

# OVERLOOKED AND UNDERUSED: CLINICAL PRACTICE GUIDELINES AND MALPRACTICE LIABILITY FOR INDEPENDENT PHYSICIANS

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*This paper discusses how the use of Clinical Practice Guidelines (CPGs) can improve the quality and delivery of healthcare in America. The author states that with the passage of the Patient Protection and Affordable Care Act of 2010 the American healthcare system is in need of re-alignment, specifically challenging the established norms for promulgating CPGs. The article explores the legal evolution of CPGs and new legal avenues for their promulgation by examining their history and purpose. The author concludes by identifying three accountability models and arguing in favor of a private competitive regime for CPGs.*

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## I. INTRODUCTION

American medical care is plagued by overuse, underuse, and misuse.<sup>1</sup> Overconsumption of medical care is one of the main contributors towards rising health care costs in the United States. A recent Institute of Medicine report estimates that unnecessary services cost \$210 billion each year.<sup>2</sup> However, even though Americans consume an enormous amount of health care, they only receive optimal care – or the care that is

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<sup>1</sup> Elise C. Becher & Mark Chassin, *Improving the Quality of Health Care: Who Will Lead?*, 20 HEALTH AFF. 164, 165–66 (2001) (defining quality problems as underuse, overuse, and misuse); Ronen Avraham, *Private Regulation*, 34 HARV. J. L. & PUB. POL'Y 543, 548–49 (2011) (discussing same) [hereinafter Avraham, *Private Regulation*]. Other papers refer to these concepts as defensive medicine, offensive medicine, and medical errors. E.g., Ronen Avraham, *Clinical Practice Guidelines: The Warped Incentives in the U.S. Health Care System*, 37 AM. J. L. & MED. 7, 9 (2011) [hereinafter Avraham, *Warped Incentives*].

<sup>2</sup> INST. OF MED., BEST CARE AT LOWER COST: THE PATH TO CONTINUOUSLY LEARNING HEALTH CARE IN AMERICA, 3-10 (Mark Smith et al. eds., 2012).

recommended by the best available information – 54% of the time.<sup>3</sup> President Obama recognized the danger of this mounting issue when, during the 2013 State of the Union, he identified rising health care costs as the biggest driver of long-term debt.<sup>4</sup> The million, or trillion, dollar question is how to reduce costs while simultaneously improving quality. This article explores an answer to that question.

Following the passage of the Patient Protection and Affordable Care Act of 2010 (PPACA), it has become clear that there needs to be a major realignment of incentives for the various players in the health care system, and this cannot occur without significant shifts in payment, the structure of care delivery, and accountability for quality and safety. PPACA contemplates, for example, bundled payment for inpatient acute care that combines revenue streams for hospitals and for physicians, episodic payment for periods of illness or complete courses of treatment, Accountable Care Organizations (ACOs) that are held to transparent standards for performance and bear financial risk for utilization of services, and patient-centered medical homes that offer comprehensive primary care services. With different models for payment, transparency, and organizational affiliation, the hope is that hospitals and other large practices will have incentives to develop or adopt protocols for optimal delivery of care even if medical liability laws are unchanged.

Because of these and other developments, physicians have been leaving solo and small-group practice for employment in larger practices and hospitals.<sup>5</sup> Notwithstanding these trends, American health care will remain more fragmented than someone unversed in history would predict given the complexity, capital requirements, and interdisciplinary nature of diagnosing and treating serious illnesses. Many physicians will continue to practice medicine in small settings,<sup>6</sup> and other health professionals, such as

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<sup>3</sup> INS. OF MED., CLINICAL PRACTICE GUIDELINES WE CAN TRUST 146 (Robin Graham et al. eds., 2011) [hereinafter 2011 IOM Report].

<sup>4</sup> FOX NEWS (Feb. 12, 2013), <http://www.foxnews.com/politics/2013/02/12/transcript-obama-state-union-speech/>

<sup>5</sup> See Mark Hagland, *One-Third of U.S. Physicians Plan to Quit Private Practice Within 10 Years*, HEALTHCARE INFORMATICS (Aug. 8, 2012), <http://www.healthcare-informatics.com/news-item/one-third-us-physicians-plan-quit-private-practice-within-10-years>.

<sup>6</sup> APA Executive Director Keynote Address to 2011 State Leadership Conference (Mar. 31, 2011) (“Eighty nine percent of all physicians work in solo practice or small group practices of 10 or fewer physicians.”), available at <http://www.apapracticecentral.org/update/2011/03-31/evolving-health.aspx>.

advanced practice nurses, are likely to secure legal privileges for independent practice as well.

This paper focuses on physicians in small practice settings and on norms rather than incentives as a way to improve the delivery of care. Incentives – sticks and carrots – dominate most discussions, particularly bonuses and penalties associated with reimbursement schemes. The problem is that these measures often provide only weak incentives to avoid errors but strong incentives to both over- and under-treat patients. In this paper, I explore a more *direct* way to influence how practitioners deliver care: clinical practice guidelines (CPGs).

CPGs are written statements of the best clinical practices to be applied to patient care based on the professional judgment of a given group of medical professionals who review the scientific evidence and assess the benefits and harms of alternative care options. CPGs can be promulgated by public or private organizations, such as specialty societies, advocacy groups, state agencies, health plans, commercial entities, and in the future, perhaps even by computers. Even IBM's supercomputer Watson is reportedly getting into the field of medical advice.<sup>7</sup> There are over 2,700 CPGs in a U.S government run depository called the National Guideline Clearinghouse – promulgated by more than 350 groups.<sup>8</sup>

The history of CPGs in the United States is intertwined with medical malpractice liability. This is particularly true for physicians in solo or small-group practice. As small businesspeople, these physicians tend to be very sensitive to the potential economic and reputational harm that allegations of malpractice can cause, and often feel very personally and intensely the uncertainty associated with litigation. As described in more detail below, early experiments with CPGs were designed to assuage physicians' fears of meritless suits and tendencies toward self-protection through costly defensive medicine. These malpractice-oriented CPGs were often the first to be debated in legislatures and tested by the courts. However, treating CPGs as relevant primarily for litigation purposes is why CPGs are overlooked and underused, as the title of this paper suggests. The potential for cost reduction and quality improvement from CPGs is much greater than malpractice reform alone could induce.

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<sup>7</sup> NEWSER (Feb. 8, 2013, 6:09 PM), <http://www.newser.com/story/162517/ibms-watson-to-start-dispensing-medical-advice.html>.

<sup>8</sup> NATIONAL GUIDELINE CLEARINGHOUSE, <http://www.guideline.gov/browse/by-topic.aspx> (last visited Feb. 12, 2014).

CPGs have the potential to reduce the prevalence of unnecessary, and often incorrect, medical procedures in fragmented environments because their focus is directly on the proper way to deliver care, rather than on providing incentives (sticks and carrots) for the providers to find the proper care themselves. As a doctor, especially as a solo practitioner, it is impossible to keep up with current medical research. So many studies are published each year that a cardiologist would have to read 10 articles per day, 365 days a year, to stay current.<sup>9</sup> Not only is this impossible, but it is a waste of the doctor's time. As science continues to build on itself, the number of studies increases exponentially, and no one person can be expected to synthesize and master it all.<sup>10</sup> Advances in technology will contribute as well. Today's young doctors use smart phones, tablets, and laptops on the job. This allows CPGs to be readily available, easily accessible, and instantaneously updated when new information is developed.

Although the concept of medical best practices may seem uncontroversial, there are substantial challenges involved in achieving compliance by practicing physicians. In 2012, for example, the U.S. Preventive Services Task Force released a new recommendation against PSA-based screening for prostate cancer.<sup>11</sup> The recommendation advised doctors to stop testing for Prostate-Specific Antigen because of its high false-positive rate for adenocarcinoma (80%), complications arising from follow-up biopsies, and its limited ability to change health outcomes from diagnosed cancers.<sup>12</sup> A survey fielded after the recommendation was issued found that 49% of physicians agreed with its reasoning, but surprisingly, only 1.8% actually planned to stop using the test.<sup>13</sup> Some doctors felt

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<sup>9</sup> IAN AYRES, SUPER CRUNCHERS: WHY THINKING-BY-NUMBERS IS THE NEW WAY TO BE SMART 92 (2007).

<sup>10</sup> Justin Kung et al., *Failure of Clinical Practice Guidelines to Meet Institute of Medicine Standards*, 172 ARCHIVES OF INTERNAL MED. 1628, 1628 (2012) (describing a “dizzying array” of CPGs that expands year after year).

<sup>11</sup> U.S. PREVENTIVE SERVICES TASK FORCE, SCREENING FOR PROSTATE CANCER: CURRENT RECOMMENDATION (May 2012), <http://www.uspreventiveservicestaskforce.org/prostatecancerscreening.htm>.

<sup>12</sup> Sarah Kliff, *Many Doctors Think PSA Tests Don't Work. But They'll Keep Doing Them Anyway*, WASH. POST, May 29, 2012, [http://www.washingtonpost.com/blogs/ezra-klein/post/many-doctors-think-psa-tests-dont-work-but-theyllkeep-doing-them-anyway/2012/05/29/gJQA0l0qyU\\_blog.html](http://www.washingtonpost.com/blogs/ezra-klein/post/many-doctors-think-psa-tests-dont-work-but-theyllkeep-doing-them-anyway/2012/05/29/gJQA0l0qyU_blog.html).

<sup>13</sup> *Id.*

patients expected to receive the test,<sup>14</sup> others did not think they had time to explain the changes to their patients, and still others worried that patients would feel their health care was being rationed.<sup>15</sup> Indeed, even doctors who wish to rely on CPGs are faced with numerous challenges because of how CPGs are currently created and regulated. Authors often have conflicts of interest that may or may not be disclosed, guidelines are created that recommend conflicting treatments, and there is no system in place to ensure that CPGs are updated or that outdated recommendations are removed from circulation.<sup>16</sup>

The importance of guaranteeing the trustworthiness of CPGs has not escaped Congress. Through the *Medicare Improvements for Patients and Providers Act of 2008*, Congress called on the Secretary of Health and Human Services (HHS) to contract with the Institute of Medicine (IOM),<sup>17</sup> through the Agency for Healthcare Research and Quality (AHRQ),<sup>18</sup> to undertake a study that focuses on how to make CPGs trustworthy. In March 2011 the IOM issued its report, which was entitled “Clinical

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<sup>14</sup> *Id.*

<sup>15</sup> *Id.* Guidelines for dealing with prostate cancer are just one example. Many more examples exist. For example, a recent study by pediatricians from the Cohen Children's Medical Center of New York that more than 90 percent of medical specialists who diagnose and manage ADHD in preschoolers do not follow treatment guidelines. See SCIENCE DAILY (May 4, 2013), <http://www.science.daily.com/releases/2013/05/130504163310.htm>.

<sup>16</sup> See *infra* Part II(B).

<sup>17</sup> “The Institute of Medicine (IOM) is an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public. Established in 1970, the IOM is the health arm of the National Academy of Sciences, which was chartered under President Abraham Lincoln in 1863. Nearly 150 years later, the National Academy of Sciences has expanded into what is collectively known as the National Academies, which comprises the National Academy of Sciences, the National Academy of Engineering, the National Research Council, and the IOM.” See *About the IOM*, INS. OF MED., [www.iom.edu/About-IOM.aspx](http://www.iom.edu/About-IOM.aspx) (last visited Feb. 12, 2014).

<sup>18</sup> “The Agency for Healthcare Research and Quality's (AHRQ) mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work with the U.S. Department of Health and Human Services (HHS) and other partners to make sure that the evidence is understood and used.” See *AHRQ Profile*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, <http://www.ahrq.gov/about/mission/glance/profile.html> (last visited Feb. 12, 2014).

Practice Guidelines We Can Trust.”<sup>19</sup> The IOM made eight recommendations (or standards) regarding various issues related to the optimal development of CPGs.<sup>20</sup> These issues, such as transparency, conflict of interest, external review, and updating are indeed crucial for ensuring trustworthy CPGs. Importantly, the IOM called on the Secretary of HHS to “establish a public–private mechanism to examine, at the request of developer organizations, the procedures they use to produce their clinical practice guidelines and to certify whether these organizations’ CPG development procedures comply with [eight] standards for trustworthy CPGs.” In other words, the IOM’s proposed model is one where a public–private entity issues a seal of approval that the *procedures* taken by guidelines developers fit the standards.

As this article argues, this is not the only possible model for optimal promulgation of CPGs.

In this article, I examine various legal models for creating and disseminating CPGs in light of the PPACA and other aspects of the new health care environment, focusing on uses by independent physicians rather than large health care organizations. In the course of analysis, I update research from almost two decades ago regarding how courts view and apply CPGs, primarily in malpractice litigation. I also critique the recent endorsements by the IOM and the AHRQ of a model of public–private certification of CPG promulgators. Recent articles by physicians “on the ground” have similarly found the IOM’s method for ensuring CPG reliability problematic.<sup>21</sup>

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<sup>19</sup> INS. OF MED., CLINICAL PRACTICE GUIDELINES WE CAN TRUST, (Robin Graham et al. eds., 2011), *available at* [http://www.nap.edu/catalog.php?record\\_id=13058](http://www.nap.edu/catalog.php?record_id=13058) (last visited Feb. 12, 2014).

<sup>20</sup> These standards include: 1) transparency, 2) management of conflicts of interest, 3) the composition of guideline development groups, 4) the intersection of CPGs and systematic review of technology, 5) evidence foundations for guidelines and rating the strength of recommendations, 6) articulation of recommendations, 7) external review of developed guidelines, and 8) updating guidelines. *Id.* at 78-139.

<sup>21</sup> For example, a recent publication by the American Medical Association found that conflicts of interest were present for 91% of the committee co-chairpersons of guideline producers. Justin Kung et al., *Failure of Clinical Practice Guidelines to Meet Institute of Medicine Standards*, 172 ARCHIVES OF INTERNAL MED. 1628, 1628 (2012). This same study found conflicts of interest present in 71% of chairpersons. *Id.* In other words, despite IOM standards that called for transparency and the removal of conflicts from guidelines, little has actually changed. Another article reported that the IOM standards are impractical

The IOM's approach asserts that CPGs on any given topic should be unbiased, expert, and convergent if not fully unitary (definitive). I suggest that these conditions often cannot be met. I advocate for a more thorough review of options, including those that accept bias as inevitable and that tolerate more diversity among CPGs. One example, particularly suited to use by independent physicians, is a market-based system that would hold private CPG creators liable for their *outcomes*, rather than only their *process* of guideline development and promulgation. CPGs produced in this market would be accurate and trustworthy because of accountability as well as transparency.

Consider, for example, conflict of interest. The IOM Report ultimately recognizes the myth of neutrality surrounding current CPGs, and acknowledges that CPG authors inevitably bring their personal and professional biases to the table. Funding of CPGs by interested parties such as medical device makers or pharmaceutical companies can also be problematic because of pressure to recommend the funder's products. Pharmaceutical companies stopped funding the creation of CPGs in 2010, but still pay for their distribution and updating.<sup>22</sup> The IOM Report attempts to address conflict of interest using procedural rules, such as requiring that the chair of the guidelines development group will have no conflict of interest, and that members of the group divest themselves of relevant financial investments. I propose that in many circumstances a different approach should be considered. If one cannot beat market forces, one might be better served by *harnessing* them to the process of creating CPGs.<sup>23</sup> In other words, a structured marketplace for guidelines may be optimal under certain circumstances.

In Part II, I describe the history of CPGs and explain their purposes. I focus on the connection between CPGs and specific attributes of the U.S. health care system. I evaluate the relative strengths of government, self-regulatory organizations, and the private sector in producing guidelines. I then outline a conceptual framework for understanding and evaluating possible accountability and governance mechanisms for the legal oversight of CPGs.

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because 0 of 114 randomly selected CPGs met the IOM's definition of trustworthy. David F. Ransohoff et al., *How to Decide Whether a Clinical Practice Guideline is Trustworthy*, 309 JAMA 139, 139–40 (2013).

<sup>22</sup> Avraham, *Warped Incentives*, *supra* note 1, at 29.

<sup>23</sup> See *infra*, Part IV(C).

Part III presents an empirical study of cases from the last decade and shows how courts regard CPGs as a practical matter. In this part, I also review more comprehensive government initiatives involving guidelines.

