails to provide a private right of action for individuals, like the Sony employees, who, as a result of their employers' inability to protect the information, have theirs stolen.[12] Congress must both strengthen HIPAA to better protect individual patient data and provide individuals with a private right of action.

This Note will discuss the need to strengthen health information data protections under HIPAA. In comparing the United States and European Union ("EU") privacy law, the Note will address the benefits and shortcomings of each approach. Furthermore, the Note will look to European law and its "right to be forgotten." Then, the Note will apply the principles of the EU right to be forgotten to American health records and health information. Finally, the Note will address issues pertaining to the right to be forgotten and the reasons why Americans do should want the right added to the constitutionally recognized right of privacy.

A. The Issue: HIPPA's Inability to Protect Patient Health Records

Health care data has increasingly become the target of data breaches accounting for nearly "43 percent of [all] major data breaches reported in 2013."[13] While some breaches are the result of employee negligence, most are done with

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with a false provider number and file made-up claims with insurers . . . .").

[11] Peterson, *supra* note 1.

[12] Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended in various sections of 42 U.S.C.).

[13] Millman, *supra* note 8.

malicious intent.[14] The trend is disturbing, because there are multiple avenues for a breach to occur, and it indicates a lack of security. Under the 2009 HIPAA Breach Notification Rule, HIPAA "covered entities" and their "business associates" must follow federal reporting requirements.[15] The requirements necessitate that covered entities notify affected individuals,[16] the Secretary of the Department of Health and Human Services (HHS),[17] and, if more than 500 residents of a State are affected, the media outlets serving the State.[18] HHS has tracked 944 major breach reports affecting nearly 30 million people.[19] Steve Weisman, a law professor and contributor to USA Today, predicts that the source of most data breaches in 2015 will target the health care industry.[20] To explain his prediction, Weisman focuses on the large amount of information being shared by entities and the lack of proper security.[21] Weisman's prediction should frighten the health care industry and the country.

Patients have few means to persuade health care corporations to adequately protect their information. Patients may "shop" around for corporations that will better protect their data. However, patients subject to a health maintenance organization ("HMO") plan provided by an employer will not have this luxury. Under an HMO plan, a patient may only go to doctors, other health care providers,

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[14] *See* Dan Munro, *Cyber Attack Nets 4.5 Million Records From Large Hospital System*, FORBES (Aug. 18, 2014, 9:01 AM), http://www.forbes.com/sites/danmunro/2014/08/18/cyber-attack-nets-4-5-million-records-from-large-hospital-system/ [http://perma.cc/ 8QY2-JYK2] ("83.2% of 2013 of patient records breached in 2013 resulted from theft").

[15] HIPAA Breach Notification Rule, 45 CFR § 164.404- (2016).

[16] 45 CFR § 164.404 (2016).

[17] 45 CFR § 164.408 (2016).

[18] 45 CFR § 164.406 (2016).

[19] Millman, *supra* note 8.

[20] Anthem's data breach provides concrete evidence that Professor Weisman's prediction holds weight and members of the health care industry must strengthen their cyber-security. Steve Weisman, *Cyber Predictions for 2015*, USA TODAY (Dec. 20, 2014), http://www.usatoday.com/story/money/personalfinance/2014/12/20/cyber-hack-data-breach/20601043/ [http://perma.cc/J33H-QJJ2].

[21] *Id.*

and hospitals on the plan's list.[22] Since the late 1990s, managed care has dominated the health care marketplace with more than 70 million Americans enrolled in HMOs and 90 million enrolled in PPOs (preferred provider organizations).[23] While HMO enrollment numbers have been in decline, managed care is still a dominant form in the health care market place[24] and limits the patient's ability to hold the company accountable in protecting their data. In a recent interview on Sound Medicine Radio, Titus Schleyer, Director of Regenstrief Center for Biomedical Informatics in Indianapolis, stated "as a patient you are so removed from control over your information that you really can't do anything."[25] Schleyer goes on to argue that stolen health information is of little use to cybercriminals, because the information does not provide as good of a benefit as stolen data like Social Security numbers and birthdates.[26] Schleyer's comments illustrate the miscommunication between patients and providers. Patients may believe their information is staying within their providers' systems when in reality it is being sent to the health storage cloud or to another corporation for storage.[27] This reality should be reflected in an informed consent form, (even if patients will

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[22] *Health Maintenance Organization (HMO) Plan*, MEDICARE.GOV, http://www.medicare.gov/sign-up-change-plans/medicare-health-plans/medicare-advantage-plans/hmo-plans.html [http://perma.cc/AX8E-CHQH] (last visited Feb. 7, 2016).

[23] *Managed Care, Market Reports and the States*, NCSL, http://www.ncsl.org/research/health/managed-care-and-the-states.aspx [http://perma.cc/H4R3-EDCS] (updated June 2013).

[24] *Id.*

[25] *In the Era of Cloud Health Data, Safety is Not Guaranteed*, SOUND MEDICINE RADIO (Feb. 27, 2015), http://soundmedicine.org/post/era-cloud-health-data-safety-not-guaranteed#.VP8DJBneQ4s.email [http://perma.cc/7RSH-F6ZP] (explaining once providers place patient information in EHRs with another corporation or in the health storage cloud, the providers are not even sure where the information is at any given time).

[26] *Id.* Schleyer's argument contradicts others regarding the use of health information for criminal purposes. *See* Verma, *supra* note 10.

[27] *See* Erin Gilmer, *Privacy and Security of Patient Date in the Cloud*, (April 16, 2013), https://www.ibm.com/developerworks/cloud/library/cl-hipaa/ [https://perma.cc/L4AS-SCHT].

never read the form), that is signed upon the collection of their information.

Health care industry expenditures made up roughly 17.1% of the United States' gross domestic product ("GDP") from 2010-2015.[28] The World Health Organization database calculates the percentage based on expenses both public and private including preventative and curative health services, family planning activities, nutrition activities, and emergency aid.[29] To contrast the United States with other economic leading countries, the United Kingdom's expenditures represent only 9.1% of its GDP, and France's expenditures represent 11.5% of its GDP from 2010-2015.[30] The United States must find a way to lower the proportion of health care spending within its GDP.

Furthermore, corporations in the United States will continue to spend in the billions to rectify patient record security breaches.[31] In August 2014, Community Health Services announced the second largest breach in U.S. history affecting more than 4.5 million patients and potentially costing above $77 million in fines and remedies.[32] Community Health Services, located in Tennessee and serving twenty-nine other states, believes "the attacker was an 'Advanced Persistent Threat' group originating from China" targeting Community Health Services systems with "highly sophisticated" technology.[33]

One of the largest fraudulent uses for stolen health records is medical insurance fraud. The most common method by which criminals fraudulently obtain patient

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[28] WHO Global Health Expenditure Database, *Health Expenditure, Total (% of GDP)*, WORLD BANK, http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS/countries/1W?display=default [http://perma.cc/6XG7-KUTP] (last visited Feb. 7, 2016).

[29] *Id.*

[30] *Id.*

[31] According to benchmark research performed by the Ponemon Institute on the cost of data breaches, each compromised record costs the company an average of $201. Taking the Anthem data breach with nearly 80 million records compromised, it would result in a cost of $16 billion. *See* PONEMON INST. LLC, 2014 COST OF DATA BREACH STUDY: UNITED STATES 1 (2014), *available at* http://public.dhe.ibm.com/common/ssi/ecm/se/en/sel03017usen/SEL03017USEN.PDF [http://perma.cc/RA6K-R4TU].

[32] Munro, *supra* note 14.

[33] *Id.*

information is by "inducing medical personnel with access to patient insurance information to copy the information and provide it to those involved in fraud schemes"[34] and "[p]urchasing the information from others involved in fraud . . . marketers of stolen patient and physician billing information."[35] "Estimates of fraudulent billings to health care programs, both public and private, are estimated between 3 and 10 percent of total health care expenditures."[36] Medicare and Medicaid have been subject to losses in the billions from healthcare fraud.[37] This amount includes provider and patient fraud outside the scope of stolen health care records.[38] The government's health care fraud prevention and enforcement recovered $4.3 billion in taxpayer dollars as part of the Obama administration's attempts to eliminate health care fraud and reduce health care costs.[39] With tax-funded programs facing fraud, taxpayers have even more incentive to protect their information in order to potentially lower the taxes necessary to fund these programs. While fraud can come from many sources, not all can be attributed to medical identity theft. For example, Stark and Anti-Kickback violations are

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[34] White-Collar Crime, *Health Care Fraud Overview*, THE FBI, http://www.fbi.gov/about-us/investigate/white_collar/health-care-fraud/health-care-overview [http://perma.cc/B96W-PMD8] (last visited Feb. 7, 2016).

[35] *Id.*

[36] *See* FED. BUREAU OF INVESTIGATION, FINANCIAL CRIMES REPORT TO THE PUBLIC 2007, at 9 (2007), *available at* https://www.fbi.gov/stats-services/publications/fcs_report2007 [http://perma.cc/FU5J-BBEQ] (explaining "[e]stimates of fraudulent billings to health care programs, both public and private, are estimated between 3 and 10 percent of total health care expenditures.").

[37] *By the Numbers: Fraud Statistics*, Coalition Against Insurance Fraud, Healthcare, (last visited May 20, 2016) http://www.insurancefraud.org/statistics.htm#.V0HcXPkrLIU. [https://perma.cc/9ACQ-X9GF].

[38] *Id.*

[39] U.S. Dep't of Justice, *Departments of Justice and Health and Human Services Announce Record-Breaking Recoveries Resulting from Joint Efforts to Combat Health Care Fraud*, (Feb. 26, 2014), http://www.justice.gov/opa/pr/departments-justice-and-health-and-human-services-announce-record-breaking-recoveries-0 [http://perma.cc/GJ5P-EKL8].

frequently found against health care providers claiming more money than they are entitled to.[40]

As the Patient Protection and Affordable Care Act ("ACA") became law, the United States started to focus on the soaring costs of the health care industry.[41] The ACA is an attempt to provide affordable coverage to Americans by creating new tax credits and new marketplaces where competition will lead to better prices and better results.[42] In the Ponemon Institute's "Benchmark Study on Patient Privacy & Data Security", two-thirds of health care organizations feel the new law increases the risk of data breaches.[43] Beginning in 2012, ACA section 1561 called for the standardization of billing and the adoption and implementation of an electronic exchange of health records.[44] The ACA increases the concerns over the "exchange of patient information between [healthcare] providers and government organizations."[45] The call for increased electronic health records ("EHR") combined with organizations' poor security practices place patient information at risk.[46] Organizations must take more responsibility under the ACA to protect patient information. For example, data encryption should be mandatory for any company device that leaves the office. The ACA's effects on patient information data breaches have yet to materialize, but providers, patients, and the government must do more to protect patient information.

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[40] U.S. Dep't of Health and Human Servs, *Medicare Fraud & Abuse*, (Aug. 2014), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Fraud_and_Abuse.pdf. [https://perma.cc/RX6U-7V6Y].

[41] *Health Care that Works for Americans*, WHITEHOUSE.GOV, http://www.whitehouse.gov/healthreform/healthhealthhealthcare-overview [http://perma.cc/W4RP-HCA6] (last visited Feb. 7, 2016).

[42] *Id.*

[43] Jeffrey Bendix, *Healthcare Data Breaches Decline, but ACA Could Be Increasing Risks*, MED. ECON. (May 15, 2014), http://medicaleconomics.modernmedicine.com/medical-economics/content/tags/affordable-care-act/healthcare-data-breaches-decline-aca-could-be-inc?page=full [http://perma.cc/8PHJ-FWBW].

[44] 42 U.S.C. § 300jj-51 (2015).

[45] Bendix, *supra* note 43.

[46] *Id.*

B. European Issues With Health Record Data Breaches

The United States is not alone in experiencing patient information data breaches. In a 2014 study, by the Central European University's Centre for Media, Data and Society (CMDS) reported that shows the European Union's twenty-eight countries of the EU have suffered 229 known data breaches "covering 227 million personal records."[47] However, the European Union addresses individual privacy rights much differently than the United States does.

The EU acknowledges privacy as a fundamental right.[48] European institutions have a difficult time defining what the right entails and instead take "a piecemeal approach to defining private life, rather than providing a general or exhaustive definition."[49] Although the right to privacy has not been given a general definition, the EU has passed several directives to bring the right into the twenty-first century. For example, the 2002 E-Privacy Directive requires breaches of personal data to be reported to national authorities and may help provide a clearer picture on the actual number and scope of breaches in European countries.[50] Finally, the EU encourages the adoption of EHRs and confirmed the broad application of privacy protections.[51] These directives and suggestions promoted the access of information across various countries. While the

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[47] John E. Dunn, *Europe Suffered 229 Public Data Breaches Since 2004*, IDG NEWS SERV. (Oct. 13, 2014), http://www.techcentral.ie/european-suffered-229-public-data-breaches-since-2004-study-suggests/ [http://perma.cc/3KCP-QJ8Z].

[48] *See* Convention for the Protection of Human Rights and Fundamental Freedoms art. 8, Nov. 4, 1950, 213 U.N.T.S. 222, 230 [hereinafter Convention].

[49] H. Tomás Gómez-Arostegui, *Defining Private Life Under the European Convention on Human Rights by Referring to Reasonable Expectations*, 35 CAL. W. INT'L L.J. 153, 154 (2005).

[50] Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 Concerning the Processing of Personal Data and the Protection of Privacy in the Electronic Communications Sector, 2002 O.J. (L 201) 37 [hereinafter E-Privacy Directive].

[51] Janine Hiller, et al., *Privacy and Security in the Implementation of Health Information Technology (Electronic Health Records): U.S. and EU Compared*, 17 B.U. J. SCI. & TECH. L. 1, 2 (2011).

United States also seems to be pushing to make EHRs the predominate form of record keeping through the HITECH Act, unfortunately they have not been able to promote patient privacy on the same level as the EU.

II. BACKGROUND

A. Development of the European Union's Right to be Forgotten

European and American ideas on individual privacy have gone in opposite directions. In 1950, the European Convention for the Protection of Human Rights and Fundamental Freedoms declared that, "[e]veryone has the right to respect for his private and family life, his home and his correspondence."[52] In 1995, the EU made the Data Protection Directive into law, which includes the principal creating the right of erasure.[53] The right of erasure allows a subject to erase data, which is "incomplete, inaccurate, or stored in a way incompatible with the legitimate purposes pursued by the controller."[54] Additionally, Article 12 of the Data Protection Directive reads, "[m]ember states shall guarantee every data subject the right to obtain from the controller . . . as appropriate the rectification, erasure or blocking of data…."[55] Furthermore, Article 2 defines "controller," as "the natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of the processing of personal data."[56] The directive allows individuals some

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[52] *See* Convention, *supra* note 48.

[53] *Factsheet on the "Right to be Forgotten" Ruling*, European Commission, (C-131/12), http://ec.europa.eu/justice/data-protection/files/factsheets/factsheet_data_protection_en.pdf. [https://perma.cc/S33F-NWHA].

[54] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L 281) 32 [hereinafter EU Data Protection Directive].

[55] *Id.* at art. 12.

[56] *Id.* at art. 2.

control over the data that is processed by corporations and other entities.

The EU Data Protection Directive would have little to no authority if it did not apply to non-EU companies, and thus, it applies to any company that may reach within the EU. In 1991, the EU council adopted recommendations governing the flow of data across its borders.[57] The adoption of these recommendations is especially important when dealing with foreign companies possessing data of EU citizens.

Additionally, Article 8 of the EU Data Protection Directive prohibits the processing of personal data, "concerning health or sex life."[58] The EU Data Protection Directive formed the Article 29 Working Party, as an advisory board on data protection.[59] The Article 29 Working Party issued the Working Document on the Processing of Personal Data Relating to Health in Electronic Health Records.[60] The report applies privacy principles to health records and "recommends [the] adoption of eleven specific legal protections to protect individual health privacy."[61] The report characterizes health data as being relevant to the treatment of the patient. Otherwise, it should not be included in the patient's medical file.[62] While these examples do not represent health data, they provide identifiable information that may trace de-identified health data back to the patient. Such information may hold relevance to a patient's history but often not to the patient's health. However, there are some exceptions where the information is extremely relevant. For example, a factory worker exposed to asbestos for thirty years will be relevant to the fact that the worker suffers from mesothelioma.

