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# ARTICLE

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## REGULATING PATIENT SAFETY: THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

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BARRY R. FURROW<sup>†</sup>

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<sup>†</sup> Professor of Law and Director, the Health Law Program, the Earle Mack School of Law at Drexel University. I want to thank Nicole Martin and Kristin Shicora for their capable research assistance, and Professor John Tingle of Nottingham Trent University for his comments on an earlier draft exploring some of these developments.

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## INTRODUCTION

Patient injury is a predictable feature of health care, particularly in hospitals, in the United States and elsewhere. Since publication of the Institute of Medicine (IOM) report *To Err Is Human* in 2000,<sup>1</sup> patient safety has come to the forefront of U.S. health care. The IOM's projection of 44,000 to 98,000 deaths per year due to hospital errors, and hundreds of thousands of avoidable injuries and extra days of hospitalization,<sup>2</sup> fueled the patient-safety movement in the United States.<sup>3</sup> Ten years after the IOM report, the level of adverse events in hospitals has not improved in any major way. A recent *HealthGrades* analysis of Medicare data estimates that more than 230,000 hospital deaths from 2007 to 2009 could have been prevented within the Medicare population alone.<sup>4</sup> A study of ten North Carolina hospitals con-

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<sup>1</sup> INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 2000).

<sup>2</sup> *Id.* at 26-27.

<sup>3</sup> See CHARLES VINCENT, *PATIENT SAFETY* 25 (Wiley-Blackwell, 2d ed. 2010) (2006) (“Without doubt the publication of th[e IOM] report was the single most important spur to the development of patient safety, catapulting it into public and political awareness and galvanizing political and professional will at the highest levels in the United States.”).

<sup>4</sup> KRISTIN REED & RICK MAY, *HEALTHGRADES, THE THIRTEENTH ANNUAL HEALTH- GRADES HOSPITAL QUALITY IN AMERICA STUDY 2* (2010), available at <http://www.healthgrades.com/business/img/HealthGradesHospitalQualityInAmericaStudy2>

cluded that the rate of patient harm from medical care had not decreased substantially over a six-year period ending in December 2007.<sup>5</sup>

Analysis of patient safety rests on four basic propositions. First, patient injury (ranging from minor injuries to death) is a recurring feature of health care and negatively affects roughly one in every ten patients, according to a systematic review of the literature.<sup>6</sup> Findings by the Inspector General within the Medicare context support this estimated patient-injury rate.<sup>7</sup> As these statistics attest, patient injury eludes easy solutions.

Second, physicians (and the hospitals in which they practice) all too often continue to practice bad medicine in spite of what is known about good medical practice.<sup>8</sup> While hospital care is indeed complicated, it is also poorly coordinated and poorly managed in many hospitals.<sup>9</sup> Hospital policing of adverse events remains inadequate,<sup>10</sup> even

010.pdf. The authors found that, while hospital quality had improved, the difference between the best ("5-star rated") and worst ("1-star rated") hospitals was significant. *Id.* at 11-12. For instance, the probability of dying in a 5-star hospital was roughly 70% lower than in a 1-star facility. *Id.* The authors concluded that of the more than 230,000 preventable deaths, over half could be attributed to four prevalent medical diagnoses: sepsis, pneumonia, respiratory failure, and heart failure. *Id.*

<sup>5</sup> Christopher P. Landrigan et al., *Temporal Trends in Rates of Patient Harm Resulting from Medical Care*, 363 NEW ENG. J. MED. 2124, 2127 (2010).

<sup>6</sup> E.N. de Vries et al., *The Incidence and Nature of In-Hospital Adverse Events: A Systematic Review*, 17 QUAL. & SAFETY HEALTH CARE 216, 216, 222 (2008).

<sup>7</sup> OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., OEI-06-09-0090, ADVERSE EVENTS IN HOSPITALS: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES, at i-ii (2010), available at <http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf> (determining that approximately 13.5 percent of Medicare hospital admissions suffered an adverse event, with an equal percentage experiencing temporary harm).

<sup>8</sup> Sana M. Al-Khatib and her coauthors offer an illustrative example in the context of implantable cardioverter-defibrillators (ICDs), which in certain circumstances can prevent sudden cardiac death. Sana M. Al Khatib et al., *Non-Evidence-Based ICD Implantations in the United States*, 305 JAMA 43, 43 (2011). The authors divided the use of ICDs in hospital patients into two categories: those uses supported by practice guidelines (evidence-based ICDs) and those that were not (non-evidence-based ICDs). *Id.* They found that the "risk of in-hospital death was significantly higher in patients who received a non-evidence-based device than in patients who received an evidence-based device." *Id.* at 46. Despite the evident risk posed by the non-evidence-based ICDs, over 20% of patients in the study received such devices, with some hospitals using them more than 40% of the time. *Id.* at 43, 48.

<sup>9</sup> Landrigan and his coauthors observe,

Despite substantial resource allocation and efforts to draw attention to the patient-safety epidemic on the part of government agencies, health care regulators, and private organizations, the penetration of evidence-based safety practices has been quite modest. For example, only 1.5% of hospitals in the United States have implemented a comprehensive system of electronic medical records,

though tools, such as computer programs, can ferret out ineffective and dangerous care and its causes.<sup>11</sup> Some health care systems function very well in coordinating care and improving outcomes, with the Veterans Administration (VA) hospitals serving as the prime example,<sup>12</sup> and private systems like the Mayo Clinic exemplifying an integrated model with seamless coordination of patient care.<sup>13</sup> The challenge is learning from their successes and applying them to other hospitals across the United States.

Third, medical practice too often ignores effective practices.<sup>14</sup> More research is needed to understand both what works in modern medicine and what barriers exist to adopting new practices. Fourth, regulatory tools need to be expanded in order to force more integration and coordination in health care delivery.<sup>15</sup>

and only 9.1% have even basic electronic record keeping in place; only 17% have computerized provider order entry. Physicians-in-training and nurses alike routinely work hours in excess of those proven to be safe. Compliance with even simple interventions such as hand washing is poor in many centers.

Landrigan et al., *supra* note 5, at 2130 (citations omitted). For further insights, see also the astringent comments of Bruce Spitz and John Abramson: "What other industry would tolerate such disregard for professional standards? Who would buy their products? What would happen if we learned that defense contractors failed to follow production protocol 45 percent of the time and that ninety-eight thousand soldiers died annually because of the low quality of their equipment?" Bruce Spitz & John Abramson, *When Health Policy Is the Problem: A Report from the Field*, 30 J. HEALTH POL. POL'Y & L. 327, 329 (2005).

<sup>10</sup> See Mark R. Chassin et al., *The Urgent Need to Improve Health Care Quality*, 280 JAMA 1000, 1002-03 (1998) (stating that "[l]arge numbers are injured [in part] because preventable complications of medical treatment are not averted").

<sup>11</sup> See generally Barry R. Furrow, *Data Mining and Substandard Medical Practice: The Difference Between Privacy, Secrets and Hidden Defects*, 51 VILL. L. REV. 803, 810-18 (2006) (discussing privacy issues arising with the use of electronic medical records).

<sup>12</sup> See, e.g., PHILLIP LONGMAN, *BEST CARE ANYWHERE: WHY VA HEALTH CARE IS BETTER THAN YOURS* 1-10 (2007) (confirming that the VA system excels at delivering high-quality, well-coordinated, and evidence-based care).

<sup>13</sup> See DOUGLAS MCCARTHY ET AL., *THE COMMONWEALTH FUND, PUB. NO. 1306, MAYO CLINIC: MULTIDISCIPLINARY TEAMWORK, PHYSICIAN-LED GOVERNANCE, AND PATIENT-CENTERED CULTURE DRIVE WORLD-CLASS HEALTH CARE* 13-14 (2009), available at [http://www.commonwealth.org/~media/Files/Publications/Case%20Study/2009/Aug/1306\\_McCarthy\\_Mayo\\_case%20study.pdf](http://www.commonwealth.org/~media/Files/Publications/Case%20Study/2009/Aug/1306_McCarthy_Mayo_case%20study.pdf) (describing the structural and cultural pillars undergirding the Mayo Clinic's integrated model of health care delivery).

<sup>14</sup> See JOHN E. WENNBERG, *TRACKING MEDICINE: A RESEARCHER'S QUEST TO UNDERSTAND HEALTH CARE* 4 (2010) ("Unwarranted variation in health care delivery—variation that cannot be explained on the basis of illness, medical evidence, or patient preference—is ubiquitous.").