Part IV identifies and analyzes three accountability models for CPGs that have attracted attention from commentators and policymakers. Early guideline projects contemplated the direct development and issuance of CPGs by government. By contrast, recent reports on CPGs issued by the IOM and the AHRQ endorse a model of legal governance based on government certification of acceptable guidelines promulgated by various parties.<sup>24</sup> I argue that exclusive reliance on public models is misplaced, and other alternatives, including private competitive regimes, should be considered as well.<sup>25</sup> I conclude by identifying ways in which a private competitive regime for CPGs might develop in the market for physician services.

## II. OVERVIEW OF CPGS

### A. WHAT ARE CPGS AND WHERE DID THEY COME FROM?

Ideally, a clinical practice guideline is a clear, succinct statement of optimal medical care based on current professional knowledge. It should provide an individual practitioner with the information needed to make a fully informed decision consistent with scientific evidence of treatment effectiveness. It should also be updated regularly as new information about medical best practices becomes known.

CPGs have existed for the last fifty years but were little known until the 1980s, when the number of guidelines being disseminated increased dramatically. Guidelines began to be produced by a variety of organizations, including professional societies, hospitals, professional review boards, and state health departments. The federal government

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<sup>24</sup> Rosoff proposes a system that would use the federal government not to develop guidelines, but to certify privately developed CPGs. See Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Health Care Reform*, 5 HEALTH MATRIX 369, 395 (1995).

<sup>25</sup> Under Avraham's model, called the Private Regulation Regime (PRR), private firms would develop and continually update medical practice guidelines, and they would compete to license their own CPGs to medical providers. Additionally, the private firms would be held liable for putting forth sub-optimal guidelines. Avraham, *Private Regulation*, *supra* note 1, at 591.

became involved as well, most notably through the Agency for Health Care Policy and Research (AHCPR), a small branch of the U.S. Department of Health and Human Services that spearheaded the development of roughly twenty different guidelines across key clinical practice areas.<sup>26</sup>

The rise of CPGs is relatively easy to explain. Beginning in the 1970s, studies by John Wennberg and his colleagues revealed substantial differences in clinical practice patterns from state to state and even from town to town that were not correlated with the severity of illness or the clinical outcome of each case.<sup>27</sup> These “small-area variation” studies quickly generated concerns about both excessive spending and suboptimal care quality. These concerns were compounded by research revealing that even published results of randomized clinical trials – the gold standard for scientific evidence – changed the delivery of care in the community very slowly, if at all. John Eisenberg, the first administrator of the Agency for Health care Research and Quality (AHRQ), suggested the root cause of this phenomenon was physician reluctance to incorporate new scientific evidence into practice.<sup>28</sup> The logical solution was the practice guideline.

The conditions that make guidelines an appealing health policy tool have developed over the course of several decades. Four assumptions plausibly comprise the foundation for guideline-based policy responses to clinical variation. These attributes of the U.S. health care system are normatively contestable and subject to various economic and social pressures. Even those that perhaps should change, however, will not change quickly.

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<sup>26</sup> This initiative attracted political opposition and the agency no longer performs this role. Eleanor M. Perfetto & Lisa Stockwell Morris, *Agency for Health Care Policy & Research Clinical Practice Guidelines*, 30 ANNALS OF PHARMACOTHERAPY 1117 (1996).

<sup>27</sup> See generally John E. Wennberg, *Dealing with Medical Practice Variations: A Proposal for Action*, HEALTH AFFAIRS, May 1984 at 6. For example, a study published in the early 1980s described how in Maine, the likelihood of a woman’s having a hysterectomy by the time she reached age 70 varied from 20 to 70 percent in different hospital markets. In Iowa, the likelihood that a man who reached the age of 85 would have had a prostatectomy varied from 15 to 60 percent in different areas. In Vermont, children who had undergone a tonsillectomy varied from 8 to 70 percent depending on geographic area. *Id.* at 9.

<sup>28</sup> John M. Eisenberg, *Quality Research for Quality Health Care: The Data Connection*, 35 HEALTH SERVS. RESEARCH xii (June 2000).

As such, it is assumed the following to be accurate characteristics of U.S. health care that are considered desirable by a substantial percentage of health care professionals and the public:

1. Confidence in the physician as a legitimate source of clinical decisions affecting patients. Respect for physicians as trained professionals, for example, conceptualizes CPGs as advisory rather than directive, rejects “cookbook medicine,” and accommodates patient variation and the exercise of medical judgment.
2. Acceptance of solo and small-group practice models, with decentralized organization and fragmented care delivery, continuing to play an important role in the delivery of health care.
3. Belief that accurate, up-to-date, and useful information about medical practice is under-produced, that and supplying this information contributes a “public good” for physicians and the health care system.

#### B. PITFALLS AND PROMISES FOR CPGS

1. What is wrong with current CPGs?

Scholars have been complaining for a long time about the quality of CPGs.<sup>29</sup> One major issue is the unstructured oversight system now in

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<sup>29</sup> Researchers at the University of Maryland summed up the complaints as follows:

Their concerns have focused on the quality of the evidence on which clinical practice guidelines are based, the tendency of guidelines to promote more care rather than more effective care, their narrow focus and use as marketing and opinion-based pieces rather than road maps to improved medical care, and the difficulties involved in customizing population-based recommendations to individual patients. Also of concern has been the lack of transparency in the process by which clinical practice guidelines are created and potential conflicts (COIs) that might bias those preparing them.

place, which the IOM Report attempted to address. Self-regulatory standards have existed for a decade. The Appraisal of Guidelines, Research and Evaluation (AGREE) was published in 2003, and since that time has become the most widely accepted standard for assessing the quality of the *process* of guideline development.<sup>30</sup> The IOM report built on and improved AGREE by addressing questions such as the funding of guideline development and managing conflict of interest.<sup>31</sup> The IOM Report does not consider accountability for drafters of CPGs, or legal recourse for injuries attributable to incorrect guidelines, even though holding drafters accountable could help ensure that guidelines are properly drafted and regularly updated.

A recent University of Maryland study of 130 clinical practice guidelines found that many do not meet IOM standards.<sup>32</sup> Fewer than half of the guidelines listed conflicts of interest, many did not offer differing committee member views, and few committees included an information scientist, a patient, or a patient representative.<sup>33</sup> It is often difficult to know what methods a drafter used in writing the guidelines or whether there are conflicts of interest of which potential users should be aware.<sup>34</sup> As mentioned above, the approach taken in this paper is that instead of accepting the myth of neutrality of current CPGs and assuming there are minimal conflicts of interests, the default view should be the opposite: CPGs are likely to be riddled with conflicts of interest.

Even if guidelines were perfect, physicians face information overload when they are willing to use guidelines. Although the number of guidelines is far less than the number of new research studies involving

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Kung et al., *supra* note 21, at 1628–29.

<sup>30</sup> See generally The AGREE Collaboration, *Development and Validation of an International Appraisal Instrument for Assessing the Quality of Clinical Practice Guidelines: The AGREE Project*, 12 QUAL SAFETY HEALTH CARE 18 (Feb. 2003).

<sup>31</sup> The IOM Report improved on other frontiers as well. It developed standards for the updating of guidelines, external review and public comment and requiring a systematic review of the literature as a necessary stage in the development. See David F. Ransohoff et al., *How to Decide Whether a Clinical Practice Guideline is Trustworthy*, 309 JAMA 139, 139 (2013).

<sup>32</sup> Kung et al., *supra* note 21, at 1629–30.

<sup>33</sup> *Id.*

<sup>34</sup> See 2011 IOM Report, *supra* note 3, at 2.

medical care,<sup>35</sup> the National Guideline Clearinghouse (NGC), a database of CPGs in the United States, currently indexes over 2,700 guidelines.<sup>36</sup> In 2008 alone, the NGC added 722 new CPGs.<sup>37</sup>

Alas, many CPGs are not user-friendly. Guidelines are often long and dense.<sup>38</sup> Even with the large amount of information they provide, they still may not offer clear instructions for doctors attempting to apply them to a specific patient.<sup>39</sup>

Moreover, it remains unclear which CPGs are still authoritative. Optimal medical procedures change over time. It is often difficult to determine when the weight of evidence has caused a justifiable shift against a certain treatment that should result in a change to the relevant CPGs. On average, CPGs cost at least \$200,000 to produce and substantial amounts to revise.<sup>40</sup> Many of the parties that can most easily afford these sums, such as pharmaceutical companies,<sup>41</sup> are particularly prone to conflicts of interest.

There is also the semi-myth of uniformity. Guidelines do not always agree even when they cover the same medical conditions or procedures. This may partly result from varying incentives for each producer. For example, a guideline created by a managed care plan may be more concerned with cost implications of treatment recommendations than a guideline created by a physician specialty society. To be clear, different guidelines based on patients' willingness to pay for procedures could make sense, like economy, business, and first-class airline seating. But there must be a good reason for the different treatment. If the reason for conflicting guidelines is just that the authors came to conflicting recommendations about the best treatment (regardless of costs) then that is an issue. In that case both guidelines cannot both be correct.

In many situations, available evidence regarding best practices is scarce. While some would argue that this means no recommendation should be made, others argue that doctors need CPGs even *more* in these

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<sup>35</sup> From 1994 to 2001, there were around 25,000 randomized controlled trials published on MEDLINE, a medical literature database. *Id.* at 1. No organization, let alone a single doctor, is able to review 70 studies per day, evaluate their credibility, and apply their findings to their practice.

<sup>36</sup> *Id.* at 2.

<sup>37</sup> *Id.*

<sup>38</sup> *See id.* at 146.

<sup>39</sup> *See id.*

<sup>40</sup> *See id.* at 62 (internal citation omitted).

<sup>41</sup> *See Avraham, Warped Incentives, supra* note 1, at 29 and accompanying text.

instances.<sup>42</sup> Without a consistent rating scale that indicates the level of support for a particular guideline, however, it can be difficult to determine which guidelines are the most reliable.<sup>43</sup> A study by Grilli and others found that 82% of guidelines studied did not expressly state the strength of their recommendation.<sup>44</sup>

The IOM Report recognizes that “[n]on-standardized development results in substantial troubling variation in clinical recommendations.”<sup>45</sup> However, the IOM Report does not attempt to eliminate this problem but only predicts that, with increased oversight and stricter CPG production procedures, the problems of inconsistent recommendations can be reduced.<sup>46</sup> In doing so the IOM Report seems to waive its hands in an attempt to address the semi-myth of uniformity with respect to current CPGs.

## 2. What is the Potential of CPGs?

Legal commentators often focus on CPGs in connection with medical malpractice reform.<sup>47</sup> In fact, CPGs’ benefits can be divided into three major categories: improving the quality of care and reducing errors, decreasing defensive medicine, and decreasing offensive medicine (overtreatment).

### a. *CPGs Can Improve Quality*

First and foremost, CPGs should assure and improve the quality of medical care. The standard for measuring quality used in health policy, articulated by Donabedian in the 1960s, distinguishes *interpersonal aspects* of quality, such as compassion, from *technical aspects* of quality, such as surgical precision. It further divides technical aspects into three categories: structure (e.g., the number of nurses per hospital ward), processes (e.g., whether patients with bacterial infections receive antibiotics), and

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<sup>42</sup> See 2011 IOM Report, *supra* note 3, at 63.

<sup>43</sup> See *id.*

<sup>44</sup> *Id.* at 64 (internal citation omitted) (reviewing 431 guidelines developed by specialty societies between 1988 and 1998). This study also concluded that CPGs were making moderate progress over time. *Id.*

<sup>45</sup> *Id.* at 65–66 (internal citations omitted).

<sup>46</sup> *Id.* at 198–99.

<sup>47</sup> See *infra* notes 93–128.

outcomes (e.g., percentage of cancer patients who survive for five years after treatment).

Few will disagree that the best way to improve health care is to evaluate outcomes such as cures, survival rates, and symptom relief. These outcome measures represent the third prong of the Donabedian definition of quality, and they are the preferred approach of proponents of new incentive systems for health care providers, such as pay-for-performance systems (P4P), and of systems that rely on transparency to motivate improvement, such as public “report cards” for hospitals and HMOs. There are various problems with evaluating outcomes. The most relevant here is that measuring outcomes in a statistically reliable manner requires large datasets. Individual physicians cannot reasonably be held accountable for clinical outcomes because of their small patient populations.<sup>48</sup>

What is, then, the role of CPGs in improving care? CPGs are primarily designed to define (technical) *processes*.<sup>49</sup> Though this may seem obvious, it establishes the limitations of CPGs and distinguishes them from other instruments that can be governed separately. Thus, interpersonal aspects of quality are monitored, if at all, through an uneasy balance between professional codes of ethics and consumer preferences. CPGs do not attempt to address these dimensions of medical performance. Similarly, structural features of care, especially those involving large capital investments, often remain absent from CPGs because they are not viewed as within the control of individual physicians, who are the principal audience for guidelines.<sup>50</sup> Governance mechanisms for structural features

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<sup>48</sup> See, e.g., Arnold Milstein & Thomas H. Lee, *Comparing Physicians on Efficiency*, 357 NEW ENG. J. MED. 2649 (2007) (discussing the pitfalls and challenges facing solo and small practitioners).

<sup>49</sup> See generally AVEDIS DONABEDIAN, *THE DEFINITION OF QUALITY AND APPROACHES TO ASSESSMENT: EXPLORATIONS IN QUALITY ASSESSMENT AND MONITORING* (Health Admin. Press 1980); Avedis Donabedian, *Evaluating the Quality of Medical Care*, 44 MILBANK MEM’L FUND Q. 166 (1966).

<sup>50</sup> Technology assessment has also been outside the mainstream of practice guidelines. To gain greater political acceptance, technology assessment will probably need to incorporate professional standards and work in tandem with practice guidelines because the public looks to physicians as experts on inventing and evaluating new clinical technology as well as on deploying it. Efforts are ongoing to integrate technology assessment with specific clinical recommendations. Notably, Congress recently chartered a new comparative effectiveness institute in the American Recovery and Reinvestment Act and the Patient Protection and Affordable Care Act, but it placed significant legal

tend to be mandatory, implemented via compliance with regulatory or accreditation standards, and are usually applied to institutions as opposed to professionals.<sup>51</sup>

Moreover, guidelines are increasingly intertwined with health information technology such as electronic health records with computerized decision support. Proponents of CPGs have generally assumed that users can easily recognize a functional guideline and therefore that using it would reflect a conscious decision to access a discrete set of recommendations. Indeed, existing technology, including tablets, smart phones, and other handheld devices with internet connectivity, makes reference information and decision support readily available to individuals performing both clinical and administrative functions.<sup>52</sup> Some of these resources can be accessed on demand by users seeking guidance, but others are seamlessly incorporated into medical information systems. Emerging technologies are likely to embed algorithms directly into the equipment, facilities, and systems that are used to deliver and manage care. Individual users may even be unaware that a guideline is being followed.

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restrictions on how findings of relative ineffectiveness can be used. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 3011, 3501, 6302 (2010).

<sup>51</sup> Examples are the conditions of participation that Medicare regulation imposes on health care facilities, and the accreditation standards for hospitals promulgated by the Joint Commission. The Center for Medicare and Medicaid Services (CMS) issued an amended guideline on December 30, 2009 for ambulatory surgical centers. *See generally* DEP'T OF HEALTH & HUMAN SERVS. CTRS. FOR MEDICARE & MEDICAID SERVS., PUB. 100-07, REVISED APPENDIX L: INTERPRETIVE GUIDELINES FOR AMBULATORY SURGICAL CENTERS (2009), *available at* <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r56soma.pdf>.

<sup>52</sup> These technologies are already in use by doctors. *See, e.g.*, Anne Eisenberg, *Those Scan Results Are Just an App Away*, N.Y. TIMES, Oct. 15, 2012, *available at* <http://www.nytimes.com/2011/10/16/business/medical-apps-to-assist-with-diagnoses-cleared-by-fda.html> (discussing one doctor's use of the Mobile MIM app, which allows his iPhone or iPad to act as a diagnostic medical instrument).

b. *Clear Standards of Care Can Decrease Defensive Medicine and Improve Safety*

Fear of malpractice liability has long been regarded as a major cause of physicians' clinical idiosyncrasies, and therefore, it seems an obvious area where CPGs should be applied. In the 1960s, the number of malpractice claims and the cost of physicians' malpractice insurance premiums began to rise rapidly. Some commentators attributed this rise to unscrupulous lawyers and corrupt expert witnesses who persuaded sympathetic juries to impose a higher "standard of care" on physicians than was required by the law or indicated by medical science.<sup>53</sup> Moreover, this trend seemed to be self-reinforcing, as customary practice was defined upwards by the courts, creating a vicious circle of defensive medicine, waste, and litigation.