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[57] *Recommendation No. R (91) 10 of the Committee of Ministers to Member States on the Communication to Third Parties of Personal Data Held by Public Bodies*, COUNCIL OF EUROPE (Sept. 9, 1991), *available at* https://wcd.coe.int/com.instranet.InstraServlet?command=com.instranet.CmdBlobGet&InstranetImage=572401&SecMode=1&DocId=597936&Usage=2 [http://perma.cc/ N3RB-39HU].

[58] EU Data Protection Directive, *supra* note 54.

[59] Hiller, et. al, *supra* note 51 at 21.

[60] *Id.*

[61] *Id.*

[62] *Id.*at 22.

The EU system represents a huge victory for individual privacy rights by giving the individual control over what information the medical provider may collect and store. In 1980, the Organization for Economic Cooperation and Development ("OECD) issued Guidelines on the Protection of Privacy and Transborder Flows of Personal Data (OECD Privacy Guidelines").[63] The OECD Privacy Guidelines operate on the principle of limiting data collection and use for only specific purposes.[64] It is noted that the guidelines put forth principles such as: "limitation of data collection, maintenance of data quality, specification of the collection purpose, limitation of data use to that specified purpose, adequate security, transparency, individual access to and control of data collected, and accountability."[65] In 1998, with the rapidly improving technological world the OECD reexamined the principles and reaffirmed their application.[66] However, OECD Privacy Guidelines remain limited in their application to health data. To protect individuals' health data, the European Union decided to address this issue.

In 2012, the European Union put forth a proposal to further protect individuals' privacy rights. The Proposal provides Article 17 the "Right to be forgotten and to erasure."[67] Three sections compose Article 17's right to be forgotten and to erasure. First, Section 1 provides individuals with the "right to obtain from the controller the erasure of personal data relating to them and the abstention from further dissemination of such data, especially in

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[63] OECD, *Guidelines on the Protection of Privacy and Transborder Flows of Personal Data* (Paris 1981), *available at* http://www.oecd.org/sti/ieconomy/oecdguidelinesontheprotectionofprivacyandtransborderflowsofpersonaldata.htm [https://perma.cc/2RN8-P425].

[64] *Id.*

[65] Hiller, et. al., *supra* note 51 at 20.

[66] *See* OECD, *Protection of Privacy and Personal Data*, OECD.GOV, http://www.oecd.org/document/26/0,3343,en_2649_34255_1814170_1_1_1_1,00.html [http://perma.cc/K8LA-GGWK] (last visited on Feb. 7, 2016).

[67] *Proposal for a Regulation of the European Parliament and of the Council on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data*, COM (2012) 11 final (Jan. 25, 2012), *available at* http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012PC0011&from=EN [http://perma.cc/4ZY8-82A4] [hereinafter General Data Protection Regulation].

relation to personal data which are made available by the data subject while he or she was a child."[68] Section 2 includes the obligation of the controller who has made the information public to inform third parties of the data subject's request "to erase any links to, or copy or replication that personal data."[69] Section 3 charges the controller to take down the information "without delay" and creates exceptions where retention of personal data is necessary.[70] The exceptions include the exercise of "freedom of expression" such as works designated as artistic, literary, or journalistic; public health interest; "historical, statistical, and scientific research"; and retention of personal data by the EU or member state under state law.[71]

The General Data Protection Regulation was designed to meet the rapid advances in technology and provide individuals with protections against companies that make use of personal data.[72] The regulation's purpose is to build trust in the online environment to propel economic development; and as of April 14, 2016, the General Data Protection Regulation passed into law.[73] The right to be forgotten had little authority over the various corporations doing business in the EU, until 2013 when Spanish courts decided a case with immense implications to the right.

In 2013, the Spanish courts decided *Google Spain SL, Google Inc. v. Agencia Espanola de Proteccion de Datos, Mario Costeja Gonzalez*. The decision required internet search engines to consider individual requests to remove links to freely accessible web pages resulting from a search of the individual's name.[74] The case was brought by a man

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[68] *Id.* at art. 17.

[69] *Id.*

[70] *Id.*

[71] *Id.*

[72] *Id.*

[73] Zlata Rodionova, *EU Data Protection Regulation Passes in Brussels Giving Citizens Right to be Forgotten Online,* (April 14, 2016), http://www.independent.co.uk/news/business/news/european-union-s-general-data-protection-regulation-privacy-facebook-data-eu-law-online-web-a6984101.html. [https://perma.cc/3RQX-4XTU].

[74] Case C-131/12, Google Spain SL v. Agencia Española de Proteccion de Datos, (AEPD), 2013 ECLI:EU:C:2014:616 (May 13, 2014), *available at*

whose name was printed in an announcement of a newspaper widely circulated throughout Spain in connection with a property that was up for auction due to Social Security debts.[75] The man was named as the owner.[76] At a later date, an electronic version of the newspaper was made available.[77] In 2009, the man searched for his name on Google and found the newspaper announcements from eleven years prior.[78] The man asserted Article 12 of the EU Data Protection Directive as the basis of his argument to require Google to erase the search results.[79]

In its decision, the court reasoned that while the General Data Protection Regulation in Article 17 provides for a right to be forgotten, it does not represent a codification of current law.[80] However, the court did find that the right of erasure is valid when Google, acting as a processor of personal data, infringes on the privacy rights of the data subject.[81] The decision gives real authority to the EU Data Protection Directive Article 12, recognizing the right to erasure in the EU common law. Furthermore, the decision requires U.S. companies to adhere to this right to be forgotten when operating within the EU. It remains to be seen the impact this will have on U.S. companies' operations within the EU and if the right to be forgotten will impact the companies' data policies within the United States.

The *Google Spain SL* decision draws parallels to the United States' Supreme Court decision in *Griswold v. Connecticut* which began the constitutionally recognized right of privacy in the United States.[82] In *Griswold*,

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http://curia.europa.eu/juris/document/document.jsf?text=&docid=152065&doclang=EN [perma.cc/9M35-KEV6] [hereinafter Google Spain].

[75] *Id.*

[76] *Id.*

[77] *Id.*

[78] *Id.*

[79] *Id.* (asserting in the complaint by Mr. Gonzalez that the proceedings that gave rise to the announcements had been resolved several years prior and were no longer relevant. The, though the court found that the newspaper publishing the announcements were right to do so but upheld the complaint against Google Spain and Google, Inc.).

[80] *Id.*

[81] *Id.*

[82] Griswold v. Connecticut, 381 U.S. 479 (1965).

Connecticut had a statute that mandated any individual be fined who used "any drug, medicinal article or instrument for the purpose of preventing conception."[83] Griswold, the Executive Director of the Planned Parenthood League of Connecticut, provided information and drugs to married persons for the "purpose of preventing contraception."[84] She was subsequently fined for her actions.[85] The Court found the Bill of Rights and its Amendments create "zones of privacy."[86] For example, the Fourth Amendment provides an individual's right from "unreasonable searches and seizures" of their homes.[87] The Court found the constitutionally guaranteed zones of privacy extended to marital privacy.[88] *Griswold*, much like *Google Spain* in the EU, represents the beginning of constitutionally protected privacy rights in the United States.

In applying the EU Data Protection Directive to the health care industry, Article 29 of the Data Protection Working Party is dispositive for the EU health care industry. Under Article 29, the Working Document on the Processing of Personal Data Relating to Health in Electronic Health Records provides requirements for health information gathered by health care professionals in electronic form.[89] Health information gathered must be for the purposes of "preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services" the health professional processing the information must be bound by law or professional rules to professional secrecy or the 'equivalent.'[90]

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[83] *Id.* at 480 (citing now repealed CONN. GEN. STAT. § 54-196 (1958)).

[84] *Id.*

[85] *Id.*

[86] *Id.* at 484.

[87] *Id.* at 484.

[88] *Id* at 485. The constitutionally guaranteed zones of privacy are no longer applicable. In subsequent cases the zones of privacy have been replaced and a right to privacy has been founded in the 14th Amendment's Due Process Clause. *See* Roe v. Wade, 410 U.S. 113 (1973), note 96.

[89] Article 29 of Directive 95/46/EC, Working Document on the Processing of Personal Data Relating to Health in Electronic Health Records (EHR), 2007 O.J. (WP 131), *available at* http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2007/wp131_en.pdf [http://perma.cc/E6SY-95PA] [hereinafter Article 29].

[90] *Id.*

The EU created eHealth as its electronic health record database.[91] The eHealth database provides Europeans with access to their medical data while incorporating the right of individuals to have their medical data safely stored on an accessible online health care system.[92] European EHRs require prior patient consent, but once given, providers can freely access, store, and transmit the information.[93] The main obstacle to eHealth's success is concern over data protection and privacy.[94] Similar to the concerns in the United States electronic health record system, in the EU "there is still lack of trust in the security of the system and [patients] are reluctant to use it."[95] This distrust stems from a concern over access to the information.[96] Additionally, patients and providers express concerns on data privacy but also concern on "overly strict data protection."[97] To combat these concerns, the eHealth stakeholders put forth recommendations as to how to properly secure patient information.[98] One recommendation, guaranteeing privacy and data protection, grants patient's control over their own medical file.[99] The patient is in charge of his or her own file, allowing the patient to "log-in" and inspect it.[100] The EU finds the option to access one's own information as a fundamental right under the EU Data Protection legislation.[101] The United States should grant patients

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[91] Directive 2011/24/EU, of the European Parliament and of the Council of 9 March 2011 on the Application of Patients' Rights in Cross-Border Healthcare O.J. (L 8845) [hereinafter Directive on Cross-Border Health care].

[92] PATIENT ACCESS TO ELECTRONIC HEALTH RECORDS, EHEALTH STAKEHOLDER GROUP, 1 (2013), *available at* http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=5169 [http://perma.cc/8G6P-YNWQ] [hereinafter EHEALTH REPORT].

[93] *Id.* at 2-3.

[94] *Id.*

[95] *Id.* at 3.

[96] *Id.* Most concern is over the "who and how" of data access. Stakeholders remain tentative, because EHRs carry a general uncertainty of who is responsible for the information.

[97] *Id.* at 4.

[98] *Id.* at 14.

[99] *Id.*

[100] *Id.*

[101] *Id.*

similar access to their own files. This way the patient will have the opportunity to become more involved in their recordkeeping and have some sense of security even if it is small.

However, it is argued that "an EHR in the United States will challenge the presumption of privacy preservation."[102] With records easily transferable between providers, the individual's ability to maintain privacy is limited. This is a problem in the EU as well, but if the recommendations presented by eHealth take hold, then the patient will be able to see who accessed their information and for what purpose.[103] Yet, with the increase in medical data breaches, EHRs should strengthen the presumption of privacy. If the United States health care industry cannot protect health records, then the decision of what non-treatment related information is in the records should be made by individuals.

B. Development of the United States' HIPAA Law

The United States codified its concern for privacy in the various Amendments constituting the Bill of Rights. For example, the Fourth Amendment protects against unreasonable search and seizures[104] and the First Amendment's freedom of association.[105] With *Griswold v. Connecticut*, the seminal case on U.S. privacy rights, the Supreme Court recognized a constitutional right to privacy.[106] *Griswold* began a snowball effect for privacy rights, including *Roe v. Wade*[107] and *Cruzan v. Director, Missouri Department of Health*.[108] However, the Court has

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[102] Hiller, et al., *supra* note 51 at 23.

[103] EHEALTH REPORT, *supra* note 92.

[104] U.S. Const. amend. IV.

[105] U.S. Const. amend. I.

[106] Griswold v. Connecticut, 381 U.S. 479, 485 (1965).

[107] Roe v. Wade, 410 U.S. 113 (1973). In this right to abortion case, the Court found "the right [of privacy]…includes the right of a woman to decide whether or not to terminate her pregnancy." *Id.* at 170.

[108] Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261 (1990). In this end of life case, the Court assumed a person's right to refuse treatment to be a liberty interest (a right not to be infringed upon by the government, state or federal) protected by the Due Process Clause and

not recognized a constitutional right to privacy of health data.

In *Whalen v. Roe*, the Supreme Court recognized a limited Constitutional right to individual privacy with respect to information held in government databases.[109] However, the decision left unresolved the issue of a constitutional protection of health information. With the Privacy Act of 1974, Congress created a law that applies to personal information in any federal government record within federal agencies.[110] Then, with the Gramm-Leach-Bliley Financial Services Modernization Act of 1999, Congress protected financial information held by health insurers.[111]

Wanting an expanded right to privacy yet to be court recognized within the various constitutional amendments, Samuel Warren and Louis Brandeis wrote that there should be a right "to be let alone" from instantaneous photographs and newspaper enterprise invading the private and domestic life.[112] However, the Supreme Court did not recognize the right to privacy within the Bill of Rights until much later.[113] Congress was the first to act to protect privacy rights regarding health data.[114]

Health Insurance Portability and Accountability Act of 1996 ("HIPAA") started the United States' move toward EHRs. The U.S. legal framework for health information privacy is codified in HIPAA.[115] HIPAA "originally gave Congress three years to pass explicit privacy rules."[116] After

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went through a Due Process Clause analysis weighing the state interests against Cruzan's liberty interests. *Id.* at 279.

[109] Whalen v. Roe, 429 U.S. 589 (1997).

[110] Privacy Act of 1974, 5 U.S.C. § 552a (2016).

[111] Gramm-Leach-Bliley Financial Services Modernization Act of 1999, Pub. L. No. 106-102, 113 Stat 1338.

[112] Samuel D. Warren & Louis D. Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193, 195 (1890).

[113] Griswold v. Connecticut, 381 U.S. 479, 481 (1965) (deciding the right to contraception was a privacy right found within the constitutional amendments, but later the right to privacy is found in the Due Process Clause of the 14th Amendment).

[114] Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1997) (codified as amended in various sections of 42 U.S.C.).

[115] *Id.*

[116] Hiller, et al., *supra* note 51 at 11.

this time expired and no privacy rules were passed, the Department of Health and Human Service ("HHS") "became the authority in privacy regulations."[117]

HIPAA was a congressional attempt to provide administrative simplification of the health care system through a health information system with the electronic transmission of certain health information.[118] HHS began to adopt a set of rules to govern health information privacy with the Privacy Rule.[119] The Privacy Rule has three purposes best described in three words: protect – safeguard the rights of consumers "by providing them access to their health information" and restricting the inappropriate use; trust – "improve the quality of health care" by "restoring trust" between those supplying and seeking health care; improve – develop a "national framework for health privacy protection" to improve "efficiency and effectiveness." [120]

Next, the HHS passed the Security Rule. The Security Rule creates standards for the measures to be taken when "covered entities" obtain custody of health information. These standards apply to communication of health information between "covered entities" and "business associates."[121] Section 160.103 of the Federal Regulations defines covered entity to mean "(1) a health plan[,] (2) a health care clearinghouse[, and] a health care provider who transmits any health information in electronic form."[122]

In 2009, Congress strengthened HIPAA's privacy and security rules through the HITECH Act. HITECH also clarified the business associate requirements.[123] HITECH defines business associate as "a person who on behalf of such covered entity or of an organized health care arrangement in

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[117] *Id.*

[118] Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended in various sections of 42 U.S.C.).

[119] *Id.*

[120] Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160, 164).

[121] Health Insurance Reform: Security Standards Final Rule, 68 Fed. Reg. 8334 (Feb. 20, 2003) (to be codified at 45 C.F.R. pts. 160, 162, 164).

[122] 45 C.F.R. §160.103 (2010).

[123] *Id.*

which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, creates, receives, maintains, or transmits protected health information."[124] The HITECH Act increased the strength of HIPAA's privacy security guidelines by increasing enforcement and civil monetary penalties.[125] Enforcement and civil monetary penalties increased in strength with the Breach Notification Rule codified within 45 C.F.R. §§ 164.400-14.[126]

The Breach Notification Rule requires "covered entities" and business associates to notify the individual affected in cases of 500 or less, but the local media must be informed when 500 or more residents of a state are affected by a breach.[127] Also, the rule allows the Secretary of HHS to post on the HHS public website the names of each covered entity involved in a breach of more than 500 individuals.[128] For example, the Community Health Systems ("CHS"), Inc. breach affected 4.5 million people, and CHS is posted on the HHS public website.[129] Applying the heightened civil penalties under the HITECH Act, CHS could be fined millions of dollars by HHS.[130]

The breach was a result of a Chinese cyberattack that affected 4.5 million patients.[131] Despite the fact that no health-related information was stolen, the stolen information included identifiable data such as birthdates and telephone numbers.[132] Although stolen in a sophisticated attack, this leak of information still constitutes a breach under HIPAA.[133] According to the HIPAA breach notification rule, HHS

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[124] *Id.*

[125] Hiller, et al., *supra* note 51 at 12.