<sup>15</sup> See generally Angus Corbett et al., *Does the Phenomenon of 'Sociological Citizenship' Provide a Pathway for Health Care Organizations to Navigate the Gap Between Expectations and Outcomes in Safety and Quality?* 8-13 (Apr. 14, 2010) (unpub-

The field of patient safety has grown in the United States as a subspecialty within health law and policy over the past fifteen years.<sup>16</sup> Patient safety efforts have included both private market-based initiatives and state and federal regulatory initiatives to reduce the problems outlined above. The general strategies can be summed up in six major regulatory categories:

(1) *Standardizing Good Medical Practices.* This method tries to reduce medical practice variation by promoting best practices, practice guidelines, and research on what works and is cost-effective.

(2) *Tracking Adverse Events in Hospitals.* Collection of adverse event data is expanding at the state and federal levels, since both health care providers and regulators need data in order to select the most serious problem areas for repair.

(3) *Disclosing Provider Performance.* Disclosure of adverse events can occur at three levels: (a) induced disclosure of hospital adverse events and “near misses” to state regulators and quasi-regulators like the Joint Commission;<sup>17</sup> (b) disclosure by the provider of adverse events to patients; and (c) publication of performance data about relative risks by private/public agents, designed for purchaser use.

(4) *Reforming Payment Systems.* These strategies include creating a range of financial incentives for providers to promote safety, through “pay for performance” initiatives, including bonuses and docking reimbursement for failures to meet minimum standards as well as using insurance exchanges to promote quality and safety improvements.

(5) *Coordinating and Integrating Care.* This strategy is the largest and most innovative category of federal health care reform, which promotes several new models for integrating health care delivery in the fragmented U.S. system.

(6) *Expanding Provider Responsibility.* This strategy includes implementing legislative requirements for disclosure, expanded fiduciary

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lished manuscript presented at the Seventh International Conference in Organisational Behaviour in Health Care, University of Birmingham, UK), available at <http://www.download.bham.ac.uk/hsmc/angus-corbett.pdf> (discussing how implementing new and innovative oversight structures can improve patient safety and health).

<sup>16</sup> See generally Barry R. Furrow, *Regulating Patient Safety: Toward a Federal Model of Medical Error Reduction*, 12 WIDENER L. REV. 1 (2005) (discussing the current regulatory structure of health care in the United States and proposing changes to strengthen federal regulation). A look at the website of the Agency for Healthcare Research and Quality (AHRQ) reveals dozens of menus and links to every aspect of the health care quality matrix. AGENCY FOR HEALTHCARE RES. & QUALITY, <http://www.ahrq.gov> (last visited Mar. 15, 2011).

<sup>17</sup> For more information on the Joint Commission, see *infra* Section II.A.

duties, and corporate-system responsibility for bad outcomes.<sup>18</sup> There are also emerging examples of providers who market safety, such as Geisinger Health System's guarantee that certain safety procedures will be undertaken during cardiac surgery.<sup>19</sup>

Many of these initiatives represent real progress, but the culture of hospitals and the structure of payment have meant that these admirable reform efforts have moved at a glacial pace. As Troyen Brennan and Donald Berwick observed fifteen years ago, "Variation in practice runs rampant—beyond the bounds of common sense. Hospitals and doctors continue to perpetrate harms in their work, albeit unintended ones. And it is no easier now to cause an alcoholic surgeon to stop operating than it was forty years ago."<sup>20</sup> Little has changed since they stated their critique.

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA).<sup>21</sup> This Act is a major attempt to improve access to health care by expanding coverage through Medicaid and by reforming the private insurance market. Quality is also an important focus of PPACA—it promotes disease management, care coordination, new payment models, value-based purchasing initiatives, and the use of comparative effectiveness research. PPACA offers a strong regulatory push toward the goal of "flawless execution," the health care equivalent of zero defects in industrial production.<sup>22</sup>

<sup>18</sup> See generally BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* chs. 1, 4-6 (6th ed. 2008) for a discussion of the various regulatory initiatives. I have considered several dimensions of the patient safety problem in a series of articles. See Furrow, *supra* note 11; Barry R. Furrow, *Medical Mistakes: Tiptoeing Toward Safety*, 3 HOUS. J. HEALTH L. & POL'Y 181 (2003); Barry R. Furrow, *Patient Safety and the Fiduciary Hospital: Sharpening Judicial Remedies*, 1 DREXEL L. REV. 439 (2009); Furrow, *supra* note 16.

<sup>19</sup> See, e.g., Thomas H. Lee, *Pay for Performance, Version 2.0?*, 357 NEW ENG. J. MED. 531, 531-32 (2007) (outlining some of the critical processes Geisinger promises to undertake to ensure patient safety).

<sup>20</sup> TROYEN A. BRENNAN & DONALD M. BERWICK, *NEW RULES: REGULATION, MARKETS, AND THE QUALITY OF AMERICAN HEALTH CARE* 339 (1996).

<sup>21</sup> Pub. L. No. 111-148, 124 Stat. 119 (2010) (to be codified as amended in scattered sections of 21, 25, 26, 29, and 42 U.S.C.).

<sup>22</sup> Robert Wachter uses the phrase "flawless execution" in relation to medical practice. Robert M. Wachter, *The End of the Beginning: Patient Safety Five Years After 'To Err Is Human'*, HEALTH AFF. W4-534, W4-535 (2004), <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.534v1>. Wachter notes that as medicine has grown more complicated and sophisticated, the need for coordination has grown. *Id.* "It should come as no surprise, then, that without a culture, procedures, and technology focused on flawless execution, errors would become commonplace." *Id.*

The passage of PPACA promises to take patient safety to the next level of regulatory intensity in American health care delivery, in part through the infusion of money into patient-safety research and into payment reforms in particular. PPACA has an astonishing variety of provisions aimed at improving the quality of the U.S. health care system, reducing errors, and generally promoting patient safety.<sup>23</sup> These provisions include new centers, demonstration projects, and funding awards for a wide range of quality improvement initiatives.<sup>24</sup> The Act sets out an ambitious research agenda for the United States and provides funding and other incentives to accomplish its goals. It establishes a mandate of continuous, data-driven testing of the performance of health care professionals and facilities. It also launches “demonstration projects” through which the federal government funds particular forms of health care or health care delivery systems with a requirement that their performance be studied, often with the intent of examining their potential for wider adoption.<sup>25</sup>

PPACA contains numerous provisions that fund research and disseminate findings to providers about what works. Some provisions define health care quality and its measures, while others attempt to generate new research findings on outcomes and best practices in the clinical setting. Still other provisions mandate broad dissemination of these findings to providers and consumers of health care through websites and other media. Finally, payment strategies will be expanded and tested to determine how the Medicare payment system can better promote best practices and outcomes.

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<sup>23</sup> See generally DEMOCRATIC POLICY COMM., THE PATIENT PROTECTION AND AFFORDABLE CARE ACT AS PASSED (2010), available at <http://dpc.senate.gov/healthreformbill/healthbill53.pdf> (providing the Democratic Party’s summary of PPACA’s contents).

<sup>24</sup> PPACA has five pilot projects and thirty demonstration projects. Pilot initiatives include, for example: National Pilot Program on Payment Bundling, PPACA sec. 3023, § 1866D, 42 U.S.C.A. § 1395cc-4 (West Supp. 1B 2010); Healthy Aging, Living Well, *id.* § 4202(a), 42 U.S.C.A. § 300u-14 (West Supp. 1A 2010); Demonstration Project Concerning Individualized Wellness Plan, *id.* sec. 4206, § 330, 42 U.S.C.A. § 245b(s); and Pilot Testing Pay-for-Performance Programs for Certain Medicare Providers, *id.* § 10326, 42 U.S.C.A. § 1395b-1 note (West Supp. 1B 2010). Demonstration projects include: Demonstration Project to Evaluate Integrated Care Around a Hospitalization, *id.* § 2704, 42 U.S.C.A. § 1396a note; Medicaid Global Payment System Demonstration Project, *id.* § 2705, 42 U.S.C.A. § 1315a note (West Supp. 1A 2010); Pediatric Accountable Care Organization Demonstration Project, *id.* § 2706, 42 U.S.C.A. § 1396a note (West Supp. 1B 2010); Independence at Home Demonstration Program, *id.* sec. 3024, § 1866D, 42 U.S.C.A. § 1395cc-5; and Medicare Hospice Concurrent Care Demonstration Program, *id.* § 3140, 42 U.S.C.A. § 1395d note.