The first CPGs offered a potential liability shield against frivolous claims by countering adverse expert witness testimony. Using national standards rather than customary practice in specific localities to define the standard of care seemed like a logical step to address the issue of unnecessary and potentially dangerous variation in quality across disparate medical practices.<sup>54</sup> Early guideline proponents hoped judges and juries would accept CPGs to define the standard of care in individual lawsuits and that states would eventually amend their laws to make compliance with CPGs a formal defense to liability. When the standard of care is clearly defined, there is no incentive to run unneeded tests or provide treatments solely for fear of future litigation.

It took several more years for policymakers and medical professionals to acknowledge that rates of medical error were unacceptably high,<sup>55</sup> and that, because of the expense and unpredictability of malpractice

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<sup>53</sup> See, e.g., Louis J. Regan, *Medicine and the Law*, 250 NEW ENGL. J. MED. 463 (1954) (blaming malpractice suits on unscrupulous lawyers and physician turncoats rather than poor care).

<sup>54</sup> Over time, the localism of malpractice law has faded both with respect to the "locality rule" for standard practice and in terms of evaluating care based on whether it was reasonable rather than merely customary. See generally E. Lee Schlender, *Malpractice and the Idaho Locality Rule: Stuck in the Nineteenth Century*, 44 IDAHO L. REV. 361 (2008); Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at The Millennium*, 57 WASH. & LEE L. REV. 163 (2000).

<sup>55</sup> There are estimates that medical errors still cause almost 100,000 deaths each year. Indeed, about 1 in 50 people who enter a medical facility will suffer an

litigation, few of these avoidable injuries were being compensated by the courts.<sup>56</sup> Revelations of rampant medical error in the late 1990s made avoiding misuse of tests and treatments a further goal of guideline compliance. The problems of medical error and defensive medicine are interrelated, as both often stem from the lack of a clear guidepost against which to measure physician performance. From this perspective, CPGs could also serve as a “liability sword,” identifying physicians who misused a given treatment.<sup>57</sup> Predictably, the potential inculpatory application of CPGs in court was far less appealing to physicians than their use in a purely exculpatory role.

*c. Guidelines Can Combat Offensive Medicine and Reduce Wasteful Spending*

The current fee-for-service payment system gives physicians a direct financial incentive to run additional tests and perform unnecessary procedures. Combined with the easy availability of advanced clinical technologies (particularly in hospitals), the financial insulation of most insured patients from the cost of this care through health insurance, and physicians’ tendency to over-test to avoid potential malpractice suits, fee-for-service payment is a major reason why the United States spends the most on health care but lags behind many developed nations in terms of health care quality.<sup>58</sup>

The FBI investigation of the Redding Medical Center in California highlights the dangers of offensive medicine. At Redding, one thousand coronary artery bypass graft operations, a very profitable surgery, were performed each year, nearly three times the average rate for a facility of its

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adverse event that could have been prevented, and most of this harm is due to negligence. Avraham, *Private Regulation*, *supra* note 1, at 548–49.

<sup>56</sup> See TOM BAKER, *THE MEDICAL MALPRACTICE MYTH* 22–44, 68–77 (2005); William M. Sage, *New Directions in Medical Liability Reform*, in *MEDICAL MALPRACTICE: A PHYSICIAN’S SOURCEBOOK* 247–78 (Richard E. Anderson ed., 2005).

<sup>57</sup> See generally Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PENN L. REV. 645 (2001).

<sup>58</sup> See Uwe E. Reinhardt et al., *U.S. Health Care Spending in an International Context*, 23 HEALTH AFF. 10, 10–12 (May/June 2004).

size. The investigators alleged that a large portion were not medically justified, but were done to boost profits for the hospital and its physicians.<sup>59</sup>

Although cost-effectiveness has rarely been an explicit element of CPGs, they can generate health care savings. Discouraging overuse of medical care is the clearest but not the only connection between CPGs and health care costs. Reducing misuse both improves safety and averts costly complications. Even rooting out underuse can have desirable economic effects. Many cost-effective tests supported by CPGs are overlooked and left unused by physicians lacking guidelines. CPGs can also align pricing with care by having gold and platinum treatment levels for those who pay more. Much like one can purchase more insurance to ensure coverage of more procedures, one could pay more to be in a higher CPG tier.

### 3. Who Might Produce and Regulate CPGs?

Guidelines may be produced by public agencies, self-regulatory bodies, or private organizations. As one might expect, the desired regulatory oversight scheme would differ significantly according to the guideline issuer's identity. Choosing among these alternatives should reflect serious thought about regulatory design. Political feasibility is also important and should be prospectively considered.

#### a. *Government*

One of the characteristics accepted in the introduction of this paper was the idea that CPGs are a public good. With that in mind, one would think that the government should be responsible for their promulgation.

Government promulgated guidelines are a more attractive policy option in countries where the government acts as a single health care payer because the government internalizes the cost of health care and, for that matter, the cost of medical liability. In Britain, the National Institute for Health and Clinical Excellence (NICE), an independent organization closely linked to the British government, evaluates new technologies for coverage by the UK's National Health Service (NHS), and considers both

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<sup>59</sup> See Kurt Eichenwald, *Operating Profits: Mining Medicare*, N.Y. TIMES, August 12, 2003, available at <http://www.nytimes.com/2003/08/12/business/operating-profits-mining-medicare-one-hospital-benefited-questionable-surgery.html?pagewanted=all&src=pm>.

quality and cost. NICE is thus well positioned to suggest best practices for NHS physicians.

In the US, the federal government exerts considerable influence over the health care system by funding the Medicare and Medicaid programs, while state government plays a more direct regulatory role in addition to its Medicaid oversight function. Payment policy offers a straightforward justification for issuing CPGs and monitoring compliance with them. Moreover, the government's incentive and ability to influence clinical practice may grow stronger as national health reform following the PPACA is implemented, creating an opportunity for a comprehensive approach to public guideline development that combines clinical quality with cost and coverage for conditions where research has revealed suboptimal quality and/or economic waste. A significant caution, however, is that political polarization over the risks of "socializing medicine" or rationing may discourage the creation of CPGs by the government, particularly for medical procedures influenced by powerful special interest groups. Indeed, despite its size, budget, and power, the government has significant drawbacks as a source of CPGs. Physicians and the public usually view the government with suspicion when it seeks to intrude on the autonomy of the medical profession in diagnosing and treating patients. Hence we have a conflict between CPGs as a public good and the autonomy of doctors. This is particularly true when the government attempts to alter a clinical norm regarding risk-benefit calculations, as exemplified by PSA-screening for prostate cancer, the recently renewed debate over mammography for middle-aged women, or the continuing controversy over the potential side-effects of childhood vaccination.<sup>60</sup>

The government has insufficient personnel with the appropriate skills to produce a large number of detailed guidelines. The cost of developing guidelines through public processes is also high and politically

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<sup>60</sup> See Sarah Kliff, *Many Doctors Think PSA Tests Don't Work. But They'll Keep Doing Them Anyway*, WASH. POST, May 29, 2012, available at [http://www.washingtonpost.com/blogs/wonkblog/post/many-doctors-think-psa-tests-dont-work-but-theyll-keep-doing-them-anyway/2012/05/29/gJQAO10qyU\\_blog.html](http://www.washingtonpost.com/blogs/wonkblog/post/many-doctors-think-psa-tests-dont-work-but-theyll-keep-doing-them-anyway/2012/05/29/gJQAO10qyU_blog.html); Eliot Marshall, *Brawling Over Mammography*, 327 SCIENCE 936 (2010) (describing the public reaction to recent mammography guidelines); H. Gilbert Welch, *Screening Mammography: A Long Run for a Short Slide?*, 363 NEW ENG. J. MED. 1276 (2010) (suggesting that the mortality benefits from mammography may have declined as treatment options have improved); Liza Gross, *A Broken Trust: Lessons from the Vaccine-Autism Wars*, 7 PLOS BIOL. (2009) (describing the long battle over thimerosal and autism).

exposed. Because guidelines must be routinely updated and corrected, the administrative burden and associated political risk would resurface frequently.<sup>61</sup> In order to properly promulgate and update CPGs, a government agency would need to be well funded, closely connected to care delivery, and sheltered from political pressure by special interest groups.<sup>62</sup>

b. *Self-Regulation*

Self-regulation in the health care system is most commonly associated with physicians and other health professionals, but it may also include health care facilities, suppliers, and even insurers. Professional organizations such as the American Medical Association and societies in each medical specialty promulgate ethical rules and standards of conduct that guide physician members' behavior. In the US, law and tradition allow the organized medical profession to maintain a surprising degree of collective control over physician education, training, licensing, disciplining, hospital affiliation, and even liability insurance. Nurses,

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<sup>61</sup> Guidelines are time-consuming and expensive both to develop and to update. See Richard Amerling et al., *Guidelines Have Done More Harm Than Good*, 26 BLOOD PURIFICATION 73 (2008). Often, the result is that guidelines are not based on the full evidence available. A 2001 study examined 17 guidelines developed by U.S. Agency for Health Care Research and Quality. See Paul G. Shekelle et al., *Validity of the Agency for Healthcare Research and Quality Clinical Practice Guidelines: How Quickly Do Guidelines Become Outdated?*, 286 JAMA 1461, 1461 (2001). Seven of the guidelines needed to be updated with new "diagnostic or therapeutic guideline recommendations" or withdrawn. *Id.* Six warranted marginal adjustments to their recommendations. *Id.* The methodology and development process for AHRQ guidelines were considered to represent a drastic improvement in the "science of practice guideline development." *Id.* at 1462. Yet, half of them were obsolete in 5.8 years and the study recommended that the guidelines be reevaluated for suitability every three years. *Id.* at 1461. Another cost-related concern is that providers do not have the necessary resources to comply with the guidelines. Ronni P. Solomon, *Clinical Guidelines in the United States: Perspectives on Law and Litigation*, in CLINICAL GUIDELINES: LAW, POLICY AND PRACTICE 137, 146 (John Tingle ed., 2002).

<sup>62</sup> See generally Bruce C. Vladeck, *The Political Economy of Medicare*, 18 HEALTH AFF. 22 (1998) (explaining interest group politics); Lawrence R. Jacobs, *Politics of America's Supply State: Health Reform and Technology*, 14 HEALTH AFF. 143 (1995) (arguing that no collective force counters the political power of provider and supplier groups).

pharmacists, and other practitioners claim similar but generally lesser privileges to regulate their own professions.

Self-regulation may be preferable to direct government control when technical expertise is required, when cooperation from the regulated entities is important, or when the regulated industry is undergoing rapid change that outpaces public oversight. Self-regulation usually will seem cheaper for the government than direct regulation because it is off-budget and less visible politically, and it may also be cheaper if compliance costs are lower. On the other hand, self-regulation can be insular, self-serving, and anti-competitive if improperly executed. Despite those concerns, medicine has historically enjoyed wide latitude to self-regulate because of public deference to physician expertise and professional ethics.

Self-regulation can take various forms pertaining to guidelines. Self-regulatory organizations can issue guidelines directly. Many current guideline producers are non-profit, educational organizations. In the US, the most prominent category of issuer is made up of medical specialty societies and other professional organizations, which promulgate guidelines focused on the effectiveness of treatment.<sup>63</sup> However, these entities are seldom well funded and may not be able to afford to update CPGs on a continuing basis in a rapidly changing world. In general, such organizations usually do not feel pressed to account for costs of care, and may be biased towards quality over efficiency.

Self-regulatory organizations can also certify guidelines produced by others and also may accredit those producers. The imprimatur of an accrediting or certification body is typically used to convey information about superior quality or reliability to a purchaser or user of a product or service. As noted above, the IOM recently recommended the establishment of a public-private partnership to certify guideline issuers in terms of compliance with best practices regarding guideline production that an IOM committee had identified.

State professional licensing boards exemplify what is often called “statutory” or “delegated” self-regulation. In this model, a legislature confers broad discretion on what is a nominally governmental body but that is practically controlled by the regulated class of individuals. Physicians often have considerable influence over medical licensing boards, for example, although public concern about safety has eroded the profession’s

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<sup>63</sup> Stefan Timmermans & Emily S. Kolker, *Evidence-Based Medicine and the Reconfiguration of Medical Knowledge*, 45 J. HEALTH & SOC. BEHAV. 177, 184 (2004).

dominance in recent years. The Joint Commission is a very powerful self-regulatory body for hospitals and other health facilities in the US, and has delegated authority insofar as its accreditation substitutes by law for direct government qualification of health facilities for participation in Medicare and Medicaid. Because of its reliance on convened groups of private experts, NICE in the UK often functions as a statutory self-regulatory body. Although existing statutory self-regulators in the US could issue or certify CPGs, none has yet done so. Even the Joint Commission standards, designed to ensure quality of care, do not specify treatment processes.

An alternative model is “supervised self-regulation.” This is something like what used to happen in the US in healthcare, as outlined in the Public Model section of Part IV. In this model, a formal government regulatory body backstops a self-regulatory organization. A prominent example of this in another field is the Securities and Exchange Commission. The SEC has the right and obligation to review the work of various self-regulatory boards that adopt standards for matters such as corporate accounting practices and the operation of securities exchanges and to overrule them if it deems necessary.

In health care, certain Medicare contractors – particularly those engaging in quality improvement activities under explicit statutory authorization – function as supervised self-regulators. Unlike delegated self-regulation, a supervised model empowers an existing agency such as AHRQ, the Center for Medicare and Medicaid Services (CMS), or the Food and Drug Administration (FDA) to ensure that self-regulatory organizations charged with issuing guidelines are honest and competent. This might take the form of certifying the processes used by each producer, as suggested in the 2011 IOM Report.

Self-regulation can operate locally as well, with monitoring and compliance systems internal to organizations being self-imposed or expressly required by the government or another self-regulator. For example, internal self-regulation by a “self-governing medical staff” is required for most hospitals by state law and by the Joint Commission accreditation standards. History, however, cautions us against locally produced or approved CPGs. The principal justification for pursuing guidelines as a regulatory enterprise was the failure of reliable professional norms to develop in local, self-regulated physician communities. It would

be ironic to turn to the same communities to create or bless guidelines.<sup>64</sup> National self-regulatory organizations would likely create better, evidence-based products.

c. *Private Sector*

Many types of private organizations produce and deploy clinical practice guidelines. These efforts vary widely with respect to the quality and impartiality of the guidelines produced and also with respect to the transparency of the process of producing them. They also vary in the degree to which guidelines are considered corporate assets intended for internal use as opposed to external dissemination.

Increasingly, guidelines are developed and/or purchased or modified prior to implementation by large clinical entities. These include closed-panel HMOs, hospital-based integrated delivery systems, prepaid group practices, multispecialty clinics, and less unitary but still structurally coherent networks ranging from the independent practice associations (IPAs) of the 1990s to the accountable care organizations (ACOs) of today. Many, but far from all of these organizations, are non-profit corporations. Health care providers compete primarily on the underlying services and may view guidelines as proprietary business tools rather than common educational resources.<sup>65</sup>

Among private, guideline-producing organizations targeting independent physicians, several are interested in reducing health care costs as well as improving quality. These producers, including managed care organizations, health insurers, and a handful of large, self-insured employers,<sup>66</sup> similarly may have business-related objectives for issuing and using guidelines on a competitive basis.<sup>67</sup>

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<sup>64</sup> See Katherine Baicker & Amitabh Chandra, *Medicare Spending, The Physician Workforce, And Beneficiaries' Quality Of Care*, 23 HEALTH AFF. 184 (2004).

<sup>65</sup> A search of private, for-profit guidelines yielded only seven guidelines, whereas the nonprofit search yielded 154 guidelines from a wide array of organizations. A search for guidelines from Hospital/Medical Centers yielded 38 guidelines (of the approximately 2356 available) from only 3-4 organizations.

<sup>66</sup> Rosoff, *supra* note 24, at 374. A search in the NGC dataset revealed, for example, that Kaiser Permanente (an MCO) has about 10 guidelines posted.