[126] 45 C.F.R. §§ 164.400-14 (2013).

[127] 45 C.F.R. § 164.408 (2013).

[128] *Id.*

[129] Munro, *supra* note 14.

[130] *Id.*

[131] Nicole Perlroth, *Hospital Company Hacked, Affecting 4.5 Million Patients (Hack of Community Health Systems Affects 4.5 Million Patients)*, N.Y. TIMES, (Aug. 19, 2014), *available at* http://bits.blogs.nytimes.com/2014/08/18/hack-of-community-health-systems-affects-4-5-million-patients/?_r=0 [https://perma.cc/RH7T-SVQJ].

[132] *Id.*

[133] Munro, *supra* note 14.

required CHS to contact the patients and notify HHS because it affected more than 500 individuals.[134]

In working through the details of HIPAA and understanding protected health information, one must understand the role played by covered entities and business associates. Originally, HIPAA only regulated covered entities with regards to protected health information.[135] It completely left out entities essential to the exchange of health information, i.e. business associates.[136] Subsequent changes to the HIPAA law broadened its application to business associates, and the HITECH strengthened its enforcement against business associates involved in a data breach.[137]

HIPAA goes on to distinguish between two types of disclosures: permissive and required disclosures. "Required disclosures include a covered entity's provision of a patient's own protected health information to the patient or patient's representative, and requests by the HHS secretary for PHI for audit or enforcement."[138] On the other hand, permissive disclosures are all other disclosures that fit two categories: those without patient authorization and those that require patient authorization.[139] Disclosures without patient authorization include exchanges between providers regarding the treatment of a patient and billing for services.[140] Disclosures requiring patient authorization include exchanging information with the patient's

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[134] *See* 45 C.F.R. § 164.408 (2013).

[135] Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended in various sections of 42 U.S.C.).

[136] Hiller, et al., *supra* note 51 at 121.

[137] With the expansion of EHRs in the last decade, this change to HIPAA has helped bring accountability to organizations that may contribute to a breach, but patients deserve heightened rights to protect their own data. *Id.* at 12-14.

[138] Melissa Goldstein, Lee Repasch & Sara Rosenbaum, *Chapter 6: Emerging Privacy Issues in Health Information Technology,* in HEALTH INFORMATION TECHNOLOGY IN THE UNITED STATES: WHERE WE STAND 97 (David Blumenthal et al. eds., 2008), *available at* https:// folio.iupui.edu/bitstream/handle/10244/784/hitreport.pdf [http:// perma.cc/ SSE5-BUHS].

[139] *Id.*

[140] *Id.*

representative and requests by the HHS for enforcement purposes.[141]

Protected health information means "individually identifiable health information" that is held or transmitted by a covered entity in any form or media.[142] Patient authorization is required when the provider is receiving some form of remunerations for the exchange.[143] However, no authorization is required to share health information when being treated, securing payment, or in performing health care operations.[144] Disclosure should be limited to the "minimum necessary."[145] A covered entity may share de-identified information to help improve the public's understanding of the quality of health care.[146]

Under HIPAA, enforcement is left to the Secretary of HHS. There is no private right of action under HIPAA (federal law).[147] Some states provide a private cause of action[148] under state HIPAA- type statutes, such as California, for example.[149] This represents a conscious decision on the part of Congress to favor the exchange of protected health information over patient privacy rights.[150]

Only HHS has jurisdiction to enforce HIPAA and seek penalties for HIPAA violations. HIPAA violations can include

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[141] *Id.*

[142] 45 C.F.R. § 160.103 (2010).

[143] SUMMARY OF THE HIPAA PRIVACY RULE, U.S. DEP'T OF HEALTH & HUMAN SERVICES, SUMMARY OF THE HIPAA PRIVACY RULE at 3 (2003), http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf.

[144] American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 13405(d), 123 Stat. 115, 264 (2009).

[145] *Id.*

[146] *Id.*

[147] *Id.*

[148] *See* Daniel J. Gilman & James C. Cooper, *There is a Time to Keep Silent and a Time to Speak, The Hard Part is Knowing Which is Which: Striking the Balance Between Privacy Protection and the Flow of Health Care Information*, 16 MICH. TELECOMM. & TECH. L. REV. 279, 302, 309 (2010).

[149] For example, the California HIPAA-type statutes regulate the disclosure of medical information by providers and actions that can be brought by unlawful disclosure of patient information. CAL. CIV. CODE § 56.10-16 (2014).

[150] *See id.*

civil and potentially criminal penalties.[151] There are differing degrees of penalties depending on the intent of the violation.[152] Penalties can be levied against both business associates and covered entities.[153] Enforcement examples can be seen on the HHS website where companies are listed that had a breach affecting more than 500 individuals.[154]

However, individuals should have a private right of action at the federal level. It is their health information that is being mishandled and stolen. They are suffering harm that may become irreparable. Stolen personal information can lead to identity theft. Identity theft can ruin an individual's credit score and lead to financial losses when the theft includes Social Security numbers and birth dates. For medical identity theft, it could lead to confusion of medical history along with financial loss. Moreover, none of these risks are confined by state borders.

After seeking treatment for an ailment, no one wants to have to worry about someone stealing that information. Health care corporations and the government must take extra steps to protect health records or give individuals the right to determine when and what nontreatment-related information is included in them.

III. ANALYSIS: APPLYING EUROPE'S RIGHT TO BE FORGOTTEN TO AMERICANS' HEALTH RECORDS

A. What an American Health Care Privacy Right to be Forgotten Might Look Like

In general, the EU has continuously provided greater individual privacy rights than the United States.[155] It is time

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[151] American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 13410 (a), 123 Stat. 115.

[152] *Id.*

[153] *Id.*

[154] 45 C.F.R. § 164.408 (2013).

[155] Bob Sullivan, *'La Difference' is Stark in EU, U.S. Privacy Laws*, NBC NEWS, (October 19, 2006), http://www.nbcnews.com/id/15221111/ns/technology_and_science-privacy_lost/t/la-difference-stark-eu-us-privacy-laws/#.V0Hn-_krLIU. [https://perma.cc/HJ33-XTMT]. *See also* Convention, *supra* note 48. *See also* Article 29, *supra* note 91. *See* Directive on Cross-Border Healthcare, *supra* note 90. *See* EU Data Protection Directive, *supra* note 53.

the United States acknowledged individual privacy rights and addressed the recent increase in data breaches by offering greater protection to individuals. To address the United States' lack of health information privacy rights, the government should consider the following steps: explicitly recognize a right to data privacy; pass legislation that strengthens HIPAA enforcement granting a private right of action on the federal level; adopt a right of erasure for health data found acceptable to be removed by HHS through administrative notice and comment proceedings; and grant a right to be forgotten in HIPAA for information that is breached and released onto the Internet.

Step One: As the United States Supreme Court has recognized the right to privacy as a fundamental right similar to the EU's right in their European Convention for the Protection of Human Rights and Fundamental Freedoms,[156] the United States needs to pass legislation that would grant an explicit right of privacy for personal data. An American right to data privacy should be similar to a right to privacy found in the French Civil Code. In Article 9, the French Code provides for the right to respect of one's private life[157] French courts have interpreted private life to mean "love life, friendships, family circumstances, leisure activities, political opinions, trade, union or religious affiliations, and state of health."[158] Acknowledgement of such a right in the United States would allow Americans an opportunity to have autonomy over their personal and private data.

Step Two: Pass legislation that strengthens HIPAA enforcement. Legislation should allow a private right of action against HIPAA violators in federal court. Under paragraph two of Article 9 in the French Civil Code, the court is given the necessary measures to stop those infringing on others' privacy.[159] The United States should address data breaches as an infringement on the patients' privacy. HIPAA

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[156] *See* Convention, *supra* note 48.

[157] CODE CIVIL [C. CIV.] art. 9 (Fr.).

[158] *French Legislation on Privacy*, EMBASSY OF FRANCE IN WASHINGTON (Dec. 2, 2007), http://ambafrance-us.org/spip.php?article640 [http://perma.cc/N7ZK-VJSC].

[159] *Id.*

should provide more specific requirements on the level of transparency between covered entities and individual patients when collecting data. More transparency would give patients a better opportunity to make an informed decision.

Step Three: Adopt comparable measures listed in the EU Data Protection Directive. The Directive applies to non-EU companies as seen in *Google Spain*[160] and, since United States' companies are already exposed to the right, a transition would not be that difficult.[161] Legislation should place the protection of data and the free access of information on a level playing field.[162] The United States should adopt a right of erasure that ensures health information no longer relevant to an individual will be removed from certain domains similar to the right found in the proposed European Directive.[163] For examples, doctors who contracted the Ebola virus while working in West Africa and returned home to be cured will not have their reputation tarnished by the information remaining on the Internet. Data becomes susceptible to exposure when it reaches a digital form, this liquidity allows for quick travel among thousands of people, versus one person viewing a paper record they were not supposed to see. It is my proposition that the right to erasure be tested on outdated and irrelevant Internet pages and then implemented into EHRs after trial and error with a right that applies to the Internet.

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[160] In the *Google Spain* decision, the court addressed the territorial issues of the EU Data Protection Directive and affirmed its application to non-EU corporations collecting and storing personal data for advertisement purposes within the EU territories such as Google, Inc. Case C-131/12, Google Spain SL v. Agencia Española de Proteccion de Datos, (AEPD), 2013 ECLI:EU:C:2014:616 (May 13, 2014), at paragraph 60-68.

[161] With the proposed EU General Data Regulation, United States businesses will be subject to EU privacy laws, even though they are located outside of EU territories if they are collecting and storing an EU citizen's personal data. *European Union Imposes Extraterritorial Privacy Obligations on U.S. Businesses*, THOMPSON HINE (May 16, 2014), http://www.thompsonhine.com/publications/european-union-imposes-extraterritorial-privacy-obligations-on-us-businesses [http://perma.cc/Z5G5-NJMF].

[162] EU Data Protection Directive, *supra* note 53.

[163] *Id.*

Step Four: Incorporate into HIPAA the EU's proposal for a right to be forgotten. HIPAA does not recognize a private right of action, and incorporating the EU's proposal for a right to be forgotten would give patients' full autonomy over their health information.[164] A private right of action would provide individuals an opportunity to protect their reputation during a breach.[165] The proposed right to be forgotten empowers individuals to assert greater control over their reputations and identities on the Internet.[166] The controversial right would grant individual citizens the ability to demand the permanent removal of personal content from the Internet.[167] There is an argument that this proposed right would have a negative impact "on freedom of expression and notions of privacy"[168]; however, such a right strengthens these freedoms by allowing revocation of certain expressions, like a painter painting over one of his pieces of artwork.[169] An individual who mistakenly posts on a social media site should have the ability to permanently delete the post from the Internet. Similarly, it allows minors accessing the Internet via social media to erase potentially reputation-destroying posts.

One may ask how this right to be forgotten will apply to EHRs? The right should be applied when a patient no longer seeks care from a certain provider. If the patient has made an affirmative action to see another provider, once the EHR is passed to the new provider, then the patient should have the right to erase the EHR from the prior provider. Additionally, irrelevant health information should be available to the right as well. HHS will play a vital role in determining which health information may be available.[170]

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[164] *Id.*

[165] Emily Adams Shoor, *Narrowing the Right to Be Forgotten: Why the European Union Needs to Amend the Proposed Data Protection Regulation*, 39 BROOK. J. INT'L L. 487, 489 (2014).

[166] Jeffrey Rosen, *The Right to Be Forgotten*, 64 STAN. L. REV. 88 (2012).

[167] Shoor, *supra* note 168.

[168] *Id* at 487.

[169] *Id.*

[170] HHS rulemaking must be done through notice and comment proceeding under the Administrative Procedure Act. Ideally this approach would allow experts to weigh in on the issue and allow HHS to

Empowering patients to control their own health information may lead to better outcomes, although there is no evidence to support this proposition.

Another possible way to protect patient data may be through the Consumer Privacy Bill of Rights Act, a draft bill proposed by the Obama administration.[171] As Nicolas Terry, a professor at Indiana University Robert H. McKinney School of Law, states, the bill goes further than current HIPAA regulations in requiring custodians to furnish a more encompassing privacy policy.[172] Additionally, the bill "presupposes some consent mechanism (removed from HIPAA in 2002) and provides for withdrawal of consent and, in some situations, erasure."[173] The Consumer Privacy Bill of Rights is a step in the right direction for the Obama administration and begins the all too important first step in the realization of a right of health data privacy mentioned within this Note.

B. Problems With An American Right to be Forgotten

Implementation of the right to be forgotten would be a difficult, but not impossible, endeavor for the United States. The right to be forgotten would have to be a legislatively-created right and the statute constitutionally permissible. The United States courts, legislature, and even the Constitution have not given an explicit right to privacy for electronic health data. While the European Union's right to

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make a rule that is as well tested as possible. *See* Administrative Procedure Act, 5 U.S.C. § 553 (2015).

[171] Nicolas Terry, *Should Health Lawyers Pay Attention to The Administration's Privacy Bill?*, HEALTH AFFAIRS (Mar. 13, 2015), http://m.healthaffairs.org/blog/2015/03/13/should-health-lawyers-pay-attention-to-the-administrations-privacy-bill/ [http://perma.cc/CA3U-ABX3] (discussing the Consumer Privacy Bill of Rights Act and its potential application to the health care industry).

[172] *Id.*

[173] *Id.* Professor Terry illustrates the difficulty in the United States allowing data minimization in the health care industry. Currently, we operate under a system that supports the transferability of data. Professor Terry argues that the greatest impact will be felt by "big data brokers and [health] app developers."

be forgotten stays within the realm of data privacy[174] and not health information, the United States form should encompass both.

Furthermore, the United States' courts have not recognized a right of privacy for health information that the right to be forgotten would require.[175] A health information right of privacy would grant individuals autonomy over what health information appears on the Internet and what non-treatment information is in the health records. Bipartisanship support in the United States legislature has proven difficult to attain. Thus, getting such a right passed through both houses and signed into law by the President may prove an immense challenge. Once passed, the implementation could take years before the right is fully available to individuals.[176] First Amendment proponents will attack the right as a way to diminish the freedom of speech and expression.[177]

The EU has not been immune from free speech arguments against their right to be forgotten. The defense was raised after the European Court of Justice issued the *Google Spain* decision.[178] The EU saw two very different principles collide: the right of privacy and the freedom of speech.[179] It reconciled the two rights by limiting removal of information to "inaccurate, inadequate, or no longer relevant" personal information.[180] However, the European Court of Justice failed to provide definitions to these terms.[181] The United

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[174] General Data Protection Regulation, *supra* note 68.

[175] Whalen v. Roe, 429 U.S. 589, 605-06 (1977).

[176] Joel Reidenberg, *Restoring American's Privacy in Electronic Commerce*, 14 BERKELEY TECH. L.J. 771, 787 (1999).

[177] *See* Shoor, *supra* note 164, at 498-500.

[178] Luciano Floridi, *Should You Have the Right to be Forgotten On Google? Nationally, Yes. Globally, No.*, HUFFINGTON POST, http://www.huffingtonpost.com/luciano-floridi/google-right-to-be-forgotten_b_6624626.html [http://perma.cc/2TGK-ZNMT] (last updated Apr. 7, 2015).

[179] *Id.*

[180] *Id.*

[181] Opponents of the decision are worried about its effects on freedom of expression, especially in the context of journalistic and artistic expression. They continue by pointing out that the court failed to explain the right to be forgotten's application to the other fundamental rights, such as the freedom of expression. Eleni Frantziou, *Further*

States Constitution protects the freedom of speech, [182] which poses an even larger hurdle for a statutorily created right to electronic data privacy. However, Congress may pass a constitutionally permissible statute allowing a right to electronic data privacy if it is similarly narrowly defined and does not infringe on the freedom of speech.[183] A right to electronic data privacy could look similar to the common law doctrine of informed consent. Informed consent provides that physicians will make a guideline as to what information the patient needs to make a reasonable decision regarding their treatment.[184] A right to electronic data privacy will require the provider to disclose to the patient where and what data will be electronically transferred. Similar to informed consent, it will require the patient to agree to the transfer of the data between "covered entities" and "business associates."[185]

Once implemented, HHS will have to decide which parts of a patient's health information will be available to be "forgotten." Any information that is not relative to a current treatment and anything past six years should be subject to the right. HHS will determine which information is available by a notice and comment rulemaking procedure.[186] HIPAA holds a similar retention period for its policies and procedures.[187] For example, someone with high blood pressure would not be able to erase any data related to the patient's heart health. However, a patient who was cured of an ailment or a symptom should be able to have that

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Developments in the Right to be Forgotten: The European Court of Justice's Judgment in Case C-131/12, Google Spain, SL, Google Inc. v Agencia Espanola de Proteccion de Datos, 14 HUM. RTS. L. REV. 761, 767 (2014).