<sup>25</sup> See sources cited *supra* notes 23-24.

## I. STANDARDIZING GOOD MEDICAL PRACTICES

The culture of medicine is constructed around the challenges presented by individual patients and the need for individual provider judgment—as well as the perceived need, at times, for clinical heroism. This culture values “expert audacity,” the insight of a brilliant clinician in solving a diagnostic puzzle.<sup>26</sup> By contrast, improvement of health care generally requires system-wide improvements—reducing medical practice variation by figuring out what works, synthesizing these findings into clinical practice guidelines and best practices, and then applying them to ensure effective treatments. Studies of American medicine have found large practice variation around the country,<sup>27</sup> and it is clear that modern medicine still lacks validation for many treatment modalities. Yet diffusion of good practice is a slow process often resisted by physicians.<sup>28</sup>

Tools are already available to improve clinical performance. One obvious example is a checklist.<sup>29</sup> Atul Gawande writes about the tension between the model of expert audacity (the doctor as medical hero) and the model of regimentation, drawn from management of complex systems.<sup>30</sup> He notes that in the intensive care unit (ICU) doctors treat very sick patients who require that hundreds of things be done right, every day, to keep them alive.<sup>31</sup> Gawande argues that simple checklists have tremendous advantages in the complex world of the ICU.<sup>32</sup> First, they help with memory recall.<sup>33</sup> Second, they make clear and explicit “the

<sup>26</sup> See Atul Gawande, *Annals of Medicine: The Checklist*, NEW YORKER, Dec. 10, 2007, at 86, 94 (comparing the culture change in test pilots during the 1950s—from brazen and unregulated to refined and systemized—to what is currently transpiring in medicine).

<sup>27</sup> See, e.g., John E. Wennberg, *Dealing with Medical Practice Variations: A Proposal for Action*, HEALTH AFF., May 1984, at 6, 9-15 (contending that norms of medical practice allow for a “wide range of professional discretion” and thus can result in significant differences in how patients are treated); *Understanding of the Efficiency and Effectiveness of the Health Care System*, DARTMOUTH ATLAS HEALTH CARE, <http://www.dartmouthatlas.org> (last visited Mar. 15, 2011) (using Medicare data to show “glaring variations in how medical resources are distributed and used in the United States”).

<sup>28</sup> The resistance of physicians to externally imposed standards and values is a recurrent theme in American health care. For an excellent summary and analysis of the reasons for this recalcitrance, see Sandra H. Johnson, *Regulating Physician Behavior: Taking Doctors’ “Bad Law” Claims Seriously*, 53 ST. LOUIS U. L.J. 973, 973-75, 992-1008 (2009).

<sup>29</sup> See Gawande, *supra* note 26, at 91-92.

<sup>30</sup> *Id.* at 94.

<sup>31</sup> *Id.* at 89-90.

<sup>32</sup> *Id.* at 91.

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

minimum, expected steps in complex processes.”<sup>34</sup> Even experienced providers do not always understand the critical importance of some precautions, such as the use of antacid medication for ventilated patients.<sup>35</sup> In Gawande’s words, “[c]hecklists establish[] a higher standard of baseline performance.”<sup>36</sup> He continues:

We have the means to make some of the most complex and dangerous work we do—in surgery, emergency care, and I.C.U. medicine—more effective than we ever thought possible. But the prospect pushes against the traditional culture of medicine, with its central belief that in situations of high risk and complexity what you want is a kind of expert audacity—the right stuff . . . Checklists and standard operating procedures feel like exactly the opposite, and that’s what rankles many people.<sup>37</sup>

Studies by Peter Pronovost and others also confirm the value of such relatively simple tools for constraining error in the hospital setting.<sup>38</sup> The infection-control checklist<sup>39</sup> is now part of a project to cut line infec-

<sup>34</sup> *Id.* at 91-92.

<sup>35</sup> *Id.* at 92.

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

<sup>37</sup> *Id.* at 94.

<sup>38</sup> For a corroborating study of the benefit of basic procedures in reducing infections, see Peter Pronovost et al., *An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU*, 355 NEW ENG. J. MED. 2725, 2729-31 (2006). This study looked at one approach to reducing catheter-related bloodstream infections in sixty-seven hospitals. *Id.* at 2726, 2728. The five procedures implemented in this approach were “hand washing, using full-barrier precautions during the insertion of central venous catheters, cleaning the skin with chlorhexidine, avoiding the femoral site if possible, and removing unnecessary catheters.” *Id.* at 2726. To increase use of these procedures, a number of steps were taken:

[C]linicians [were educated] about practices to control infection and harm resulting from catheter-related bloodstream infections, a central-line cart with necessary supplies was created, a checklist was used to ensure adherence to infection-control practices, providers were stopped (in nonemergency situations) if these practices were not being followed, the removal of catheters was discussed at daily rounds, and the teams received feedback regarding the number and rates of catheter-related bloodstream infection at monthly and quarterly meetings, respectively.

*Id.* at 2726-27. After three months of employing the procedures, the median rate of infection dropped from 2.7 infections per 1000 catheter days to zero infections; this zero infection rate was sustained during the subsequent fifteen months of follow-up. *Id.* at 2729-30.

<sup>39</sup> For a copy of the checklist, see AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, AHRQ PUB. NO. 09(10)-P013-2, FACT SHEET: ENDING HEALTHCARE-ASSOCIATED INFECTIONS 4 (2009), available at <http://www.ahrq.gov/qual/haicusp.pdf>.

tions by fifty percent by 2013.<sup>40</sup> The Agency for Healthcare Research and Quality (AHRQ) has launched a project, “On the CUSP: Stop BSI,” currently involving hundreds of hospitals across thirty-five states and the District of Columbia.<sup>41</sup> The project aspires to emulate the success of hospitals in Michigan, where more than one hundred ICUs sliced their median rate of infection to zero per 1000 catheter days, which was significantly less than the national average of 1.8 to 5.2.<sup>42</sup>

Practice guidelines are also needed in current medical practice. Current guidelines are often not grounded in good science but rather serve primarily as self-protective shields created by insurers and medical societies.<sup>43</sup> Many of PPACA’s proposed reforms will have to confront this larger issue of physician resistance to change. PPACA operates as a top-down model of regulation, but the general use of research dollars and financial payment incentives seeks to alter provider behavior from the bottom up. PPACA, along with the stimulus bill entitled the American Recovery and Reinvestment Act of 2009 (Recovery Act),<sup>44</sup> represents a major federal initiative to standardize medical practice—a systematic and well-funded national effort to improve American medicine. Together they pour millions of dollars into government-funded research on effectiveness, best practices, and practice guidelines.<sup>45</sup> This research is backed by new centers and initiatives to disseminate findings and motivate providers to incorporate them into practice.

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<sup>40</sup> *National Targets and Metrics*, U.S. DEPARTMENT HEALTH & HUM. SERVICES tbl.1, <http://www.hhs.gov/ash/initiatives/hai/nationaltargets/index.html> (last visited Mar. 15, 2011).

<sup>41</sup> *Map of Hospitals Participating in the “On the CUSP: Stop BSI” Project*, ON THE CUSP: STOP HAI, <http://www.onthecuspstophai.org/AboutStat-7954.html> (last visited Mar. 15, 2011).

<sup>42</sup> Pronovost et al., *supra* note 38, at 2726, 2728-30.

<sup>43</sup> See, e.g., Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 653 (2001) (noting the varying quality of such guidelines, which are often drafted to meet the goals of the drafting organization).

<sup>44</sup> Pub. L. No. 111-5, 123 Stat. 115.

<sup>45</sup> See, e.g., *id.* at 176-78 (allocating hundreds of millions of dollars to the AHRQ). Dissemination has been happening for more than a decade. The AHRQ sponsors the National Guideline Clearinghouse, which reviews all guidelines for the quality of the evidence supporting them. NAT’L GUIDELINE CLEARINGHOUSE, <http://www.guideline.gov> (last visited Mar. 15, 2011) (describing the website as a “public resource for evidence-based clinical practice guidelines”).

