Malpractice Liability and the Future of Clinical Practice Guidelines for Independent Physicians

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Introduction

American medical care is plagued by overuse, underuse, and misuse.¹ Overconsumption of medical care is one of the main contributors to rising health care costs in the United States. It has been estimated that extra tests and procedures cost $700 billion each year, and many of the procedures are dangerous to patients, unnecessarily increasing patients’ risk.² Even though an enormous amount of health care is consumed, Americans only receive optimal care, as recommended by the best-available information, 54% of the time.³ There are no easy solutions to these problems. The answer to excess consumption of medicine and suboptimal patient treatment requires a realignment of the incentives in the American healthcare system—something that cannot occur without significant changes to current structural and payment models of care delivery.

Clinical practice guidelines (CPGs) have the potential to reduce unnecessary and incorrect medical procedures. CPGs are publicly available written statements of best clinical practices intended to be applied to patient care in conjunction with professional judgment. As described in more detail below, CPGs have been thought of principally as decision aids for physicians in independent practice, many of whom continue to work alone or in small groups. It is well known that American health care remains more fragmented organizationally than one would predict given the complexity, capital intensiveness, and interdisciplinarity of diagnosing and treating serious illness. Although a secular trend toward increased employment of physicians by hospitals and other larger clinical entities has accelerated in recent years, a sufficient percentage of US physicians will remain in independent practice to warrant the refinement of CPGs as a quality-improvement and cost-reduction tool.

A recent episode provides an enlightening example of the challenges involved in providing CPGs to physicians. In 2012, the US government released a new, controversial guideline: doctors should stop performing a popular screening test for prostate cancer, the PSA (Prostate-Specific Antigen) test, because its high false-positive rate (80%) and low preventative value (prostate cancer grows very slowly) means it may do more harm than good.⁴ A recent survey of doctors found that 49% agreed with the new recommendation, but

³ IOM Report at 146.
⁴ http://www.washingtonpost.com/blogs/ezra-klein/post/many-doctors-think-psa-tests-dont-work-but-theyll-keep-doing-them-anyway/2012/05/29/gJQAOl0qyuU_blog.html.
only 1.8% planned to actually stop using the PSA. There were a variety of explanations. Some felt that patients would still expect the test; others didn’t think they had time to explain the changes to patients so they would just keep doing the test; and others worried their patients would think health care was being rationed. Even a test that half of doctors thought should not be used is still likely to be done by 98% of doctors.

In this paper we explore the question of how to create and implement clinical practice guidelines in the new health care environment, including the Patient Protection and Affordable Care Act of 2010 ("Obamacare"). In the course of our analysis, we provide the first case review in almost two decades of how courts regard and apply clinical practice guidelines, primarily in malpractice litigation, and discuss recent reports on CPGs by the Institute of Medicine issued in 2011 and by the Agency for Healthcare Research and Quality (AHRQ) issued in 2012. These reports both endorse a model of legal governance based on government certification -- a seal of approval – of acceptable guidelines. We argue that exclusive reliance on this public model is misplaced, and that other alternatives such as a private regulation regime could be more effective.

This paper begins by looking briefly at CPGs— their origins, use, and what is wrong with the current system—and then examines in more detail three potential solutions to use CPGs as a way of combating unnecessary medical costs that come from defensive and offensive medicine. Part I lays out a conceptual framework for understanding and evaluating possible accountability and governance mechanisms for clinical practice guidelines. It defines CPGs and then discusses why they are needed and which entities produce them. Part II also presents an empirical study of cases from the last decade and presents findings as to how court’s use CPGs in the real world. Part II addresses what is wrong with the current system of CPGs by focusing on three problems: the lack of accountability for guideline drafters, inconsistent use and lack of agreement between guidelines, and the lack of a holistic solution to the problems facing the healthcare system. Part III explains in greater detail three accountability models that have attracted attention from commentators and policymakers. It also provides a conceptual framework against which the various models can be compared. This part includes sections on government production of guidelines, Rosoff’s government certification model, and Avraham’s private regulation regime. A brief conclusion follows.

5 _Id._
6 _Id._
7 Rosoff proposes a system that would use the federal government not to develop guidelines, but to certify privately developed CPGs. Under Rosoff’s model, CPGs would continue to stem from multiple interested and qualified parties – as they currently do. The difference would be that a government agency would guarantee the CPGs meet some quality control standards. Arnold J. Rosoff, _The Role of Clinical Practice Guidelines in Health Care Reform_, 5 HEALTH MATRIX 369, 395 (1995) at 356, 363.
8 Under Avraham’s model, called the Private Regulation Regime (PRR), private regulators would develop and continually update medical practice guidelines which they would then compete to license to medical providers. These private firms would offer the organizations that licensed their guidelines, their client-providers, safe-harbor
I. Overview of CPGs

1. What are CPGs?

Clinical practice guidelines have existed for the last fifty years. Starting in the 1980s, however, the number of guidelines being disseminated increased dramatically. Guidelines are produced by a variety of organizations, including professional societies, hospitals, health plans, professional review boards, and state-health departments. The federal government became involved as well: what was originally called the Agency for Health Care Policy and Research spearheaded the development of roughly twenty different guidelines across key clinical practice areas.

The rise of clinical practice guidelines is relatively easy to explain. Beginning in the 1970s, studies by John Wennberg and colleagues revealed substantial differences in practice patterns from state to state and town to town that were uncorrelated with either severity of illness or clinical outcome. Clinical variation studies quickly generated concerns over excessive costs and suboptimal quality of care. These questions were compounded by research revealing that even published results of randomized clinical trials—the gold standard for scientific evidence disseminated in the traditional way—changed physician practice in the community very slowly (if at all). The late John Eisenberg, first administrator of the renamed Agency for Healthcare Research and Quality (AHRQ), suggested the root cause for this variation was physicians’ reluctance to incorporate new scientific evidence in their practices. The logical solution was the practice guideline: a clear, succinct statement of optimal medical care based on current professional knowledge.

from medical malpractice lawsuits as long as the providers follow the guidelines. Additionally, the private firms, unlike current organizations that create guidelines, would be held liable for putting forth sub-optimal guidelines. Ronen Avraham, Private Regulation, 34 HARV. J. L. & PUB. POL’Y 543 (2011)

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

10 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. John E. Wennberg, Dealing with medical practice variations: a proposal for action, 3 HEALTH AFFAIRS 6, 6–32 (1984).

11 This agency is the same one mentioned in the previous paragraph, formally known as the Agency for Health Care Policy and Research.

12 John M. Eisenberg, Quality Research for Quality Health care: The Data Connection, 35 HEALTH SERVS. RES. 12 (2000).
The conditions that made guidelines an appealing health policy tool developed over the course of several decades. We suggest four assumptions that 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 are subject to various economic and social pressures. Even those that perhaps should change, however, will not change quickly. In our view, clinical practice guidelines assume the following to be accurate and desirable characteristics of U.S. health care:

1. Confidence in the physician as a legitimate and authoritative source of clinical decisions affecting patients. This includes respect for physicians as professionals, leading to an advisory rather than directive approach that rejects “cookbook medicine” and accommodates patient variation and the exercise of judgment by physicians.

2. Acknowledgment that solo and small-group practice models for physician services, with decentralized organization and fragmented care, will continue play an important role in the delivery of healthcare.

3. Belief that accurate, up to date, and useful information about the medical practice is under-produced, so that supplying this information contributes a “public good” to physicians and the health care system.

4. A “medicalist” view of optimal clinical practice derived from objective science rather than a “marketist” view of clinical practice to suit the individual economic preferences of medical consumers or healthcare providers.

**a. Why are CPGs needed?**

Clinical practice guidelines have three major goals: improving quality of care, decreasing the use of defensive medicine by establishing the standard of care for medical malpractice liability disputes, and combating rising healthcare costs by eliminating offensive medicine. We discuss those three goals in order.

i. Improving the Quality of Medical Care and Reducing Medical Errors

Clinical practice guidelines are foremost about assuring and improving quality of care. The standard taxonomy for measuring quality used in health policy, articulated by Donabedian in the 1960s, distinguishes interpersonal aspects of quality, such as compassion, from technical quality, such as surgical precision. It further divides technical quality into three categories: structure (e.g., the number of nurses per hospital ward), processes (e.g., whether patients with
bacterial infections receive antibiotics), and outcomes (e.g., the percentage of patients with cancer who survive for five years).

The assumptions upon which clinical practice guidelines are based all point in one direction with regard to the definition of quality: Clinical practice guidelines are about defining technical processes.\(^\text{13}\)

Although this may seem obvious, it is an important insight for designing accountability models for clinical practice guidelines because it distinguishes them from other guideline-like instruments that can be governed separately. Interpersonal aspects of quality are monitored, if at all, through an uneasy balance of professional ethics and consumer preferences, and have not been included in practice guidelines. Structural features of care, especially those involving large capital investments, are often absent from guidelines because they are not seen as within individual physician control.\(^\text{14}\) Governance mechanisms for these matters tend to be mandatory, and are typically applied to institutions as opposed to professionals.\(^\text{15}\)

One may argue that the best way to improve health care quality is to evaluate outcomes, such as cures, survival rates, and the relief of symptoms. These outcome measures are the third prong of the Donabedian definition of quality, and are the preferred approach among proponents of new incentive structures for health care providers such as value-based health care purchasing and pay-for-performance (P4P). But to measure outcome in a statistically reliable manner one needs large datasets. Unfortunately, for physicians in solo or small-group practice, responsibility for clinical outcomes cannot be calculated reliably for their patient populations.\(^\text{16}\) As a result, measuring their compliance with process-based guidelines is a more practical method of evaluation. This is especially important because the vast majority of physicians in the U.S. are in solo or small-group practice.\(^\text{17}\) For larger and more integrated provider organizations, by

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\(^\text{13}\) Avedis Donabedian, *The Definition of Quality and Approaches to Assessment: Explorations in Quality Assessment and Monitoring* (1980); Avedis Donabedian, *Evaluating the Quality of Medical Care*, 44 MILBANK MEMORIAL FUND Q. 166 (1966).

\(^\text{14}\) 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, although it placed significant legal 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, 124 Stat. 119, 378, 507-10, 747 (2010).