[182] U.S. CONST. amend. I.

[183] *See* Floridi, *supra* note 177.

[184] *See generally* Canterbury v. Spence, 464 F.2d 772 (1972).

[185] *Id.*

[186] This procedure could include looking at allowing patients to revoke all consent for providers to collect and store their information, or it could include patients being able to remove certain ailments such as a sprained ankle that experts feel may not affect other ailments. Administrative Procedure Act, 5 U.S.C. § 553 (2015).

[187] Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended in various sections of 42 U.S.C.).

information forgotten until the patient is ready to disclose it. Merriam-Webster Dictionary defines cure as "recovery or relief from a disease,"[188] and symptom as "a change in the body or mind which indicates that a disease is present."[189] However, the HHS department will likely need to create a board with members appointed by the President to determine which symptoms and ailments will be available for removal. The President has the power of appointment under Article II of the Constitution[190] to appoint leading minds in the medical field to the board. Community insight from the notice and comment requirements under the Administrative Procedure Act could be a valuable tool in determining the ailments and diseases to be subject to the right.[191]

Further, the patient will have the ability to revoke consent to the transmission of their information at any time in the health care delivery system. Every company with access to protected information will be subject to HIPAA right to be forgotten, and must relay notification of their access to such data to each individual.

Push back from "covered entities" and "business associates" in the health care industry will be significant. The health care industry will likely argue that the past legislation has pushed them to have electronic health records be more accessible, whereas this would attempt to restrict the free flow of records.[192] Providing a private right of action for violations of the right to be forgotten and subsequent data breaches would place added liability on these health providers.[193] This will likely lead to an increase in health care costs in the U.S. However, the higher costs to a strengthened HIPAA will ideally reflect in lower fraud costs. Once the

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[188] *Cure Definition*, MERRIAM-WEBSTER DICTIONARY, http://www.merriam-webster.com/dictionary/cure [http://perma.cc/59L5-3LFB] (last visited Feb. 7, 2016).

[189] *Symptom Definition*, MERRIAM-WEBSTER DICTIONARY, http://www.merriam-webster.com/dictionary/symptom [http://perma.cc/YRU8-ZMW6] (last visited Feb. 7, 2016).

[190] U.S. CONST. art. II, § 2.

[191] Administrative Procedure Act, 5 U.S.C. § 553 (2015).

[192] Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended in various sections of 42 U.S.C.).

[193] Shoor, *supra* note 164 at 491.

system is in effect, then costs will likely fall, and fraud costs will remain at a low rate. Another provider criticism will point to the lack of patient awareness or patients not being informed enough to make reasonable decisions on what information to erase.[194] While this may always be the case with some patients, educating the population may be able to increase patient awareness and use of the right.

The EU model for the right of erasure and right to be forgotten places the onus on the consumer (in this case the patient) to make an informed decision.[195] This could prove difficult for an American populace that has historically been far removed from the health delivery system. Patients can become quickly overwhelmed when asked to make a medical decision on their own,[196] however, a push for more health care education regarding price and options should be available. Patients also rarely know the prices of the treatment they receive beforehand. This lack of knowledge is largely due to the third party payer system the United States has adopted. Today, patients under HMOs have very little say in their own health care. The HMOs provide a list of physicians and networks in which the patient may choose.[197] The average patient will have little choice but to accept what the HMOs have already decided for them.[198] The cost of health care will continue to rise under such a system, because the patient is far removed from the payment process.

C. Solutions

First for such a plan to work, the legislature must recognize a right to electronic data privacy of the individual.

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[194] Reed Abelson & Julie Creswell, *Report Finds More Flaws in Digitizing Patient Records*, N.Y. TIMES (Jan. 8, 2014) *available at* http://www.nytimes.com/2014/01/08/business/report-finds-more-flaws-in-digitizing-patient-files.html?_r=0 [http://perm.cc/ SJK4-9J4W].

[195] General Data Protection Regulation, *supra* note 68.

[196] Jan Hoffman, *Awash in Information, Patients Face a Lonely, Uncertain Road*, N.Y. TIMES (Aug. 14, 2005), *available at* http://www.nytimes.com/2005/08/14/health/14patient.html?pagewanted=all&module=Search&mabReward=relbias%3Aw%2C%7B%222%22%3A%22RI%3A14%22%7D [http://perma.cc/V84D-6V26].

[197] *Id.*

[198] *Id.*

As a society, we must continue to push for greater data privacy rights. The right to electronic data privacy encompasses the requirement of consent for nontreatment-related information in a patient file and the removal of articles and health-related posts on social media. Such a right should be granted to all individuals. A right to electronic data privacy allows individuals autonomy over what information is disclosed to the public rather than third party corporations.[199]

Second, the ACA's push for a national electronic health records system must be realized.[200] This would improve the accessibility, effectiveness and security of electronic health records. It would also allow for easy removal of unnecessary information from patient records.[201] For example, a patient who removes consent to a provider holding nontreatment related information such as the patient's birthdate or Social Security Number. Once the patient pays his or her bill for the services provided, the patient will have the opportunity to remove that information from their file. In this way, the patient is afforded some protection in case of a data breach.

Under the HITECH act, Congress provided for billions of dollars in incentives for physicians and hospitals to move to electronic health records.[202] However, with vast amounts of health care providers' records not on the same system, the easy flow of information from one system to another has proven to be difficult.[203] Further, Congress failed to understand how valuable medical information was to hackers and identity thieves. Networks are not protected nor compatible to move information.[204] For security to properly

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[199] Shoor, *supra* note 164.

[200] *Key Features of the Affordable Care Act By Year*, U.S. DEP'T HEALTH & HUMAN SERVS., http://www.hhs.gov/healthcare/facts-and-features/key-features-of-aca-by-year/index.html [http://perma.cc/23S6-UMYX] (last updated Aug. 13, 2015).

[201] *See* Abelson & Creswell, *supra* note 194.

[202] 42 U.S.C. § 300jj-31 (2016).

[203] Julie Creswell, *Doctors Find Barriers to Sharing Digital Medical Records*, N.Y. TIMES, (Sept. 30, 2014)http://www.nytimes.com/2014/10/01/business/digital-medical-records-become-common-but-sharing-remains-challenging.html [http://perma.cc/6JGR-YNHA].

[204] *See id.*

protect health records, the exchange system must be properly tested and run smoothly. Employees operating the system must be adequately trained, as the most common form of data breach is employee related.[205] Employee breaches include lost or stolen computer equipment and "unintentional employee action."[206] Even though rigorous employee training accidents will still occur, the government can mitigate and limit the number of accidents.

In Britain, they attempted a similar national health electronic records system, but it failed.[207] British Parliament attempted to install such a system without working with health care providers.[208] It appears that the current United States attempt to install a national system of electronic health records will fail without a cohesive effort by everyone involved.[209] A national system of electronic health records could prove a valuable defense against hackers and medical identity thieves. For such a system to work, health care providers, legislators, and electronic health tech companies would have to work hand in hand. Otherwise, electronic health records will continue to have problems in exchanges.

There needs to be more transparency in the health care system. Patients are disconnected from the health care system.[210] Patients have limited autonomy outside of choosing whether or not to adhere to a treatment plan.[211] Patients are not given enough information to determine which provider to attend or what procedure is most effective.[212] Along with needing more information on data privacy, the American system of third party payers leaves many patients unaware of treatment costs. Data regarding

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[205] Bendix, *supra* note 42.

[206] *Id.*

[207] Steve Lohr, *Lessons from Britain's Health Information Technology Fiasco*, N.Y. TIMES BITS BLOG (Sept. 27, 2011, 7:40 AM) http://bits.blogs.nytimes.com/2011/09/27/lessons-from-britains-health-information-technology-fiasco/?module=Search&mabReward=relbias%3Aw%2C%7B%222%22%3A%22RI%3A14%22%7D/ [http://perma.cc/58Y3-4H4V].

[208] *Id.*

[209] *Id.*

[210] Abelson & Creswell, *supra* note 194.

[211] Hoffman, *supra* note 196.

[212] *Id.*

care and privacy needs to be readily available to the average layperson in order for them to make an informed decision.

IV. CONCLUSION

The United States must address its lack of individual privacy protections. The United States needs to address the lack of health data privacy protections. In today's technological world, individual privacy rights must be strengthened to the point individuals can trust providers to keep their information safe. American citizens should have the right to be forgotten rather than have their information lost or stolen.

Similarly, technology is constant and everywhere in today's world, and the United States has provided limited protections to personal data. The United States must move quickly towards a legislative solution to solve the data protection issues facing the nation.[213] The current EU Data Protection Directive took five years to implement.[214]

The United States should adopt the EU's right of erasure to protected health information. A right of erasure would require extensive cooperation between the two political parties to adopt such a differing stance on privacy rights.[215] A right of erasure would allow patients complete control over the transmission of their information, along with the ability of patients to revoke consent to providers collecting and storing their information. Such a right would also allow patients to erase prior treatments, ailments, and symptoms that are no longer related to the patients care. For example, after the Ebola crisis, patients should not have to keep in their records retained by their health care providers that they were diagnosed with the virus.

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[213] Reidenberg, *supra* note 176, at n.1. (examining surveys that show ". . . 82 % of those surveyed feel that consumers have lost all control over how companies collect and use their personal information.").

[214] *Id.* at 787.

[215] *See generally* Terry, *supra* note 171. (explaining the changes under the 1015 draft bill). Under the Democratic Obama administration, the 2015 Consumer Privacy Bill or Rights Act will extend HIPAA to greater protect health data, but it is yet to be passed in a Republican-controlled Congress.

Kaci Hickox returned from West Africa aiding the nations stricken most severely by the Ebola virus.[216] Upon her return and an elevated temperature at the airport, Hickox was quarantined by airport officials and required to stay home for a 21-day period.[217] She engaged in a public fight with Maine officials over whether her travel after the 21-day monitoring period should be restricted.[218] Even though she won, her name will remain on the Internet for years to come. Patients like Kaci Hickox should have the right to be forgotten.

The Obama administration's Consumer Privacy Bill, or Rights Act, is an important first step for the United States toward a right to be forgotten. Data privacy is increasingly becoming a major issue in the both political and economic spheres of the country.[219] It is important to solidify the right to health data privacy to protect against the ever-present threat of cybercriminals.

Imagine once more Jane Doe waking to a breaking story on the news that her health insurance provider's system was the victim of a cyberattack. However, Jane rests easy, because she can exercise her right of erasure and her right to be forgotten, and her highly sensitive health data and private information may be removed with a click of a button. These rights place the power to access, collect, and store this information where it should be, in the individual's hands. The health care industry has continually failed to protect individuals' information, and it is time the United States has addressed the issue with stronger protections for individual data privacy.

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[216] Dana Ford, *Ebola Nurse Kaci Hickox, Boyfriend Plan to Leave Maine Town*, CNN (Nov. 10, 2014, 11:30 AM), http://www.cnn.com/2014/11/09/health/ebola-nurse/ [http://perma.cc/4C5X-TGNM].

[217] *Id.*

[218] *Id.*

[219] *See* PONEMON INST. LLC, *supra* note 31, at 1 (according to the Ponemon Institute study, a compromised file could cost a company up to $200).

A HOSPITAL-WITHIN-A-HOSPITAL: GOOD FOR HOSPITALS, GOOD FOR PATIENTS

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I. INTRODUCTION

Hospitals face constant pressure to achieve both financial health and their mission of promoting health and wellness within the communities they serve. The ever-changing regulatory landscape of the health care industry forces hospitals to constantly adapt to new methods of treating patients while meeting specific quality measures and managing their budgets. Hospitals are complex organizations and keeping them afloat operationally is a difficult task, fraught with financial penalties and bad publicity for any missteps. Credit rating agencies are forecasting a negative outlook for non-profit healthcare due to credit ratings downgrades, decreases in cash, and the uncertainty that the newly elected 2015 Republican-led Congress will make changes to the Patient Protection and Affordable Care Act, also known as the Affordable Care Act ("ACA") or "Obamacare."[1]

As hospitals adjust to the new regulatory requirements of the Affordable Care Act, like value-based purchasing, more penalties for hospital acquired conditions, and the

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[1] Robin Respaut, *Grim Outlook for Healthcare, Hospital Sector in 2015: Rating Agencies*, REUTERS (Dec. 16, 2014, 7:08 PM), http://www.reuters.com/article/2014/12/17/us-healthcare-nonprofit-ratings-idUSKBN0JV00R20141217 [http://perma.cc/LY5C-YZNY]. Under a Republican majority, the House of Representatives has held more than 50 votes to either repeal or defund parts of the ACA or the entire ACA since it became law in 2010. *House GOP to Hold First ObamaCare Repeal Vote of New Congress*, FOX NEWS (Jan. 27, 2015), http://www.foxnews.com/ politics/2015/01/27/house-gop-to-hold-first-obamacare-repeal-vote-new-congress/ [http://perma.cc/357Q-ZS5M].

readmissions reduction program, they are forced to make adjustments.

Value-based-purchasing is an incentive system that will change the amount hospitals are paid based on their performance. Payments to hospitals will be adjusted based "on their performance on 4 domains that reflect hospital quality: the clinical process of care domain, the patient experience of care domain, the outcome domain, and the efficiency domain."[2] The ACA mandates "a hospital value-based purchasing program in Medicare to pay hospitals based on performance on quality measures."[3] Fee-for-service models of reimbursement, where hospitals charge for each service performed on the patient as opposed to overall outcome, are being supplanted by value-based care. Value-based care is a growing trend among the biggest insurance companies, because insurance companies tend to follow Medicare and Medicaid trends.[4] A shift toward

> value-based reimbursements has been a major driver of healthcare reform, and United Healthcare is not the only commercial payer to signal a major shift toward this strategy. Aetna and Cigna have been two of the most active private health insurers to create ACOs and

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[2] *Hospital Value-Based Purchasing*, MEDICARE.GOV, http://www.medicare.gov/hospitalcompare/Data/hospital-vbp.html [http://perma.cc/A9K8-HCFC] (last visited Feb. 12, 2016).

[3] *Summary of the Affordable Care Act*, THE KAISER FAM. FOUND. (Apr. 25, 2015), http://kff.org/health-reform/fact-sheet/summary-of-the-affordable-care-act/ [http://perma.cc/5NNP-WCKV].

[4] Bob Herman, *United HealthCare to Double Value-Based Contracts with Providers by 2017*, BECKER'S HOSP. REV. (July 10, 2013), http://www.beckershospitalreview.com/accountable-care-organizations/unitedhealthcare-to-double-value-based-contracts-with-providers-by-2017.html [http://perma.cc/ZK4N-WJYH].

> accountable care deals with hospitals and physicians.[5]

Seeking to reduce inefficiencies in care is important to insurers as well.[6] Value-based care will pressure hospitals and health care providers to shift resources toward improving areas measured by these metrics.

Beginning in October of 2008, hospitals had to supply information about conditions present on admission ("POA") and did not "receive additional payment for cases in which one of the selected conditions was not present on admission. That is, the case would be paid as though the secondary diagnosis were not present."[7] Basically, the policy is based

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[5] *Id.*

[6] Bruce Japsen, *Blue Cross' $65 Billion Move Away From Fee-For-Service Medicine*, FORBES (July 9, 2014, 11:00 AM), http://www.forbes.com/sites/brucejapsen/2014/07/09/blue-cross-65-billion-move-away-from-fee-for-service-medicine/ [http://perma.cc/XDK5-47TW].