### A. Quality Priorities and Measurement

Several sections of PPACA discuss health care quality and its measurement in extensive detail, as they relate to major funding programs that will focus research on outcomes, best practices, and comparative effectiveness. Section 3011 of PPACA articulates a national strategy for improving “the delivery of health care services, patient health outcomes, and population health.”<sup>46</sup> The priorities identified include (1) “improving health outcomes, efficiency, and patient-centeredness of health care for all populations”; (2) “identifying areas . . . that have the potential for rapid improvement”; (3) “address[ing] gaps in quality, efficiency, comparative effectiveness information, and health outcomes measures and data aggregation techniques”; (4) “improv[ing] Federal payment policy to emphasize quality and efficiency”; (5) “enhanc[ing] the use of health care data to improve quality, efficiency, transparency, and outcomes”; and (6) “improv[ing] research and dissemination of strategies and best practices to improve patient safety and reduce medical errors, preventable admissions and readmissions, and health care-associated infections.”<sup>47</sup> Little is overlooked on this list of ideas for quality improvement.

Section 3013 mandates the development of quality measures.<sup>48</sup> A “quality measure” is defined as “a standard for measuring the performance and improvement of population health or of health plans, providers of services, and other clinicians in the delivery of health care services.”<sup>49</sup> Such quality measures will include, among others, “health outcomes and functional status of patients”; “the management and coordination of health care across episodes of care and care transitions for patients across the continuum of providers, health care settings, and health plans”; the quality of information provided to patients; “use of health information technology”; and the safety, effectiveness, patient-centeredness, appropriateness, timeliness, and efficiency of care.<sup>50</sup>

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<sup>46</sup> PPACA sec. 3011, § 399HH(a)(1), 42 U.S.C.A. § 280j(a)(1) (West Supp. 1A 2010).

<sup>47</sup> *Id.*, § 399HH(a)(2)(B)(i)–(v), (vii), 42 U.S.C.A. § 280j(a)(2)(B)(i)–(v), (vii).

<sup>48</sup> *Id.* sec. 3013(a)(4), § 931, 42 U.S.C.A. § 299b-31.

<sup>49</sup> *Id.*, § 931(a), 42 U.S.C.A. § 299b-31(a).

<sup>50</sup> *Id.*, § 931(c)(2)(A)–(F), 42 U.S.C.A. § 299b-31(c)(2)(A)–(F).

### B. *Research on Outcomes and Outcome Measures*

Section 10303 of PPACA instructs the Secretary of Health and Human Services (HHS) to develop provider-level outcome measures for hospitals, physicians, and other providers.<sup>51</sup> Such measures will include at least ten outcome measurements for acute and chronic diseases, including the five most prevalent and resource-intensive conditions, within two years; for primary and preventative care, the Secretary will develop ten measurements for distinct populations within three years.<sup>52</sup> This is a short timeline, and the focus on outcome measures represents a significant step toward a pay-for-performance system.

Section 6301 mandates patient-centered outcomes research as a part of the larger goal of developing comparative clinical effectiveness research (CER).<sup>53</sup> The section defines “comparative clinical effectiveness research” to mean “research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments [and] services . . .”<sup>54</sup> PPACA further defines medical treatments and services broadly, to include the provision of care as well as the use of medical devices, pharmaceuticals, and “integrative health practices.”<sup>55</sup>

CER is well funded, with \$1.1 billion provided by the Recovery Act divided among the AHRQ (\$300 million), the National Institutes of Health (\$400 million), and the Office of the HHS Secretary (\$400 million).<sup>56</sup> PPACA created a new oversight entity, the Patient-Centered Outcomes Research (PCOR) Institute, to direct the CER program.<sup>57</sup> Section 6301 requires broad dissemination of research findings.<sup>58</sup> AHRQ’s Office of Communication and Knowledge Transfer will broadcast the research findings published by the PCOR Institute and other

<sup>51</sup> *Id.* sec. 10303(a), § 931(f)(1), 42 U.S.C.A. § 299b-31(f)(1).

<sup>52</sup> *Id.*, § 931(f)(2), 42 U.S.C.A. § 299b-31(f)(2).

<sup>53</sup> *Id.* sec. 6301(a), § 1181, 42 U.S.C.A. § 1320e.

<sup>54</sup> *Id.*, § 1181(a)(2)(A), 42 U.S.C.A. § 1320e(a)(2)(A).

<sup>55</sup> *Id.*, § 1181(a)(2)(B), 42 U.S.C.A. § 1320e(a)(2)(B).

<sup>56</sup> American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, tit. VIII, 123 Stat. 115, 176-77 (2009); see also *Comparative Effectiveness Research Funding*, HHS.GOV/RECOVERY, <http://www.hhs.gov/recovery/programs/cer/index.html> (last visited Mar. 15, 2011) (showing research funding allocation among government entities). The Recovery Act created the Federal Coordinating Council for Comparative Effectiveness Research to organize such research across the federal government. Recovery Act § 804, 42 U.S.C.A. § 299b-8.

<sup>57</sup> See *infra* Section I.C.

<sup>58</sup> PPACA sec. 6301(b), § 937, 42 U.S.C.A. § 299b-37.

agencies that are relevant to comparative CER.<sup>59</sup> The office also must create “tools that organize and disseminate research findings for physicians, health care providers, patients, payers, and policy makers.”<sup>60</sup> It must “develop a publicly available resource database that collects and contains government-funded evidence and research from public, private, not-for-profit, and academic sources.”<sup>61</sup> By improving access to research, the office should help clinicians incorporate the latest findings into their practice.<sup>62</sup> Commentators expect that this focus on CER will have a profound effect on standardizing physician practice.<sup>63</sup>

The PCOR Institute functions as a non-profit institute—not a government agency.<sup>64</sup> The institute’s purpose is

to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a) (2) (B).<sup>65</sup>

The institute will establish priorities for research in light of evidence gaps in clinical outcomes, medical practice variation, and other quality issues articulated in the national strategy for quality care.<sup>66</sup> The institute must also release its research findings to clinicians, patients, and the public within ninety days of receiving them.<sup>67</sup> These findings will be made available on the Institute’s website.<sup>68</sup>

<sup>59</sup> *Id.*, § 937(a) (1), 42 U.S.C.A. § 299b-37(a) (1).

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*, § 937(b), 42 U.S.C.A. § 299b-37(b).

<sup>63</sup> See, e.g., Mohammad N. Akhter & Richard A. Levinson, Editorial, *Comparative Effectiveness Research and the Future Practice of Medicine*, 101 J. NAT’L MED. ASS’N 1301, 1301 (2009) (“CER clearly has the potential to reshape major portions of the practice of medicine.”).

<sup>64</sup> PPACA sec. 6301(a), § 1181(b) (1), 42 U.S.C.A. § 1320e(b) (1).

<sup>65</sup> *Id.*, § 1181(c), 42 U.S.C.A. § 1320e(c).

<sup>66</sup> *Id.*, § 1181(d) (1) (A), 42 U.S.C.A. § 1320e(d) (1) (A).

<sup>67</sup> *Id.*, § 1181(d) (8) (A), 42 U.S.C.A. § 1320e(d) (8) (A).

<sup>68</sup> *Id.*, § 1181(h) (3), 42 U.S.C.A. § 1320e(h) (3).

### C. Evidence-Based Practices

The Center for Quality Improvement and Patient Safety is created by section 3501 of PPACA to “identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices . . . in health care quality, safety, and value” in collaboration with other federal agencies.<sup>69</sup>

This Center will support (1) the development of “best practices for quality improvement practices in the delivery of health care services”; (2) the redesign of systems to improve outcomes and patient safety, as well as to limit medical errors; (3) the identification of high-quality providers; (4) the assessment of research; and (5) the rapid dissemination of information into practice.<sup>70</sup> It will also support, through contracts or other means, research on system improvements and the “development of tools to facilitate adoption of best practices that improve the quality, safety, and efficiency of health care delivery services.”<sup>71</sup>

Such support includes the establishment of a Quality Improvement Network Research Program for “testing, scaling, and disseminating . . . interventions to improve quality and efficiency in health care.”<sup>72</sup> Findings will be released through multiple media, and shared with the Office of the National Coordinator of Health Information Technology.<sup>73</sup> This data will help “inform the activities of the health information technology extension program under section 3012, as well as any relevant standards, certification criteria, or implementation specifications.”<sup>74</sup>

Section 6301 also requires the HHS Secretary to

provide for the coordination of relevant Federal health programs to build data capacity for comparative clinical effectiveness research, including the development and use of clinical registries and health outcomes research data networks, in order to develop and maintain a comprehensive, interoperable data network to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records.<sup>75</sup>

<sup>69</sup> *Id.* sec. 3501, § 933(a), 42 U.S.C.A. § 299b-33(a).