\(^\text{17}\) APA Executive Director Keynote Address to 2011 State Leadership Conference, http://www.apapracticecentral.org/update/2011/03-31/evolving-health.aspx (“Eighty nine percent of all physicians work in solo practice or small group practices of 10 or fewer physicians.”).
contrast, outcomes are measurable and process-based guidelines potentially become less important for quality control but may still be a useful trust-building step signaling to patients, payers, and regulators that quality is being maintained.\textsuperscript{18}

Increasingly, clinical applications of guidelines are intertwined with health information technology such as EHRs with CDS. Proponents of guidelines have generally assumed that a functional guideline is recognizable as such to its users, and that using it would reflect a conscious decision to access a discrete set of recommendations. Existing technology, including tablet computers, smartphones, and other handheld devices that connect to the Internet, makes reference information and decision support readily available to individuals performing clinical and administrative functions.\textsuperscript{19} Some of these resources are accessed separately by users seeking guidance, but others are seamlessly incorporated into medical information systems. Moreover, emerging technologies are likely to embed algorithms directly into the equipment, facilities, and systems that deliver and manage care, with individual users often unaware that a guideline is being deployed. Under these circumstances, different models for accountability will probably be necessary.

ii. Decreasing Defensive Medicine by Establishing the Standard of Care for Medical Malpractice Litigation

In addition to habit and fee-for-service payment incentives, fear of malpractice liability has long been regarded as a major cause of physicians’ clinical idiosyncrasies and therefore an obvious area to which clinical practice guidelines should be applied. When malpractice claims and physicians’ malpractice insurance premiums began to climb rapidly in the 1960s, the cause of instability was generally believed to be that juries sympathetic to plaintiffs were being swayed by unscrupulous trial lawyers and corrupt expert witnesses to impose a higher “standard of care” on physicians than was required by the law or indicated by medical science.\textsuperscript{20} Moreover, this trend seemed to be self-reinforcing as customary practice was defined upwards by the courts, apparently creating a vicious circle of defensive medicine, waste, and litigation.

The first clinical practice guidelines offered a potential “liability shield” against frivolous claims by countering adverse expert testimony. Using national standards rather than customary practice in specific localities to define the standard of care also seemed a logical component of efforts to address the variation problems in medical practice.\textsuperscript{21} Early guideline

\textsuperscript{19}These technologies are already in use by doctors.
\textsuperscript{20}Not surprisingly, most physicians viewed other physicians who testified in court on behalf of plaintiffs as traitors to their profession, rather than regarding as problematic the conspiracy of silence that had previously made such expert testimony unavailable in most localities. [CITSES]
\textsuperscript{21}See 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); E. Lee Schlender, \textit{Malpractice And
proponents therefore hoped that judges and juries would accept CPGs as defining the standard of care in individual lawsuits, and eventually that states would amend their laws to make compliance with CPGs a formal defense to liability.

It took several more years for policymakers and the medical profession to acknowledge that rates of medical error were unacceptably high, and that, because of the expense and unpredictability of malpractice litigation, few of these avoidable injuries were being compensated through the courts. From this perspective, clinical practice guidelines could also serve as a “liability sword,” establishing tests for a given treatments’ misuse or underuse (or overuse with unnecessary complications) by physicians who failed to comply with the CPGs. Predictably, this potential inculpatory use of guidelines in court was far less acceptable than exculpatory use to ordinary physicians.

While using a widely accepted, medically vetted standard of care in courts has immense surface appeal, problems arise when trying to implement such a system. One quick example of the dangers of such a liability shield or sword is that special interests groups may influence the standards-writing process such that the guidelines do not actually reflect medical best practices, and yet doctors following the guidelines would still be immune from malpractice suits. These issues are explored in more detail in Part III.

iii. Combating Offensive Medicine

Clinical practice guidelines can generate savings in health care as well as improve quality in the disorganized, local markets for physician services that have long prevailed in the United States. In addition to curtailing waste, limiting overuse of risky procedures can also improve quality by exposing fewer patients to harm. As noted, revelations of rampant medical error in the late 1990s made avoiding misuse of tests and treatments a further goal of guideline compliance, one that could both improve safety and avert costly complications. At about the same time, empirical studies exposed many physicians’ failure to offer patients clearly beneficial benefits.

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22 There are estimates that medical errors cause almost 100,000 deaths each year. Ronen Avraham, Private Regulation, 34 HARV. J. L. & PUB. POL’Y 543, 548–49 (2011). Indeed, about 1 in 50 people who enter a medical facility will suffer an adverse event that could have been prevented, and most of this harm is due to negligence. Id. at 621.


24 See Michelle Mello, Of swords and shields: the use of clinical practice guidelines in medical malpractice litigation, 149 U. PENN L. REV 645 (2001)

tests and treatments—many highly cost-effective—adding concerns about underuse to the rationales for guidelines.  

The current fee-for-service payment system for doctors gives them a financial incentive to run additional tests and perform unnecessary procedures. When combined with the incentive to over-test to avoid a potential malpractice suit, this can create strong incentives for doctors to expend too many resources in the treatment of patients, and may partly explain why the United States is first in the world in health care spending but far behind in quality.

The FBI investigation into Redding Medical Center in California shows the danger that stems from a lack of oversight of medical treatment—oversight that well-written and enforced CPGs could provide. At this medical center one thousand bypasses were performed each year, three times the normal rate for a facility of its size. An FBI investigation claimed that up to fifty percent of them were not medically justified. Bypasses are tremendously expensive, and so these additional procedures were likely done to line the pockets of the doctors and the hospital. While this is a demonstration of offensive medicine on a large scale, most people, including doctors, think that US patients receive too much health care. CPGs provide an easy way to counter the overuse of medicine by establishing the correct treatment of a patient who presents with a given set of symptoms.

b. Who Might Produce/Regulate CPGs?

As one might expect, decisions about the desired governance structure of a guideline promulgation initiative or regulatory oversight regime differ significantly according to the nature of the issuer. Guidelines can be produced by public agencies, self-regulatory bodies, or private actors. Accountability and governance mechanisms range from direct government sponsorship to regulated private-sector control. Choosing among these alternatives should reflect serious engagement with regulatory design. Political feasibility is also important, and should be considered prospectively rather than being confronted later as an external constraint.

i. Federal or State Governments

Despite its size, wealth, and power, government has significant disadvantages as a source of clinical practice guidelines. Physicians and the public regard the government with suspicion when it seeks to intrude on the decisional autonomy of the medical profession on behalf of

26 See COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY (2001)
28 See Ronen Avraham, Clinical Practice Guidelines: The Warped Incentives in the U.S. Healthcare System, 37 AM. J. L. & MED. 7, 8 n.6 (2011). (discussing examples of offensive medicine, including the Redding Medical Center bypasses)
individual patients. This is particularly true when the government attempts to alter a clinical norm regarding risk-benefit calculations, as has been seen recently in the renewed debate over mammography for middle-aged women and in the controversy over the potential side effects of childhood vaccines.29

In addition, the government has insufficient personnel with appropriate skills to produce a large number of detailed guidelines, the cost of developing guidelines through public processes is both high and politically exposed, and the fact that guidelines must be routinely updated and corrected increases the administrative burden and the associated political risk.30 Government also must adhere to procedures for reaching its conclusions that comport with administrative law and state and federal constitutions, which can make some decision-making cumbersome. Government generation of CPGs therefore may be preferable for applications in which the objectivity of guidelines is relatively more important than their adaptability.

A government agency must be well funded, closely connected to care delivery, and yet sheltered from political pressure by interest groups in order to properly promulgate and update CPGs.31 For example, government guidelines are an attractive policy option in countries where the government acts as a single health care payer because that government internalizes the cost of health care (and, for that matter, the cost of malpractice liability). For example, the National Institute for Health and Clinical Excellence (NICE)—an independent organization closely connected to the British government—is well positioned to suggest best practices for


30 Guidelines are time-consuming and expensive both to develop and to update. Richard Amerlinga, James F. Winchestera, Claudio Roncob, 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, development of which was facilitated by the U.S. Agency for Health Care Research and Quality (AHRQ). 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, 1464 (2001). Seven of the guidelines needed to be updated with new “diagnostic or therapeutic guideline recommendations” or withdrawn. Six warranted marginal adjustments to their recommendations. 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. Another cost-related concern is that providers do not have the necessary resources to comply with the guidelines. RP Solomon, Clinical Guidelines in The United States: Perspectives On Law and Litigation, in CLINICAL GUIDELINES: LAW, POLICY, AND PRACTICE (Tingle ed, 2002), pp 137-159, at 146.

31 See Bruce C. Vladeck, The Politics of Medicare, 18 HEALTH AFF. (1998) (explaining interest group politics); Lawrence R. Jacobs, Politics of America’s Supply State: Health Reform and Technology, HEALTH AFF., Mar.–Apr. 1995, at 143 (arguing that no collective force counters the political power of provider and supplier groups);
practitioners in the U.K.’s National Health Service (NHS). In the U.S., the incentives of the government have never been aligned with health care costs in the same way as they are in the UK, which means that the U.S. government does not have the same level of accountability when it produces CPGs.

While they lack the same level of accountability as in the UK, the U.S. federal and state governments have a lot of influence over the health care system via their role as provider for Medicare and Medicaid. The size and scope of the Medicare and Medicaid programs give the federal government a very strong voice in health care, which will only grow stronger as national health reform is implemented. The federal government is therefore potentially in a good position to take a comprehensive, prioritized approach to guideline development, and to combine clinical quality with cost and coverage in designing guidelines. Medicare payment is so important to providers, however, that guideline-based federal payment policies might also be interpreted by physicians as de facto regulatory standards, creating increased political opposition. Partly for this reason, the Medicare Improvements for Patients and Providers Act of 2008 required the Secretary of HHS to contract with the IOM to recommend standards for creating and sustaining CPGs.

ii. Self-Regulation

Governmental health care regulation frequently occurs through or in conjunction with self-regulation, which is most commonly enjoyed by physicians but has expanded to other health care providers and suppliers. Professional organizations such as the American Medical Association promulgate ethical rules and standards of conduct that regulate their members’ behavior. Nurses, physicians’ assistants, and other practitioners have claimed similar privileges. In the U.S., the medical profession also maintains a surprising degree of collective control over physician education and training, licensing and discipline, hospital affiliation, and even liability insurance.

Self-regulation may be preferable to direct government control when technical expertise is required, cooperation from the regulated entities is important, or the regulated industry is undergoing rapid structural change. Self-regulation may also be cheaper than direct regulation if compliance costs are lower. On the other hand, self-regulation can be insular, self-serving, and

It is worth noting that the federal and state governments have divided authority in some areas, notably in employment-based health coverage and Medicaid. It is not clear how this division of authority will evolve as “health insurance exchanges” are implemented across the nation in connection with the recently enacted health reform legislation.