[7] *Hospital-Acquired Conditions (Present on Admission Indicator)*, CMS.GOV, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html?redirect=/hospitalacqcond/06_hospital-acquired_conditions.asp [http://perma.cc/9ATZ-9HU2] (last visited Feb. 28, 2016). The details of this program are as follows:

> On February 8, 2006, the President signed the Deficit Reduction Act (DRA) of 2005. Section 5001(c) of DRA requires the Secretary to identify conditions that are: (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines. Section 5001(c) provides that CMS can revise the list of conditions from time to time, as long as it contains at least two conditions. *Id.*

on the idea that the government should not reward hospitals for treating patients for conditions that a patient contracted while at the hospital that could have potentially been avoided by better hospital practices.

This payment structure encouraged hospitals to take measures to combat Hospital-Acquired Conditions ("HACs"). Additional penalties for Hospital-Acquired Conditions ("HACs") were implemented by Obamacare.[8] This program will result in reduced Medicare payments to hospitals that do not meet quality metrics involving hospital acquired conditions. A score is created for hospitals based on

> rank in the worst performing quartile . . . with respect to hospital-acquired conditions . . . . identified by calculating a Total HAC score which is based on the hospital's performance on risk adjusted quality measures. Hospitals with a Total HAC score above the 75th percentile of the Total HAC Score distribution may be subject to payment reduction beginning October 1, 2014.[9]

Hospitals must make investments to develop or refine internal processes that prevent patients from acquiring additional illnesses during their stay.

Established by the Affordable Care Act, the Readmissions Reduction Program also imposes penalties on hospitals.[10] The Secretary of the Health and Human Services agency

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[8] *Hospital-Acquired Condition Reduction Program*, MEDICARE HOSP. COMPARE, http://www.medicare.gov/hospitalcompare/HAC-reduction-program.html [http://perma.cc/T6WE-6Q35] (last visited Mar. 12, 2015).

[9] *Linking Quality to Payment*, MEDICARE HOSP. COMPARE, http://www.medicare.gov/hospitalcompare/linking-quality-to-payment.html?AspxAutoDetectCookieSupport=1 [http://perma.cc/3EGD-CAWK] (last visited Feb. 28, 2016).

[10] *Id.*

("HHS") is charged with taking excess readmissions into consideration when making payments to hospitals.[11] In addition to financial penalties, the readmissions rates will also be posted on the CMS website "Hospital Compare."[12] This will impact hospitals as consumers will have the opportunity to research prices for different procedures before selecting a hospital or outpatient clinic.

Carrots and sticks like value-based purchasing, the Readmissions Reductions program, and HAC program are "the wave of the future for hospital payments and should be viewed as a cumulative force demanding performance improvement[.]"[13] Additionally, "[b]y 2017, the combined penalties will put as much as 6% of inpatient Medicare reimbursements at risk."[14] This will put pressure on hospitals to react to this new status quo.

In March of 2015, the Supreme Court heard oral arguments on *King v. Burwell*, where it was argued that the subsidies from the federal government for people who purchased health insurance from the federal health insurance exchange were illegal, based on the interpretation of an IRS rule.[15] The outcome of *King v. Burwell* was to have an impact on whether individuals, in states that only use the federal health insurance exchange market,

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[11] 42 U.S.C. § 1395ww(q) (2016).

[12] 42 U.S.C. § 1395ww(q)(8)(B) (2016).

[13] Sabriya Rice et al., *More Hospitals to Get Bonuses Than Penalties in 2015 Under Value-Based Purchasing*, MODERN HEALTHCARE (Dec. 18, 2014), http://www.modernhealthcare.com/article/20141218/NEWS/141219982 [http://perma.cc/FM58-28T9].

[14] *Id.*

[15] King v. Burwell, 135 S. Ct. 2480, 2482 (2015).

HealthCare.gov,[16] would receive subsidies to help them afford health insurance.[17] Thirty-four states relied on the federal exchange for their insurance market, and roughly six and a half million people stood to lose their subsidies if the Supreme Court found that the federal health insurance exchange markets were illegal.[18] Without the subsidies, less patients would have insurance, and the amount of uninsured patients would likely increase.

Subsidies have made an impact on hospital debt because they result in less uninsured patients whose costs hospitals have to absorb.[19] In 2015, there was an increase in the number of Indiana residents who enrolled through the federal marketplace.[20] Enrollment for Hoosiers was 132,423 in 2014, and in 2015 it increased to 218,617.[21] The increased number of insured patients has resulted in a surge in patient volume, but hospitals are struggling with the costs of increasing staff to handle the patient volume.[22] The uncertainty around the *King* decision made it difficult for hospitals to operate efficiently while they evaluated whether or not they should maintain staff at current levels and proceed as if the number of insured patients will continue to increase or if they need to reduce staff if the pool of insured patients decreases if subsidies are not preserved. Although

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[16] HEALTHCARE.GOV, http://www.healthcare.gov/ [http://perma.cc/GV8C-UEDT68H4-JNJ3] (last visited Feb. 12, 2016).

[17] King v. Burwell, 135 S. Ct. 2480, 2482 (2015).

[18] *The Health Care Supreme Court Case: Who Would Be Affected?* N.Y. TIMES, http://nytimes.com/interactive/2015/03/03/us/potential-impact-of-the-supreme-courts-decision-on-health-care-subsidies.html?_r=0 [http://perma.cc/82CE-2KJU] (last updated June 22, 2015).

[19] Caroline Humer & Bill Berkrot, *U.S. Hospitals Optimistic They'll Dodge Bullet With Obamacare Ruling*, REUTERS (Mar. 4, 2015, 6:16 PM), http://www.reuters.com/article/2015/03/04/us-usa-court-healthcare-hospitals-idUSKBN0M02NC20150304 [http://perma.cc/3PU9-C9SR].

[20] Barbara Brosher, *More Hoosiers Enroll in Healthcare Coverage for 2015*, IND. PUB. MEDIA (Feb. 18, 2015), http:// indianapublicmedia.org/news/hoosiers-enroll-healthcare-coverage-2015-78383/ [http://perma.cc/95DG-ELDG].

[21] *Id.*

[22] Beth Kutscher, *Reform Update: Hospitals See More Paying Patients, but There's a Hitch*, MODERN HEALTHCARE (Aug. 20, 2014), http://www.modernhealthcare.com/article/20140820/NEWS/308209965 [http://perma.cc/WA5A-8SKK].

the outcome of *King* maintained the subsidies, hospitals will continue to face great uncertainty as different aspects of the ACA are attacked and reviewed, especially during the upcoming presidential election.

The competition among hospitals and the internal pressures within hospitals is fierce. Pressure to gain new patients, maintain prowess in the community, achieve financial stability, and provide the best care possible to all patients is intense. As a result of this increasing competitive pressure, it is not uncommon for the public to frequently encounter commercials and billboards advertising shorter wait times in emergency rooms, new specialty centers, and a facility's latest ranking of varying significance. The inundation of advertisements gives the prospective patient the impression that the hospitals are all trying to shout over one another in an effort to attract the patient's attention and business.

As more people are covered by high-deductible insurance plans, where patients must pay a greater amount out of pocket before their health care costs are covered by their insurance, there is a general sense that patients are interested in greater price transparency. The Indiana Hospital Association created a tool called CareINSight for patients to view aggregated hospital price and quality data for the more than 165 hospitals in Indiana based on the chargemasters hospitals submit to the Indiana State Department of Insurance.[23] While this tool is not a perfect

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[23] J.K. Wall, *Hoosier Hospitals Create New Tool to Help Health Care Shoppers*, IND. BUS. J. (Jan. 5, 2015), http://www.ibj.com/blogs/12-the-dose/post/51173-hoosier-hospitals-create-new-tool-to-help-health-care-shoppers?utm_source=ibj-

way to view all relevant data because it does not include information from all of the different payers who will pay for hospital procedures, the number of all-payer claims databases is likely to grow.[24] All-payer claims databases will put pressure on hospitals to incur additional administrative costs in order to maintain this information.

There are many pressures on hospitals to be more efficient without sacrificing quality. These challenges present an opportunity for hospitals to create new structures to adjust to this pressure while managing patient satisfaction, quality, and their bottom line.

A. The Issue

As discussed above, the health industry is facing many new regulatory changes that present operational and financial challenges. Colocation via the hospital-within-a-hospital structure could relieve some of the pressures hospitals must navigate. The unique structure of a hospital-within-a-hospital provides a means for hospitals to gain financial efficiencies, and improve patient care–by reducing readmission rates by ensuring patients receive better care, and providing a means for Catholic hospitals that acquire secular hospitals to address the needs of the communities they serve while adhering to their moral objectives.

B. Roadmap

This Note will examine the "hospital-within-a-hospital" structure under the general rules for hospitals excluded from the prospective payment systems[25] and analyze the advantages and disadvantages of this structure for hospitals and patients. Also analyzed is how the hospital-within-a-hospital structure provides a means to ease the impact of

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daily&utm_medium=newsletter&utm_content=the-dose&utm_campaign=2015-01-06 [http://perma.cc/3WNX-WQS2].

[24] *Id; See also* APCD Council, *The Basics of All-Payer Claims Databases: A Primer for States*, ROBERT WOOD JOHNSON FOUND. (Jan. 2014), http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2014/rwjf409988 [http://perma.cc/39AF-N7XX].

[25] 42 C.F.R. § 412.22 (2016).

regulatory uncertainty on hospitals and how the type of hospitals, currently allowed to operate hospitals-within-hospitals, should be expanded to include hospitals other than specialty hospitals.

Part II of this Note will discuss the Medicare reimbursement for a hospital-within-a-hospital, the design and operation of the hospital-within-a-hospital, the requirements hospitals must adhere to in order to be compliant with the regulation and therefore receive the appropriate type of Medicare reimbursement, and alternatives to hospitals-within-hospitals.

Part III of this Note will analyze the advantages of the hospital-within-a-hospital including: potential reduction in readmission rates for the host hospital which in turn benefits the patients as consumers of health care, an increase in access to specialty hospitals, and how the separateness of the structure could increase access to certain services.

Explored in Part IV of this Note are the disadvantages of the hospital-within-a-hospital, including overbilling, which leads to Medicare overpayment, and complications that arise when disaster preparedness is inadequate between the hospital-within-a-hospital and the host hospital.

II. BACKGROUND

A. Medicare Reimbursement for Hospitals-Within-Hospitals

Even though participation is voluntary, hospitals choose to participate in the Medicare program for a variety of

reasons, such as tax exemptions.[26] Health care providers who want to accept Medicare payments must abide by CMS regulations. Medicare is a health insurance program run by the Centers for Medicare and Medicaid Services ("CMS"), as the operating agent of the Department of Health and Human Services ("HHS"), meant to assist both the elderly and the disabled.[27] Hospitals agree to provide hospital services to those eligible for Medicare when hospitals file their agreement with the Secretary of HHS.[28] Acute care hospitals agree to accept Inpatient Prospective Payment System ("IPPS") payments when they deliver inpatient care to Medicare patients.[29] Medicare pays for acute care hospital operating costs under a system called the prospective payment system ("Inpatient PPS"), where each discharge is paid for according to a predetermined specific rate.[30] The prospective payment system was established for:

> the operating costs of inpatient hospital services furnished to Medicare beneficiaries in cost reporting periods beginning on or after October 1, 1983 and a prospective payment system for the capital-related costs of inpatient hospital services furnished to Medicare beneficiaries in

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[26] *Underpayment by Medicare and Medicaid Fact Sheet*, AM. HOSP. ASS'N, 1 (Nov. 2009), www.aha.org/content/00100010001000-100010/09medicunderpayment.pdf [http://perma.cc/5RFM-DN3R].

[27] Select Specialty Hosp. Akron, LLC v. Sebelius, 820 F. Supp. 2d 13, 15-16 (D.D.C. 2011).

[28] 42 U.S.C. § 1395cc (2016).

[29] Dept. of Health and Human Svcs. Ctrs. for Medicare & Medicaid Svcs., *Acute Care Hospital Inpatient Prospective Payment System* (Apr. 2013), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AcutePaymtSysfctsht.pdf [http://perma.cc/Y2PN-35XV]. .

[30] *See Select Specialty Hosp.*, 820 F. Supp. 2d at 17.

> cost reporting periods beginning on or after October 1, 1991.[31]

Payments made to participating hospitals are made on the basis of prospectively determined rates and applied on a per discharge basis.[32] The payment system is not structured in a way to reimburse hospitals for long-term hospital care because the average stay for Medicare patients at general acute-care hospitals is roughly six days.[33] A hospital-within-a-hospital is excluded from this payment system. Instead, they are compensated at a level that is often more favorable.

B. Hospital-Within-a-Hospital Design and Operation

Under 42 C.F.R. § 412.22(e), "Excluded hospitals and hospital units: General rules", a hospital-within-a-hospital is a hospital that operates in the same building as its host hospital or in a building on the same campus as its host hospital.[34] This is sometimes referred to as co-location.[35] The host hospital is "a general acute care hospital located in the same building or on the same campus as [a long-term-care-

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[31] 42 C.F.R. § 412.1(a) (2016).

[32] *Id.*

[33] *See Select Specialty Hosp.*, 820 F. Supp. 2d at 17.

[34] 42 C.F.R. § 412.22(e) (2016).

[35] Cherilyn G. Murer, Separate But Related—Hospitals Within Hospitals and the 15 Percent Inpatient Operating Costs Limitations 1, available at http://murer.com/pdfs/articles/thecolocationequation.pdf [http://perma.cc/6295-Z3SH].

hospital]."[36] Colocation is typically arranged through a lease arrangement.[37]

Facilities that meet the requirements for a hospital-within-a-hospital are excluded from this Medicare Inpatient prospective payment system.[38] In order to be the type of facility allowed to become a hospital-within-a-hospital, the facility must be licensed as of the several classes of "excluded hospitals."[39] These facilities include:

1. Psychiatric hospitals, which must primarily provide psychiatric care, including the diagnosis and treatment of the mentally ill,[40]

2. Rehabilitation hospitals, which must comport with specific requirements,[41]

3. Children's hospitals, which must have a provider agreement and provide care to patients under eighteen years of age,[42] and

4. Long-term care hospitals ("LTCH"), which are one of the types of specialty hospitals permitted to operate as hospitals-within-hospitals, must have an average length of stay that is greater than twenty-five days.[43] Because of concerns involving overbilling Medicare, a moratorium on all new long-term care hospitals has been established.[44]

In part, due to concerns about hospitals working together to double bill Medicare for the same patient, there are requirements in place for a host hospital and hospital-within-a-hospital to qualify for reimbursement under 42 C.F.R. § 412.22(e). Maintaining separateness is at the root of the

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[36] *Select Specialty Hosp.*, 820 F. Supp. 2d at 17.
[37] Murer, *supra* note 35, at 1.
[38] 42 C.F.R. § 412.22(e) (2016).
[39] 42 C.F.R. § 412.22(a) (2016).
[40] 42 C.F.R. § 412.23(a) (2016).
[41] 42 C.F.R. § 412.29 (2016).
[42] 42 C.F.R. § 412.23(d) (2016).
[43] 42 C.F.R. § 412.23(e) (2016).
[44] 42 C.F.R. § 412.23(e)(6) (2016).

requirements for fulfilling the criteria to qualify as a hospital-within-a-hospital. The operations of both the host hospital and the hospital-within-a-hospital are structured in a way to prevent collusion between the host hospital and the hospital-within-a-hospital.

This separateness is often signified in terms of control. Control is defined as having "the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution."[45] The governing body of the hospital-within-a-hospital must be separate from the governing body of the host hospital.[46] The chief medical officer of the host hospital, who is responsible for the actions of the medical staff, may not be employed by or have a contract with the hospital-within-a-hospital.[47] The medical staff must also be separate. This means that the host hospital's medical staff has nothing to do with the hospital-within-a-hospital's staffing activities, including granting privileges.[48] The chief executive officer of the host hospital may not be "employed by or under contract with the hospital occupying space in the same building or on the same campus or any third entity that controls both hospitals."[49]

However, in addition to requirements on separate governance and staffing the hospital-within-a-hospital also has to meet one of the three criteria explored in further detail below to establish the separateness of the two hospitals and qualify as a hospital-within-a-hospital:

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[45] 42 C.F.R. § 412.22(g) (2016).
[46] 42 C.F.R. § 412.22(e)(1)(i) (2016).
[47] 42 C.F.R. § 412.22(e)(1)(ii) (2016).
[48] 42 C.F.R. § 412.22(e)(1)(iii) (2016).
[49] 42 C.F.R. § 412.22 (e)(1)(iv) (2016).