<sup>70</sup> *Id.*, § 933(b)(2)–(5), 42 U.S.C.A. § 299b-33(b)(2)–(5).

<sup>71</sup> *Id.*, § 933(c)(1), 42 U.S.C.A. § 299b-33(c)(1).

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*, § 933(d), 42 U.S.C.A. § 299b-33(d).

<sup>74</sup> *Id.*, § 933(d)(2), 42 U.S.C.A. § 299b-33(d)(2).

<sup>75</sup> *Id.* sec. 6301(b), § 937(f), 42 U.S.C.A. § 299b-37(f).

Section 3501 provides for “quality improvement technical assistance and implementation.”<sup>76</sup> The Center for Quality Improvement and Patient Safety will award technical assistance and implementation grants to health care providers and delivery institutions so that they “understand, adapt, and implement the models and practices identified in the research conducted by the Center, including the Quality Improvement Networks Research Program.”<sup>77</sup>

Section 10303(c), “Clinical Practice Guidelines,” requires the HHS Secretary to identify existing and new clinical practice guidelines.<sup>78</sup> Government-generated practice guidelines and best practices are likely to be an improvement over the currently predominant medical-specialty-created guidelines. Consider the case of *Trowbridge v. United States*.<sup>79</sup> The daughter of the plaintiffs suffered from cerebral palsy, allegedly due to the negligence of the doctor treating her mother during labor and delivery.<sup>80</sup> The plaintiffs argued that the doctor did not exercise due care because he failed to monitor the pattern of fetal contractions and continued to administer a drug that caused excessive contractions, which led to their daughter’s cerebral palsy.<sup>81</sup> The case turned on expert testimony based on medical treatises, journal articles, and standards for the interpretation of fetal heart rate strips produced by the American Congress of Obstetricians and Gynecologists (ACOG).<sup>82</sup> One witness, Dr. Richard Depp, was a long-time medical legal consultant who almost exclusively (ninety-five percent of the time) worked for defendants in medical malpractice cases.<sup>83</sup> Dr. Depp also contributed to “consensus guidelines” crafted by the ACOG.<sup>84</sup>

Judge Bush, in evaluating Dr. Depp’s credibility as an expert witness, made a series of telling observations about how practice guidelines are created. He observed that guidelines might be representative of pure “best practices,” but that conflicts are often apparent:

The Court understands from the testimony at trial that these guidelines have a purpose of identifying common ground and uniform clinical prac-

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<sup>76</sup> *Id.* sec. 3501, § 934, 42 U.S.C.A. § 299b-34.

<sup>77</sup> *Id.*, § 934(a)(1), 42 U.S.C.A. § 299b-34(a)(1).

<sup>78</sup> *Id.* sec. 10303(c), § 304(b)(4)(A), 42 U.S.C.A. § 299 note.

<sup>79</sup> 703 F. Supp. 2d 1129 (D. Idaho 2010).

<sup>80</sup> *Id.* at 1130.

<sup>81</sup> *Id.* at 1131.

<sup>82</sup> *Id.* at 1132-37.

<sup>83</sup> *Id.* at 1136.

<sup>84</sup> *Id.*

tices across the country. However, the Court was also left with a concern that the motivation of some who would press for such “consensus guidelines” is to revise terminology and set practice standards in a manner intended to provide litigation safe-harbors for delivery physicians.<sup>85</sup>

This sophisticated judicial analysis exposes the risks of self-interested medical society guideline development.

Medicine is not a science, and medical practice is subject to tremendous variation. Physicians practice all too often in spite of evidence-based guidelines because they are ignorant of best practices or resist them for a range of reasons.<sup>86</sup> However, it is clear from the medical error literature that best practices need to be disseminated and incorporated to a much greater extent.<sup>87</sup> Since surgery-based and drug-related events are the majority of adverse events,<sup>88</sup> regulatory efforts must push evidence-based interventions to reduce these events.

Will providers respond positively to these incentive-based devices to promote quality and standardization? What kinds of strategies might we expect from providers to push back both against the standardization that will be more likely and the links of payment to performance?<sup>89</sup> PPACA offers some incentive strategies, but very few that will directly accelerate the incorporation of practice guidelines; there are no mandates, no liability shields to buy physician compliance, and no strong incentives. To the contrary, Subtitle D of Title VI of PPACA, which provides for patient-centered outcomes research in sections 6301 and 6302, requires the Institute to ensure that research findings “not be construed as mandates for practice guidelines, coverage recommendations, payment, or policy recommendations.”<sup>90</sup> Perhaps PPACA’s logic makes sense in this area—going slow in forcing standardization to avoid building provider resistance too early in the research process.

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<sup>85</sup> *Id.* (footnote omitted).

<sup>86</sup> See Johnson, *supra* note 28, at 973-75, 992-1008.

<sup>87</sup> See generally INST. OF MED., *supra* note 1, at 26-43.

<sup>88</sup> *Id.*; see also *Reducing Errors in Health Care: Translating Research into Practice*, AGENCY FOR HEALTHCARE RES. & QUALITY, <http://www.ahrq.gov/qual/errors.htm> (last visited Mar. 15, 2011) (disclosing categories of errors, including surgical errors).

<sup>89</sup> For a discussion of the sources of physician resistance to CER and guidelines generally, see Richard S. Saver, *Health Care Reform’s Wild Card: The Uncertain Effectiveness of Comparative Effectiveness Research*, 159 U. PA. L. REV. 2147 (2011). For a critique of practice guidelines, see generally Harold C. Sox & Sheldon Greenfield, *Quality of Care—How Good Is Good Enough?*, 303 JAMA 2403 (2010).

<sup>90</sup> PPACA § 6301(a), 42 U.S.C.A. § 1320e(d)(8)(a)(iv) (West Supp. 1A 2010).

## II. TRACKING ADVERSE EVENTS IN HOSPITALS

Reports from the IOM, beginning with *To Err Is Human*, focused attention on medical systems and the level of errors they produced. Hospitals and other providers were urged to develop error-tracking systems and strategies for improvement, including disclosure of both errors and so-called “near misses,” events that could have resulted in patient injury but were detected in time.<sup>91</sup>

Reporting errors or adverse events is essential to system approaches.<sup>92</sup> Underreporting in states with mandatory reporting is too often the norm,<sup>93</sup> but a push for mandatory reporting models has begun to take root. The Pennsylvania patient-safety statute, for example, requires error disclosure,<sup>94</sup> while the Joint Commission Sentinel Event Policy encourages but does not require disclosure of sentinel events.<sup>95</sup> Poor compliance with such disclosure requirements is inexcusable, particularly as to “near misses.”<sup>96</sup>

<sup>91</sup> See INST. OF MED., *supra* note 1, at 5-14 (summarizing the IOM’s recommendations).

<sup>92</sup> See Peter J. Pronovost et al., *Improving the Value of Patient Safety Reporting Systems* (discussing patient safety reporting systems and the need for data to identify and treat safety hazards), in 1 ADVANCES IN PATIENT SAFETY: NEW DIRECTIONS AND ALTERNATIVE APPROACHES 52, 52-53 (Kerm Henriksen et al. eds., 2008).

<sup>93</sup> There are several reasons for such poor performance. Mandatory systems lack support from physicians, who are worried about liability, damage to reputation, and the hassle of any reporting system. See JILL ROSENTHAL ET AL., NAT’L ACAD. FOR STATE HEALTH POLICY, CURRENT STATE PROGRAMS ADDRESSING MEDICAL ERRORS: AN ANALYSIS OF MANDATORY REPORTING AND OTHER INITIATIVES 80-81 (2001) (discussing state-mandated adverse event reporting and barriers to such reporting even when mandated); Bryan A. Liang, Dr. Arthur Grayson Distinguished Lecture in Law & Medicine, *Promoting Patient Safety Through Reducing Medical Error: A Paradigm of Cooperation Between Patient, Physician, and Attorney*, 24 S. ILL. U. L.J. 541, 555 (2000) (noting that because “patient safety medical error information” can be used in litigation, there is a “tremendous negative incentive” to report such errors).

<sup>94</sup> 40 PA. CONS. STAT. ANN. § 1303.308(a) (West Supp. 2010) (“A health care worker who reasonably believes that a serious event or incident has occurred shall report the serious event or incident . . .”).