[Need MIPPA cite] Robin Graham, Michelle Mancher, Dianne Miller Wolman, Sheldon Greenfield, and Earl Steinberg, Editors; Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, *Institute of Medicine Clinical Practical Guidelines We Can Trust.*
anticompetitive. Despite those concerns, medicine has historically enjoyed wide latitude to self-regulate because of deference to physician expertise and trust in professional ethics and the charitable mission of academic and community hospitals.

Self-regulation can take various forms relevant to guidelines. Self-regulatory organizations can issue guidelines directly. Many current guideline producers are non-profit organizations operating for a charitable and educational mission, including professional societies. In the U.S., the most prominent category of issuer consists of medical specialty societies and other professional organizations, which promulgate guidelines focused on treatment effectiveness.35 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, moreover, such organizations usually do not feel pressed to account for costs of care, and thus may be biased towards quality over efficiency.

Self-regulatory organizations can also certify guidelines produced by others or certify or accredit those producers. The imprimatur of a certifying or accrediting body is typically used to convey information about superior quality or reliability to a purchaser or user of a product or service. Certification of specialist physicians operates through a system of national specialty organizations that supplements state licensing. These or other certification or accreditation systems could be used to validate guidelines or attest to their appropriate use by a physician or other health care provider. As noted above, the IOM recently recommended the establishment of a public-private partnership to certify guideline issuers for compliance with best practices regarding guideline production.

Professional licensing boards exemplify what is often called “statutory” or “delegated” self-regulation. In this model, a legislature confers broad discretion on a nominally governmental body 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 dominance in recent years. Guideline development or review could be done at the state level by existing licensing agencies, or could be delegated by federal or state government to newly chartered bodies.

An alternative model is “supervised self-regulation.” In supervised self-regulation, a formal government regulatory body backstops a self-regulatory organization. An example is the Securities and Exchange Commission, which has the right and obligation to review the work of various self-regulatory boards and overrule them if necessary. In health care, certain Medicare contractors—particularly those conducting peer review or quality improvement activities with explicit statutory authorization such as QIOs—function as supervised self-regulators. Unlike delegated self-regulation, under a supervised model an existing agency such as the Food and Drug Administration or the Agency for Health care Research and Quality would be empowered to ensure that self-regulatory organizations charged with issuing guidelines were honest and

35 Stefan Timmermans & Emily S. Kolker, Evidence-Based Medicine and the Reconfiguration of Medical Knowledge, 45 J. HEALTH & SOC. BEHAV. 177, 184 (2004).
competent. This might take the form of certifying the processes used by each producer, as suggested in the 2011 IOM Report.

Self-regulation operates locally as well as centrally, with internal monitoring and compliance systems either being self-imposed or expressly required by government. Acute care hospitals are the most common sites, where internal self-regulation by the “medical staff” is essentially made mandatory by Joint Commission accreditation standards. Guidelines could be produced or their use monitored by these bodies as well, albeit with processes more suited to local adaptation and with greater local buy-in. History offers a significant caution, however. The principal justification for pursuing the guideline regulatory enterprise was the failure of reliable professional norms to develop in local self-regulated physician communities, rendering it ironic to turn to the same communities to create or bless guidelines. National self-regulatory organizations would likely create better, evidence-based products.

iii. Private Sector

Many types of private organizations produce and deploy clinical practice guidelines. These efforts vary widely with respect to quality, impartiality, and transparency of the process of producing guidelines and/or the actual guidelines produced.

A large group comprises organizations with an obvious interest in health care costs as well as quality, including managed care organizations, health insurers, and self-insured employers. These producers have business objectives for issuing and using guidelines on a competitive basis. Health care providers, such as physicians and hospitals, compete primarily on the underlying services, and may view guidelines as proprietary business tools rather than common educational resources. Benefits consultants, pharmacy benefit managers, disease management companies, and similar entities also may 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 the guidelines do not support such use, as

\[\text{36 See Katherine Baicker & Amitabh Chandra, Medicare Spending, The Physician Workforce, And Beneficiaries' Quality Of Care, 23 HEALTH AFFAIRS 184 (2004).}\]

\[\text{37 Arnold J. Rosoff, The Role of Clinical Practice Guidelines in Health Care Reform, 5 HEALTH MATRIX 369, 374 (1995). A search in the NGC dataset revealed, for example, that Kaiser Permanente (an MCO) has about 10 guidelines posted.}\]

\[\text{38 Two private for-profit firms that came up in NGC’s database were the Reed Group, which is a company dedicated to getting injured employees back to work at full-productivity (see for example http://www.guideline.gov/summary/summary.aspx?doc_id=14583&nbr=7257), and the Smith & Nephew, which is primarily a medical device manufacturer in Ireland, see http://www.guideline.gov/summary/summary.aspx?doc_id=9830&nbr=5254.}\]

\[\text{39 A search of private for-profit guidelines yielded only seven guidelines, whereas the nonprofit search yielded 154 guidelines from a wide array of organizations. A search for guidelines from Hospital/Medical Centers yielded 38 guidelines (of the approx. 2356 available), from only 3-4 organizations. The largest hospital contributor was the Cincinnati Children’s Hospital Medical Center.}\]
potentially significant threats to their revenues. Malpractice insurers for physicians or hospitals may issue or use guidelines in connection with their risk management activities. [FN needed]

These entities are usually well funded and have the requisite expertise to write effective CPGs. Yet they have very different financial incentives, particularly if the cost of systematically suboptimal guidelines is borne elsewhere. For example, guidelines issued by physician groups anticipating fee-for-service payment may emphasize quality over cost control. In contrast, CPGs produced by third-party payers may emphasize cost control over quality, possibly externalizing costs onto liability insurers if safety is compromised and injury ensues. 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. Thus, physicians are sometimes forced to choose among conflicting guidelines with different goals: to provide the best care for patients, to secure reimbursement, or to avoid malpractice liability.

Some private producers of guidelines have primarily political objectives. Certain professional or trade groups seek to influence public opinion and legislation or regulation determining which health professions and which treatments should 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 included in expert recommendations, and therefore private formularies and Medicare benefits.

If guidelines are challenged in court, these varying incentives and potential biases may become a focal point of litigation. During the 1980s and 1990s, courts were sensitized to the risk of bias in health insurance standards as managed care became more aggressive about denying coverage for lack of medical necessity. More recently, financial relationships between pharmaceutical manufacturers and health care providers have raised concerns about conflicts of interest influencing clinical standards and practices.

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40 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.

41 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.

42 Patricia R. Recupero, *Clinical Practice Guidelines as Learned Treatises: Understanding Their Use as Evidence in the Courtroom*, 36 J. AM. ACAD. PSYCHIATRY L. 290, 290-301 (2008)

43 See, for example, Quigley v. Jobe where a Colorado appellate court held 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.” Quigley v. Jobe, 851 P.2d 236, 238 ( Colo. Ct. App. 1992).


iv. Courts

In the United States, the health care system tends to be monitored by an ad hoc mixture of public law (such as the Medicare program) and private law (such as individual litigation over contractual agreements or personal injuries). It is possible for judges—typically those serving on state rather than federal courts—to create “common law” regarding clinical practice guidelines by interpreting contracts, determining the scope of fiduciary duties, allocating property rights, and holding producers of clinical practice guidelines or health care providers relying on clinical practice guidelines liable to patients or others under tort law. Should such cases occur frequently, an accountability regime for guidelines might emerge organically without the creation of a legislative or regulatory framework, but that seems unlikely.

A more plausible scenario is that episodic litigation would result in judicial decisions that send strong, albeit indirect, signals to health care stakeholders regarding the value and enforceability of clinical practice guidelines. Litigated cases involving guidelines most often implicate medical malpractice, which plays an important role in molding physicians’ opinions about the acceptability of any proposed alteration of their clinical practices. Product liability lawsuits are equally important indicators for makers 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.

Medical malpractice litigation, for example, generates accountability mechanisms for guidelines that have particular characteristics. Civil litigation is ordinarily very deferential to individual judges’ discretion to make evidentiary rulings in specific cases. 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 rather than conclusive determinations of liability or immunity from liability.

2. How are CPGs Currently Used?

47 Like medical malpractice, insurance coverage law has both a technical and a symbolic importance to oversight of health care quality. 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, 23 DUKE L. J. 597 (2003); Mark A. Hall & Gerard F. Anderson, Health Insurers’ Assessment of Medical Necessity, 140 U. PA. L. REV. 1637 (1992).]
Although systematic efforts to provide governance and accountability mechanisms for clinical practice guidelines have been lacking in the United States, substantial experience has accumulated over the last two decades regarding the relationship between guidelines and the law. On the whole, these experiences and applications support the desirability of more consciously designing accountability into the world of guidelines, but do not themselves offer clear lessons for how accountability should be achieved.

The success of CPGs in replacing customary care with evidence-based medicine depends upon their acceptance within the medical profession. Similarly, the law’s treatment of guidelines is critical to their acceptance not only by physicians, but also by other stakeholders whose confidence in guidelines as a policy innovation is affected by how they are perceived by independent legal decision-makers such as judges and legislators. This section looks briefly at how CPGs have been used by courts, insurance companies, and states in recent times.

**a. Use in litigation: a study of cases from 1990–2010.**

There is not a great deal known about how courts and lawyers are using CPGs in malpractice litigation. The most comprehensive empirical study of the courts’ use of CPGs was conducted by Hyams, Shapiro and Brennan in 1995. They conducted surveys of medical malpractice attorneys and a review of all relevant case law from January 1, 1980 through May 31, 1994. They found just 37 published cases involving CPGs, but their surveys indicated that the profession was aware of CPGs and that guidelines figured into both decisions to take certain cases and settlement negotiations.

Of the 37 total published cases, the Hyams study identified 22 cases of successful inculpatory use and six cases of successful exculpatory use. As that study and subsequent articles suggest, courts historically have made only hesitant and conservative use of CPGs in medical malpractice cases.

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51 Id. at 295.