<sup>67</sup> Two private for-profit firms that came up in NGC's database were the Reed Group, which is a company dedicated to getting injured employees back to work at

Benefits consultants, pharmacy benefit managers, disease management companies, and similar entities may also regard guidelines as proprietary. Health care suppliers, such as pharmaceutical and medical device companies, frequently see guidelines as critical marketing tools for their products, or, if a particular guideline does not support that purpose, they view them as a threat to revenue. Malpractice insurers for physicians or hospitals may also issue or use guidelines in connection with their risk management activities. Some of these organizations already have the structures in place to organically develop a private model of CPGs similar to the private regulation regime discussed in Part IV.

These various entities are usually well funded and have the requisite expertise to write useful guidelines. However, they all have very different financial goals, particularly if the cost of suboptimal guidelines is borne elsewhere. For example, CPGs produced by third-party payers may emphasize cost control over quality, possibly externalizing costs onto liability insurers if injury ensues.<sup>68</sup> In contrast, guidelines issued by physician groups anticipating fee-for-service payment may emphasize quality over cost control. CPGs produced by liability insurers, in turn, may emphasize claims avoidance, with safe care a secondary objective and efficient care not prioritized, which tends to externalize costs onto both patients and third-party payers.<sup>69</sup> Thus, physicians are sometimes forced to choose among conflicting guidelines with different goals.<sup>70</sup>

Other private producers of guidelines have primarily political objectives. Certain professional and trade groups seek to influence public

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full-productivity and the Smith & Nephew, which is primarily a medical device manufacturer in Ireland.

<sup>68</sup> For example, HMOs may prefer fewer treatments to contain costs because they fully bear the costs of treatments, but do not fully bear the costs of malpractice.

<sup>69</sup> For example, malpractice insurers would require doctors to perform mammograms every year to prevent breast cancer, even if they are not needed, because the malpractice insurers do not bear the costs of extra mammograms, but do bear the costs of lawsuits from late diagnosis of breast cancer.

<sup>70</sup> Patricia R. Recupero, *Clinical Practice Guidelines as Learned Treatises: Understanding Their Use as Evidence in the Courtroom*, 36 J. AM. ACAD. PSYCHIATRY L. 290, 298 (2008). Guidelines need not all be the same – for example a guideline could call for a more expensive treatment than is necessary – but to be covered under this premium guideline, rather than a standard guideline, one should be required to pay more into the system and thus be financially accountable for their choice of coverage.

opinion, legislation, and regulation that determine which health professions and which treatments receive favorable consideration. Similar risks may arise when leading physician researchers are called upon to develop CPGs because they may have financial relationships with pharmaceutical or medical device manufacturers who wish to have their products recommended by experts.

If guidelines are challenged in court, these varying incentives and potential biases may become a focal point of litigation rather than the guidelines being regarded as “a generally recognized standard of care within the medical profession”.<sup>71</sup> During the 1980s and 1990s, courts were sensitized to the risk of bias in health insurance contracts as managed care became more aggressive about denying coverage for lack of medical necessity.<sup>72</sup> More recently, financial relationships between pharmaceutical manufacturers and health care providers have raised concerns about conflicts of interests influencing clinical standards and practices.<sup>73</sup> Fortunately, we now recognize neutrality as the myth that it is and can adjust our governance models to account for the fact that CPG authors bring their own biases to the drafting process.

#### d. *Courts*

In the US, the health care system tends to be monitored by an ad hoc mixture of public law (i.e. Medicare and Medicaid) and private law represented by individual litigation over contractual agreements or personal injuries. In this system, it is possible for judges – typically those serving on state rather than federal courts – to create “common law” regarding CPGs by interpreting contracts, determining the scope of fiduciary duties, allocating property rights, and holding producers of CPGs and other health

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<sup>71</sup> See *Quigley v. Jobe*, 851 P.2d 236, 238 (Colo. App. 1992) (holding that guidelines written by a liability insurance carrier did not meet the relevance test for scientific evidence, because they were created “by a private insurance company as part of an insurance contract and did not reflect a generally recognized standard of care within the medical profession.”).

<sup>72</sup> *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 112-13 (1989)

<sup>73</sup> See COMM. ON CONFLICT OF INTEREST IN MED. RESEARCH, EDUC., & PRACTICE, INST. OF MED. OF THE NAT'L ACADS, CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE (Bernard Lo & Marilyn J. Field, eds., 2009); William M. Sage, *Some Principles Require Principals: Why Banning “Conflicts of Interest” Won't Solve Incentive Problems in Biomedical Research*, 85 TEX. L. REV. 1413 (2007).

care providers liable to patients under tort law. Should such cases occur frequently, an accountability regime for guidelines might emerge organically without the creation of an explicit legislative or regulatory framework. But this seems unlikely to occur as the most victims of medical errors are not aware of them, and of those aware the vast majority does not file suits, and of those filing suits, the vast majority settle, never making it to courts.

A more plausible outcome is episodic litigation resulting in judicial decisions that send strong, albeit indirect, signals to health care stakeholders regarding the value and enforceability of CPGs. Normally, CPGs are brought up in the context of medical malpractice litigation, which usually plays an important role in molding physicians' opinions about the acceptability of any proposed alteration to their clinical practices and standards.<sup>74</sup> Product liability lawsuits are also important indicators for manufacturers of drugs, medical devices, vaccines, and diagnostic tests. For health insurers, guidelines typically surface in disputes over benefits and coverage denials, such as in the interpretation of policy provisions regarding medical necessity or experimental treatment.<sup>75</sup>

Medical malpractice litigation, for example, generates accountability mechanisms for guidelines that have particular characteristics. Civil litigation ordinarily gives considerable deference to the discretion of individual judges in making evidentiary rulings. Accordingly, only a small number of structured guideline programs have been attempted in the malpractice context, and those have been heavily negotiated to respect judicial prerogatives and to operate through presumptions and affirmative defenses as opposed to conclusive determinations of liability or immunity from liability.

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<sup>74</sup> William M. Sage, *Reputation, Malpractice Liability, and Medical Error*, in ACCOUNTABILITY: PATIENT SAFETY AND POLICY REFORM 159 (2004).

<sup>75</sup> Like medical malpractice, insurance coverage law has both a technical and a symbolic importance to oversight of health care quality. See Nan D. Hunter, *Managed Process, Due Care: Structures of Accountability in Health Care*, 6 YALE J. HEALTH POL'Y L. & ETHICS 93 (2006); William M. Sage, *Managed Care's Crimea: Medical Necessity, Therapeutic Benefit, and the Goals of Administrative Process in Health Insurance*, 53 DUKE L.J. 597 (2003); Mark A. Hall & Gerard F. Anderson, *Health Insurers' Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637 (1992).

### III. HOW ARE CPGS CURRENTLY USED?

Although systematic efforts to provide governance and accountability mechanisms for CPGs have been lacking in the US, substantial experience has accumulated over the last two decades regarding the relationship between guidelines and the law. While these experiences underscore the desirability of consciously creating accountability in the world of guidelines, they do not offer clear lessons for how such accountability should be achieved.

The success of CPGs in replacing customary care with evidence-based medicine depends primarily upon the level of acceptance of CPGs within the medical profession.<sup>76</sup> The law's treatment of guidelines is critical to this process and to their acceptance by other stakeholders whose confidence in guidelines as a policy innovation is affected by how such guidelines are perceived by independent legal decision-makers such as judges and legislators.<sup>77</sup> This section surveys the way CPGs have been treated by courts, insurance companies and various state level initiatives.

#### A. CPG USE IN LITIGATION: A CASE STUDY FROM 2000-2010

How courts and lawyers are actually using CPGs in malpractice litigation has not been definitively established. The most comprehensive study of court usage of CPGs was published almost two decades ago by Hyams, Shapiro, and Brennan.<sup>78</sup> They conducted surveys of medical malpractice attorneys and reviewed of all relevant case law from January 1, 1980 through May 31, 1994.<sup>79</sup> That study and subsequent articles suggest

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<sup>76</sup> Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Healthcare Reform: An Update*, 21 ANNALS HEALTH L. 21, 25-26 (2012).

<sup>77</sup> Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POLIT., POL. & L. 327, 331 (2001) [hereinafter Rosoff, *Evidence-Based Medicine*]; see also Arnold J. Rosoff, *On Being a Physician in the Electronic Age: Peering into the Mists at Point-&-Click Medicine*, 46 ST. LOUIS L.J. 111, 115 (2002) (outlining the use of Clinical Decision Support Systems as a form of Clinical Practice Guidelines).

<sup>78</sup> Andrew L. Hyams et al., *Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective*, 21 J. HEALTH POLIT., POL. & L. 289 (1996) [hereinafter Hyams et al.].

<sup>79</sup> *Id.* at 295.

that courts have historically been hesitant to use CPGs in medical malpractice cases.<sup>80</sup>

Hyams and colleagues found only thirty-seven published cases involving the use of CPGs. Of those published decisions, the Hyams study identified twenty-two cases of successful inculpatory use and six cases of successful exculpatory use.<sup>81</sup> However, the attorney surveys indicated that the profession was indeed aware of CPGs, and that guidelines aided in settlement negotiations and even in the decision of whether or not to take certain cases.<sup>82</sup>

I extended the Hyams study by finding and analyzing judicial decisions involving CPGs in any context published between January 2000 and March 2010.<sup>83</sup> The review indicates that use of guidelines by courts continues to be sporadic and mostly conservative. The use of guidelines for inculpatory purposes has tended to increase, though the sample size is so small that few conclusions can be drawn. Of the twenty-eight cases found with parties using guidelines in some form, sixteen (57%) involved their use by plaintiffs as swords compared to 78% of cases in the Hyams study. Twelve cases (43%) involved CPG use by defendants as shields compared to 22% in the Hyams study.<sup>84</sup> Interestingly, in eight of the twelve

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<sup>80</sup> *Id.* at 310. See also Rosoff, *Evidence-Based Medicine*, *supra* note 77, at 352; see also Mello, *supra* note 57 (discussing the different ways in which courts have approached medical malpractice). For a more detailed discussion of the Hyams et al. study, see Avraham, *Warped Incentives*, *supra* note 1, at 18–19.

<sup>81</sup> Hyams et al., *supra* note 78, at 296.

<sup>82</sup> Rosoff, *Evidence-Based Medicine*, *supra* note 77, at 341.

<sup>83</sup> The search was performed looking for the appearance of “medical” or “medicine” as well as “guideline” in all 50 state jurisdictions and in federal courts. Sometimes courts may discuss guidelines without necessarily referring to them as such, so a second search was run using terms like “algorithm” and “standard.” To attempt to weed out results where “standard” appeared merely as a part of “standard of proof” or a legal “standard,” cases also were required to have “medicine,” “medical,” “hospital,” “doctor,” or “physician” in the text. While these results are likely not comprehensive (and there were surely cases missed which might have discussed clinical practice guidelines in some form), it’s most probable that these cases would not have dealt with guidelines extensively and thus would not have added a great deal to the discussion.

<sup>84</sup> Hyams et al., *supra* note 78, at 296.

cases where guidelines were used for exculpatory purposes, the defendant was successful.<sup>85</sup>

These cases devoted little significant analysis to what organization drafted the relevant guidelines, and there was not a clear plurality of any one association's guidelines being used successfully. Guidelines written by the American College of Obstetricians and Gynecologists (ACOG) and the Centers for Disease Control did appear repeatedly, but whether this was a function of the guidelines or a correlate of the type of injury alleged is not clear. Discussion tended to center on applicability, relevance, or evidentiary acceptability and not on the quality of the guidelines themselves.

While the full extent of court use of CPGs is unknown, if they are to eventually be effective in reducing the costs of medical malpractice litigation, the legal system will need to accept generalized use more definitively than published cases suggest. As reflected in the cases, current obstacles to CPG adoption in court include the connection between evidence-based guidelines and the concept of a professionally determined standard of care, hearsay objections,<sup>86</sup> the battle between competing guidelines or experts,<sup>87</sup> and how seemingly "one-size-fits-all" guidelines should yield to physician judgment in individual cases.<sup>88</sup>

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<sup>85</sup> There are several caveats. First, our findings are based on published judicial decisions, which are uncommon in medical malpractice litigation. Second, trials are rare events in malpractice litigation, so that the evidentiary use of guidelines does not necessarily capture the impact guidelines may have on the vast majority of malpractice cases that settle. Lastly, because it is so difficult to determine when the use of guidelines is dispositive, these figures do not necessarily indicate whether the cases were successful *because* of the use of guidelines.

<sup>86</sup> The Hyams study notes increasing willingness of courts to use the hearsay exception for learned treatises as an avenue to admitting guidelines as evidence. The trend towards the admissibility of guidelines has continued, although they are still not accepted to prove standard of care on their own. Rather, litigants almost always employ an expert witness to act as the conduit for admitting guidelines. Hyams et al., *supra* note 78.

<sup>87</sup> See Mello, *supra* note 57, at 684; see also Avraham, *Private Regulation*, *supra* note 1, 618–19 (discussing the so called "battle of the guidelines" and the solution provided by Avraham's private model for CPGs).

<sup>88</sup> 978 So.2d 1257 (La. App. 2008). In *Bond v. U.S.* the court quoted the ACC/AHA guidelines to make this point: "These practice guidelines are intended to assist physicians in clinical decision-making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific

## B. CPG USE BY THE INSURANCE INDUSTRY

The law has also accounted for guidelines in regulation and litigation concerning health insurance coverage. Before the 1960s, health insurers and the community of medical professionals maintained a general understanding that those responsible for payment would not interfere with clinical decisions. As the cost of health care began to rise, however, this understanding was revisited and eventually abrogated, particularly in the 1980s and 1990s.<sup>89</sup>

CPGs have been connected with the insurance industry primarily through regulation and litigation over the definition of “medically necessary care,” and the related question of whether or not a proposed treatment should be excluded from coverage because it is “experimental” or “investigational.” Over the last few decades, hundreds of judicial decisions have interpreted these contractual exclusions from coverage in disputes between patients and private insurers, Medicaid, and Medicare.<sup>90</sup> A common theme in the decisions is the desire of judges to assure themselves that coverage denials are not merely financially motivated efforts that incidentally deprive patients of scientifically correct care. As a result, the law has struggled to find preferred sources of evidence about optimal practice procedures – in other words, CPGs.

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diseases or conditions . . . The ultimate judgment regarding the care of a particular patient must be made by the physician and patient in light of all of the available information and the circumstances presented by that patient.” 2008 U.S. Dist. LEXIS 19881 at \*25 (D. Or. 2008). For more information on these problems and more see Avraham, *Warped Incentives*, *supra* note 1, at 18–20.

<sup>89</sup> Indeed, virtually all the fashionable innovations in health care organization, payment, and accountability today – including ACOs – are direct descendants of 1990s-style managed care. See Kip Sullivan, *The History and Definition of the “Accountable Care Organization”* (October 2010), Physicians for a National Health Program California, <http://pnhpcalifornia.org/2010/10/the-history-and-definition-of-the-%E2%80%9Caccountable-care-organization%E2%80%9D/>.

<sup>90</sup> See Mark A. Hall & Gerald F. Anderson, *Health Insurers' Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637 (1992); Mark A. Hall, Teresa Rust Smith, Michelle Naughton & Andrea Ebbers, *Judicial Protection of Managed Care Consumers: An Empirical Study of Insurance Coverage Disputes*, 26 SETON HALL L. REV. 1055, 1056, 1058 (1996); William M. Sage, *Judicial Opinions Involving Health Insurance Coverage: Trompe L'oeil or Window on the World?*, 31 IND. L. REV. 49, 49 (1998).

During the 1990s, some state lawmakers also began to combine health insurance benefit mandates with evidence-based coverage standards in particularly contentious scenarios, like in regard to access to clinical trials and denials of coverage involving potentially lifesaving treatments.<sup>91</sup> These laws are important to a discussion of governance and accountability for CPGs because they involve the government in establishing a hierarchy of evidence and mandatory procedures to be used to regulate access to cutting-edge clinical resources.

More generally, mandated benefit laws for a variety of health care services are common at the state level, although the federal ERISA statute prevents them from being applied to self-insured employer-based coverage. Requirements that health plans in a state cover certain benefits are typically enacted at the behest of providers with focused interests and/or patient groups with sympathetic needs. This has resulted in a large set of statutes that define a specific, favored clinical service. Mandated benefit laws are not CPGs in intent or substance, but they are important to understanding how the law can explicitly specify clinical tasks that were historically left up to physician discretion.