<sup>95</sup> THE JOINT COMM’N, SENTINEL EVENTS (SE), at SE-8 (2011), available at [http://www.jointcommission.org/assets/1/6/2011\\_CAMH\\_SE.pdf](http://www.jointcommission.org/assets/1/6/2011_CAMH_SE.pdf). The Joint Commission stresses the advantages to hospitals that self-report, including early consultation with the Joint Commission during the hospital’s development of its root-cause analysis and action plan. *Id.* at SE-8 to -9.

<sup>96</sup> See John R. Clark, *Leadership Series: Is Your Institution Leaving Patient Safety Information at the Bedside?*, 5 PA. PATIENT SAFETY ADVISORY 109, 109 (2008), available at [http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Dec5\(4\)/documents/109.pdf](http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2008/Dec5(4)/documents/109.pdf) (“Hospitals that are not capturing near-miss . . . events are hurting their ability to identify and correct problems before they harm patients.”).

### A. Sentinel Events and the Joint Commission

The Joint Commission is a private accreditor, granted authority by federal and state governments to accredit hospitals.<sup>97</sup> Through its Sentinel Event Policy, the Joint Commission urges reporting of sentinel events by hospitals on two levels: first to the Joint Commission, and second to patients. A “sentinel event” is defined as “an unexpected occurrence involving death or severe physical or psychological injury, or the risk thereof,”<sup>98</sup> including (1) unanticipated death or major loss of functioning unrelated to the patient’s condition; (2) patient suicide; (3) wrong-side surgery; (4) infant abduction/discharge to the wrong family; (5) rape; and (6) hemolytic transfusion reactions.<sup>99</sup> If hospitals elect not to report sentinel events to the Joint Commission, and the Commission learns of the events from a third party, the hospital must conduct an analysis of the root cause and report its findings and plan of action to the Commission or risk loss of accreditation.<sup>100</sup> It is likely, however, that many so-called “sentinel events” are not reported,<sup>101</sup> and the Joint Commission rarely takes away the accreditation of a hospital.<sup>102</sup>

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<sup>97</sup> See *About the Joint Commission*, JOINT COMMISSION, [http://www.jointcommission.org/about\\_us/about\\_the\\_joint\\_commission\\_main.aspx](http://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx) (last visited Mar. 15, 2011) (describing the Joint Commission as a nonprofit organization accrediting and certifying U.S. health care organizations and programs).

<sup>98</sup> THE JOINT COMM’N, *supra* note 95, at SE-1.

<sup>99</sup> *Id.* at SE-5 to -7.

<sup>100</sup> *Id.* at SE-9. While reporting of sentinel events is not mandatory, the Joint Commission bases its accreditation decisions in part on how hospitals respond to such events.

Accredited hospitals are expected to identify and respond appropriately to all sentinel events . . . occurring in the hospital or associated with services that the hospital provides . . . . Appropriate response includes conducting a timely, thorough, and credible root cause analysis; developing an action plan designed to implement improvements to reduce risk; implementing the improvements; and monitoring the effectiveness of those improvements.

*Id.* at SE-2.

<sup>101</sup> In fact, the Joint Commission itself acknowledges this reality by including a disclaimer in its review of sentinel event data: “The reporting of most sentinel events to the Joint Commission is voluntary and represents only a small proportion of actual events. Therefore, these data are not an epidemiologic data set and no conclusions should be drawn about the actual relative frequency of events or trends in events over time.” THE JOINT COMM’N, SENTINEL EVENT DATA: EVENT TYPE BY YEAR: 1995–FOURTH QUARTER 2010, at 4 (2011), available at [http://www.jointcommission.org/assets/1/18/Event\\_Type\\_by\\_Year\\_1995\\_4Q2010\(v2\).pdf](http://www.jointcommission.org/assets/1/18/Event_Type_by_Year_1995_4Q2010(v2).pdf).

<sup>102</sup> See Lisa Girion & Rong-Gong Lin II, *Healthcare: Drastic Setback for OC Hospital*, L.A. TIMES, Dec. 6, 2008, at 1, available at 2008 WLNR 23460341 (noting that the Joint Commission revocation of accreditation is a “rare occurrence”).

## B. “Never Events”

The concept of “never events” was first developed by the National Quality Forum (NQF)<sup>103</sup> to describe gross medical errors, “errors in medical care that are clearly identifiable, preventable, and serious in their consequences for patients, and that indicate a real problem in the safety and credibility of a health care facility.”<sup>104</sup> Examples of never events include: “surgery on the wrong body part; foreign body left in a patient after surgery; mismatched blood transfusion; major medication error; severe ‘pressure ulcer’ acquired in the hospital; and preventable post-operative deaths.”<sup>105</sup> More than twenty states have now adopted a reporting requirement for “never events,” forcing providers to disclose adverse outcomes to the appropriate state department, with the goal of improving their operations.<sup>106</sup> Such disclosure allows states to systematically record and track errors, in order to analyze patterns of adverse events, give feedback to hospitals, and in some states, provide information for consumers about the relative performance of hospitals and other providers. Many states have enacted legislation requiring reporting of incidents on the NQF list.<sup>107</sup> In 2003, Minnesota was the first state to mandate reporting of “never events.”<sup>108</sup> Other states, including New Jersey, Connecticut, and Illinois, have also adopted such reporting requirements.<sup>109</sup>

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<sup>103</sup> See Press Release, Ctrs. for Medicare & Medicaid Servs., Eliminating Serious, Preventable, and Costly Medical Errors—Never Events (May 18, 2006), available at <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1863> (attributing the definition of “never events” to the NQF).

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

<sup>105</sup> *Id.*

<sup>106</sup> See *Patient Safety Primers: Never Events*, AHRQ PATIENT SAFETY NETWORK, <http://psnet.ahrq.gov/primer.aspx?primerID=3> (last visited Mar. 15, 2011) (“Since the NQF disseminated its original Never Events list in 2002, 11 states have mandated reporting of these incidents whenever they occur, and an additional 16 states mandate reporting of serious adverse events (including many of the NQF Never Events).”). Some states, like Minnesota, require a root-cause analysis after such events are reported. *Id.*

<sup>107</sup> See Press Release, Ctrs. For Medicare & Medicaid Servs., *supra* note 103 (describing a few states’ reporting requirements to the NQF).

<sup>108</sup> *Id.*; see also MINN. STAT. ANN. § 144.7065 (West Supp. 2009) (requiring the reporting of certain adverse health care events to the state).

<sup>109</sup> See Press Release, Ctrs. For Medicare & Medicaid Servs., *supra* note 103 (summarizing the reporting requirements of these states).

### C. Patient Safety Organizations

In 2005, Congress passed the Patient Safety and Quality Improvement Act (Patient Safety Act)<sup>110</sup> to encourage the expansion of voluntary, provider-driven initiatives to improve the quality and safety of health care.<sup>111</sup> The Patient Safety Act promotes cooperation between health care providers and patient-safety research entities to improve patient safety.<sup>112</sup> It creates various legal protections and frameworks to encourage the voluntary collection and reporting of safety information by providers.<sup>113</sup> The goal is to minimize patient care errors in the U.S. health system through improved data analysis.<sup>114</sup>

Patient Safety Organizations (PSOs) serve as the primary entities “responsible for aggregating and analyzing provider error data.”<sup>115</sup> They work with clinicians and health care organizations to identify, analyze, and reduce the “risks and hazards associated with patient care.”<sup>116</sup> Entities eligible to become PSOs may be public or private, for-profit or not-for-profit, or even health care providers, such as hospital chains.<sup>117</sup> PSOs will be responsible for compiling and analyzing error information provided by health care providers.<sup>118</sup> With this information, PSOs will be able to make recommendations to providers on how to avoid errors in health care practice.<sup>119</sup> Further, on a national level, PSOs will provide their collected data to the Network of Patient Safety Databases (NPSD).<sup>120</sup> These networks, also created by the Patient Safety Act, will work to analyze error trends on both a national and regional level, re-

<sup>110</sup> Pub. L. No. 109-41, 119 Stat. 424 (2005) (codified at 42 U.S.C. §§ 299b-21 to -26 (2006)); *see also* Patient Safety Rule, 42 C.F.R. § 3 (2010) (implementing the Patient Safety Act).

<sup>111</sup> *See Welcome to AHRQ's Patient Safety Organization Web Site*, AGENCY FOR HEALTHCARE RES. & QUALITY, <http://www.pso.ahrq.gov> (last visited Mar. 15, 2011) (introducing the role played by Patient Safety Organizations (PSOs) within the Patient Safety Act and providing information about them).