52 Rosoff, supra note 52, at 341.

53 Id. at 296.

This paper extends the Hyams research by reviewing judicial decisions that were published between January 2000 and March 2010. Our review indicates that use of guidelines by courts continues to be occasional and largely conservative. The use of guidelines for inculpatory purposes in malpractice cases has tended to decrease while use for exculpatory purposes has tended to increase, although the number of cases is so small that no conclusions can be drawn from the data. Of the 28 cases found with parties using guidelines in some form, 16 (57%) involved use by plaintiffs (as “swords”) compared to 78% in the Hyams study, and 12 (43%) involved use by defendants (as “shields”), compared to 22% in the Hyams study. Interestingly, in 8 of the 12 cases where guidelines were used for exculpatory purposes, the defendant was successful.

Published cases from the past ten years do not tend to devote significant analysis to what organization drafted the relevant guidelines, nor was there a clear plurality of any one association’s guidelines being used successfully (although guidelines written by the ACOG and the CDC did appear repeatedly). Discussion tends to center on applicability, relevance, or evidentiary acceptability, not on the quality of the guidelines themselves. One case with

55 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) most likely, these cases would not have dealt with guidelines extensively and thus would not have added a great deal to the discussion.

57 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.
particularly interesting analysis is *NY Assoc. of Nurse Anesthesists v. Novello*.\(^{58}\) The Nurse Anesthetists Association sued the state commissioner of health for promulgating guidelines the association claimed would essentially prohibit their private practices. The commissioner argued that the guidelines were merely recommendations provided to establish some consistency in an otherwise unregulated area of medicine, but did acknowledge that the guidelines would have to be followed “because the methods…would become the standard to be applied in physician disciplinary proceedings and would be evidence of local community medical standards in medical malpractice actions.”\(^{59}\) The Superior Court decided the guidelines were regulations because they were specific enough to “dictate the result of a proceeding.” Because the commissioner promulgated them without the proper legislative approval, the guidelines were held illegal.

While the full extent of courts’ use of CPGs in unknown, it is clear that the legal system’s acceptance of CPGs is needed to reduce costs through CPGs. However, the adoption of CPGs in court currently faces many problems, including the application of evidence based guidelines to a professional standard of care,\(^{60}\) hearsay objections to guidelines,\(^{61}\) the battle between competing guidelines or experts,\(^{62}\) and how “one-size-fits-all” guidelines should be.\(^{63}\)

**b. Use by the Insurance Industry**

The second area in which the law has taken account of guidelines is health insurance coverage. Beginning in the 1960s, persistent increases in the cost of health care forced a

\(^{58}\) 301 A.D. 2d 895 at 899 (NY Supr. Ct. 2003).

\(^{59}\) Id. at 619. The decision was later reversed because the Association could not demonstrate an injury in fact, thus it lacked standing. *N.Y. State Ass'n of Nurse Anesthetists v. Novello*, 2 N.Y.3d 207 (NY Ct. App. 2004).

\(^{60}\) This presents something of a paradox: evidence-based guidelines are generally preferred to consensus-based guidelines as statements of correct medical practice, but the professional standard of care traditionally applied under tort law is explicitly based on physician custom (i.e., consensus) as opposed to objective reasonableness.

\(^{61}\) The Hyams study notes courts’ increasing willingness 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.

\(^{62}\) See discussion at Mello, supra note 54, at 684. See also, Ronen Avraham, *Private Regulation*, 34 Harv. J. L. & Pub. Pol'y 543, 618–19 (2011) (discussing the so called “battle of the guidelines” and the solution provided by Avraham’s private model for CPGs).

revisiting of the original political compromise between health insurers and the medical profession that those responsible for payment would not interfere with clinical decisions. This movement progressed through the 1980s and 1990s. The closest connection between insurance coverage and CPGs has been regulation and litigation over the definition of “medically necessary” care, and the related question of whether a proposed treatment should be excluded from coverage as “experimental” or “investigational.” Over the last several decades, hundreds of judicial decisions have interpreted these contractual exclusions in disputes between patients (and their physicians) and private insurers, Medicaid, or Medicare. A common theme in these decisions is the desire of courts to reassure themselves that coverage denials are not merely financially motivated efforts by insurers to prevent patients from receiving scientifically correct medical care. As a result, the law has struggled to find preferred sources of evidence about optimal practice—in other words, CPGs. During the 1990s, some state lawmakers also began to combine benefit mandates with evidence-based coverage standards in particularly contentious areas, such as access to clinical trials and denials of coverage involving potentially lifesaving therapies. These laws are highly relevant to the question of governance and accountability for CPGs because they involve government in establishing a mandatory hierarchy of evidence supporting a critical and discretionary clinical decision by a physician.

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 doing business in a state specifically cover certain benefits are typically enacted at the behest of providers with focused interests and/or patient groups with sympathetic needs. The result has been a large set of statutes that define legislatively a particular favored clinical need (see Appendix II). Mandated benefit laws are not CPGs in intent or in substance, but are very important to understanding how the law can explicitly specify clinical tasks that were historically left to physician discretion.

c. Systematic Guideline Initiatives

Attempts to confer a larger public policy role on clinical practice guidelines have also occurred at both state and federal levels. These efforts have tended to coincide with periods of interest in comprehensive health care reform, with one peak in the late 1980s and early 1990s,

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64 Indeed, virtually all the fashionable innovations in health care organization, payment, and accountability today are direct descendants of managed care.

and another peak just emerging now in connection with the Obama administration’s successful enactment of near-universal health insurance coverage. Systematic guidelines initiatives have focused on both medical malpractice reform and more general improvement in the cost-effectiveness of health care, with unnecessary health care spending (such as defensive medicine) representing the conceptual connection between them.66


Maine was home to the most famous of a number of projects that established clinical practice guidelines as statutory standards of care for physicians to use as a defense in malpractice suits.67 The project was the Maine Medical Liability Demonstration Project, a ten-year pilot study that expired in 1999. The Maine project instituted special advisory committees in charge of developing clinical practice guidelines for four practice areas classified as hotbeds for malpractice litigation and suspected defensive medicine.68 Maine subsequently adopted twenty practice guidelines in anesthesiology, emergency medicine, obstetrics/gynecology, and radiology.

Physicians, hospitals, and managed care organizations that elected to participate could introduce the guidelines into evidence as an affirmative defense to any malpractice claim. Plaintiffs bringing such claims, however, could not introduce the guidelines into evidence to argue that failure to comply with a guideline was malpractice.69 The guidelines were used as only a shield and not a sword because the purpose of the reform was to reduce liability.

However, the Maine project had little practical effect.70 Few doctors believed that these regulations had any discernible effect, and in only one case was the affirmative defense even raised.71 The superintendent of the Maine Bureau of Insurance explained that "the medical demonstration project had no measurable effect on medical professional liability claims, claims settlement costs, or malpractice premiums."72


70 LeCraw, supra note 86. By one estimate, the guidelines affect 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, 19JOINT COMMISSION J. ON QUALITY IMPROVEMENT 355, 361 (1993).


72 LeCraw, supra note 86 (citing ME. BUREAU OF INS. AND BD. OF LIC. IN MED., MEDICAL LIABILITY DEMONSTRATION PROJECT 2AND 5 (2000)). Similar to Maine, Minnesota in 1990 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
ii. Florida’s C-Section Guideline Project

In 1994, concerns for the costs of defensive medicine prompted Florida to initiate its own clinical practice guidelines demonstration project, which was administered by the state’s Agency for Health Care Administration (AHCA). Similar to the Maine project in many respects, the Florida project created an affirmative defense for participating physicians provided that they followed clinical practice guidelines (guidelines as a shield). The primary difference from Maine was that Florida did not explicitly prevent plaintiffs from using guidelines to prove that physicians did not meet the standard of care (guidelines as a sword). However, proving that physicians did not comply 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.

Florida’s project concentrated on guidelines for cesarean section deliveries to test the potential of CPGs for use in other procedures. Florida chose to focus on cesarean section deliveries for their test project because this was the most common surgical procedure performed in Florida hospitals at the time. It was predicted that cesarean rate would decline if physicians practiced in accordance with clinical practice guideline. However, the affirmative defense proved to be an inadequate incentive to convince physicians to participate in the project. The project found that only 20 percent of the eligible physicians participated, and the ones who did participate were the physicians that were less likely to do cesarean deliveries.

Overall, Florida’s effort had little effect on physician behavior. Few physicians changed their practices regarding caesarean section to comply with the guideline standards.
Barriers primarily included lack of awareness, lack of familiarity, lack of agreement with the validity of guidelines, and external barriers.  

**d. Ongoing Initiatives**

This section provides a brief overview of some of the current attempts to combat health care costs through the use of clinical practice guidelines.

**i. Federal Malpractice Reform Demonstrations**

There is renewed interest in creative approaches to medical malpractice reform, including the incorporation of guidelines. The Obama administration’s most recent budget proposal includes $250 million for state-based alternatives to tort litigation for medical malpractice, with guidelines prominently featured among the favored reform approaches. These funds have not yet been authorized or appropriated by Congress. Previously, AHRQ had announced awards of $25 million for planning and implementation grants in states, communities, and provider organizations that integrate improvements in patient safety with improvements in medical malpractice litigation. CPGs clearly fit this description, along with programs of error disclosure and offers of compensation, health courts, and a few other innovations.

Congress asked the IOM through the *Medicare Improvements for Patients and Providers Act of 2008* to conduct a study on effectively creating CPG’s. In March 2011, IOM released a report with eight standards for developing CPG’s and a process for systematic review of the CPGs. These standards include: 1) establishing transparency 2) management of conflict of interest 3) guideline development group composition 4) CPG-systematic review intersection 5) establishing evidence foundations for and rating strength of recommendations 6) articulation of sufficiently documented reason, was at most eight percent.”  