### C. SYSTEMATIC GUIDELINE INITIATIVES

Both state and federal governments have attempted to confer a larger public policy role on clinical practice guidelines in the recent past. These efforts have tended to coincide with periods of interest in comprehensive health care reform, with peaks in the late 1980s and the early 1990s, and another peak just emerging in connection with the advent of Obamacare. Systematic guideline initiatives have focused on medical malpractice reform as well as more general improvements in the cost-effectiveness of health care, with unnecessary health care spending (such as defensive medicine) representing the conceptual connection between them.<sup>92</sup>

#### 1. AHCPR's Guideline Program

The first major attempt at using medical guidelines reform to spur broader healthcare improvement was in 1989 when Congress created the

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<sup>91</sup> See CAL. WELF. & INST. CODE §14132.98 (West 2002).

<sup>92</sup> For more on state specific projects, see Avraham, *supra* note 1 (discussing other projects in Vermont, Minnesota, Kentucky, Maryland, and Texas).

Agency for Health Care Policy and Research (AHCPR) to “enhance the quality, appropriateness, and effectiveness of health care services” through, among other things, “the development and periodic review and updating of . . . clinically relevant guidelines.”<sup>93</sup> Several years later, the Clinton administration attempted to take this initiative a step further by proposing a medical liability pilot program based on the practice guidelines developed by the AHCPR. Under the pilot program, doctors who could show that their actions were consistent with relevant practice guidelines could avoid medical malpractice liability.<sup>94</sup>

Because of political opposition to President Clinton’s healthcare reform and fierce interest group politics, President Clinton’s experimental initiative stalled and the AHCPR was almost completely eliminated in 1995.<sup>95</sup>

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<sup>93</sup> Mello, *supra* note 57, at 651 (quoting Stephen M. Merz, *Clinical Practice Guidelines: Policy Issues and Legal Implications*, 19 JOINT COMMISSION J. ON QUALITY IMPROVEMENT 306, 307 (1993)).

<sup>94</sup> U.S. GEN. ACCOUNTING OFFICE, MEDICAL MALPRACTICE: MAINE’S USE OF PRACTICE GUIDELINES TO REDUCE COSTS 1–2 (Oct. 1993), *available at* <http://biotech.law.lsu.edu/policy/150172.pdf>.

<sup>95</sup> The conflict that nearly eliminated the AHCPR emerged from a debate regarding spinal fusion surgery. Following many years of controversy over the merits of surgical procedures for low-back disorders, AHCPR funded a study that concluded that there was no evidence to support the use of spinal fusion surgery, that such surgery commonly had complications, and that more randomized controlled trials were needed to compare fusion surgery with non-surgical treatment. An association of back surgeons who disagreed with the conclusions launched an attack on the study and the agency itself. Bradford H. Gray, et al., *AHCPR and The Changing Politics Of Health Services Research*, HEALTH AFFAIRS W3-283, W3-297, *available at* <http://content.healthaffairs.org/content/early/2003/06/25/hlthaff.w3.283>. The Center for Patient Advocacy, which was formed by a back surgeon to lobby on the issue, mobilized an effort in the House of Representatives to end the agency’s funding. Only on the night of the vote was an amendment to reduce the agency’s budget to zero withdrawn, leaving the agency instead with a 21% budget cut. *Id.* at W3-295. The 1995 battle between the AHRQ and the back physicians was not the first time AHRQ faced attacks by physician groups. Earlier in 1993, an AHCPR study came under attack from various ophthalmology associations. *Id.* at W3-297. However, that attack never extended to attempts to defund AHCPR, and it came to an end when the ophthalmologists discovered they could use the data to discredit a GAO study alleging that inappropriate cataract surgery was widespread and to get insurers to pay for some surgery. *Id.*

One of the consequences of this battle was that the agency dropped its CPG development program and initiated support for external evidence-based practice centers that organize data to help private-sector organizations develop CPGs. In 1999, Congress passed legislation that changed the agency's name to the Agency for Healthcare Research and Quality (AHRQ). AHRQ has since become a major force in the dissemination of medical guidelines, though the actual creation of CPGs was eliminated from its mission.<sup>96</sup>

## 2. Maine's Malpractice Guideline Project

Maine was home to the most famous project that established clinical practice guidelines as statutory standards of care for physicians to use as a defense in malpractice suits.<sup>97</sup> The Maine Medical Liability Demonstration Project was a ten-year pilot study that began in 1989 and expired in 1999. It instituted special advisory committees in charge of developing CPGs for four practice areas viewed as hotbeds for malpractice litigation and suspected defensive medicine. Maine subsequently adopted twenty guidelines in anesthesiology, emergency medicine, obstetrics/gynecology, and radiology.

Physicians, hospitals, and managed care organizations that elected to participate could use the guidelines as an affirmative defense against any malpractice claim. Plaintiffs bringing such claims, however, could not introduce the guidelines into evidence to argue that failure to comply was malpractice.<sup>98</sup> The guidelines were only available as a shield because the purpose of the reform was to reduce overall liability, a common purpose for reforms adopted during or after the malpractice insurance crisis of the mid-1980s.

The Maine project had little practical effect.<sup>99</sup> Few doctors believed these regulations had any discernible impact on the malpractice system, and

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<sup>96</sup> See Avraham, *Private Regulation*, *supra* note 1, at 577–78.

<sup>97</sup> Linda L. LeCraw, *Use of Clinical Practice Guidelines in Medical Malpractice Litigation*, 3 J. ONCOLOGY PRAC. 254 (2007).

<sup>98</sup> ME. REV. STAT. Tit. 24, §§ 2975, 2977 (1993).

<sup>99</sup> LeCraw, *supra* note 97. By one estimate, the guidelines affected only about three to four percent of medical practice in Maine. See Gordon H. Smith, *A Case Study in Progress: Practice Guidelines and the Affirmative Defense in Maine*, 19 Joint Commission J. ON QUALITY IMPROVEMENT 355, 361 (1993).

the affirmative defense was raised in only one case.<sup>100</sup> The superintendent of the Maine Bureau of Insurance concluded “the medical demonstration project had no measurable effect on medical professional liability claims, claims settlement costs, or malpractice premiums.”<sup>101</sup>

### 3. Florida’s C-Section Guideline Project

In 1994, concerns over the cost of defensive medicine prompted Florida to initiate its own CPG project to be administered by the state’s Agency for Health Care Administration (AHCA).<sup>102</sup> Similar to the Maine project in many respects, the Florida project created an affirmative defense for participating physicians, provided that they followed specific clinical practice guidelines.

The primary difference from the Maine project was that Florida did not explicitly prevent plaintiffs from using the guidelines to help prove physicians failed to meet the standard of care, or from using the guidelines as a liability sword.<sup>103</sup> However, lack of physician compliance with guidelines did not create a prima facie case of negligence, and physicians were given leeway to demonstrate whether their decision to deviate from the guidelines was prudent given the specific circumstances of the case.<sup>104</sup>

Florida’s guideline project concentrated on only one procedure.<sup>105</sup> Florida chose deliveries by caesarean section for their test project because it was the most common surgical procedure performed in Florida hospitals

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<sup>100</sup> Howard Zonana, *Commentary: When Is a Practice Guideline Only a Guideline?*, 36 J. AM. ACAD. PSYCHIATRY L., 302, 303 (2008).

<sup>101</sup> LeCraw, *supra* note 97, at 254 (citing ME. BUREAU OF INS. AND BD. OF LIC. IN MED., MEDICAL LIABILITY DEMONSTRATION PROJECT 2 AND 5 (2000)). Similar to Maine, in 1992 Minnesota also attempted to use clinical practice guidelines as a tool for health care reform, but the state never created the required guidelines to get the project off the ground. 1992 Minn. Sess. Law Serv. Ch. 549 art. 7 (H.F. 2800); 1995 Minn. Sess. Law Serv. Ch. 234; *see also* William Trail & Brad Allen, *Government Created Medical Practice Guidelines: The Opening of Pandora's Box*, 10 J.L. & HEALTH 231, 247 (1995).

<sup>102</sup> FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION, PRACTICE GUIDELINES AS AFFIRMATIVE DEFENSE: THE CESAREAN DEMONSTRATION PROJECT REPORT (1998).

<sup>103</sup> Trail, *supra* note 101, at 246.

<sup>104</sup> *Id.*

<sup>105</sup> FLA. STAT. § 408.02(9) (1996).

at the time.<sup>106</sup> Supporters predicted that the C-section rate would decline if physicians practiced in accordance with the guidelines. However, the affirmative defense proved to be an inadequate incentive to convince physicians to participate. Only 20% of eligible physicians participated, and it was determined that the ones who did participate were already less likely to perform C-sections.

Overall, Florida's effort had little effect on physician behavior. The primary barriers included lack of awareness, lack of familiarity with the guidelines, and lack of agreement with the validity of the guidelines.<sup>107</sup>

#### 4. Ongoing Initiatives

This section provides a brief overview of some of the current attempts to improve quality and reduce health care costs using CPGs.

##### a. *Federal Malpractice Reform Demonstrations*

The Obama administration's 2012 budget proposal included \$250 million for state-based alternatives to tort litigation for medical malpractice, with guidelines prominently featured among the favored reform approaches.<sup>108</sup> These funds were not authorized or appropriated by Congress, but the proposal still represents a renewed interest in CPG use.

Previously, AHRQ had awarded \$25 million for planning and demonstration grants in states, communities, and provider organizations that integrate improvements in patient safety with improvements in medical malpractice litigation.<sup>109</sup> CPGs fit this description, along with programs of error disclosure and offers of compensation, health courts, and a few other

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<sup>106</sup> J. Rosser Matthews, *Practice Guidelines and Tort Reform: The Legal System Confronts the Technocratic Wish*, 24 J. HEALTH POL. POL'Y & L. 275, 284 (April 1999).

<sup>107</sup> In a study of the project, 54.5% of doctors surveyed attributed their failure to adhere to medical guidelines in part to a lack of awareness that relevant guidelines existed. Lack of familiarity with Florida's guidelines was cited by 56.5% as a cause of failure to adhere.

<sup>108</sup> Emily P. Walker, *Obama's Budget Includes \$250M in Malpractice Grants*, MED PAGE TODAY (Feb. 16, 2011), <http://www.medpagetoday.com/PracticeManagement/Medicolegal/24904>.

<sup>109</sup> *Medical Liability Reform and Patient Safety*, AGENCY FOR HEALTH CARE RESEARCH AND QUALITY, <http://www.ahrq.gov/qual/liability/>.

innovations.<sup>110</sup> However, only one of the 13 small planning grants – a project from the Office of Oregon Health Policy and Research – and none of the seven larger demonstration grants initially awarded involved CPGs.<sup>111</sup>

b. *The Oregon Health Authority*

Between 1987 and 1994, the Oregon Legislature ratified several laws that established the structure for a public and private partnership that cumulatively constituted the Oregon Health Plan (OHP).<sup>112</sup> The Oregon Health Plan was originally designed to increase access to health care for lower income groups while controlling costs. Under the plan, prioritized medical services were to be incorporated into the basic benefit package for both Medicaid beneficiaries as well as people covered by private insurance in the state.<sup>113</sup> In order to maintain budgetary restraint, the plan aimed to ration care by limiting the range of services covered under the basic benefits package.<sup>114</sup> The program was cancelled in 2003 due to rising costs.

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<sup>110</sup> Additional funds were committed to AHRQ for malpractice and patient safety demonstrations in connection with the new health reform law, and a substantial expansion of federally funded experimentation is possible.

<sup>111</sup> *Medical Liability Reform & Patient Safety Grants*, AGENCY FOR HEALTHCARE RESEARCH QUALITY, <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/liability/medliabrep.html> (last updated June 2010).

<sup>112</sup> See generally OR. REV. STAT. §§ 413.006 – 413.100, 414.065 (2013) (discussing the Oregon Health Authority and its policy-making and oversight body the Oregon Health Policy Board).

<sup>113</sup> Seventeen types of health ailments (including fatal acute conditions that can be fully treated, less serious acute problems, chronic conditions, maternity care, and preventative treatments) were established. Then, all diagnoses and corresponding care in both medical and surgical arenas were assigned to a particular category of health ailments. These diagnosis-treatment pairs were subsequently prioritized according to thirteen attributes (including life expectancy, quality of life, cost containment, clinical efficacy, net benefits, and number of people assisted by the treatment). Finally, based on the prioritized list and the state's appropriations for the OHP, services and practices on the prioritized list above a certain level or ranking would be covered and those below the ranking would not be reimbursed.

<sup>114</sup> Vidhya Alakeson, *Why Oregon Went Wrong*, 337 BRITISH MED. J., 900, 901 (2008); *Oregon Health Plan: An Historical Overview*, OREGON DEPARTMENT OF HUMAN SERVICES, 3 (July 2006), available at

The rise in the number of uninsured residents, increased medical expenses, and reductions in employer-based health care prompted Oregon to revisit reform. In 2009, the state ratified HB 2009, which established the Oregon Health Authority (OHA) and empowered it to streamline and harmonize the state's health care programs.<sup>115</sup> The OHA is responsible for improving efficiency, coordinating health administration, and executing the reforms mandated by HB 2009.<sup>116</sup> These reforms included developing "evidence-based clinical standards and practice guidelines that may be used by providers."<sup>117</sup> The guidelines promulgated by the OHA, though not expressly given the force of law, could eventually come to represent the standard of care in disciplinary proceedings and malpractice suits.

As noted, the OHA received one of the initial AHRQ planning grants for liability and patient safety innovation. The results of the planning process were mixed. In a report to AHRQ, the grantees estimated that 5% of malpractice injuries could have been avoided if clinicians had followed guidelines, but also found that cost savings from reduced defensive medicine and safe harbor laws would be minimal or non-existent.<sup>118</sup> Although Oregon would have saved \$4 million in medical liability costs under a safe harbor program, the additional administrative costs of such a program likely would have negated any savings.<sup>119</sup> Given the patient safety benefits, one of the two pillars that support an increased role for CPGs, the report recommends additional research.<sup>120</sup>

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<http://www.oregon.gov/oha/healthplan/DataReportsDocs/Oregon%20Health%20Plan%20-%20An%20historical%20overview.pdf>.

<sup>115</sup> Establishing Oregon Health Policy Board, H.R. HB 2009-C, 75th Leg. §20 (Or. 2009).

<sup>116</sup> *Id.* at §§1, 9. HB 2009 effectively dissolved the Oregon Health Fund Board and replaced it with the Oregon Health Policy Board (OHPB), which formulates policy and acts as the oversight body for the Oregon Health Authority. The nine-member group is required to widen access, control the cost and quality of the health care delivery system, and enhance the health of Oregonians by developing state public health objectives, policies, initiatives, and benchmarks.

<sup>117</sup> OR. REV. STAT. § 413.011(e) (2013).

<sup>118</sup> *Medical Liability & Patient Safety Planning Grant: Final Progress Report*, AGENCY FOR HEALTHCARE RESEARCH QUALITY 1, 10-11 (2012), [http://www.oregon.gov/oha/OHPR/PSDM/AHRQ\\_MLPS\\_Report.pdf](http://www.oregon.gov/oha/OHPR/PSDM/AHRQ_MLPS_Report.pdf).

<sup>119</sup> *Id.* at 11.

<sup>120</sup> *Id.* at 14.

c. *The American Recovery and Reinvestment Act*

Signed into law in 2009 by President Obama, the American Recovery and Reinvestment Act (ARRA) included funding and administrative support for comparative effectiveness research, an area where CPGs play a prominent role.<sup>121</sup> The ARRA appropriated \$1.1 billion for comparative effectiveness studies, including comparative trials, medical registries, clinical databases, and methodical appraisals.<sup>122</sup> Furthermore, ARRA directed the IOM to conduct a national study of critical areas that could utilize comparative effectiveness and could capitalize on the appropriated funds.<sup>123</sup> The 2009 law also created the Federal Coordinating Council for Comparative Effectiveness Research; a committee chaired by the Secretary of DHHS and composed of federal administrators and clinicians.