<sup>112</sup> *See* Frederick Levy et al., *The Patient Safety and Quality Improvement Act of 2005: Preventing Error and Promoting Patient Safety*, 31 J. LEGAL MED. 397, 407 (2010) (describing the Patient Safety Act's purposes and goals).

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

<sup>116</sup> *Patient Safety Organization Information*, AGENCY FOR HEALTHCARE RES. & QUALITY, <http://www.pso.ahrq.gov/psos/overview.htm> (last visited Mar. 15, 2011).

<sup>117</sup> *Id.*

<sup>118</sup> Levy et al., *supra* note 112, at 408 (describing how the Patient Safety Act works).

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

<sup>120</sup> 42 U.S.C. § 299b-23(a) (2006).

commending strategies for the health care system as a whole.<sup>121</sup> This is not a regulatory strategy aimed directly at providers but rather an accumulation of public health data to be used later by policymakers.

### III. DISCLOSING PROVIDER PERFORMANCE

Reporting of hospitals' comparative outcomes could be valuable to patients as they try to choose the best place for their operations, although studies suggest consumer use of such reporting is minimal.<sup>122</sup> Certainly, private and government payers can evaluate provider quality more effectively as the data improve over time.<sup>123</sup> Comparative data need to be carefully extracted and presented; while it may not be easy to evaluate and compare institutions,<sup>124</sup> the technologies of data comparison can only improve under external pressure to disclose such data. The marketplace has been willing to offer such comparisons as specialty groups reach agreement about what are relevant data. In one dramatic example, *Consumer Reports* partnered with the Society of Thoracic Surgeons to rank over two hundred heart-bypass groups on a scale of one star (the worst) to three stars (the best) based on their performance against their peers.<sup>125</sup>

The first regulatory step toward this larger goal of comparing outcomes has been the disclosure of adverse events to injured patients.

<sup>121</sup> *Id.* § 299b-23(c); see also Levy et al., *supra* note 112, at 408.

<sup>122</sup> See, e.g., Martin N. Marshall et al., *The Public Release of Performance Data: What Do We Expect to Gain? A Review of the Evidence*, 283 JAMA 1866, 1867 (2000) (reviewing studies that analyzed the impact of publicly releasing health care performance data and finding that consumer use was minimal at best); Eric C. Schneider & Arnold M. Epstein, *Use of Public Performance Reports: A Survey of Patients Undergoing Cardiac Surgery*, 279 JAMA 1638 (1998) (assessing patient use of a publicly available report card listing hospital mortality rates for cardiac surgery and finding that patients rarely used such information when choosing between health care providers).

<sup>123</sup> See M.N. Marshall & P.S. Romano, *Impact of Reporting Hospital Performance*, 14 QUALITY & SAFETY HEALTH CARE 77, 77 (2005) (noting the lack of evidence that public disclosure improves the quality of care, even though provider organizations are sensitive to the publication of such data).

<sup>124</sup> See Ashish K. Jha et al., *Care in U.S. Hospitals—The Hospital Quality Alliance Program*, 353 NEW ENG. J. MED. 265, 271-72, 274 (2005) (noting the “hard work that lies ahead” in expanding and refining health care comparative data analyses).

<sup>125</sup> *Heart-Bypass Surgery: 50 Top-Rated Surgical Groups*, CONSUMER REP., Oct. 2010, at 40, 40. Only subscribers of ConsumerReportsHealth.org have access to the full rankings and the detailed statistical information used to rank the surgical groups, but the top fifty groups are listed in the October 2010 edition of *Consumer Reports*. *Id.* For more background and a critical assessment of the rankings, see Timothy G. Ferris & David F. Torchiana, *Public Release of Clinical Outcomes Data—Online CABG Report Cards*, 363 NEW ENG. J. MED. 1593 (2010).

A. *Disclosing Adverse Events to Patients: The Veterans  
Administration and Joint Commission Models*

Adverse-event reporting is often coupled with disclosure of classes of bad outcomes to patients and their families. This disclosure idea developed as the result of a program begun by a VA hospital, and has been adopted by the VA system. The VA disclosure model served as the foundation for Pennsylvania's legislation that created the Patient Safety Authority.<sup>126</sup> As of 2005, the VA requires disclosure of "adverse events to patients and their representatives, including adverse events that have had or are expected to have a clinical effect on the patient" or "necessitate a change in the patient's care."<sup>127</sup>

The Joint Commission, the accrediting body for most U.S. hospitals, has imposed a disclosure standard requiring that "[p]atients and, when appropriate, their families [be] informed about the outcomes of care, including unanticipated outcomes."<sup>128</sup> Pennsylvania created a Patient Safety Authority which mandates that hospitals report all "serious event[s]."<sup>129</sup> Fines may be levied for failures to report,<sup>130</sup> and the statute provides for whistleblower protections.<sup>131</sup> Pennsylvania also adopted a patient notification requirement.<sup>132</sup>

If administered well, the patient-notification requirements of the Joint Commission, the VA, and the Pennsylvania statute have the potential not only to reduce medical errors but also the frequency of

<sup>126</sup> Conversation with Stanton Smullens, Member, Pa. Patient Safety Auth., in Wilmington, DE (Mar. 10, 2004).

<sup>127</sup> VHA Directive 2005-049, Disclosure of Adverse Events to Patients (V.A. 2005), available at [http://www.sorrywork.net/pdf/VA\\_Link.pdf](http://www.sorrywork.net/pdf/VA_Link.pdf). The VA issued a revised directive in 2008. See VHA Directive 2008-002, Disclosure of Adverse Events to Patients (V.A. 2008), available at [http://www.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=1637](http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=1637).

<sup>128</sup> STANDARDS IN SUPPORT OF PATIENT SAFETY AND MEDICAL/HEALTH CARE ERROR REDUCTION RI.1.2.2 (The Joint Comm'n 2001); see also JOINT COMM'N RES., THE JOINT COMM'N, PATIENT SAFETY: ESSENTIALS FOR HEALTH CARE 88 (5th ed. 2009) ("[A] licensed independent practitioner or another caregiver responsible for a patient's care should explain all outcomes of care, including any unexpected outcomes of that care, to that patient/family. This standard specifically includes unanticipated outcomes that relate to sentinel events that are considered reviewable by the Joint Commission.").

<sup>129</sup> 40 PA. CONS. STAT. ANN. § 1303.308(a) (West Supp. 2010). For a discussion of the origins of the Authority, see Stanton N. Smullens et al., *Pennsylvania's Approach to Reducing Medical Error: The Story of the Patient Safety Authority*, 12 WIDENER L. REV. 39, 45-52 (2005).

<sup>130</sup> *Id.* § 1303.313(f).

<sup>131</sup> *Id.* § 1303.308(c).

<sup>132</sup> *Id.* § 1303.308(b).

malpractice litigation. We see again a developing regulatory duty, both state and federal, to force hospitals to gather data and share it with the public.

### B. PPACA and Disclosure

The public reporting of performance information is a central feature of the patient-safety provisions of PPACA. The Act establishes a wide range of demonstration projects and awards to fund research on outcomes and effectiveness.<sup>133</sup> Once those data become available, PPACA mandates their wide dissemination to other government agencies, providers, and the public generally.<sup>134</sup> Comparative information moves beyond disclosure of adverse events to patients or future patients to a much broader set of comparative factors to aid in selecting a health care provider. For example, the Physician Compare website will include not only patient outcomes and functional status, but also efficiency, patient and family experiences, effectiveness, and timeliness of care.<sup>135</sup>

PPACA creates several new entities to disseminate findings. The Center for Quality Improvement and Patient Safety is required by section 3501 to make its findings available to the public “through multiple media and appropriate formats to reflect the varying needs of health care providers and consumers and diverse levels of health literacy.”<sup>136</sup> Its research findings are to be shared with the Office of the National Coordinator of Health Information Technology and “used to inform the activities of the health information technology extension program under section 3012, as well as any relevant standards, certification criteria, or implementation specifications.”<sup>137</sup> Section 3015 mandates the collection of “data on quality and resource use measures” in order to “implement the public reporting of performance information”; grants can be given to fund this data collection.<sup>138</sup>

Section 3015 further provides for performance websites, which are to “make available to the public . . . performance information summarizing data on quality measures. Such information will be tailored to respond to the differing needs of hospitals and other institutional

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<sup>133</sup> See *supra* Section I.B.

<sup>134</sup> PPACA sec. 6301(b), § 937(a), 42 U.S.C.A. 299b-37(a) (West Supp. 1A 2010).