**See note supra and accompanying text.**

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80 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. *Id.*
81 See note __ supra and accompanying text.
82 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 likely.
recommendations 7) external review and 8) updating. While several examples of how to encourage CPG adoption are discussed in the report, it fails to give a conclusive solution on how to force adoption of the CPG’s. Instead it states that some guideline developers will easily adapt to these standards, but “a process of evolutionary adoption overtime” may work for the rest of the developers. Without a solution to adoption, the IOM’s suggestion for improving CPG’s falls to the other approaches.

ii. The Oregon Health Plan Revisited

Between 1987 and 1994, the Oregon Legislature ratified several laws that established the structure for a private/public partnership that cumulatively constituted the Oregon Health Plan (OHP). The Oregon Health Plan was originally designed to increase access for lower income groups to health care (either private health insurance or Medicaid) and control costs. Under the plan, prioritized medical services were incorporated into the basic benefit package for both Medicaid beneficiaries as well as people covered by private insurance in the state. To maintain budgetary restraint, the plan set out to ration care by limiting the range of services covered under the basic benefits package. Rising costs, from $1.33 billion in 1993–1995 to $2.36 billion in 1999–2001, caused the budget for the program to be cancellation in 2003. The rise in the number of uninsured residents, increased medical expenses, and reductions in employer-based health care prompted Oregon to target reform again. The state’s legislature ratified a new law, House Bill 2009 (HB 2009), to reform health care in June 2009. HB 2009 established the Oregon Health Authority (OHA), empowering it to streamline and harmonize the state’s health care expenditures and programs. The OHA is responsible for improving efficiency, coordinating health administration and health services, and executing the reforms mandated by HB 2009. This includes developing “evidence-based clinical standards

Robin Graham, Michelle Mancher, Dianne Miller Wolman, Sheldon Greenfield, and Earl Steinberg, Editors; Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, *Institute of Medicine Clinical Practical Guidelines We Can Trust* at 4-6

Id. Seventeen types of health ailments (including fatal acute conditions that can be fully treated, less serious acute problems, chronic conditions, maternity care, and preventive treatments) were established. Then, all diagnoses and corresponding care in both medical and surgical arenas (700 diagnosis-treatment pairs in total) were assigned to a particular category of health ailments. These diagnosis-treatment pairs were subsequently prioritized according to 13 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 be not reimbursed.


HB 2009 effectively dissolved the Oregon Health Fund Board and replace 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.
and practice guidelines that may be used by providers.” Guidelines promulgated by the Board, even though they are not expressly given the force of law, are closely connected with the state’s continuing efforts to expand health insurance coverage through benefit design that emphasizes cost-effective care, and could eventually come to represent the standard of care in disciplinary proceedings and malpractice suits.

Early results from Oregon’s most recent attempt at CPGs are inconclusive. An AHRQ study found that while 5% of injuries could have been avoided if clinicians had followed guidelines, the cost savings from reduced defensive medicine via CPGs and safe harbor laws were minimal or non-existent. Although Oregon would have saved $4 million dollars in medical liability costs under a safe harbor program, the additional administrative costs of such a program likely would have negated any savings. Given the benefits to patient safety, one of the two pillars (along with cost reduction) that supports an increased role for CPGs, the AHRQ report recommended additional research on the topic.

iii. The American Recovery and Reinvestment Act (ARRA)

Signed into law on February 17, 2009 by President Barack Obama, the American Recovery and Reinvestment Act (ARRA) included funding and administrative support for comparative effectiveness research, an area where CPGs are important. The ARRA appropriated $1.1 billion for comparative effectiveness studies, including comparative trials, medical registries, clinical databases, and methodical appraisals. Furthermore, ARRA directed the Institute of Medicine to conduct a national study of critical areas that could utilize comparative effectiveness research and could capitalize upon the money appropriated to DHHS. 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 to implement

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89 AHRQ MEDICAL LIABILITY AND PATIENT SAFETY PLANNING GRANT: FINAL PROGRESS REPORT 10–11 (2012)
90 Id.
91 Id.

92 The Agency for Health care Research and Quality (AHRQ) was designated 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). American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009).
93 Institute of Medicine, Initial National Priorities for Comparative Effectiveness Research 2 (National Academy of Sciences 2009).
changes in coverage/reimbursement procedures. Even though these are not CPGs, these studies will provide important information that can be used by others in the creation of clinical practice guidelines.

iv. Patient Protection and Affordable Care Act (PPACA)

Paralleling renewed state interest in evidence-based guidelines and cost-effective treatment, the 2010 Patient Protection and Affordable Care Act recently upheld by the U.S Supreme Court expands comparative effectiveness research. The federal government has designated a minimum of $500 million to pursue statistical studies that judge the efficacy of drugs, devices, and treatments. The law also experiments with "new payment systems for doctors," fines hospitals 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, which is authorized to determine research needs and perform studies that evaluate the relative usefulness of medical therapies.

Lastly, under the PPACA, the AHRQ will play a critical and integral role in designing, pursuing, and disseminating clinical effectiveness research. The reform law places the AHRQ on the Board of Governors for the Patient-Centered Outcomes Research Institute. The agency also must work with the NIH to train researchers for the new studies and to convey findings. In concert with the DHHS, the AHRQ and CMS are granted $75 million over five years to jointly formulate benchmarks and standards for quality. To improve quality in the delivery and provision of medical care, the PPACA allocates $20 million to the AHRQ for the agency to determine, formulate, assess, and teach new processes and approaches in clinical practice between 2010 and 2014.

II. What is Wrong with the Current System?

One of the issues facing doctors in today’s world is an over-availability of information. From 1994–2001 there were around 25,000 randomized controlled trials published in MEDLINE (a medical literature database). This barrage of information would overwhelm even the most sophisticated medical operation, as no organization, let alone a single doctor, can review 70 studies per day and evaluate their credibility and applicability to its best practices. This is one of

96 Alex Nussbaum et al., Obamacare’s Cost Scalpel, Businessweek, April 5, 2010 at 64-5.
97 Patient Protection and Affordable Care Act of 2010, §§ 3013, 3501, 6301, 106002, P.L. 111-148
98 IOM Report at 1.
the reasons that clinical practice guidelines present such as opportunity. Properly drafted and updated, they have the potential to outsource the evaluation of medical best practices so that doctors can refer to a final summary of the best practices for any given treatment rather than having to sift through thousands of studies—that may have conflicting results—in the search for the most current information on a procedure.

However, the current system is not perfect, and the guidelines that are being created cannot be relied upon by doctors. This is occurring for three main reasons. First, there is a lack of accountability for the drafters of guidelines, which means that there are fewer incentives to make sure that the CPGs an organization publishes are current and updated. If the drafters of the guidelines had to indemnify doctors who followed them, then this would create a powerful set of incentives for drafters to ensure their CPGs really represented current best practices, and also for doctors to follow these best practices. Second, the use of guidelines by doctors is inconsistent, perhaps because they are not always reliable. Further, guidelines often call for conflicting treatments, and there is a general lack of agreement amongst published guidelines. Lastly, the current use of guidelines does not provide a holistic solution to the problems facing the American healthcare system. With increasing costs, caused in part by defensive and offensive medicine, a more radical solution to implement CPGs to ensure best practices and control costs may be necessary.

1. Lack of Accountability/Liability for Guideline Drafters

Under the current guidelines regime there is no accountability or liability for the drafters of guidelines. With this lack of accountability comes a lack of transparency for CPGs. For example, it is often difficult to know what methodologies the group used in writing the guidelines, and if there are any conflicts of interest that the reader should be aware of before accepting the recommendations of the CPGs.99 These conflicts of interest are real and are present even in the most respected studies. For example, even the best commercial clinical investigations are 5.3 times more likely to recommend the product of the sponsor of the study.100 If guideline drafters were made financially liable for their recommendations, this would ensure that the best products, and not the funders’ products, were being recommended.

The IOM Report calls for increased transparency for CPGs to be considered trustworthy, with an emphasis on eliminating and disclosing conflicts of interest.101 However, it also admits that “mandating courts to rely on CPGs or some other enforcement mechanism is well beyond the scope of this committee[.].”102 The IOM Report also does not recommend any type of liability for guideline drafters.

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100 Als-Nielsen et al 2003 (see IOM Report at 55).
102 IOM Report at 174.
Accountability of the guideline drafter provides an important role in ensuring that guidelines are properly drafted. For example, everyone likely agrees that a trustworthy CPG should be regularly updated but without some sort of liability for the drafters there are fewer incentives for the continued updating of guidelines. The average guideline costs at least $200,000 to produce, and these costs would likely increase if liability was attached to the recommendations. This means that there must also be some benefit attached to producing the guideline, like the ability to sell or otherwise profit from the recommendations, or else no one would produce guidelines that involved increased accountability.

2. Inconsistent Use and Lack of Agreement

The current CPG system produces an enormous number of guidelines, but not all of them agree on the proper medical procedure. The National Guideline Clearinghouse (NGC), a database of CPGs in the United States, currently has over 2,700 guidelines in its database. This again creates a system where doctors and even sophisticated medical organizations like insurance companies face an overwhelming number of guidelines. In 2008, 700 new CPGs were added to the NGC database, which is a large amount of information to be processed and reviewed. Plus, without constant updating it is not clear whether these now four year old guidelines are still supported by the most current medical research.

This paper has already discussed the various entities that produce CPGs. The problem with the current system is that all the entities create guidelines, but they do not always recommend the same procedures. Part of this may be a result of the varying incentives that each group has. For example, a guideline created by an insurance company will likely give more weight to the cost concerns than a guideline created by a group of practicing physicians. Further, medical best-practices change over time. This was seen in the discussion of prostate exams that opens this paper. Like mass change in opinion, it is unclear when the weight of the evidence has changed against a procedure. Also, experimental new procedures may be the best option in some circumstances, but they may not even have been around when earlier studies were created. As the IOM Report recognized, “[n]on-standardized development results in substantial variation in clinical recommendations.” However, the IOM Report also predicts that with increased oversight and stricter procedures for producing CPGs the problems of inconsistent recommendations will be reduced.

Faced with an overwhelming number of CPGs, many doctors just ignore new recommendations. Returning to the new recommendations for prostate cancer screening, many doctors gave non-medical reasons for their decision to continue the screening even though they

104 IOM Report at 2.
105 IOM Report at 2.
106 IOM Report at 2.
thought it was a good idea to stop. This is a situation where doctors were aware of the newest information and declined to utilize it, but in many cases doctors’ may not even know about the latest procedures for a given illness.

In many situations, the evidence on the best procedure is scarce. While some would argue that this means no recommendation should be made, others would argue that doctors need guidance in these areas more than others and CPGs can help them make a decision with the best available data. Without a consistent rating scale that indicates the level of evidence supporting the guideline, it can also be difficult to determine which guidelines fall into which category. For example, a study by Grilli and others found that 82% of guidelines studied did not expressly state the strength of the recommendation. However, this study also found that CPGs were improving over time.

Another reason for the disuse of CPGs is that many guidelines are not user friendly. Guidelines often are long and dense. Even with the large amount of information they still may not provide enough guidance for doctors to make decisions based upon a patient’s specific medical history and relevant symptoms. The use of CPGs varies based upon a number of factors, but studies have shown that in many cases only half of patients are receiving the type of care recommended by the guidelines.