1. Perform "basic functions" without contracting with the host hospital to provide these services,[50]

2. No more than fifteen percent of the host hospitals' inpatient operating costs may come from contracts with the hospital-within-a-hospital,[51] or

3. Seventy-five percent of the hospital-within-a-hospital's inpatient population must be referred from somewhere besides the host hospital.[52]

1. Separateness Requirement: Basic Functions

As the first option to establish separateness between the host hospital and the hospital-within-a-hospital, the hospital-within-a-hospital must perform basic hospital functions "through the use of employees or under contracts or other agreements with entities other than the hospital occupying space in the same building or on the same campus, or a third entity that controls both hospitals."[53] Basic functions are defined as: "quality assurance, medical staff services, nursing services, medical record services, pharmaceutical services, radiologic services, laboratory services, utilization review, and infection control."[54] It is permissible for the hospital-within-a-hospital to contract with the host hospital or any third party that controls both hospitals to provide "food and dietetic services and housekeeping, maintenance, and other services necessary to maintain a clean and safe physical environment."[55]

One of the issues with this rule is that the host hospital could provide basic functions in the most cost-effective

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[50] 42 C.F.R. § 412.22(e)(1)(v)(A) (2016).
[51] 42 C.F.R. § 412.22(e)(1)(v)(B) (2016).
[52] 42 C.F.R. § 412.22(e)(1)(v)(C) (2016).
[53] 42 C.F.R. § 412.22 (e)(1)(v)(A) (2016).
[54] Murer, *supra* note 35, at 2.
[55] 42 C.F.R. § 412.22(e)(1)(v)(A) (2016).

manner for the hospital-within-a-hospital.[56] A hospital-within-a-hospital that is, for example, only comprised of twenty beds would not see operational efficiencies if it were forced to procure costly assets like radiological or laboratory equipment.[57] Additionally, it would inconvenience patients and increase costs if the hospital-within-a-hospital needed to call an ambulance any time a patient needed a test that the hospital-within-a-hospital was not equipped to perform and is then obligated to arrange and pay for an ambulance to transport the patient to a facility that did have the equipment.[58]

This option is still available. However, in response to the concerns about the lack of convenience and cost effectiveness of the basic services rule, CMS added two alternatives that a hospital-within-a-hospital could choose to fulfill the idea of separate function while easing the burden of the original rule.[59]

2. Separateness Requirement: Contracts with Hospital-Within-A-Hospital No More Than Fifteen Percent of Host's Total Inpatient Operating Costs

As another option to establish separateness between the host hospital and the hospital-within-a-hospital, the hospital can ensure that

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[56] Murer, *supra* note 35, at 2.
[57] *Id.*
[58] *Id.*
[59] *Id.*

> the cost of the services that the hospital obtains under contracts or other agreements with the hospital occupying space in the same building or on the same campus, or with a third entity that controls both hospitals, is no more than 15 percent of the hospital's total inpatient operating costs . . . .[60]

The fifteen percent of total inpatient operating costs cap on services rule has been described as the most confusing rule for hospitals-within-hospitals because of the difficulty in accounting for which services count towards the fifteen percent.[61] However, most hospitals choose to abide by this rule.[62] Inpatient operating costs include costs for routine services, like the cost of the room and board and nursing, ancillary services including inpatient radiology and laboratory services, and the malpractice insurance costs associated with inpatient care.[63] Costs that must be included in the fifteen percent maximum a hospital-within-a-hospital may contract with the host for includes equipment and facility repairs and maintenance, cleaning, utilities, and general liability insurance.[64] The hospital-within-a-hospital may not contract with the host hospital or an entity that controls the host hospital for pharmacy, nursing services or medical records.[65] However, the hospital-within-a-hospital is permitted to attempt to realize cost efficiencies by contracting with the host hospital for "dietetic, housekeeping, and maintenance services."[66]

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[60] 42 C.F.R. § 412.22(e)(1)(v)(B) (2016).
[61] Murer, *supra* note 35, at 1.
[62] *Id.*
[63] 42 C.F.R. § 412.2(c) (2016).
[64] Murer, *supra* note 35, at 4.
[65] *Id.*
[66] *Id.*

3. Separateness Requirement: Inpatient Population Referral

If a hospital chooses to adhere by the "75% Rule," no more than twenty-five percent of the inpatient population of the hospital-within-a-hospital can be referred by the host hospital.[67] This means that seventy-five percent of the referrals to the hospitals must come from a source other than the host hospital.[68] If a hospital-within-a-hospital chooses this option as the means to establish separateness from the host hospital, it will deny itself the opportunity to form a mutually beneficial relationship with the host hospital because most hospitals-within-hospitals "receive the bulk of their referrals from the host hospital."[69]

C. Alternatives to Hospitals-Within-Hospitals

It is important to note that the term "hospital-within-a-hospital" is used to refer generally to any arrangement that has multiple hospitals in the same physical location, but that does not mean that the facility is a true "hospital-within-a-hospital" under the statute. Some hospitals market specialty floors as "hospitals-within-hospitals" when in fact they are just remote locations or satellite facilities, subject to other requirements. A satellite facility is a part of a hospital that provides inpatient services in a building also used by another hospital.[70] Satellite facilities are also restricted to "hosting"

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[67] 42 C.F.R. § 412.22(e)(1)(v)(C) (2016).
[68] *Id.*
[69] Murer, *supra* note 35, at 3.
[70] *Select Specialty Hosp.*, 820 F. Supp. 2d at 17.

only psychiatric, rehabilitation, children's, and long-term care hospitals.[71] Satellite facilities are also similar to hospitals-within-hospitals because they may not be controlled by the same board or CEO as the host hospital, "and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located."[72]

Hospitals are accredited by surveyors who evaluate whether or not the hospital is complying with Medicare's Conditions of Participation "for all services, areas and locations covered by the hospital's provider agreement under its CMS Certification Number (CCN)."[73]

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[71] 42 C.F.R. § 412.22 (h) (2016).

[72] 42 C.F.R. § 412.22 (h)(2)(iii)(A) (2016).

[73] *Hospitals*, CMS.GOV, http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Hospitals.html [http://perma.cc/5CNH-NZDF] (last visited Feb. 28, 2016).

The satellite hospital has a "home" facility. The satellite hospital may have the same CMS Certification number as its originating facility.[74]

III. ADVANTAGES OF HOSPITALS-WITHIN-HOSPITALS

A. A Hospital-Within-A-Hospital Increases Physician Empowerment

Clinical co-management is the means by which a hospital and an independent physician group (made up of physicians who are not employed by the hospital) form a relationship to

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[74] The Joint Commission describes the CCN as:

> A hospital's CMS' Certification Number (CCN), is the hospital's identification number and is linked to its Medicare provider agreement. The CCN is used for CMS certification. Certain types of health care facilities, including hospitals, seeking to participate in the Medicare program are required not only to satisfactorily complete the Medicare enrollment application, but also to be certified as meeting the Medicare health and safety standards. The CCN is also used for submitting and reviewing the hospital's cost reports. The CCN number used to be called the "provider number," but with the advent of the statutorily mandated National Provider Identifier (NPI) number for claims processing, the CCN now plays a different role within the Medicare program.

Frequently Asked Questions about Accrediting Hospitals in Accordance with their CMS' Certification Number (CCN), THE JOINT COMMISSION (Oct. 15, 2010), http://www.jointcommission.org/faqs_ccn/ [http://perma.cc/VEK6-5KBK].

work together to manage a particular area of a hospital.[75] Physicians struggle to maintain control of their independence as "mom and pop" shops are gobbled up by large hospital systems and they are forced to work for a large system. There are several types of relationships physician groups may form with hospitals. These include joint ventures, where the hospital and physician group form a limited liability company or other "joint venture business entity [ ] [that] then contracts with the hospital to provide defined management services and leadership."[76] The physician group then receives payment through "management fees paid by the hospital to the new entity[.]"[77] Physicians may also create a physician entity that contracts with the hospital, where physicians are reimbursed for "management time and incentive for achieving certain goals."[78] A hospital could "designate[] a few key administrators to sit on a council, or board, with select physicians" and work to "[d]efine[] service line or program goals and initiatives and helps to lead and coordinate hospital resources in achieving the objectives. Under the broad definition, hospital leadership and physicians are working collaboratively to achieve mutually beneficial objectives."[79] None of these would compare to the freedom the physicians could have if they ran a specialty hospital-within-a-hospital.

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[75] Samuel G. Agnew & Bryan J. Warren, *When Does Clinical Co-Management Make Sense? 8 Considerations for Selecting the Model Right for Your Hospital*, BECKER'S HOSP. REV. (Feb. 1, 2012), http://www.beckershospitalreview.com/hospital-physician-relationships/when-does-clinical-co-management-make-sense-8-considerations-for-selecting-the-model-right-for-your-hospital.html [http://perma.cc/RRR7-ZAJZ].

[76] *Id.*

[77] *Id.*

[78] *Id.*

[79] *Id.*

There have been concerns related to physician referral patterns when physicians own health care facilities, specifically that they are "more likely than other physicians to refer well-insured patients to their facilities and route Medicaid patients to hospital outpatient clinics."[80] In the case of hospitals-within-hospitals, the physicians are not operating outpatient clinics. Rather, they have managerial control at the hospital for which they work. This set-up will not lead to excessive or inappropriate referrals as long as guidelines are in place and physicians and hospitals understand ethical limitations.

The hospital-within-a-hospital structure is highlighted as a way for physicians to regain control and be empowered to reduce medical errors. By

> sell[ing] off operational units to physician specialists. In a sense, hospitals would [break apart] the hospital [into smaller pieces], vesting clinical and operational control to physician owners. Such a development follows a natural progression from the joint venture arrangements hospitals have engaged in with specialists in the outpatient area, and that are now seen on the inpatient side, most typically in the creation of "hospitals within" hospitals.[81]

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[80] Jon R. Gabel, et al., *Where do I Send Thee? Does Physician-Ownership Affect Referral Patterns to Ambulatory Surgery Centers?*, 27 HEALTH AFF. w165 (2008), *available at* http://content.healthaffairs.org/content/27/3/w165/suppl/DC2 [http://perma.cc/L98L-DYMU].

[81] John D. Blum, *Feng Shui and the Restructuring of the Hospital Corporation: A Call for Change in the Face of the Medical Error Epidemic*, 14 HEALTH MATRIX J.L. MED. 5 (2004).

Any arrangements made by physicians and hospitals must not violate any health care fraud and abuse statutes. The analysis depends on the specific arrangement with the hospital and host hospital, and while the analysis is beyond the scope of this Note, it is necessary to draw attention to these two important statutes. The Stark Law prohibits physician "self-referrals."[82] Physicians are not permitted to make referrals for health services classified as "designated health services" ("DHS").[83] The Stark Law also "prohibits the entity from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third party payer) for those referred services[]" and "[e]stablishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse."[84]

Another ethical minefield that impacts the health care industry and hospitals is what is known as the federal Anti-Kickback Statute ("AKS").[85] This statute calls for criminal penalties for making false statements and also for arranging for or offering illegal remunerations, meaning incentives like a bribe, to take certain actions.[86] Illegal remunerations are an issue with the hospital-within-a-hospital because the structure could be impermissible if hospitals were involved in schemes to exclusively refer patients to the hospital-within-a-hospital.

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[82] *Physician Self-Referral*, CMS.GOV, http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html?redirect=/physicianselfreferral/ [http://perma.cc/SL2F-65VJ] (last updated Jan. 5, 2015, 10:59 AM).

[83] 42 U.S.C. § 1395nn(h)(6) (2016). DHS includes: clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; inpatient and outpatient hospital services. *Id.*

[84] *Physician Self-Referral*, *supra* note 82.

[85] 42 U.S.C. § 1320a-7b (2016).

[86] *Id.*

The hospital-within-a-hospital and the host hospital will need to ensure that any arrangements are not in violation of these regulations.

B. Reduction in Readmission Rates

Readmission penalties from the Affordable Care Act make the hospital-within-the-hospital structure attractive as an incentive for hospitals to ensure readmission rates are low and for patients, who understandably do not wish to spend any more time than necessary in the hospital. Medicare payments will be reduced as a way to penalize hospitals for readmissions. Penalties have been doled out to three-fourths of hospitals that are included in the Hospital Readmissions Program and some have said that the pressure of penalties has encouraged hospitals to improve communications with other health care providers.[87]

Excess readmissions are a focus of the Affordable Care Act, which established the Hospital Readmissions Reduction Program. The Secretary of HHS was tasked with establishing a program for hospitals to reduce readmission rates for certain conditions.[88] The policy defines readmission for certain conditions and a calculation for them.[89] CMS

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[87] Jordan Rau, *Medicare Fines 2,610 Hospitals in Third Round of Readmission Penalties*, KAISER HEALTH NEWS (Oct. 2, 2014), http://kaiserhealthnews.org/news/medicare-readmissions-penalties-2015/ [http://perma.cc/A2FG-GYLP].

[88] 42 U.S.C. § 280j-3 (2016).

[89] *Readmissions Reduction Program (HRRP)*, CMS.GOV, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html

started adjusting payments to IPPS hospitals that are calculated to have excess readmissions on October 1, 2012.[90] Excess readmissions are calculated by a specific formula through CMS.[91]

[http://perma.cc/RJH2-SXXT] (last modified Feb. 4, 2016, 1:55 PM). The policy

> [d]efined readmission as an admission to a subsection (d) hospital within 30 days of a discharge from the same or another subsection (d) hospital; Adopted readmission measures for the applicable conditions of acute myocardial infarction (AMI), heart failure (HF) and pneumonia (PN); Established a methodology to calculate the excess readmission ratio for each applicable condition, which is used, in part, to calculate the readmission payment adjustment. A hospital's excess readmission ratio [for AMI, HF and PN] is a measure of a hospital's readmission performance compared to the national average for the hospital's set of patients with that applicable condition. Established a policy of using the risk adjustment methodology endorsed by the National Quality Forum (NQF) for the readmissions measures [for AMI, HF and PN] to calculate the excess readmission ratios, which includes adjustment for factors that are clinically relevant including certain patient demographic characteristics, comorbidities, and patient frailty. Established an applicable period of three years of discharge data and the use of a minimum of 25 cases to calculate a hospital's excess readmission ratio for each applicable condition. *Id.*

[90] *Id.*

[91] *See* Julimes, *Health Policy Brief: Medicare Hospital Readmissions Reduction Program*, HEALTH AFF. (Nov. 12, 2013), *available at* http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_102.pdf [httpshttp://perma.cc/P52M-R55R]. Excess readmissions are defined as follows:

> [f]or purposes of the HRRP, *excess readmissions* are defined as those that exceed a hospital's "expected

When a patient is discharged from a hospital, it is likely that some sort of follow-up or additional action has been advised, from taking medication on a certain schedule to asking the patient to be sure to check in with their primary care physician. A hospital-within-a-hospital may reduce transitional care issues between the host hospital and the specialty facility. This would benefit both the patient, who will not have to endure another hospital stay, as well as the host hospital, who will not be penalized for a readmission.

A 2014 report by Kaiser Health News, a nonprofit health policy news service, illuminates reasons that CMS is increasing its efforts to prevent readmissions.[92] According to the report, "[n]early one in five fee-for-service Medicare patients returns to the hospital within 30 days of being discharged[.]"[93] A high readmission rate is sometimes an

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> readmission rate." A hospital's expected readmission rate for each of the HRRP conditions is the national mean readmission rate, risk-adjusted for the demographic characteristics (for example, age and sex) and severity of illness of the hospital's patients. The penalty is calculated using a complex formula based on the amount of Medicare payments received by the hospital for the excess readmissions. The penalties are collected from the hospitals through a percentage reduction in their base Medicare inpatient claims payments, up to a cap. The ACA set the penalty cap at 1 percent of aggregate IPPS base payments for the first year, 2 percent for the second year, and 3 percent for each year thereafter.

Id. at 3.

[92] Niall Brennan, *Findings from Recent CMS Research on Medicare*, CMS 28, http://kaiserhealthnews.files.wordpress.com/2014/10/brennan.pdf [http://perma.cc/L6LZ-B774] (last visited Feb. 28, 2016).

[93] *Id.* at 28.