Interestingly, while the council was directed to propose and organize research efforts, it was *prohibited* from using the studies to specify clinical practice guidelines or implementing changes in coverage and reimbursement procedures.<sup>124</sup> Still, this series of studies can provide once completed important information that can be used by others to create effective CPGs

d. *Patient Protection and Affordable Care Act*

Paralleling renewed interest in evidence-based guidelines and cost-effective treatment, the 2010 Patient Protection and Affordable Care Act (PPACA) expands comparative effectiveness research.<sup>125</sup> The federal government designated a minimum of \$500 million to pursue statistical studies that judge the efficacy of drugs, devices, and treatments. PPACA also experiments with “new payment systems for doctors,” fines hospitals

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<sup>121</sup> American Recovery & Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009).

<sup>122</sup> *Id.* The Agency for Health care Research and Quality (AHRQ) was designed to oversee \$300 million of the \$1.1 billion total, with \$400 million directed by the National Institute of Health (NIH) and \$400 million administered by the Department of human and Human Services (DHHS).

<sup>123</sup> *Initial National Priorities for Comparative Effectiveness Research*, INSTITUTE OF MEDICINE 2 (2009).

<sup>124</sup> Robert Steinbrook, *Health Care & the American Recovery & Reinvestment Act*, 360 NEW ENG. J. MED. 1057, 1058 (2009).

<sup>125</sup> Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566 (2012).

for “high readmission rates,” and establishes an independent commission to determine which procedures Medicare should reimburse. The studies will be overseen by the newly created Patient-Centered Outcomes Research Institute (PCORI), which is authorized to determine research needs and perform studies that evaluate the relative usefulness of medical therapies.<sup>126</sup>

Lastly, under the PPACA, AHRQ will occupy an integral role in designing, pursuing, and disseminating clinical effectiveness research. The Act places AHRQ on the Board of Governors for the PCORI, and the agency must also work with the NIH to train researchers for the new studies and convey its findings. In concert with DHHS, AHRQ and CMS will be granted \$75 million over five years to jointly formulate quality standards. To improve the quality of the provision of medical care, the PPACA also allocates \$20 million to the AHRQ for the agency to determine, formulate, assess, and teach new processes and approaches in clinical practices between 2010 and 2014.<sup>127</sup>

The next section of the paper discusses three main models for ensuring trustworthiness of CPGs: the Public Model, the Semi-Public Model, and the Private Model. The first two models exist or existed in the U.S and the U.K, the third is novel. These discussions will highlight the benefits and drawbacks of each method.

#### IV. MODELS FOR STRUCTURED ACCOUNTABILITY FOR CPGS

In its 2011 Report, the IOM lays out eight standards that focus on the procedures by which CPGs are to be developed. To enforce these standards the IOM recommends forming a private–public entity, which will provide a seal of approval to CPGs that meet those eight standards. But that is just one possible model (and one that I argue cannot work well in practice). In this section I describe the several broad approaches to CPG quality control and explain the advantages and disadvantages of each one. One option is to approve the guideline itself. Here the certifier (public, semi-public, or private) reviews the CPG and makes sure that it is optimal. A regime with a public certifier existed in the US in the past but no longer exists in pure form in the US or in the UK. Part of this is because it can be

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<sup>126</sup> Alex Nussbaum et al., *Obamacare's Cost Scalpel*, BLOOMBERG BUS. WK., Apr. 5, 2010, at 66.

<sup>127</sup> Patient Protection & Affordable Care Act, Pub. L. No. 111-148, §§ 3013, 3501, 6301, 10602, 124 Stat. 119, 381, 507, 727, 1005 (2010).

difficult to employ due to the time, resources, and expertise necessary to approve an individual guideline. The more realistic method focuses on approving the *process* used to develop individual CPGs. Professor Rosoff offered this model almost two decades ago.

Alternatively, the certifier can approve the legitimacy of the institution that develops them. In this system, the certifier provides a seal of approval for the entity promulgating the CPGs. This gives the entity an approved status based on more general checkups and not based on any one individual guideline. The downside of this approach is that the individual CPGs are not reviewed. Such a system exists in the UK with a public certifier, and was proposed by the IOM (but with a public-private certifier) for the US.

Lastly, there is a private model, proposed by Avraham, where guidelines are promulgated by private entities and compete in the market for the endorsement of practitioners. The private model can take hold in two ways. First, and most obvious, it can be created by legislation that changes our current system such that new organizations will emerge. Secondly, and perhaps more realistically, the regime will evolve incrementally from organizations that realize it is in everyone's best interest to implement a private model of accountability to ensure high quality guidelines are drafted and used by physicians.

The following table roughly summarizes this and demonstrates how the different models match the analysis:

**Table 1: Models of CPG Quality Control**

		Certifier		
		Public Model	Semi Public Model	Private Model
Inspected	Output (CPGs themselves)	US (old model), UK		Avraham
	Credentials of Promulgators	UK	US (IOM)	
	Procedures Used in specific Guidelines	Rosoff		

## A. THE PUBLIC MODEL

The Public Model actually consists of three variations, each of which is covered in this section of the Article. The government can be the entity that actually drafts and publishes CPGs, it can certify entities that it deems qualified to publish reliable CPGs, or it can itself provide an approval system that evaluates the process by which CPGs are created and approves CPG meeting the stated requirements on an individualized basis.

### 1. Government Promulgating CPGs (UK & Old US Model)

In general, the UK uses a public model, although promulgation of CPGs in the UK is not entirely centralized. The Department of Health (DH)<sup>128</sup> oversees the government health care system, the National Health Service (NHS).<sup>129</sup> The NHS, in turn, coordinates with the DH's various Arm's Length Bodies (ALB),<sup>130</sup> which are financed by the government but act independently, in order to help implement various functions of the NHS. The ALB for standards of promulgation is the National Institute for Health and Clinical Excellence (NICE),<sup>131</sup> which is responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health within the NHS.<sup>132</sup> Through collaboration and a series of researching steps, NICE develops guidelines that suggest optimal practices for NHS health care practitioners.<sup>133</sup>

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<sup>128</sup> *The Department of Health*, GOV. UK, <https://www.gov.uk/government/organisations/department-of-health> (last visited Sept. 3, 2012).

<sup>129</sup> *The National Health Service*, GOV. UK, <http://www.nhs.uk/Pages/HomePage.aspx> (last visited Sept. 3, 2012).

<sup>130</sup> *Arm's length bodies*, DEPT. OF HEALTH, <http://www.dh.gov.uk/government/publications/arms-length-bodies/our-arms-length-bodies> (last visited Apr. 26, 2014).

<sup>131</sup> THE NATIONAL INSTITUTE FOR HEALTH & CLINICAL EXCELLENCE, <http://www.nice.org.uk/> (last visited Sept. 2, 2012).

<sup>132</sup> *About NICE*, NAT'L INST. FOR HEALTH & CARE EXCELLENCE, <http://www.nice.org.uk/aboutnice/> (last visited Feb. 16, 2014).

<sup>133</sup> Nat'l Inst. For Health and Care Excellence (NICE), *Developing NICE Clinical Guidelines*, [http://www.nice.org.uk/aboutnice/howwework/developing-niceclinicalguidelines/developing\\_nice\\_clinical\\_guidelines.jsp](http://www.nice.org.uk/aboutnice/howwework/developing-niceclinicalguidelines/developing_nice_clinical_guidelines.jsp) (last visited Feb. 11, 2014).

In the US, as mentioned earlier in the paper, after a fierce political battle in the early 1990s, the AHRQ stopped promulgating guidelines. The AHRQ now perceives itself as facilitating the creation of CPGs by other actors.

Still, there are good reasons to think that the government *should* write and publish guidelines. Other government agencies – such as CMS – write guidelines, and governments in other countries like the UK do as well. For example, in September 2006, the Center for Disease Control and Prevention issued its “Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings.”<sup>134</sup> These examples of the public model point towards government agencies as a potentially desirable source of CPGs.

On the surface there is something appealing about the government writing guidelines because CPGs are, after all, a public good. But how does this model of promulgation affect the quality of health care? The foremost concern with this model is the issuing agency’s ability to keep its guidelines up-to-date. Because medical research evolves very quickly, it is likely that government CPGs would fail to keep up with current medical research. A 2001 study found thirteen out of seventeen CPGs developed by the AHRQ to be outdated.<sup>135</sup> The study also found that it was estimated to cost \$4 million per guideline to properly update them using the AHRQ’s Evidence Based Practice Center Program.<sup>136</sup> Unfortunately, medical research does not evolve on a rigid timetable, so agency guidelines may significantly lag behind cutting-edge medical advances. There are, therefore, reasons to think government promulgation of CPGs may actually impede quality improvement.

In addition to quality problems, government authorship of guidelines could easily create greater cost-inefficiency in the health care system. Various dynamics suggest that government agencies may create overly lax guidelines (or under-enforce them).<sup>137</sup> First, agencies will often lack the resources to set the regulations efficiently (and as discussed above,

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<sup>134</sup> *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*, CENTER FOR DISEASE CONTROL & PREVENTION (2006), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm> (last visited Feb. 11, 2014).

<sup>135</sup> Shekelle, *supra* note 61, at 1464.

<sup>136</sup> *Id.* at 1462.

<sup>137</sup> See Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 494-95 (2008).

update them regularly).<sup>138</sup> Second, as the history of the AHRQ revealed, agencies are vulnerable to the political preferences of the administration in power, to self-aggrandizing administrators, and interest group capture.<sup>139</sup> A change in the government can lead to ossification of standards. Administrators operating in a revolving door environment may advance their post-agency careers by catering to interest groups that favor lax standards. Most importantly, interest group capture can lead to under enforcement and, as in the case of the AHRQ, may hamstring guideline development or even cause the abandonment of CPG promulgation altogether.<sup>140</sup> Interest group capture can also lead to subtle biases and conflicts of interest in the guidelines that promote one company's products or services over another's at the expense of the patient.

At the same time, there are reasons why some federal agencies might adopt overly strict guidelines. Occasionally, agencies regulate in response to crises, and this may lead to reactionary guidelines being promulgated. Second, agencies lack the financial accountability necessary to incentivize efficient rulemaking. Government agencies cannot be sued for making poor guidelines in a classic example of who watches the watchmen.<sup>141</sup> As it is, an agency rule maker would be less likely to fully internalize the financial consequences of their own guidelines and may choose to overregulate. Third, the overregulation may become even more exaggerated because, while the regulator may not be financially accountable, they will be *politically* accountable, which usually leads to more defensive policies. If the agency errs by failing to regulate, its political accountability assures their punishment. However, an agency can scarcely be punished politically for overly stringent regulations.<sup>142</sup> More

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<sup>138</sup> Jeffrey J. Rachlinski, *A Positive Theory of Judging in Hindsight*, 65 U. CHI. L. REV. 571, 609 (1998).

<sup>139</sup> Interest group capture occurs when special interest groups gain a disproportional share of influence over a government agency. This can happen because of, for example, campaign donations or the revolving door between government and the private sector.

<sup>140</sup> See *supra* note 95 and accompanying text (describing how the AHRQ had to stop promulgating guidelines due to interest group pressure).

<sup>141</sup> In the US one cannot sue the FDA or any other agency for a wrong decision within their discretion. See 28 U.S.C. §2680(a) (2006) (imposing this exception to the general waiver of sovereign immunity created by the Federal Tort Claims Act).

<sup>142</sup> See Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, J. Tort L., at

likely they will be commended for taking such a stern stance against liability prevention, but this does nothing to alleviate the economic pressures faced by the modern health care system.

Due to these countervailing considerations, there is uncertainty whether agencies would regulate in an overly strict or overly lax manner. The efficiency, however, would be diminished in either scenario.<sup>143</sup> As a result the pure public model would probably do little to contain health care costs and might impair quality. In sum, the chance that government promulgation of CPGs would directly improve the quality of care while being systematically and continuously efficient is slim.

## 2. Certification of CPG Promulgators (UK Model)

While part of the UK Model involves the government promulgating CPGs, the part of the UK Model I want to focus on is when the government approves other entities that in turn create CPGs. This certification process is done by the NHS Evidence Advisory Committee, created by the Board of NICE as an independent, standing committee. The NHS Evidence Advisory Committee does not verify the efficacy of the individual guidelines, but chooses to focus on the methods used by guideline creators in guidelines production.<sup>144</sup> These guidelines, along with others from accredited and non-accredited producers alike, are posted to the

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22 (2006) (arguing agencies have incentives to regulate in an overly risk-adverse fashion because of self interest); *see also* Daniel P. Carpenter, *The Political Economy of FDA Drug Review: Processing, Politics, and Lessons for Policy*, 23 HEALTH AFFAIRS 1, (2004).

<sup>143</sup> Most agencies seem to regulate only minimum standards of care. A possible exception is the FDA. *See Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) (acknowledging that the FDA seeks to encourage the optimal level of use in light of reasonable safety concerns, by requiring scientific evidence that establishes an association between a drug and a particular hazard before warning of that association on a drug's labeling).

<sup>144</sup> NAT'L INST. FOR HEALTH AND CARE EXCELLENCE (NICE), PROCESS MANUAL FOR ACCREDITING PRODUCERS OF GUIDANCE, ADVICE, AND RECOMMENDATIONS FOR PRACTICE: A GUIDE FOR PRODUCERS AND STAKEHOLDERS, *available at* <http://www.evidence.nhs.uk/Accreditation/Document s/NHSEvidenceAccredManual.pdf> [hereinafter *Accreditation Manual*].

committee's website, NHS Evidence.<sup>145</sup> Since 2009, NICE has accredited sixty organizations.<sup>146</sup> Guidelines from these organizations are marked on the NICE website with a symbol indicating the approval from the government.

How is the quality of care impacted by guidelines and guideline promulgation in the UK? To try to understand the impact on health care costs and quality of the NICE accreditation system it is helpful to think about the themes of accountability, guideline agreement, and consistent use by doctors that an ideal CPG system would have. Beginning with accountability, it is easy to see that a system focusing on process rather than output may have some issues. Organizations that have been accredited are accountable to NICE for their processes, but not for the contents of the guideline. If an organization creates a guideline that turns out to be incorrect, there is no liability that would hold that organization responsible for its recommendation. There is also no promise that CPGs created by certified organizations will not be biased. With no accountability, doctors would instead be on their own in defending their actions and would have less of an incentive to adopt CPGs.

A second issue with the UK Model flows out of the lack of accountability. Having a certification process that does not review individual guidelines or compare them to each other allows for the certification and publication of conflicting guidelines. In the case of CPGs, more information is not always a good thing. Conflicting CPGs, especially when both are stamped with government approval, may make doctors less likely to follow any guideline because they will not know which guideline actually represents the current best practices. As we mentioned above, it is unrealistic for doctors to keep up with ongoing medical research given the enormous volume of studies and reports that are published each year. Synthesizing new studies and providing recommendations is one of the benefits of CPGs because they can reduce the information costs to doctors, especially those in solo practice. When conflicting guidelines are certified, however, this benefit is largely lost and the implementation rate by doctors will likely drop.

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<sup>145</sup> *Frequently Asked Questions*, NAT'L INST. FOR HEALTH & CARE EXCELLENCE (NICE), <http://www.nice.org.uk/aboutnice/accreditation/FAQs.jsp> (last visited Feb. 11, 2014).

<sup>146</sup> *NICE Accreditation*, NAT'L INST. FOR HEALTH & CARE EXCELLENCE (NICE), <http://www.nice.org.uk/aboutnice/accreditation/index.jsp> (last visited Feb. 11, 2014).

Relatedly, a third issue with the UK Model is inconsistent use of guidelines by doctors. This final and equally important issue with the UK Model is that it does not take full advantage of CPG's potential to increase the quality of health care. While having a system that certifies certain organizations that follow a specific process will improve the quality of guidelines, it will not achieve the same level of quality that could be achieved if, for example, the guideline producers were held accountable for the correctness of their guidelines. If doctors are faced with a multitude of options, they may choose none since they will have reduced incentives to use CPGs and their trust in the system will have diminished. If we assume that CPGs represent that best and most cost effective treatment for a disease, then when doctors do not follow CPG recommendations, the quality of health care drops.

### 3. Certification of CPGs (Rosoff)

Rosoff puts forth a CPG model where the government would stamp adequate guidelines with a seal of approval. Rosoff is primarily interested in the role of CPGs in courts, yet he keeps one eye on the impact they have on the optimal delivery of care.<sup>147</sup> Rosoff calls for a system of voluntary federal government certification for CPGs in order to clarify the role they play in medical malpractice litigation. CPGs would continue to emanate from "all interested and qualified parties"<sup>148</sup> as is currently the case. Out of this free-market for guidelines, those that are submitted for review and satisfy the government's criteria would receive a seal of approval.