As the current CPG system stands, with CPGs used as neither a shield nor a sword in malpractice litigation, the incentives for doctors to implement the newest CPGs, if it could be synthesized, are not present. If doctors knew that their following of guidelines would prevent malpractice litigation, they would likely take the recommendations of the guidelines more seriously. Following a given set of guidelines might even become a requirement for malpractice insurance coverage and would allow for lower rates. Of course this cannot occur until other issues with CPGs, like improving accountability, are addressed. This brings us to the next issue with the current state of CPGs, which is the lack of a holistic solution to the problems that CPGs might help solve.

3. Lack of Holistic Solution to Problems Facing Healthcare System

While the IOM Report creates “Guidelines for Guidelines,” it only addresses one part of the issues with the healthcare system that CPGs have the potential to solve. Reforming how

108 See IOM Report at 63.
109 See IOM Report at 63.
111 Id.
112 IOM Report at 146.
113 IOM Report at 146.
114 IOM Report at 146.
115 IOM Report at 4–5 (discussing a new definition of CPGs and listing requirements for trustworthy guidelines).
CPGs are made is an important first step, but it is also necessary to create an environment where CPGs are used in malpractice lawsuits as both a sword and a shield.\textsuperscript{116} This is just one example of how CPGs can be used to align the economic cost incentives with the best medical care for patients. If CPGs are used as a shield, then a doctor will not be liable for performing what are considered by the medical community to be medically unnecessary tests. Further, using CPGs are a sword, a doctor who fails to run a required test—as determined by the best practices for a given set of symptoms—will be liable in a malpractice lawsuit. This ensures two things. First, excess costs will not be generated by defensive medicine because doctors will not run unneeded tests. Second, doctors will be sure to run any required tests, and will not skip a test just because it is expensive or hard to do.

Defensive medicine and its elimination (or at least reduction) are an important part of reducing health care costs in the United States. Estimates vary, but a consistent dollar figure for the cost of defensive medicine is around $50 billion per year.\textsuperscript{117} While this only accounts for 2.4\% of the total health care costs in the United States,\textsuperscript{118} it is an easy target for regulations because it is medical care that is by definition unnecessary. Malpractice liability is also one of the biggest concerns amongst doctors, and 90\% of them agree that the unneeded diagnostic tests will continue to be run unless protections for physicians are implemented. Clinical practice guidelines have the potential to create these protections.

One of the issues with the current system is that CPGs are not being used as a holistic solution to these problems. As technology increases and the American health care system becomes more digital, the ability of doctors to stay current on CPGs and to reference CPGs as they interact with patients increases. With increased wireless internet access available almost everywhere the idea that a doctor can pull up a patient’s chart, enter new information following a checkup, and be quickly directed to the best option for the patient is just around the corner. Facilitating electronic access is one of the recommendations made by the 2011 IOM Report,\textsuperscript{119} and would be an important step in the process of using CPGs to tackle health care costs.

The next section discusses three proposals for using CPGs as a form of quality and cost control.

\section*{III. Three Proposals for Quality Control of CPGs}

It may be helpful to those considering accountability and governance structures for CPGs to explore some specific options in greater detail. Three approaches that have generated

\begin{itemize}
\item \textsuperscript{116} Rosoff, 2001 (from IOM Report at 173).
\item \textsuperscript{117} IOM Report at 172.
\item \textsuperscript{118} IOM Report at 172.
\item \textsuperscript{119} IOM Report at 145.
\end{itemize}
scholarly attention can be called the Public Model, The Semi-Public Model, and the Private Model. The main difference between these three models is the identity of the “controller”—the entity which approves the guidelines. Under the Public model, CPGs are submitted to some government entity for approval. Under the Semi-Public model, CPGs are submitted to a private party with which the government contracts. Under the Private Model, CPGs are submitted to a reputable private entity which provides a seal of approval. Unlike the previous two cases, in the Private Model the private entity may be subject to liability for negligently providing seal of approval. This accountability, not present in other systems, aligns the incentives of the relevant parties in a way not possible with either the Public or Semi-Public Models.

The question of what is being inspected is also important. Here again there are three broad approaches to quality control of CPGs. One option is approving the guideline itself. Here the controller (public, semi-public or private) reviews the quality of the CPGs themselves and makes sure they are optimal. This regime does not exist in a pure form in the US or in UK, and can be difficult due to the time, resources, and expertise necessary to approve of a guideline. The other options are approving the process used to develop the CPGs or relying on the reputation and legitimacy of the institution that develops them, but in the current system the lack of liability and widespread conflicts of issue among the entities creating CPGs undermines many potential benefits.

In practice, these options sometime overlap and reinforce each other. For process approval, the controller reviews the procedures which led to the promulgation of the CPGs. Guidelines submitted to NGC, for example, must adhere to four basic requirements (including the requirement that they be sponsored by a reputable organization) in order to be included in the database.  

Another option is that the entity that promulgated the CPGs will be inspected. Here, the controller provides a seal of approval for the entity which promulgated the CPGs as being an approved entity based on more general checkups and not based on any individual CPGs. For example, in the UK, the NHS Evidence Advisory Committee (Advisory Committee) awards an Accreditation Mark for organizations that establish high standards in their research in the development of guidelines. The Advisory Committee is an independent standing committee of the Board of NICE that provides accreditation recommendations and support for the implementation of NHS Evidence accreditation scheme.

120 Id. The guidelines must contain “systematically developed statements” that assist in making appropriate health care decisions for specific clinical situations. Second, the guidelines must be produced or sponsored by a reputable organization or government agency. Thirdly, and perhaps most importantly, the producer must be able to demonstrate that a systematic review of existing scientific evidence published in peer review journals was conducted during the guideline development. Finally, the guideline must be current and produced within the last five years, and it must be made available in the English language. See supra note 54


122 NICE, Invitation to apply for the role of member to the NHS Evidence Advisory Committee, [http://www.nice.org.uk/getinvolved/joinwc/MemberForTheNHSEvidenceAdvisoryCommittee.jsp](http://www.nice.org.uk/getinvolved/joinwc/MemberForTheNHSEvidenceAdvisoryCommittee.jsp) (last visited Sept. 3, 2012).
The following table roughly summarizes this and demonstrates how the different models which will be discussed below match the analysis:

Table 1: Various Models of CPG Quality Control.

<table>
<thead>
<tr>
<th>Who the controller is</th>
<th>Public (Gov’t Agency)</th>
<th>Public/Private</th>
<th>Private</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What is being inspected</strong></td>
<td>Output (CPGs themselves)</td>
<td>Avraham</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Procedures and reputation of entities</td>
<td>Rosoff, UK</td>
<td>US (NGC), UK</td>
</tr>
</tbody>
</table>

1. The Public Model

a. Government Promulgating CPGs (Old US Model)

As was mentioned above, after a fierce political battle in the early 1990s AHRQ no longer promulgates guidelines. Instead, AHRQ perceives itself as facilitating the creation of CPGs by other actors. Still, there are good reasons to think that the government should write guidelines. Other government agencies—such as CMS—write guidelines, as do governments in other countries such as the UK. For example, in September, 2006, the Center for Disease Control and Prevention (CDC) issued its “Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings.” These examples of the public model for guideline implementation seem to point to government agencies as potentially a desirable source of clinical practice guidelines.

Certainly, on the surface there is something very appealing in the government writing guidelines insofar as CPGs are a public good. But how would this model for guideline 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.

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A 2001 study found 13 of 17 CPGs developed by the AHRQ to be out of date.\textsuperscript{124} The study also found that it was estimated to cost $4 million per guideline to properly update them using AHRQ’s Evidence Based Practice Center Program.\textsuperscript{125} Unfortunately, medical research does not evolve on a rigid timetable, and agency guidelines can lag significantly behind cutting-edge medical advances. Thus, rather than increase the quality of care, there is reason to think government promulgation of CPGs might actually impede quality improvement.

In addition to problems with the quality of health care, 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).\textsuperscript{126} First, agencies will often lack the resources to set the regulations efficiently and then periodically update them.\textsuperscript{127} Second, as the history of AHRQ revealed, agencies are vulnerable to the political preferences of the administration in power, to self-aggrandizing administrators, and to interest-group capture. A change in the government can lead to ossification between 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 AHRQ, can hamstring guideline development or even cause the abandonment of CPG promulgation altogether.\textsuperscript{128}

At the same time, there are reasons why some federal agencies might adopt overly strict guidelines. First, occasionally agencies regulate in response to crises. Second, agencies lack the financial accountability necessary to incentivize efficient rule-making. Government agencies cannot be sued for making poor guidelines.\textsuperscript{129} Due to this, an agency rule-maker is less likely to fully internalize the financial consequences of his rule-making and may over-regulate. Third, the over-regulation can be enhanced because, while the regulator is not financially accountable, it is politically accountable, which can lead to a defensive policy. If the agency errs by failing to regulate, their political accountability assures they will be punished, but the agency will seldom be punished politically for overly stringent regulation.\textsuperscript{130} Due to these countervailing considerations, there is uncertainty whether agencies regulate in an overly strict or overly lax manner. This uncertainty, however, says nothing about efficiency, which is diminished in either scenario.\textsuperscript{131} The pure public model, then, would probably do little to contain health care costs.

\begin{itemize}
\item \textsuperscript{124} Shekelle, supra, n. 38 at 1464.
\item \textsuperscript{125} Id. at 1462.
\item \textsuperscript{127} Rachlinski, supra note 54, at 609.
\item \textsuperscript{128} See supra around footnote 100 (describing how the AHRQ had to stop promulgating guidelines due to interest group pressure).
\item \textsuperscript{129} In the US one cannot sue the FDA or any other agency for a wrong decision within their discretion.\textsuperscript{130} See Epstein, supra note 78, at 22 (arguing agencies have incentives to regulate in an overly risk-adverse fashion because of self interest). [CITE Health Affairs article on the political economy of the FDA.]
\item \textsuperscript{131} 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) (No. 05-CV-05500-MMB) (“FDA seeks to encourage the optimal level of use in light of reasonable safety concerns, by requiring scientific evidence that
In sum, the chance that government promulgating CPGs directly would improve the quality of care while being systematically and continuously efficient is small.

b. Certification of CPGs’ Promulgators (UK Model)

In general, the U.K. uses a public model, although promulgation of clinical guidelines in the U.K. is not totally centralized. The Department of Health (DH)\(^{132}\) oversees the government’s health care system, the National Health Service (NHS),\(^{133}\) which in turn coordinates with the DH’s arm’s length bodies (ALBs)\(^{134}\) to help implement various functions of the NHS. The standards ALB is the National Institute for Health and Clinical Excellence (NICE),\(^{135}\) which is responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health within the NHS.\(^{136}\) Through collaboration and a series of researching steps, NICE develops clinical guidelines (CGs) that suggest best practices for health care practitioners in the NHS.\(^{137}\) The Board of NICE created the NHS Evidence Advisory Committee, an independent standing committee, that reviews the methods with which other CG creators produce their information, rather than verifying the efficacy of the CGs themselves.\(^{138}\) These CGs, along with various other forms of guidelines—both from accredited and unaccredited producers—are posted to the website, NHS Evidence.\(^{139}\) Since 2009, NICE has accredited 40 guidance development processes.\(^{140}\)

How is the quality of care impacted through guidelines and their promulgation in the U.K.? **Apart from the NHS Evidence accreditation scheme,**\(^{141}\) NICE develops its own guidelines “using the best available evidence and involving stakeholders in a transparent and

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\(^{141}\) See supra note 7, Accreditation Manual.
collaborative manner,” according to The Guidelines Manual.\textsuperscript{142} The NICE guidelines are developed in light of the AGREE instrument and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system for the assessment of the evidence underlying the guidelines.\textsuperscript{143} These evaluative tools, similar to the criteria and standards already used by AHRQ and proposed by Rosoff in his public certification model, advance the goal of higher quality of care.