"indicator of poor quality care[.]"[94] Additionally, of the $26 billion that readmissions will cost Medicare each year, $17 billion of the costs may be avoidable.[95]

The hospital-within-a-hospital structure can be an effective tool to prevent excess readmissions, saving patients the hardship of enduring an additional stay at the hospital and saving Medicare, and ultimately the taxpayer, the costs related to readmissions. The hospital-within-a-hospital arrangement can alleviate issues with transitional care when a host hospital transfers a patient to the hospital-within-a-hospital so that the individual can receive specialized services, which in turn could improve the readmission rates for the host hospital. Under the Affordable Care Act, hospitals will face reductions in their Medicare payments as a penalty for excessive readmissions.[96] This means there is a financial incentive for hospitals to ensure patients receive appropriate transitional treatment.

C. Specialty Hospitals Expand Access to Care

There are financial restraints that prevent hospitals from opening up new children's hospitals in order to capture more business and serve additional populations. Construction costs often make new hospitals cost prohibitive. The hospital-within-a-hospital can be a means to create additional profit centers and improve the hospital's image or reputation. By arranging to lease space in a host hospital, the hospital-within-a-hospital can deliver care in an area where it previously did not make financial sense to set up an entire hospital to serve a smaller number of patients. This can expand access to a specific specialty hospital, like a

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[94] *Id.*
[95] *Id.*
[96] *Id.* at 42.

children's hospital establishing a hospital-within-a-hospital in a rural host hospital.

In the past decade, there was an increase in specialty hospitals,[97] which could lead to improvements in care because of the increased competition. Some groups are not in favor of an increase in specialty hospitals because general hospitals are unable to capitalize on these specialty cases the way a specialty hospital can because they cannot pick and choose their patients as easily.[98] General hospitals may fail to capture revenue for procedures that would help them finance other low-profit cases.[99]

Hospitals across the country are developing centers geared towards specific health concerns and patients.[100] This increase in specialty facilities demonstrates a "simple unifying theme behind this multifaceted array of institutions: specialty medicine."[101] Of the specialty endeavors, they "may be housed on separate floors within a hospital, be in separate administrative units (in- or outpatient) within a hospital, represent organizations within a hospital but with a distinct managerial structure ("hospital within a hospital"), be an entirely separate specialty hospital, or be physician owned."[102]

Hospitals-within-hospitals are able to capitalize on the demand for specialty medicine. The hospital-within-a-hospital arrangement is advantageous for certain hospitals

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[97] David Shactman, Specialty Hospitals, Ambulatory Surgery Centers, and General Hospitals: Charting a Wise Public Policy Course, 24 HEALTH AFF. 868, 868 (2005), *available at* http://content.healthaffairs.org/content/24/3/868.full.pdf [http://perma.cc/89WH-CMU4].

[98] *Id.*

[99] *Id.*

[100] Robert A. Berenson et al., *Specialty-Service Lines: Salvos in the New Medical Arms Race*, 25 HEALTH AFF. w337, w337-w339 (2006), *available at* http://content.healthaffairs.org/content/25/5/w337.full.pdf [http://perma.cc/K36F-EPN9].

[101] *Id.* at w337.

[102] *Id.* at w339.

because they can "brand" their specialty and then offer their services at a remote location.

D. A Unique Model of "Separateness"

Although maternity units are not one of the care facilities excluded under the prospective payment system, a careful implementation of the "separateness" requirement could allow hospitals to use the hospital-within-a-hospital structure to facilitate delivery of certain types of health care services while protecting Catholic hospitals from violating deeply held convictions over permissible and impermissible health care services. Compelled to adhere to the *Ethical and Religious Directives for Catholic Health Care Services*, ("*Ethical and Religious Directives*"), moral guidelines created by the United States Conference of Catholic Bishops, Catholic hospitals usually have policies in place to refuse to provide certain services generally considered standard on moral grounds.[103] Although individual providers practicing at a Catholic hospital may bend these rules at the hospital on an individual level (where they would likely be subject to discipline), or maintain separate offices to perform these services, Catholic hospitals typically do not offer reproductive services. Reproductive services usually include contraception,[104] sterilization, abortion and infertility

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[103] *See* UNITED STATES CONFERENCE OF CATHOLIC BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH CARE SERVICES (5th ed. 2009), *available at* http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf [perma.cc/9PYG-5NC5].

[104] Lois Uttley & Ronnie Pawelko, No Strings Attached: Public Funding of Religiously-Sponsored Hospitals in the United States (2002), *available at* http://www.mergerwatch.org/storage/pdf-files/bp_no_strings_hilights.pdf [http://perma.cc/9J9G-EKEK]. This prohibition is of particular interest to some advocacy groups who fear that

services, and counseling for safe sex.[105] There may also be restrictions on a patient's end of life choices, as the medical team that handles end of life wishes may be required to follow the patient's wishes only to the extent that the wishes comport with the *Ethical and Religious Directives*.[106] Certain treatments derived from embryonic stem cell research, even those accepted in the wider medical community, may also be prohibited.[107] This is because according to the *Ethical and Religious Directives*, the Catholic Church "cannot approve medical practices that undermine the biological, psychological, and moral bonds on which the strength of marriage and the family depends."[108]

There was a sixteen percent increase in the number of Catholic hospitals from 2001 to 2011.[109] In light of this increase, the hospital-within-a-hospital structure could be an opportunity to better serve the patient population of a geographic area where people only have convenient access to a Catholic hospital.[110] For example, a Catholic health care system that hosts an independent, secular hospital-within-a-hospital could provide treatment that the *Ethical and Religious Directives* do not allow. This would make additional healthcare services available to the local population and quell fears that the increase in Catholic hospital systems merging or acquiring secular hospitals will

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the refusal to administer emergency contraception, even to victims of rape, will place an unfair and uncontrollable burden on the community served by the Catholic hospital.

[105] *Id.*

[106] *Id.*

[107] *Id.*

[108] UNITED STATES CONFERENCE OF CATHOLIC BISHOPS, *supra* note 103, at 23.

[109] Lois Uttley, Sheila Reynertson, Lorraine Kenny & Louise Melling, Miscarriage of Medicine: The Growth of Catholic Hospitals and the Threat to Reproductive Health Care 4 (2013), *available at* http://www.aclu.org/sites/default/files/field_document/growth-of-catholic-hospitals-2013.pdf [http://perma.cc/2NR4-CRKU].

[110] *See id.*

lead to a reduction in available health care services for a community. This could also be a business opportunity for a hospital to specialize in operating hospitals-within-hospitals in Catholic hospitals. Of course, Catholic hospitals should not be compelled to participate in or endorse a practice that they find morally objectionable. There are many issues with Catholic hospital mergers that are outside the scope of this Note, but they include first amendment rights for medical staff that do not wish to compromise their moral beliefs by mandates that they provide certain types of treatments; issues with the providers who do not want a different kind of institutional conscience imposed on what they believe is their right to practice medicine as they see fit; and contentions that hospitals that treat Medicare and Medicaid patients, who may be elderly, disabled, and impoverished, should offer basic care.

A few Catholic hospitals have created models with similar "separateness" requirements, and one example is a hospital in Austin, Texas. This hospital used an arrangement that resembled the "hospital within a hospital" requirements, required by 42 C.F.R. § 412.22, to allow a community "safety net" hospital to survive financially while not depriving members of the community of reproductive services like emergency contraception.[111] Seton, a Catholic hospital that the Daughters of Charity of St. Vincent De-Paul owned and managed, entered into a public-private partnership lease agreement with Brackenridge Hospital, owned and operated by the city of Austin, Texas, where Seton leased buildings from Brackenridge.[112] Brackenridge, the city-owned hospital, was in serious financial trouble and was looking for

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[111] Barbra Mann Wall, *Conflict and Compromise: Catholic and Public Hospital Partnerships*, 18 NURSING HIST. REV. 100 (2010), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2886734/pdf/nihms204840.pdf [http://perma.cc/Q7XK-4UCM].

[112] *Id.* at 100.

a lifeline to prevent its seemingly inevitable closure.[113] Brackenridge Hospital played a crucial role in providing health services to community members of limited means, and its closure would have had a detrimental impact on this population.[114] The fact that if Brackenridge Hospital was forced to shut its doors because of its financial situation, the poor would effectively be denied health care because the only other option was a for-profit hospital that would not provide the same amount of charity care led to the acceptance of this arrangement.[115] This risk to the poor served as a powerful impetus to come to an arrangement that would allow Seton, as a Catholic entity, to serve the health care needs of the poor in the community while not compromising the moral principles to which Seton was ethically and morally compelled to adhere.[116]

Initially, the terms of the arrangement were organized so that Seton, the Catholic hospital, never performed and was never directly involved in care that was designated as morally objectionable by the *Ethical and Religious Directives,* but these reproductive services forbidden by the *Ethical and Religious Directives* were allowed to take place at Brackenridge.[117] This type of compromise was in compliance with the *Ethical and Religious Directives* at the time due to a number of nuances in the arrangement,

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[113] *Id.*
[114] *Id.*
[115] *See generally id.*
[116] *Id.* at 101.
[117] *Id.*

including that Brackenridge was not deemed a Catholic hospital.[118]

When the *Ethical and Religious Directives* were later updated to forbid any type of working arrangement with a group that facilitated services the Catholic Church perceived as intrinsically evil, the hospitals had to adjust the arrangement, again to fulfill their duty to serve the needs of the poor in the community while still adhering to the highly-regarded *Ethical and Religious Directives* essential to their operation as a Catholic hospital .[119] Seton paid to create a solution that embodied similar characteristics to the hospital-within-a-hospital authorized by statute and allowed the hospital to continue to meet the medical needs of the poor community while maintaining "separateness." They included remodeling a floor of the hospital so that the secular, separately licensed facility could have "its own pharmacy, medical records area, nursing unit, housekeeping, and separate elevator."[120] This floor of the building was where all sterilization and contraceptive services, services the *Ethical and Religious Directives* does not support or allow on moral grounds, took place.[121] The parties involved believed there were sufficient restrictions on contraceptives provided on an emergency basis that it was morally permissible for the Catholic hospital to allow the distribution of emergency contraceptives.[122] Before transferring a woman in need of emergency contraceptives to the hospital-within-a-hospital "secular" floor, the woman had to be tested to ensure she was not ovulating at the time the medication was administered because otherwise the use of contraceptives would be morally impermissible.[123] Although this arrangement might even surprise some devout Catholics as overly permissive, critics of the compromise said the restrictions interfered with and unnecessarily complicated the care female patients received.[124]

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[118] *Id.* at 105-106.
[119] *Id.* at 109-110.
[120] *Id.* at 111.
[121] *Id.* at 110.
[122] *Id.*
[123] *Id.* at 111.
[124] *Id.* at 110-11.

As the *Ethical and Religious Directives* tightened to forbid associations and compromises, this type of arrangement became more difficult, but if the *Ethical and Religious Directives* are ever modified to allow close relationships between secular and Catholic health care providers, the hospital-within-a-hospital structure is a novel framework to structure an arrangement through the separateness requirements, basic function, or the fifteen percent rule.

Burdett Care Center in Troy, New York is another example of a Catholic host hospital with a secular "hospital-within-a-hospital" that, like Brackenridge and Seton, embodies the structure of the hospital-within-a-hospital authorized by statute and shows that if separateness can be established to a level where a Catholic institution can share space with a hospital engaging in acts the Catholic institution believes is morally wrong, surely the statutory requirements are sufficient for operational separateness.[125] Samaritan Hospital's parent corporation, Northeast Hospital, engaged in merger discussions with a Catholic hospital system, St. Peter's Health Care Services, regarding a merger with St. Mary's Hospital.[126] Initially, there was alarm that the merger would restrict access to reproductive services.[127] As a compromise, the new parent corporation of the two new partners was St. Peter's Health Partners, where

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[125] Lois Uttley, et al., *Merging Catholic and Non-Sectarian Hospitals: New York State Models for Addressing the Ethical Challenges*, 17 N.Y. ST. B.A. HEALTH L.J. 38, 41 (2012), *available at* http://static1.1.sqspcdn.com/static/f/816571/23042588/1372882137057/Models+of+Catholic-secular+hospitals+mergers+in+NYS.pdf?token=8wf9c2JeNXfIN8cT4A4olwNiuSo%3D/ [http://perma.cc/3PXC-J6QQ].

[126] *Id.*

[127] *Id.*

"corporate 'members' St. Peter's and Seton Health retain[ed] their identities as Catholic facilities and member Northeast Health (including Samaritan Hospital) retain[ed] its identity as a non-sectarian health care system."[128] This arrangement resulted in the creation of Burdett Care Center, a "hospital-within-a-hospital" on the second floor of Samaritan Hospital.[129] The Burdett Care Center is a fifteen bed maternity hospital that "preserves services that can no longer be offered by Samaritan itself, under the terms of the merger: sterilization procedures, birth control and treatment of certain pregnancy emergencies."[130] In line with the separateness requirements, Samaritan provided a five million dollar trust to serve as a "financial buffer" and the Burdett Care Center established a different board and different staff than Samaritan.[131]

It should be noted that while a specific hospital board and the bishop of a Catholic diocese who controls whether or not the agreement is allowed may agree to a similar arrangement, the strongly held call to respect and protect life means that many Catholics may still find these arrangements objectionable and consider them to be an unconscionable compromise. Additionally, changes to the *Ethical and Religious Directives* could bar this type of arrangement as well, and Catholic hospitals should not be compelled to arrangements that violate them. For instance, in November of 2014, the U.S. Conference of Catholic Bishops voted to update the *Ethical and Religious Directives* as they relate to the relationships of Catholic hospitals with secular hospitals.[132] Specifically, this encompasses "matters such as

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[128] *Id.*

[129] *Id.*

[130] *Id.*

[131] *Id.*

[132] Nina Martin, *Catholic Bishops Vote to Revise Rules for Health Care Partnerships*, PROPUBLICA (Nov. 11, 2014, 10:17 AM),

decisions of hospital administrators regarding possible cooperative arrangements with non-Catholic entities; distinctions between formal and material cooperation with evil; and moral decision-making as it applies to joint actions with partners, boards and other bodies."[133] There is speculation that the revisions will most likely make arrangements more difficult and less compromising. Regardless, the separateness and the benefits of the hospital-within-a-hospital system are a beneficial solution for the merging of Catholic and secular hospitals without compromising the types of services offered to women in the community. These secular-Catholic arrangements are examples of how two hospitals with different missions can coexist and serve the diverse needs of a community.

IV. PROBLEMS ASSOCIATED WITH A HOSPITAL-WITHIN-A-HOSPITAL

A. Overbilling

Fear of hospitals overbilling or double billing for services is a common reason hospitals-within-hospitals are discouraged or disliked by those charged with protecting tax dollars and evaluating the expenditure of American dollars allocated to health care. Concerns that an LTCH hospital-

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http://www.propublica.org/article/catholic-bishops-weigh-tightening-rules-for-health-care-partnerships [http://perma.cc/T244-37HZ].

[133] Bishops to Vote on Proposal To Revise 'Ethical and Religious Directives for Catholic Health Care Services' at November Meeting, UNITED STATES CONFERENCE OF CATHOLIC BISHOPS (Oct. 27, 2014), http://www.usccb.org/news/2014/14-171.cfm [http://perma.cc/7ZTP-YGLL].

within-a-hospital can lead to overbilling of Medicare resulted in a moratorium for new LTCH hospitals.[134] In 2006, these concerns were best articulated by Herb B. Kuhn, then the director of CMS, who said at a hearing that nearly half of LTCHs were hospitals-within-hospitals, and over a ten-year period the number of LTCH hospitals-within-hospitals grew thirty-five percent.[135] Kuhn contended that while CMS acknowledged that the arrangement can benefit patients and generate many operational efficiencies, "[colocation] also leads to patient shifting from one part of a hospital to another, resulting in two Medicare payments for what is essentially one episode of patient care."[136]

A common perception of the LTCH, and the hospital-within-a-hospital in general, is that hospitals-within-hospitals create a mutually beneficial arrangement where the hospital-within-a-hospital is able to lease out an acute care hospital's extra space and empty beds and use the host hospital as a pipeline for patients.[137] The argument is that the host hospital "gets a rent-paying tenant for its formerly unused space, and the LTCH saves the cost of building a free-standing facility and gets a steady provider of sick people."[138]

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[134] 42 C.F.R. § 412.23(e)(6) (2016). "[F]or the period beginning December 29, 2007 and ending December 28, 2012, [ ] a moratorium applies to the establishment and classification of a long-term care hospital [ ] or a long-term care hospital satellite facility . . . ." *Id.*

[135] *Long Term Acute Care Hospitals: Hearing before the Subcomm. on Health of the Comm. on Ways and Means*, 109th Cong. 2 (2006) (statement of Director Herb B. Kuhn, Center for Medicare Management, Ctrs. for Medicare and Medicaid Svcs., U.S. Dept. of Health and Human Svcs), *available at* http://www.gpo.gov/fdsys/pkg/CHRG-109hhrg30439/html/CHRG-109hhrg30439.htm [http://perma.cc/74EP-NJ7F].