The government review process would focus primarily on guideline development. The certification would require that the guideline be developed:

- (1) through solid, scientific outcomes research, using an appropriate and adequately large clinical practice data base;
- (2) using appropriate methodology, as defined by DHHS regulations;
- (3) with input from qualified medical professionals; and
- (4) with provision for prompt, periodic updating . . . . The applicant would pay both the

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<sup>147</sup> Rosoff, *The Role of Clinical Practice Guidelines*, *supra* note 24, at 371.

<sup>148</sup> *Id.* at 395.

cost of the initial review process and subsequent updating or recertification.<sup>149</sup>

As Rosoff acknowledges, difficulties would arise in implementation because, while certification would be a part of a national program, the litigation process it intends to affect mostly occurs in state courts. Of course, any number of states could voluntarily accept the certification program via their legislatures.<sup>150</sup>

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<sup>149</sup> *Id.*

<sup>150</sup> For those states that do not join, Rosoff offers four mechanisms to force implementation. The first possibility is the commerce power. Rosoff proposes that Congress preempt state law regarding medical litigation by use of the commerce power. Rosoff, *Evidence-Based Medicine*, *supra* note 77, at 364. He acknowledges, however, that such preemption would be problematic, as the object to be regulated in this instance is not commercial like health care or insurance, but the legal mechanisms usually reserved to the states. Indeed, a similar Congressional provision that preempted such state law, the Employee Retirement Income Security Act of 1974 (ERISA), received criticism. *Id.* Rosoff next proposes attaching the requirement of acceptance of the certification program to federal funding, an exercise of the spending power. This would likely be a legitimate use of the spending power, provided the funding to which the program was tied was optional to the states. *See* *South Dakota v. Dole*, 483 U.S. 203 (1987). Similarly, Rosoff suggests attaching the CPG program to other federal health care programs. Citing the example of the Emergency Medical Treatment and Active Labor Act of 1985 (EMTALA), he recommends tying his proposed use of CPGs to the Medicare and/or Medicaid programs. Rosoff, *Evidence-Based Medicine*, *supra* note 77, at 365. Finally, there is the possibility of a less straightforward approach, which Rosoff describes as “an artful use of ‘carrot and stick’ mechanisms.” *Id.* Presumably, an act could be written that would incentivize adoption of the CPG certification program. Implicit in each of these possibilities (other than the use of the commerce power) is that states would still ultimately have the power to decide whether to join in the program. As with all such scenarios, however, the incentives to accept the program could be structured to leave little for states to ponder. The second and third possibilities are the spending power and attachment to other health care programs. Citing the example of EMTALA, Rosoff recommends tying his proposed use of CPGs to the Medicare and/or Medicaid programs. *Id.* The last method he suggests is “the carrot and stick” approach. *Id.* He points to the National Health Planning and Resources Development Act of 1975, which permits the granting of funding to states “on the basis of an established competitive review process” to be used for a variety of programs aimed at reducing the incidence and mortality rate of breast and cervical cancer. 42 U.S.C. § 300k (2006).

Similar to the case with NICE, the stamp of approval for these guidelines focuses on the process by which the guidelines were created, not the properness of the actual CPG. Yet, while NICE gave a stamp of approval for a guidelines *developer*, under Rosoff's model the stamp of approval will be for each individual guideline.

Rosoff argues the certification program would increase the quality of care and also the quality of the guidelines themselves. Increased reliance on CPGs would eliminate the guesswork of choosing between alternatives, which would result in faster, more effective treatment.<sup>151</sup> Rosoff asserts that another benefit of his model would be the reduction of health care costs nationwide. Because CPGs would have to be derived from evidence-based research, they would provide direction for medical professionals from a much larger cost-conscious perspective than such practitioners typically consider in treatment.<sup>152</sup> Further, CPGs will typically recommend the *most* cost-effective treatment considered in light of its success rate and that of similar treatments.<sup>153</sup> Finally, clinicians should be more inclined to follow the guidelines given the prospect of proposed liability shields. Combined, these aspects of the Rosoff model should generally reduce costs.

Rosoff also envisions significant changes to the current medical malpractice regime by using CPGs to set the standard of care at trial and raising a presumption against negligence rebuttable only by "clear and convincing evidence."<sup>154</sup> Rosoff intends to substantially reduce the expenditures associated with medical malpractice litigation. The implementation of this proposal would reduce the actual need for litigation and those disputes that do reach litigation would be resolved in a less costly manner. Using CPGs to set the standard of care would streamline one of the major questions present in malpractice cases.<sup>155</sup>

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<sup>151</sup> Rosoff, *The Role of Clinical Practice Guidelines*, *supra* note 24, at 371.

<sup>152</sup> *See id.* at 372.

<sup>153</sup> *Id.*

<sup>154</sup> Rosoff, *Evidence Based Medicine*, *supra* note 77, at 361. It should be noted that the opposite application of the presumption is also true: noncompliance would raise the same, strong presumption of a breach.

<sup>155</sup> *Id.* at 363. Rosoff argues this conclusion must follow if doctors are permitted to use the guidelines in defending malpractice suits. *Id.* Though Rosoff brushes over the possibility of liability of developers in the current system, another commentator suggests that possibility is a very real one. *See supra* note 45 and accompanying text.

Putting aside issues with feasibility,<sup>156</sup> Rosoff's model is problematic because there are doubts as to its ability to ensure CPGs meet the goals of improved healthcare quality and reduced costs. To begin, the proposal itself ignores the problem of convergent guidelines recommending different treatments for the same conditions. In fact, Rosoff seems to encourage this occurrence rather than deter it.<sup>157</sup> While the problem may be resolved by the courts, it does nothing for medical professionals seeking evidence-based clarity. Conflicting guidelines also likely means wasteful offensive and defensive medicine costs if the guidelines differ because solo practitioners, concerned about litigation, will not know *ex ante* if they will be protected by Rosoff's proposed liability shield.

Looking closer at Rosoff's proposal, the basic idea of a federal certifying agency poses special problems. If the certification standards are too low, as some claim the NGC standards are, then the certification is essentially useless. If, in contrast, the standards are too high, the agency will suffer criticism for being a government enforcer of only one "right way" to conduct medical practice.<sup>158</sup> How to determine which standards are too stringent or which are too lax remains an open question. For example, the National Guidelines Clearinghouse (NGC), supported by the AHRQ,

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<sup>156</sup> It is worth mentioning that even if Rosoff's model was consistent with the goals set out at the beginning of this section, there may still be other issues with its implementation. First, the IOM's endorsement notwithstanding, it would be difficult for the proposal to garner the political support necessary to push through Congress a certification program that impacts the courts in such a broad manner. Also, the sheer size of a federal agency such a system would require in order to address the volume of extant and newly produced guidelines would make the undertaking prohibitive. It would also be difficult to ensure the competence of the people certifying the guidelines in such a large agency. The roller-coaster ride of Obamacare is evidence enough of Congress's reluctance to directly alter the health care delivery system. There would also be a constitutional question as to whether Congress could alter state medical malpractice rules to the extent of wholly extinguishing state law claims or providing an alternative federal remedy meeting Seventh Amendment standards. See Abigail Moncrieff, *Federalization Snowballs: The Need for National Action in Medical Malpractice Reform*, 109 COLUM. L. REV. 844, 846-47 (2009). It is possible that courts could develop a more friendly view of CPGs, but as discussed above, this has not happened yet.

<sup>157</sup> See Rosoff, *Evidence-Based Medicine*, *supra* note 77, at 356.

<sup>158</sup> The same is not true for other countries such as the UK, where the health care system is structured differently than in the US and there is much more trust in the government and willingness to accept its mandates for medical care.

looks to “maintain a certain degree of quality control.”<sup>159</sup> The NGC’s criteria offer similar points of evaluation to those suggested by Rosoff. One criterion requires, for instance, that “a systematic literature search and review of existing scientific evidence published in peer reviewed journals [be] performed during the guideline development.”<sup>160</sup> This is consistent with Rosoff’s criteria (1) and (2) above.<sup>161</sup> For the NGC, a CPG must also be “produced under the auspices of medical specialty associations; relevant professional societies, public or private organizations, government agencies at the Federal, State or local level; or health care organizations or plans.”<sup>162</sup> This is consistent with Rosoff’s criterion (3).<sup>163</sup> Moreover, the NGC does not review the guidelines themselves, but instead outsources that task to private entities. Thus, but for this latter point it is not entirely clear how Rosoff’s model differs from the existing NGC model. And higher standards cannot always be met. Indeed, in a recent study it was found that the majority of guidelines sampled from the NGC website meet less than half of the IOM’s stricter requirements.<sup>164</sup>

The final problem with Rosoff’s model is that it suffers from the same lack of accountability found in the public model. While there will be reputational incentives to promulgate accurate CPGs, this may not be enough to achieve the maximum result. Without accountability, removing conflicts of interest is more difficult. A recent study in the *Journal of the American Medical Association* supports this theory, finding that for the committees that produced guidelines appearing on the NGC website, 71% of the committee chairpersons had a conflict of interest and 91% of

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<sup>159</sup> See NATIONAL GUIDELINE CLEARINGHOUSE, <http://www.guideline.gov/index.aspx> (last visited Feb. 12, 2014).

<sup>160</sup> *Inclusion Criteria*, NATIONAL GUIDELINE CLEARINGHOUSE, [www.guideline.gov/about/inclusion-criteria.aspx](http://www.guideline.gov/about/inclusion-criteria.aspx) (last visited Feb. 18, 2014).

<sup>161</sup> “(1) through rigorous, scientific outcomes research, based upon an appropriate and adequately large set of clinical practice data; (2) using appropriate methodology, as defined by AHRQ regulations . . . .” Rosoff, *Evidence-Based Medicine*, *supra* note 77, at 360.

<sup>162</sup> NATIONAL GUIDELINE CLEARINGHOUSE, *supra* note 160. NGC lists only the following types of qualifying organizations: medical specialty associations; relevant professional societies, public or private organizations, government agencies at the Federal, State, or local level; or health care organizations or plans.

<sup>163</sup> “(3) with input from qualified medical professionals . . . .” Rosoff, *Evidence-Based Medicine*, *supra* note 77, at 360.

<sup>164</sup> See Kung et al., *supra* note 21 and accompanying text.

committee co-chairpersons also had a conflict of interest.<sup>165</sup> This is a huge problem, and will require a more comprehensive approach than that provided for by Rosoff.

The lack of accountability, conflicts of interest, and potential for conflicting guidelines that appear in the Rosoff model will likely lead to inconsistent use among physicians, especially those who are solo-practitioners. Doctors face their own set of incentives and costs when it comes to the care that they provide to patients, and the best model is one that will align these incentives with those of the guideline producer and the other healthcare players.

#### B. THE SEMI-PUBLIC MODEL (IOM)

Rosoff rejects the possibility of private certification for CPGs in favor of a federal certification program. Because an objective of his certification program is to assist judges in distinguishing reliable, valid guidelines from those that are not, he argues that private certification would lack the “official” certainty necessary to achieve that objective. Courts, he continues, would be confused over the validity of conflicting guidelines if private certification reigned.<sup>166</sup> Indeed, if one assumes that helping courts is the main goal of a certification program, as Rosoff does, a governmental system might make more sense.

But CPGs should do more than just help courts gauge the standard of care. CPGs should, above all, foster better delivery of care. When viewed with this objective in mind, a private entity could implement the same criteria as Rosoff’s proposed government certifier. This would allow the government to outsource its quality control to a private entity.<sup>167</sup> I call this the Semi-Public Model and this is what the IOM recommended when it called for the establishment of a public–private mechanism to certify CPG development processes.

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<sup>165</sup> See *id.* at 1630. Other authors have discussed different ways that companies try to influence CPGs. See, e.g., Marc A. Rodwin, *Conflicts of Interest, Institutional Corruption, and Pharma: An Agenda for Reform*, 40 J.L. MED. & ETHICS 511, 518 (2012) (“[F]irms fund physician and medical society activities to influence their clinical practice guidelines, which influences physician prescribing.”).

<sup>166</sup> Rosoff, *Evidence-Based Medicine*, *supra* note 77, at 357-58.

<sup>167</sup> The National Commission on Quality Assurance (NCQA) and the Joint Commission (JC) are examples of similar private certification programs.

As was mentioned above, the IOM Report is based around eight standards that all CPGs should attempt to achieve compliance with. These standards are process oriented such that they focus on the creation of the guideline rather than its contents. Now is the time to review them more closely. The IOM's first requirement for CPGs is transparency, with a focus on ensuring that the way the guideline was developed and the source of its funding are easily accessible.<sup>168</sup> Second, CPGs must be free from conflicts of interest. To achieve this, the IOM Report calls for the disclosure of any and all COIs by guideline authors, the divestment of financial investments that could be affected by CPG recommendations, and the exclusion of authors with a COI whenever possible.<sup>169</sup> The chair and co-chairs of the guideline committee especially should not have a COI.<sup>170</sup>

Third, the guideline development group members should come from a variety of backgrounds including experts, clinicians, and patients.<sup>171</sup> This will help to ensure that all voices are heard during the process. Fourth, systematic review is the desired method for guideline drafting.<sup>172</sup> Fifth, and relatedly, the strength of the recommendation should be included in the guideline.<sup>173</sup> This rating should include a description of the harms and benefits, also an explanation of the role that opinion and theory (as opposed to facts and systematic review of the evidence) played in the recommendation.<sup>174</sup> Sixth, the recommended action should be stated precisely so that it can be more easily understood and implemented by doctors.<sup>175</sup>

Seventh, CPGs should undergo a process of external review from all the relevant health care players, including the public and the federal government.<sup>176</sup> These reviewers should be allowed to comment confidentially and the guideline authors should keep a record of why (or why not) they took the comments into account.<sup>177</sup> Eighth, and lastly, CPGs should be regularly updated. This includes monitoring the literature so that

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<sup>168</sup> 2011 IOM Report, *supra* note 3, at 6.

<sup>169</sup> *Id.* at 7.

<sup>170</sup> *Id.*

<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

<sup>173</sup> *Id.* at 7–8.

<sup>174</sup> *Id.*

<sup>175</sup> *Id.* at 8.

<sup>176</sup> *Id.*

<sup>177</sup> *Id.*

new evidence can be incorporated when it becomes known and the continued validity of the CPG can be ensured.<sup>178</sup>

Given the similarities between this Semi-Public model and Rosoff's and the UK models, it seems likely the same general effects would be observed and the same criticisms raised above will apply here as well. Well-defined development and evaluation criteria should elevate the quality of care, while financial incentives for developers should increase efficiency and reduce costs. One important point of divergence, though, could be the role of CPGs in malpractice litigation under this model. Without government involvement, courts might still be reluctant to give weight to guidelines.

As discussed in the previous section, there is also the problem of conflicts of interest. Although the standards may call for screening such guidelines out during the certification process, it has been shown that the vast majority of CPGs on the NGC website were created by a committee for which the chairperson or co-chairperson had a conflict of interest.<sup>179</sup> The Semi-Public Model also suffers from the same issues related to conflicting guidelines.<sup>180</sup> All of these problems make CPGs certified under this model less helpful to doctors, and especially unhelpful to solo practitioners who have little time to review multiple guidelines for every procedure.

At their most basic level, CPGs should be trustworthy. The IOM attempts to implement a system whereby trustworthy guidelines can be easily identified. However, it has become clear that “[w]hile the IOM committee provided a comprehensive set of standards, it imposed an impractical definition of trustworthiness.”<sup>181</sup> By requiring adherence to eight standards, the system established by the IOM Report resulted in none of the current CPGs meeting the IOM's definition of trustworthy.<sup>182</sup> Not only do none of the existing CPGs meet, and perhaps can never meet, all eight standards, the majority of the CPGs in the NGC meet less than half of the IOM standards.<sup>183</sup> While an unregulated system of CPGs does not help

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<sup>178</sup> *Id.* at 8–9.

<sup>179</sup> *Id.*

<sup>180</sup> See *supra* note 222 and accompanying text.