Economic considerations are also taken into account throughout the process.\textsuperscript{144} Again, similar to Rosoff’s model, the inclusion of efficiency concerns during the development stage, coupled with greater reliance on guidelines by clinicians, should lead to greater cost-efficiency in the system as a whole.

Health care professionals are expected to take NICE clinical guidelines fully into account when exercising their clinical judgment, but they do not override the professionals’ individual decision-making responsibility under the varying circumstances of each patient.\textsuperscript{145} Without mandatory adherence to the guidelines, whether CGs actually exert a net effect on the quality of care or efficiency of the health care system is uncertain.

In sum, although the NICE Guidelines are not absolutely mandatory, as they allow for the practitioner’s judgment to consider the particular facts of the patient’s case, the program is only 11 years old and will likely continue to gain credibility and effectiveness. The biggest obstacle to the NICE guidelines is the implementation phase. Aside from general administrative costs that might accrue, NICE recognizes other barriers to the dissemination of the guidance it produces and has created a variety of implementation tools to help in the transitions.\textsuperscript{146}

c. Government Providing Seal of Approval (Rosoff Model)

Rosoff puts forth a CPG model where the government would give adequate guidelines a seal of approval. His is a typical example of the semi-public model of implementation described above. Rosoff is primarily interested in the role of CPGs in courts, yet he keeps one eye on the impact they will have on the optimal delivery of care.\textsuperscript{147} Rosoff calls for a system of federal government certification for clinical practice guidelines to clarify the role they play in medical malpractice litigation and to diminish the need for and cost of such litigation. CPGs would continue to emanate from “all interested and qualified parties”\textsuperscript{148} in the same manner as they do currently. Out of this free-market of guidelines, those that are submitted for review and fulfill

\textsuperscript{142} NICE, THE GUIDELINES MANUAL (Jan. 2001), at 9
\textsuperscript{143} Id. at 71 (Chapter 6); and GRADE Working Group, http://www.gradeworkinggroup.org/ (last visited Sept. 3, 2012).
\textsuperscript{144} THE GUIDELINES MANUAL at 81 (Chapter 7).
\textsuperscript{145} See THE GUIDELINES MANUAL, supra note 11, at 11.
\textsuperscript{147} Rosoff supra n. 12 at 371–72.
\textsuperscript{148} Rosoff supra n. 9 at 395
the government’s criteria would receive a seal of approval. As Rosoff makes clear, his proposal envisions multiple, even conflicting guidelines achieving certification for any given condition.

The review process undertaken by the assigned government agency would focus primarily on the guideline’s development. A federal agency, according to Rosoff, is preferable to either a private or state-level certifier because of the resulting impact on the court system and the size and complexity of the issue. He proposes the Agency for Healthcare Research and Quality (AHRQ) for the role of certifier, citing its mission and contributions to the development of CPGs over the 1990s. The certification would require, in addition to being clearly and simply written, that the guideline be developed:

(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; (3) with input from qualified medical professionals; and (4) with provision for frequent updating…

The cost of both the initial review process and subsequent updating and recertification would be paid by the applicant.

As Rosoff acknowledges, difficulties would arise in implementing his model in that, while the certification program would be a national one, the litigation process it is intended to affect occurs in state courts. Of course, any number of states could voluntarily accept the certification program via their legislatures. For those states who do not join, Rosoff suggests four possible mechanisms for forced implementation: the commerce power, the spending power, attachment to other health care programs, and a “carrot and stick” approach.

149 Id. at 360.
150 The first possibility Rosoff proposes is for Congress to preempt state law regarding medical litigation by use of the commerce power.Id. 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 which 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, 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.

151 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, at 365

152 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
The IOM adopted Rosoff’s model in its 2011 report on CPG development. Like Rosoff’s suggestion of tying CPG’s to federal health care programs, the studies for the report were contracted out by Congress through an act for Medicare. The report determined that CPG’s should be “based on a system of systematic review of the existing evidence” in order to keep the guidelines up to date and trustworthy.\textsuperscript{153} The IOM Report also called for the NGC to eliminate CPGs for which the accuracy and trustworthiness could not be determined.\textsuperscript{154} While not a seal of approval, this is similar in that only government approved guidelines would be available in the NGC. The AHRQ also recently released a report that appears to embrace Rosoff’s model.\textsuperscript{155} Neither report fully examined the other options of CPG improvement such as Avraham’s Private Regulation model, which is discussed later.

On the first major issue to be examined, the potential effects of the model on the quality of health care, Rosoff argues the certification program should increase the quality of care and also of the guidelines themselves. Increased reliance on CPGs should eliminate the guess-work associated with choosing between alternatives, usually resulting in faster, more effective treatment.\textsuperscript{156} With regard to guidelines, the certification program will, presumably, encourage the use of certified CPGs while discouraging the use of those not certified. Developers, therefore, will likely create guidelines so that they will be certified. With that goal in mind, their research will have to conform to the fairly demanding criteria Rosoff sets out, which should improve the quality and reduce the possibility of the influence of detrimental bias in creating CPGs. Greater reliance on higher quality guidelines, in turn, should also have a positive influence on the quality of care.

On the potential effects of his model on health care costs, Rosoff asserts that another major benefit to his model would be reduced costs of health care nationwide. Foremost, 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 treating a patient.\textsuperscript{157} Further, CPGs will typically recommend the most cost-effective treatment, considered in light of its success rate and that of similar treatments.\textsuperscript{158} Additionally, clinicians should be more inclined to follow the guidelines with the prospect of the proposed liability shield and the improved quality, reliability, and clarity of the guidelines; and increased adherence would lead to greater realization of cost savings. Finally, CPGs also provide greater awareness of which treatment alternatives work best. This will eliminate the

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Robin Graham, Michelle Mancher, Dianne Miller Wolman, Sheldon Greenfield, and Earl Steinberg, Editors; Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, \textit{Institute of Medicine Clinical Practical Guidelines We Can Trust} at 3.\textsuperscript{153} IOM Report at 11.\textsuperscript{154} AHRQ M\textsc{edical} L\textsc{iability} and P\textsc{atient} S\textsc{afety} P\textsc{lanning} G\textsc{rant}: F\textsc{inal} P\textsc{rogress} R\textsc{eport} 13 (2012) (referring to a “state-endorsed evidence-based guideline”).\textsuperscript{155} \textit{Id.} at 371.\textsuperscript{156} Rosoff, The Role, at 372.\textsuperscript{157} Id. at 372.\textsuperscript{158}
\end{flushright}
tendency to simply guess among alternatives, searching for the best one and wasting money. Combined, these aspects of the Rosoff model should generally reduce costs in the health care system.

Rosoff also envisions significant changes to the current medical malpractice regime. Certified guidelines would provide a significant defense to malpractice liability for clinicians who follow them by setting the standard of care at trial and raising a presumption against negligence rebuttable only by “clear and convincing evidence.” By establishing a clear standard of reasonable care for the clinical setting, Rosoff intends to reduce substantially the expenditures associated with medical malpractice litigation. It does so in two ways. First, the implementation of this proposal would reduce the need for litigation. Second, those disputes that do reach litigation would be resolved in a more efficient and less costly manner. Rosoff believes that using CPGs in accordance with this model would eliminate the problem of deciding between conflicting guidelines, expert testimony, or other proposed standards of care. Importantly, guideline developers whose products received certification would be shielded from any liability by that certification. In Rosoff’s view this program would also yield significant cost savings by cutting the number of cases that reach the courts and also streamlining the process of litigation. In total, these savings on legal expenditures could also generally reduce health care costs.

Rosoff’s model is problematic for several reasons. First, the most rudimentary difficulty for Rosoff’s proposal is garnering the political support necessary to push a certification program that has an impact on courts through Congress. Possible concerns include the size of the federal agency needed to address the volume of extant guidelines and those being newly produced and revised in the US, the funding of such agency, the competence of the people certifying the guidelines as well as the incentives they operate under. The roller-coaster ride undergone by President Obama’s health-care reform bill is evidence of Congress’s reluctance to directly alter the health care delivery system. There also may be a constitutional question as to whether Congress could alter state medical malpractice rules as such a program would require without wholly extinguishing state law claims or providing an alternative federal remedy meeting Seventh Amendment standards.

Second, 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. While the problem may be solved by courts in that any certified guideline

159 Id. 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.

160 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 infra note 45 and accompanying text.

161 See Abigail Moncrief, 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.

162 See Rosoff, Evidence-Based Medicine, at 356.
could serve as the basis for a standard of care, it does nothing for medical professionals who seek clarity. An approach that would result in multiple guidelines for the same condition seems inconsistent with CPG strategies to reduce clinical variation such as Knowing What Works.

Third, and most significant, the basic idea of a federal certifying agency poses its own special problems. If the standards for certification are too low, as some claim the standards of the NGC are, then the certificate is useless. If, in contrast, the standards are too high, the agency will suffer criticism for being a government enforcer of the “right way to conduct medical practice.”163 How to determine which standards are too stringent and which are too lax remains an open question.