[136] *Id.*

[137] Josh Levin, *The Other Katrina Hospital Mystery*, SLATE (Sept. 4, 2009, 7:03 AM), http://www.slate.com/articles/news_and_politics/prescriptions/2009/09/the_other_katrina_hospital_mystery.single.html [http://perma.cc/9XR5-PXD6].

[138] *Id.*

In agreement, concerns have been articulated that "because the relationship between long-term care [hospitals-within-hospitals] and their host hospitals is necessarily close, the two institutions could easily work together to circumvent the cost control intent of Medicare's PPS payments." [139]

This concern has also been expressed in case law, where there are concerns that the hospital-within-a-hospital arrangement would tempt the acute care host hospital to abuse the system. For example,

> [a]n acute care hospital that consistently discharges a higher cost patient to a postacute care setting for the purpose of lowering its costs undercuts the foundation of the IPPS DRG system, which is based on averages. In this circumstance, the hospital would recoup larger payments from the Medicare system than is intended under the DRG system because the course of acute treatment has not been completed. At the same time, the patient, still under active treatment for an acute illness, will be admitted to a LTCH, thereby generating a second admission and Medicare payment that would not have taken place but for the fact of co-location.[140]

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[139] Susan E. Cancelosi, Fighting Medicare Fraud in Long-Term Care Hospitals-within-Hospitals: OIG Documents Ongoing Failures while Industry Groups Complain 2 (unpublished), *available at* http://www.law.uh.edu/healthlaw/perspectives/(SC)LTCHWHrev.pdf [http://perma.cc/38VP-K455].

[140] *Select Specialty Hosp.*, 820 F. Supp. 2d 13, at 18 (quoting 69 Fed. Reg. 28196, 28325 (May 18, 2004)). "Since 1983, under 42 U.S.C. §

In this scenario, Medicare pays more than the necessary amount to the host hospital for the same patient. A letter from the Office of the Inspector General indicated that many LTCHs have not notified Medicare of their co-located status, which will lead to overpayment by Medicare.[141] A hospital-within-a-hospital structure that benefits from the payment system could be bad for taxpayers and may signal that LTCHs need to scrutinize their own adherence to the standards set by Medicare. However, careful adherence to permissible billing practices and clear guidelines from Medicare will help prevent overbilling.

B. "Separateness" as an Impediment to Disaster Preparedness

Beyond payment issues with Medicare that give rise to concerns about the hospital-within-a-hospital structure, another significant barrier that the hospital-within-a-hospital might face is the effectiveness of their plan of action in the event of an emergency. Sharing a physical location while the leadership and staff are independent can lead to difficulties.

The pressure of an impending emergency situation can bring internal hospital system failures to the surface, sometimes in tragic ways. The events that took place at a hospital in New Orleans when the host hospital and hospital-

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1395ww(d) the Medicare program has paid for an acute care hospital's operating costs in furnishing inpatient services to Medicare beneficiaries under a prospective payment system ("Inpatient PPS" or "IPPS"), in which payment is made at a predetermined, specific rate for each discharge." *Id.* at 17.

[141] Daniel Levinson, *Vulnerabilities in Medicare's Interrupted-Stay Policy for Long-Term Care Hospitals*, DEPARTMENT HEALTH & HUM. SERVICES 19 (June 2014), http://oig.hhs.gov/oei/reports/oei-04-12-00490.pdf [http://perma.cc/489R-DLAS].

within-a-hospital, failed to work together in a time of severe crisis brought on by Hurricane Katrina and her aftermath, to illustrate how deadly serious it is for the host hospital and the hospital-within-a-hospital to maintain separate control but also to be aware of emergency plans and coordinate in a permissible manner.

In this case, the hospital-within-a-hospital was an LTCH where patients were extremely ill and in need of constant life-sustaining treatment, that makes any evacuation more dangerous to the health and safety of the patient and more complicated on a logistical level. When Hurricane Katrina struck New Orleans in late August of 2005, chaos ensued. On Sunday, August 28, 2005, Hurricane Katrina was a Category Five storm.[142] Hospitals should have been well-prepared for the destruction that would occur based on warnings from the National Oceanic and Atmospheric Administration, who warned the public that

> [m]ost of the area will be uninhabitable for weeks . . . perhaps longer. At least one half of well constructed homes will have roof and wall failure. . . . The majority of industrial buildings will become non functional . . . . Airborne debris will be widespread and may include heavy items such as household appliances and even light vehicles. . . . Persons, pets, and livestock exposed to the winds will face certain death if struck. Power outages will last for weeks. . .

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[142] *14 Days A Timeline*, FRONTLINE (Nov. 25, 2005), http://www.pbs.org/wgbh/pages/frontline/storm/etc/cron.html [http://perma.cc/LJY6-K54Y].

> water shortages will make human suffering incredible by modern standards.[143]

The mayor of New Orleans at the time, Mayor Ray Nagin, initiated a mandatory evacuation that resulted in 30,000 people placed in emergency shelter at the Superdome.[144] The Superdome was only stocked with enough emergency provisions to feed half the number of people there for three days.[145] Due to the severity of the storm, emergency workers were unable to respond to people in need of help.[146] Once the eye of the storm passed through the city, officials were prepared to begin clean-up efforts.[147] However, the city was unprepared for the still-rising floodwaters that resulted after the levees that protect the city from flooding broke.[148] By Wednesday, August 31, officials estimated that eighty percent of the city was under water, there was rampant looting throughout the city by both opportunistic and desperate individuals, and the focus shifted to evacuating the individuals in the Superdome.[149] Lack of coordination between then-governor of Louisiana, Kathleen Blanco, Federal Emergency Management Agency ("FEMA") director Michael Brown, and New Orleans Mayor Ray Nagin was blamed for the absence of an appropriate and efficient response to the emergency.[150] Frustrated by what he saw as an inadequate response, Mayor Nagin inflamed the public after he spoke on a radio show, with disparaging pronouncements on the action officials had taken.[151] Michael

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[143] *Id.*
[144] *Id.*
[145] *Id.*
[146] *Id.*
[147] *Id.*
[148] *Id.*
[149] *Id.*
[150] *Id.*
[151] *Id.*

Brown, then-FEMA director, admitted to misleading the public in order to maintain calm, despite the fact that the FEMA Situation Update reported that the situation had escalated to the point where, shockingly,

> [l]aw and order all but broke down in New Orleans over the past few days. Storm refugees reported being raped, shot and robbed, gangs of teenagers hijacked boats meant to rescue them, and frustrated hurricane victims menaced outmanned law officers. Police Chief Eddie Compass admitted even his own officers had taken food and water from stores. Officers were walking off the job by the dozens. . . .[152]

Reflecting the significant coordination problems that federal, state and local officials encountered during Hurricane Katrina, LifeCare, a hospital-within-a-hospital, experienced significant difficulties coordinating an evacuation plan with its host hospital that arguably led to patients being euthanized.[153] A contributing factor to the difficulties of the evacuation of this hospital was the lack of understanding about how the two separate hospitals should interact.[154] LifeCare leased the seventh floor at Memorial Medical Center in New Orleans, Louisiana.[155] LifeCare,

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[152] *Id.*

[153] Sheri Fink, *The Deadly Choices at Memorial*, N.Y. TIMES (Aug. 25, 2009), http://www.nytimes.com/2009/08/30/magazine/30doctors.html?pagewanted=all&_r=0 [http://perma.cc/YS7M-3FRQ].

[154] *Id.*

[155] *Id.*

which adhered to the separateness tenant required of LTCHs in the sense that it credentialed its own staff, worked to keep patients who were elderly or incredibly ill alive with technology that some doctors at Memorial believed was too drastic for the patient and a waste of resources.[156] This attitude that patients on the LifeCare floor were "chronically deathbound" contributed to what some experts say was the euthanasia of patients that hospital workers considered too sick to move.[157]

LifeCare was not invited to the discussions that happened among hospital staff over their plan of evacuation when the situation took a turn for the worse.[158] LifeCare had an incident commander who was responsible for organizing the evacuation of the LifeCare patients and had requested that the LifeCare patients be included in Memorial's evacuation plans.[159] The incident commander was told that Memorial would ask their corporate owner, Tenet, for permission to include them in Memorial's evacuation plans.[160] Tenet claims that LifeCare workers rejected an offer of evacuation assistance.[161] Regardless of which side is right, it is clear there was a breakdown in communication among staff and multiple layers of leadership.

In response to the Fink article, Ellen B. Griffith, a spokesperson for CMS, said that because it was not clear there was a LifeCare physician available on the LifeCare floor, it "raises questions about whether the LifeCare facility really was a separately certified hospital from Memorial Medical Center or was actually functioning as a unit of Memorial."[162] This indicates that disregarding the separateness rule can lead to the hospital-within-a-hospital being taken advantage of by host hospital doctors, in addition to contributing to a dangerous silo where communication does not flow freely.

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[156] *Id.*
[157] *Id.*
[158] *Id.*
[159] *Id.*
[160] *Id.*
[161] *Id.*
[162] Levin, *supra* note 137.

Although the issues at Memorial demonstrate the devastating effects of a hospital-within-a-hospital that lacks structures and protocols for their own patients and a lack of understanding of how the hospital-within-a-hospital and the host hospital need to interact, there are examples of hospitals-within-hospitals that have successfully managed emergency situations. An example of a hospital-within-a-hospital that successfully and smoothly handled an emergency evacuation is Triumph Hospital. Triumph Hospital is a long term acute care hospital-within-a-hospital whose host at the time was MeritCare hospital.[163] In the face of dangerous floods as the nearby Red River rose, the health care workers were able to act to prevent threats to patient safety.[164]

When the "evacuation trigger was pulled at MeritCare, patients had been ready to roll for hours, [with] baggies of medicines at their bedsides, checklists on their doors, and bar-coded triage bracelets on their wrists whose colors indicated the type of transport required."[165] The chief clinical officer of Triumph said she felt like she was "overly prepared," a sentiment that the officials at Memorial likely did not experience.[166] The health care providers said that several factors contributed to their success: "flexibility, days

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[163] Sheri Fink, *Disaster Preparedness Pays off in North Dakota*, PROPUBLICA (Mar. 31, 2009, 11:52 AM), http://www.propublica.org/article/disaster-preparedness-pays-off-in-North-Dakota-20090331 [http://perma.cc/8LYJ-2YGJ].

[164] *Id.*

[165] *Id.*

[166] *Id.*

of advance planning, and strong collaboration between health facilities and local, state and federal government."[167]

Other external risks besides natural disasters can present challenges to hospitals-within-hospitals. Another risk to both the host hospital and the hospital-within-a-hospital is infection control. As evidenced by the 2014 Ebola outbreak, infectious diseases can severely impact the health of the community, as well as the public's perception of community safety.[168] Appropriate protocols need to be in place to prevent transferring infections from one institution to another.

Although the events at Memorial Care Center in New Orleans show that a poorly organized plan of action in the face of a disaster can have devastating consequences for patients of a hospital-within-a-hospital, this is something that hospitals-within-hospitals should be able to overcome with careful planning. Hospitals-within-hospitals should be able to work with their host hospital in a way that does not endanger the safety of patients in emergency situations but also avoiding impermissible acts of control by one hospital over another. During emergencies, hospitals in a community typically collaborate with each other, even if they are bitter rivals every other day of the year. In the event of a catastrophe, hospitals need to be able to handle the "surge" that occurs during emergencies and need "the ability to respond to mass casualty events and adequately care for a sudden influx of patients with common or unusual medical needs."[169]

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[167] *Id.*

[168] *See 2014 Ebola Outbreak in West Africa*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/ [http://perma.cc/P7WY-SAVX] (last visited Feb. 28, 2016).

[169] *Public Health Emergency Preparedness and Response*, U.S. GOV'T ACCOUNTABILITY OFF., http://www.gao.gov/key_issues/public_health_emergency_preparedness_response/issue_summary [http://perma.cc/BH3V-DKDC] (last visited Feb. 28, 2016).

A community-wide disaster preparedness committee with all hospital stakeholders represented is an innovative solution to the issue. In Indiana, hospitals participate in a public-private coalition called Managed Emergency Surge for Healthcare Coalition, or MESH.[170] MESH "creates a forum for healthcare organizations to collaboratively address issues ranging from operational readiness to reimbursement following a catastrophic disaster."[171] MESH "brings the pieces of the emergency healthcare puzzle together."[172] The MESH Coalition provides a forum for hospitals to distribute resources as needed and creates centralized "preparedness functions."[173] Currently, MESH is comprised of both public and private members and it includes the Marion County Public Health Department and other hospitals.[174] This type of community-wide collaboration would be ideal because it would help all health care providers in the event of an emergency. The hospital-within-a-hospital should not be considered under the "control" of its host hospital because it is simply a participating member of a community-wide disaster plan. An organization like MESH would alleviate confusion and would serve to prevent catastrophes like the situation that happened with Memorial and LifeCare. Disaster preparedness concerns should not bar the formation of a hospital-within-a-hospital; rather it is another factor to take into consideration when forming a hospital-within-a-hospital.

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[170] *See* MESH COALITION, http://www.meshcoalition.org [http://perma.cc/H5CU-DSMD] (last visited Jan. 29, 2016).

[171] MARION COUNTY ARES, http://www.mcinares.org/mesh-coalition [http://perma.cc/5R2W-8SGE] (last visited Jan. 29, 2016).

[172] MESH COALITION, *supra* note 170.

[173] Justin Mast, *Fostering Community: How One Indiana Community Meshed its Resources to Improve Preparedness*, TRUST FOR AM.'S HEALTH (June 4, 2015), http://healthyamericans.org/health-issues/prevention_story/mesh-community-resilience/ [http://perma.cc/96G5-CMTE]; *see* MESH COALITION, *supra* note 170.

[174] MESH COALITION, *supra* note 170.

V. CONCLUSION

The hospital-within-a-hospital is a structure that provides opportunities for the host hospital that benefits both hospitals involved and the patients in the geographic area. The hospital-within-a-hospital benefits outweigh the operational difficulties in ensuring adherence to the requirements of the statute, especially the more complicated "separateness" requirement, in addition to concerns about violating the Stark Law or AKS. Reduced readmissions through better transitional care benefits both the patient who must endure the difficulty of additional time in the hospital and the hospital that will suffer from financial penalties for excessive readmissions. Reduced readmission allows the host hospital to avoid readmission penalties from Medicare. The hospital-within-a-hospital is a means for host hospitals to achieve both financial and quality goals, despite payment issues and operational difficulties that arise due to CMS constraints on the hospital-within-a-hospital. Physicians could use the hospital-within-a-hospital structure to maintain their power and autonomy during an era of physician practices being purchased by large health systems.

Catholic hospitals, which are growing in number as regulator pressure drives increases in hospital consolidations and mergers, could authorize an arrangement with a hospital-within-a hospital to preserve certain patient services that would otherwise be limited. This could also be effective for other religious hospitals that are guided by moral principles that forbid offering certain treatments. The benefits to patients in terms of convenience and cost efficiency outweigh any potential risks that a hospital-within-a-hospital will take advantage of the payment systems and churn bills.

Disaster preparedness arrangements, like MESH, will alleviate concerns that host hospitals will cross into dangerous territory of making life or death decisions for the hospital-within-a-hospital's patients. MESH would also alleviate issues of impermissible lack of separation if the host hospital and the hospital-within-a-hospital need to work together to coordinate their emergency response plans.

Overall, the separateness requirements of the host hospital and the hospital-within-a-hospital ensure that this

system will not result in unethical arrangements. The chief medical officer of the host hospital is separate from the hospital-within-a-hospital as well as the medical staff. The CEO is not permitted to be employed by the hospital-within-the-hospital. These safeguards should allow for the creation of more of these entities to better serve patients and offer more diverse services in areas that need them the most.