<sup>181</sup> David F. Ransohoff et al., *How to Decide Whether a Clinical Practice Guideline is Trustworthy*, 309 JAMA 139, 140 (Jan. 9, 2013).

<sup>182</sup> *Id.*

<sup>183</sup> See Kung et al., *supra* note 21, at 1629.

doctors, neither does a model where no guideline can be certified. This is what is happening in practice with the Public and Semi-Public Models.

### C. THE PRIVATE MODEL (AVRAHAM)

In a series of recent popular press articles and papers Avraham proposed a model for private regulation of CPGs.<sup>184</sup> While it is still a new proposal in the field, it has received some attention in the literature.<sup>185</sup> In contrast to Rosoff, Avraham's *main* goal is to use CPGs to achieve optimal

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<sup>184</sup> Avraham, *Private Regulation*, *supra* note 1 at 547; Avraham, *Warped Incentives*, *supra* note 1; Ronen Avraham, *Private and Competitive Regulation of Medicine*, 34 THE ECONOMISTS' VOICE 546, 547 (2009); Ronen Avraham, *A Market Solution for Malpractice* (N.Y. TIMES, Mar. 28, 2011) available at [http://www.nytimes.com/2011/03/29/opinion/29Avraham.html?\\_r=1&ref=opinion](http://www.nytimes.com/2011/03/29/opinion/29Avraham.html?_r=1&ref=opinion); Ronen Avraham, *Private Regulation of Medicine: A Win-Win-win For Doctors, Patients and Public*, HUFFINGTON POST (July 22, 2009) [http://www.huffingtonpost.com/ronen-avraham/private-regulation-of-med\\_b\\_242937.html](http://www.huffingtonpost.com/ronen-avraham/private-regulation-of-med_b_242937.html).

<sup>185</sup> See, e.g., Alex Stein, *Toward A Theory of Medical Malpractice*, 97 IOWA L. REV. 1201, 1245 n.248 (2012) (describing Avraham's Private Model as "an insightful reform proposal"); Nathan S. Richards, *Judicial Resolution of Emtala Screening Claims at Summary Judgment*, 87 N.Y.U. L. REV. 591, 629 n.194 (2012) (noting Avraham's proposal as "fascinating and novel"); Katharine A. Van Tassel, *Blacklisted: The Constitutionality of the Federal System for Publishing Reports of "Bad" Doctors in the National Practitioner Data Bank*, 33 CARDOZO L. REV. 2031, 2080 n.309 (2012) (citing Avraham's model for CPG regulation as a way of enhancing quality of care while decreasing healthcare costs); Omri Ben-Shahar & Kyle D. Logue, *Outsourcing Regulation: How Insurance Reduces Moral Hazard*, 111 MICH. L. REV. 197, 201 n.9 (2012) (citing Avraham's model as a way to privatize the regulation of medical care); Jonathon H. Roth, *Regulating Your Medical History Without Regulations: A Private Regulatory Framework to Electronic Health Record Adoption*, 91 B.U. L. REV. 2103, 2122 (2011) ("Professor Ronen Avraham proposes a unique solution to rectify the inherent deficiencies in self-regulation: private regulation."); Adam Candeub, *Contract, Warranty, and the Patient Protection and Affordable Care Act*, 46 WAKE FOREST L. REV. 45, 58 (2011) (arguing for warranties but admitting that "as medicine becomes more algorithmic, Avraham's position makes complete sense"); David A. Hyman & Charles Silver, *Medical Malpractice and Compensation in Global Perspective: How Does the U.S. Do It?*, 87 CHI.-KENT L. REV. 163, 172 (2012) (citing to Avraham's proposal while discussing clinical practice guidelines); Nadia N. Sawicki, *Patient Protection and Decision-Aid Quality: Regulatory and Tort Law Approaches*, 54 ARIZ. L. REV. 621, 635, n.75 (2012) (citing to Avraham's op-ed in the NY Times on private regulation).

care delivery.<sup>186</sup> The role of CPGs in court proceedings is only one aspect of achieving this goal. In contrast to the IOM proposal, Avraham's model focuses on the guidelines themselves, and not on the procedures by which they were developed. In contrast to the old US model and the current UK model, Avraham's certifiers are not the government but the private market. The proposed regime purports to align society's incentives in a socially and economically efficient manner, thereby improving the quality of care and reducing costs.<sup>187</sup>

In the most general terms, the Private Model would consist of private firms competing to provide evidence-based medical guidelines and to offer liability protection to complying providers. Doctors, especially solo practitioners, would be (at least in the beginning) required to purchase guidelines from a provider in order to be licensed by the state or as a condition of participation in government health programs. Because of the proposed "private regulatory-compliance defense" doctrine that is part of the model, CPG subscriptions fees under the Private Model would replace the medical malpractice insurance premiums that doctors currently pay.<sup>188</sup> As will be discussed, the price paid for CPGs should be lower than current medical malpractice insurance premiums because, assuming the doctor follows the guidelines, there will be no liability.

The Private Model achieves the triplet goals of improving the quality of care, increasing cost-efficiency and respecting patients' preferences for the tradeoff between risk and coverage.<sup>189</sup> Free market

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<sup>186</sup> Michelle Mello also sees only a limited role for CPGs. She has argued that, given the current state of CPGs, they should not be used for inculpatory or exculpatory purposes. This is because CPGs did not generally represent the best practices in medicine. Mello instead advocated for expert's use of CPGs to supplement their testimony. Given the advances in CPGs since the 2001 article was published, it could be that Mello's views have changed. *See generally* Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645 (2001).

<sup>187</sup> The contours of the proposal are laid out in full in Avraham, *Private Regulation*, *supra* note 1.

<sup>188</sup> If a doctor was concerned about potential liability that much being incurred by the failure to follow a guideline for a given procedure, he or she might obtain insurance coverage but since the chance of that happening should be very small the corresponding premium would also be very low.

<sup>189</sup> Under the current system a patient can have no insurance, insurance with a high deductible that does not cover every treatment, or a "Cadillac" health insurance plan that has a low deductible and covers every conceivable treatment

competition should keep costs low and legal liability for producing inadequate guidelines would force private firms to keep patient safety high. In order to attract customers (patients) seeking to minimize costs, private regulators would be forced to offer competitively priced guidelines without sacrificing quality or ease of use. To achieve this, private regulators would have to discard unduly expensive or ineffective procedures. Defensive medicine would not be an option. At the same time, in contrast to current regimes in the US and the UK, and to the proposed regime by the IOM or Rosoff, patients would have a cause of action against the promulgating firm if the firm issued substandard guidelines that, directly or indirectly, caused injury to a patient. The fear of liability may well cause firms to push medical standards higher, elevating the general quality of health care.

Unlike other models, accountability is one of the pillars of the Private Model. This will ensure that the neutrality of CPGs is not a myth. Instead of a government agency that is subject only to administrative review of its rulemaking, the private firms would be held liable for damages caused by inefficient prescriptions. Moreover, unlike an agency, a private firm could expect to legitimately profit from making safer, more efficient standards. This proposal would also eliminate biased guidelines because they would be disciplined by market forces or legal liability. As a result, the influence of other interested actors – namely drug and device manufacturers – would substantially decrease. Lastly, unlike current medical practices a private firm's profit margin would be closely aligned with patient safety, so these firms would have the financial incentive to invest in continuous improvement without relying on groups that have a conflict of interest. At the same time, these firms would not feel so held hostage by the threat of litigation that they would advocate wasteful defensive medicine like unnecessary tests and procedures. Outside influences from other actors in the healthcare industry can probably not be eliminated completely, but the introduction of market forces via the Private Model should cause conflicts to substantially decrease.<sup>190</sup>

The Private Model also successfully addresses the issue of inconsistent use. Health care providers, especially solo practitioners,

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option. Under the Private Model there would also be variations. One can imagine a tiered system with different levels of CPGs that patients can choose much like they select their health insurance plans today. This model would more directly reflect patients' preferences regarding the cost and quality of care. For more on this, see Avraham, *Private Regulation*, *supra* note 1, at 631.

<sup>190</sup> Avraham, *Private Regulation*, *supra* note 1, at 584.

would be incentivized to use guidelines for two primary reasons. First, reduction in bias would lead to better guidelines, allowing doctors to trust their recommendations. The financial interests and professional responsibilities of providers would align, making it likely that they would utilize the techniques prescribed by the guidelines. With hundreds of available CPGs, often with conflicting recommendations, doctors will benefit from having the guideline producer review, synthesize, and approve CPGs. Through the Private Model doctors would not have to worry about multiple CPGs being certified for the same procedure. As it stands now it is impossible for doctors to keep current with new guidelines because of their volume, something the guideline producer is better situated to deal with. Second, if a doctor purchased the guidelines and followed them in treating patients, that person would be immune from malpractice liability. In other words, purchasing a CPG subscription from a firm would dilute the need for malpractice insurance, as long as the provider followed the guidelines. The sum effect of increased reliance on better guidelines and decreased liability should reduce costs throughout the entire system.

To provide optimal incentives to putative private “regulators”, the legal infrastructure would have to have these five characteristics: (1) guideline evaluation from the ex ante perspective, (2) recognition of a new legal doctrine called the private regulatory-compliance defense, (3) provision of intellectual property protection for issued guidelines, (4) elimination of the state-of-the-art defense, and (5) imposition of solvency requirements on private firms producing guidelines. It is possible that many of these will develop organically as healthcare players and judges recognize the benefits of such a system, but it is also possible that legislation would be required to fully implement this model. The five characteristics are detailed below.

First, in order to properly incentivize private guideline producers, those firms must be exposed to legal liability for promulgating sub-optimal guidelines. To create these optimal incentives, this liability must be judged in a courtroom from the ex ante perspective. This would avoid hindsight bias and, importantly, it would take into account all potential beneficiaries, not just the specific plaintiff in a case. Because firms know they could be subject to review at any time, they would be incentivized to develop efficient, impartial, and reliable guidelines.<sup>191</sup>

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<sup>191</sup> Without further protection, however, there would still be an incentive for overly safe guidelines. A simple way to deal with the problem is by using contracts between payers and providers that link reimbursements to the optimal level of

Second, in order to incentivize providers to purchase and follow guidelines, a private regulatory compliance defense, essentially a safe-harbor, would have to be added to the legal landscape. This defense would be available to any doctor or hospital that purchased guidelines *and* then followed them, and private regulatory compliance with guidelines would have to be a complete defense.<sup>192</sup> Third, it may be necessary to provide intellectual property (IP) protection for CPGs. The concern is that, without protection, no private firm would have an incentive to develop CPGs. The fear is that as soon as a guideline was published, other firms would free-ride, thus making the production unprofitable.<sup>193</sup> Fourth, it would be necessary to eliminate the state-of-the-art defense. Some states currently allow defendants to escape liability if their product or procedure was state-of-the-art at the time it was originally made, even if research since that time has proven it to be dangerous.<sup>194</sup> Under the Private Model, this defense would have to be eliminated in claims against the guideline producers in order to incentivize firms to continuously research better medical procedures and incorporate them into their guidelines.

Fifth, the solvency of the private firms promulgating guidelines would be necessary. Otherwise, firms would have an incentive to

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safety and cost-effectiveness. *See* Avraham, *Private Regulation*, *supra* note 1, at 594.

<sup>192</sup> In order to maintain doctors' discretion failure to comply with CPGs will not determine she was negligent – the physician still has the opportunity to convince the court that its deviation was clinically justified. (Granted, given the respect CPGs will get in court the task of convincing the court will not be an easy one.) Thus, CPGs serve as a “short sword” to distinguish from a regular sword because deviating from them does not determine liability, but only make it harder for the defendant to win the case. We do not find this asymmetry problematic on Equal Protection grounds at all. Patients are not a suspect class and there is no fundamental interest involved. The Equal Protection analysis would follow the traditional rational basis review standard. The rational basis is the legislature's interest in lowering health care costs and rewarding doctors that follow certain standards of care while enabling individualized care when needed. Moreover, counter-intuitively, the short-sword property of CPGs, benefits doctors because it is this property that conserves their autonomy to deviate from the guidelines. And doctors' autonomy, as is well known, is extremely important to them. *See* Avraham, *Private Regulation*, *supra* note 1.

<sup>193</sup> *See* Avraham, *Private Regulation*, *supra* note 1.

<sup>194</sup> Traditionally limited to product liability cases, this defense has penetrated medical malpractice law. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §§ 1–2 (1998).

promulgate overly risky guidelines because they would know that the worst thing that could happen is bankruptcy. The solvency guarantee could be obtained by requiring firms to have minimum assets or liability insurance.<sup>195</sup> These requirements would mirror the solvency requirements currently in place for insurance companies. As one can see, much of this reform could be accomplished with willing judges and/or private arrangements between relevant healthcare organizations.

While the multitude of changes needed to make this model work make it seem like more of a theoretical solution, entities in the medical field already operate under similar arrangements. In the health care market, there are already private companies that create and market guidelines. For example, McKesson is a company that provides CPGs as a part of its service package.<sup>196</sup> These proprietary guidelines are not made publically available and McKesson has research staff that continuously reviews new literature and revises its recommendations as new information emerges.<sup>197</sup> Other companies providing similar services include UpToDate, FirstConsult, and Dynamed, several of which cater specifically to general practitioners.<sup>198</sup> Further, these CPGs are integrated with other software tools to improve workflow and cost efficiency. This model is close to the Private Model proposal and provides hope that this system could be successful.

## V. CONCLUSION

Putting effective CPGs in place is only one part of reforming the health care delivery system. Major structural reorganizations of health care delivery are also necessary – particularly for specialty services and the management of complex patients with multiple chronic diseases – and will be accompanied by radical changes in payment policy (e.g., bundled payment) and a serious commitment to outcomes measurement.

Still, process-based health policy tools such as CPGs will be very useful in the transition to an improved delivery system. An effective

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<sup>195</sup> S. Shavell, *The Judgment Proof Problem*, 6 INT'L REV. L. ECON. 45 (1986); Steven Shavell, *Minimum Asset Requirements and Compulsory Liability Insurance as Solutions to the Judgment Proof Problem* (Nat'l Bureau of Econ. Research, Working Paper No. 10341, 2004).

<sup>196</sup> 2011 IOM Report, *supra* note 3, at 41.

<sup>197</sup> *Id.*

<sup>198</sup> Avraham, *Private Regulation*, *supra* note 1, at 612–13.

governance structure and accountability mechanism for CPGs need not solve every information or incentive problem in the health care system. But it must be broadly acceptable to physicians and the public, it must acknowledge the importance of cost-effectiveness as well as clinical effectiveness, and it must not become an independent power center that could end up working at cross-purposes to other goals and institutions that are critical components of health care reform.

Clinical practice guidelines serve an important role in helping physicians who will remain in independent practice navigate the challenging waters of health care reform. Going forward, CPGs should not be viewed primarily as a solution for problems with malpractice liability but as broader tools for quality improvement and cost reduction.<sup>199</sup> Moreover, malpractice liability itself should be accepted only as part of the solution to problems that plague the promulgation and dissemination of CPGs. Specifically, malpractice policies should be harnessed to help implement CPGs that can improve care.

I argue that the exclusive reliance on public or semi-public models by the 2011 IOM Report is misplaced, and other alternatives, including private competitive regimes, should be considered as well, especially for solo practitioners. Under the model selected by the IOM, issues with accountability and conflicts of interest in guideline production will continue to hinder the creation and widespread adoption of CPGs. CPGs must be promulgated with assurances of both substantive and procedural integrity, disseminated to providers in an accessible manner, and used appropriately by consumers and payers in addition to courts. This is likely to be true whether CPGs remain as standalone protocols or become embedded in other practice tools used by physicians in independent practice such as electronic medical decision aids, electronic health records with decision support, coding/billing software, and malpractice risk management guides. It is also applicable to new models of primary care based on advanced practice nurses rather than physicians or using interdisciplinary teams that constitute “medical homes” for patients. In the battle to reduce healthcare costs while improving patient care, CPGs are a powerful tool; but to be utilized to their full potential policymakers must

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<sup>199</sup> Of course there still remains a place for CPGs in malpractice reform. For example, the Obama administration’s \$250 million package of grants to encourage states to overhaul their malpractice systems by, among other things, creating “safe harbor” laws based on CPGs may well prove beneficial. *See* Walker, *supra* note 108.

keep an open mind and be willing to consider proposals that are outside the box.