Given these deficiencies it is disconcerting that both the IOM and AHRQ, as mentioned previously, created standards that adopted Rosoff’s model of government review.

2. The Semi Public Model (Modified Rosoff’s Model)

Rosoff rejects the possibility of private certification for CPGs in favor of federal government certification. Because the objective of his certification program is to assist judges in distinguishing reliable, valid guidelines from those which should be granted less weight, he argues that private certification would lack the “official” thrust and certainty necessary to that objective and would only add to the courts’ confusion over the validity of various and conflicting guidelines.164 Indeed, if one assumes that helping courts is the main goal of any certification program, as Rosoff does, a governmental system indeed makes more sense.

But as was mentioned above, CPGs should do more than just help courts gauge the standard of care. CPGs should, before anything else, foster better delivery of care. Seen in this way, a private entity could implement the exact same criteria as would Rosoff’s proposed government certifier. This would in effect allow the government to outsource its quality control of guidelines to a private entity.165

In the contexts of CPGs, this is exactly what the National Guideline Clearinghouse, supported and sponsored by AHRQ, is doing when it applies its inclusion criteria. The NGC similarly looks to “maintain a certain degree of quality control.”166 In the previous section the four requirements of the certification process in Rosoff’s model were discussed.167

NGC’s criteria offer similar points of evaluation. One requires, for instance, that “a systematic literature search and review of existing scientific evidence published in peer reviewed

163 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.
165 The National Commission on Quality Assurance (NCQA) and the Joint Commission (JC) are examples of similar private certification programs.
167 Supra note ___ and accompanying text.
journals [be] performed during the guideline development.” 168 Compare this with Rosoff’s criteria (1) and (2). 169 For 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.” 170 Compare Rosoff’s criterion (3). 171 Moreover, NGC does not review the guidelines themselves, but instead outsources that task to private entities. Thus, it is not entirely clear how Rosoff’s model is different than the existing NGC model. It may be that Rosoff would apply stricter acceptance criteria than those implemented by the NGC (which is known to having a low acceptance bar), but that is merely speculation.

Given the similarities between this and Rosoff’s model, it seems likely the same general effects would be observed. Well-defined development and evaluation criteria should elevate the quality of care, while developers’ own financial incentives should increase efficiency and reduce costs. One important point of divergence, though, could be the place of CPGs in malpractice litigation under this model. Without government involvement, courts might still be reluctant to grant guidelines any weight.

3. The Private Model (Avraham’s Model)

A model for private regulation of CPGs model was proposed by Avraham in 2011. In contrast to Rosoff and Mello, 172 Avraham’s goal is using CPGs to achieve the optimal delivery of care. His interest in the role that CPGs need play in courts is only as a tool to achieve this goal. The proposed regime would align the incentives of all parties with the interests of society.

169 “(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.” Arnold J. Rosoff, Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines, 26 J. OF HEALTH POLITICS, POLICY, & L. 327, 360 (2001).
170 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. Id.
172 Mello 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 (Jan. 2001).
Although a full account of the model, called the Private Regulation Regime (PRR) is outside the scope of this article, a summary is appropriate.\textsuperscript{173}

In the most general terms, the PRR would consist of private firms competing to provide evidence-based medical guidelines that offer liability protection to complying providers. Hospitals would be (at least in the beginning) required to purchase guidelines as a requirement of state licensure or as a condition of participation in government health programs. Such a system ties together the dual goals of improving the quality of care and of increasing cost-efficiency. The private firms would be forced to keep patient safety high and costs low by the dual forces of free market competition and legal liability. In order to attract customers (e.g. hospitals) seeking to minimize costs, the private regulators would have to offer guidelines that compete on price, quality, and ease of use. To achieve this, private regulators would be forced to discard unduly expensive (and ineffective) procedures; they could not be too defensive. At the same time, and in contrast to the current legal regime both in the US and the UK, patients on whom the guidelines were used would be given a cause of action against the promulgating firm if the firm issued substandard guidelines that caused injury to a patient. The fear of liability may well cause firms to push medical standards higher, elevating the quality of health care generally.

Other incentives for promulgators in the PRR would also contribute to the dual effects for quality and efficiency. Unlike a government agency that is subject only to administrative review of its rulemaking (or any other guideline promulgator which is not subject to review), the private firms would continuously be held liable for damages caused by its inefficient prescription. Moreover, unlike an agency or any other guideline promulgator, a private firm could expect to legitimately profit from making standards safer and more efficient. Because potentially biased guidelines in the PRR would be disciplined by market forces or legal liability, the influence of other interested actors—namely drug and device manufacturers—would substantially decrease. Lastly, unlike current medical guideline providers, a private firm’s profit margin would be closely aligned with patient safety, so these firms would have the financial incentive needed to invest in continuous improvement without relying on groups who have a conflict of interest.

Health care providers would be incentivized to utilize the guidelines for two primary reasons. First, reduction in bias would lead to better guidelines and allow doctors to trust the guidelines’ recommendations. Thus, the providers’ financial interests and professional responsibilities would be aligned, making it highly likely that they would utilize the evidence-based medical techniques prescribed by the guidelines. Second, if a doctor or hospital purchased the guidelines and followed them when treating patients, that provider would be immune from malpractice liability. In other words, purchasing a subscription to CPGs from a firm would replace the need for malpractice insurance (so long as the provider followed the guidelines). The sum effect of increased reliance on better guidelines and decreased liability should be reduced costs throughout the system.

\textsuperscript{173} The contours of the proposal are laid out in full in Avraham, Private Regulation, 34 HARV. J.L. & PUB. POL’Y 543 (2011).
To provide optimal incentives to putative private regulators, the legal infrastructure would have to change in five ways: (1) evaluate guidelines from the ex ante perspective, (2) recognize a new legal doctrine called the private regulatory-compliance defense, (3) provide intellectual property protection for issued guidelines, (4) eliminate the state-of-the-art defense (at least as it would apply to guidelines or medical practice), and (5) impose solvency requirements on the private firms that would be producing the guidelines. These changes are explored in more detail in the following paragraphs.

First, in order to properly incentivize the private firms promulgating guidelines, those firms must be exposed to legal liability for promulgating suboptimal guidelines. This is one of the biggest differences between the private model and the other possible models for CPG promulgation. Such liability will prevent the firms from lowering their costs by promulgating excessively risky guidelines or otherwise inadequate guidelines, such as guidelines which favor industry players. To create the optimal incentives, this liability must be judged in a courtroom from the ex ante perspective of efficient care. This perspective avoids hindsight bias and, importantly, would take into account all potential beneficiaries, not just the specific plaintiff in front of the court. In contrast to government certification of guidelines, under the private regulation regime, guidelines will be officially evaluated by a court only if their optimality is challenged, and will be expected to meet the medical standards relevant at the date of the trial and not merely when they were initially promulgated. Because guideline-producing firms know that they will be subject to review, they will develop guidelines that are efficient, impartial, and reliable.174

Second, in order to incentive 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 followed them. Regardless of the consequences of a procedure, if the doctor follows her guidelines she will not face malpractice liability. The defense would not apply, however, to doctors who do not officially purchase or license guidelines or who deviate from the guidelines’ instructions. Unlike existing defenses based on legal compliance, which attach less than conclusive evidentiary weight to the fact that a statute or regulation is followed,175 private regulatory compliance with guidelines would have to be a complete defense.176

174 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 which link reimbursements to the optimal level of safety and cost-effectiveness. See Avraham (2010) for details.

175 See RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM § 16 (2005); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 (1998). In several states, when a product manufacturer complies with a federal or state regulatory standard, it entitles the manufacturer to a “rebuttable presumption” against a finding of negligence or product defect. See supra note 83.

176 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
Third, it may be necessary to provide some sort of intellectual property (IP) protection for guidelines. The concern is that without protection no private firm would have the proper incentives to develop guidelines because they would fear as soon as the guidelines were promulgated, other PR firms would free-ride. It is possible, however, to imagine business models which would make IP protection unnecessary. For example, an evidentiary rule which requires the provider to have actually purchased the guidelines in order for the court to admit them into evidence would help. Alternatively, private firms could bundle the licensing of their guidelines with other clinical or administrative support services.\(^{177}\)

Fourth is the elimination of the state of the art defense. Some states currently allow defendants to escape liability if their product or, in medical cases, procedure, was the state of the art.\(^{178}\) Under the PRR, this defense would have to be eliminated in claims against the guideline producer in order to incentive producing firms to research better medical procedures and incorporate them into their guidelines.

Fifth, the solvency of the private firms promulgating guidelines would have to be ensured. Otherwise, the firms would have an incentive to promulgate overly risky guidelines because they would know that the worst thing that could happen is they declare bankruptcy. Declaring bankruptcy would externalize any cost above a firm’s value onto the patient that the overly risky guideline harmed. The solvency guarantee could be obtained by requiring firms which have the potential for being judgment proof to have minimum assets or liability insurance.\(^{179}\) These requirements would mirror the solvency requirements currently in place for insurance companies.

While the multitude of changes needed to make this model work might make it seem like more of a theoretical—rather than a practical—solution, entities in the medical field are already operating 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 clinical practice guidelines as part of its services.\(^{180}\) These proprietary guidelines are not made publically available and McKesson has research staff that continuously review new literature and revise the

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 which conserves their autonomy to deviate from the guidelines. And doctors' autonomy, as is well known, is extremely important to them. (See Avraham, supra note ___ for details).

\(^{177}\) See Avraham, *supra* note ___ for more details.

\(^{178}\) Traditionally limited to product liability cases, this defense has penetrated medical malpractice law. See *Restatement (Third) of Torts: Products Liability* §§ 1-2 (1998).


\(^{180}\) IOM Report at 41.
recommendations as new information emerges. Further, these CPGs are integrated with other software tools and management programs to improve workflow and cost efficiency. This model is close to the PRR proposal and provides hope that one might be successful in the future.

IV. Conclusion

Going forward, CPGs should not be viewed primarily as a solution for problems in malpractice liability. Instead, malpractice liability should be accepted as part of the solution to problems that plague the promulgation and dissemination of CPGs. Specifically, malpractice policy should be harnessed to help implement CPGs that can improve care.

There 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.

More generally, however, 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 requires a vigorous private market in guideline development. Limited, focused liability associated with substandard CPGs can help this market emerge. 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.

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 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-effective as well as clinically effective practice, 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.

181 Id.