<sup>135</sup> *Id.* § 10331(a)(2), 42 U.S.C.A. § 1395w-5(a)(2) (West Supp. 1B 2010).

<sup>136</sup> *Id.* sec. 3501, § 933(d)(1), 42 U.S.C.A. § 299b-33(d)(1) (West Supp. 1A 2010).

<sup>137</sup> *Id.*, § 933(d)(2), 42 U.S.C.A. § 299b-33(d)(2).

<sup>138</sup> *Id.* sec. 3015, § 399II(a), 42 U.S.C.A. § 280j-1(a).

health care providers, physicians and other clinicians, patients, consumers, researchers, policymakers, States, and other stakeholders, as the Secretary may specify.”<sup>139</sup> This performance information “shall include information regarding clinical conditions to the extent such information is available, and the information shall, where appropriate, be provider-specific and sufficiently disaggregated and specific to meet the needs of patients with different clinical conditions.”<sup>140</sup>

The assumption behind such public posting of outcome and performance information on websites is that consumers will access the site and use it to make choices among providers.

### 1. Physician Compare

Comparison websites existed prior to PPACA, most notably Hospital Compare<sup>141</sup> and Nursing Home Compare.<sup>142</sup> PPACA institutes several new sites to complement these. Section 10331 provides that physician-performance information will be made available online to consumers through a Physician Compare Internet website.<sup>143</sup> Via this website, the public will be able to compare physicians along various performance indicia, including “measures collected under the Physician Quality Reporting Initiative”; “patient health outcomes and the functional status of patients”; “continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use”; “efficiency”; “patient experience and patient, caregiver, and family engagement”; and “safety, effectiveness, and timeliness of care.”<sup>144</sup>

Physicians will be able to review their results before they are publicly reported,<sup>145</sup> and the HHS Secretary must ensure the statistical validity and reliability of the data, including that “risk adjustment me-

<sup>139</sup> *Id.*, § 399JJ(a), 42 U.S.C.A. § 280j-2(a).

<sup>140</sup> *Id.*, § 399JJ(b), 42 U.S.C.A. § 280j-2(b).

<sup>141</sup> See *Hospital Compare*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, <http://www.hospitalcompare.hhs.gov> (last visited Mar. 15, 2011) (enabling users to compare hospitals along various criteria). For a fuller description, see *Hospital Compare*, CENTERS FOR MEDICARE & MEDICAID SERVICES, [http://www.cms.gov/HospitalQualityInits/11\\_HospitalCompare.asp](http://www.cms.gov/HospitalQualityInits/11_HospitalCompare.asp) (last visited Mar. 15, 2011).

<sup>142</sup> See *Nursing Home Compare*, MEDICARE.GOV, <http://www.medicare.gov/NHCompare> (last visited Mar. 15, 2001) (providing “detailed information about every Medicare and Medicaid-certified nursing home” in the United States).

<sup>143</sup> PPACA § 10331(a), 42 U.S.C.A. § 1395w-5(a) (West Supp. 1B 2010).

<sup>144</sup> *Id.* § 10331(a)(2)(A)–(G), 42 U.S.C.A. § 1395w-5(a)(2)(A)–(G).

<sup>145</sup> *Id.* § 10331(b)(2), 42 U.S.C.A. § 1395w-5(b)(2).

chanisms” be used;<sup>146</sup> that it “provide a robust and accurate portrayal of a physician’s performance”; that there be “appropriate attribution of care when multiple physicians and other providers are involved”; that “timely statistical performance feedback” be provided; and that the Centers for Medicare & Medicaid Services have computer and data systems capable of “supporting valid, reliable, and accurate public reporting activities.”<sup>147</sup>

## 2. Infection Compare

PPACA also mandates the reporting of outcome measures for hospital-acquired infections. Section 10303(b) mandates that “the Secretary . . . publicly report on measures for hospital-acquired conditions that are currently utilized by [CMS] for the adjustment of the amount of payment to hospitals based on rates of hospital-acquired infections.”<sup>148</sup> Since hospital infections are a major source of patient injury and death, the outcome reports for the purposes of payment are also likely to set a baseline beyond which infections may be considered unacceptable for liability purposes. Infection-control report cards are an example of how infection compare can be used.<sup>149</sup>

Consumer-oriented performance websites raise interesting issues about likely effects on consumer choices of providers. Studies of consumer behavior have found, for example, that consumers have rarely used the comparative assessments that were available, and that quality may even be reduced.<sup>150</sup> On the other hand, providing patients with quality information about what to expect from providers might encourage those providers to vouch for their work. Publication of performance information can also stimulate quality improvement.<sup>151</sup> As

<sup>146</sup> *Id.* § 10331(b)(1), 42 U.S.C.A. § 1395w-5(b)(1).

<sup>147</sup> *Id.* § 10331(b)(3)–(7), 42 U.S.C.A. § 1395w-5(b)(3)–(7).

<sup>148</sup> *Id.* sec. 10303(b), § 1890A(f), 42 U.S.C.A. § 1395aaa-1(f).

<sup>149</sup> See Robert A. Weinstein et al., *Infection-Control Report Cards—Securing Patient Safety*, 353 NEW ENG. J. MED. 225, 227 (2005) (arguing for the use of report cards that would allow patients to compare infection rates among hospitals).

<sup>150</sup> See, e.g., Rachel M. Werner & David A. Asch, *The Unintended Consequences of Publicly Reporting Quality Information*, 293 JAMA 1239, 1240 (2005) (noting that consumers often do not utilize quality information when making health care decisions); see also Mark A. Hall & Carl E. Schneider, *Patients as Consumers: Courts, Contracts, and the New Medical Marketplace*, 106 MICH. L. REV. 643, 688-89 (2008) (discussing consumers’ problems in the medical market, including selecting doctors).

<sup>151</sup> See, e.g., Judith H. Hibbard et al., *Does Publicizing Hospital Performance Stimulate Quality Improvement Efforts?*, HEALTH AFF., Mar.–Apr. 2003, at 84, 92-94 (discussing a study indicating that public disclosure of performance encourages quality improvement); Dana

regulators increase the pressure for disclosure of such data, and data improve, hospital performance is likely to improve. I would even argue that both physicians and hospitals should have a duty to inform patients of “hospital outcome disparities”—as a logical extension of the informed consent doctrine.<sup>152</sup>

#### IV. REFORMING PAYMENT SYSTEMS

Insurance generally covers treatment costs induced by errors and adverse events; if insurance does not cover them, these costs must be absorbed by patients, families, employers, and state and private disability and income-support programs. As a result, “[A]dverse outcomes are externalized to other payers and not internalized by providers best able to reduce these hazards or prevent them.”<sup>153</sup> Lucian Leape and Donald Berwick point out that “[i]n most industries, defects cost money and generate warranty claims. In health care, perversely, under most forms of payment, health care professionals receive a premium for a defective product; physicians and hospitals can bill for the additional services that are needed when patients are injured by their mistakes.”<sup>154</sup> Given this cost-shifting feature of health insurance, tort suits have been the primary, if not only, mechanism for making hospitals and providers internalize these excess costs.<sup>155</sup>

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B. Mukamel et al., *Quality Report Cards, Selection of Cardiac Surgeons, and Racial Disparities: A Study of the Publication of the New York State Cardiac Surgery Reports*, 41 INQUIRY 435, 443-44 (2004) (“[P]ublished quality rankings have both a direct effect and indirect effect, substituting at least partially for implicit signals for quality.”). *But see* Zoltan G. Turi, *The Big Chill: The Deleterious Effects of Public Reporting on Access to Health Care for the Sickest Patients*, 45 J. AM. C. CARDIOLOGY 1766, 1766-67 (2005) (raising skepticism about the claimed benefit of publicly reporting physician performance data and arguing that such reporting might even diminish health outcomes for the highest-risk patients).

<sup>152</sup> For a debate on this issue, see Nadine Housri et al., *Should Informed Consent for Cancer Treatment Include a Discussion About Hospital Outcome Disparities?*, 5 PUB. LIBR. SCI. MED. 1413 (2008), available at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0050214>. In this debate, Robert Weil acknowledges the difficulty of gathering reliable data but argues for a “principle of transparency,” which demands that the data be disclosed to patients. *Id.* at 1415-16.

<sup>153</sup> Furrow, *Patient Safety and the Fiduciary Hospital*, *supra* note 18, at 482.

<sup>154</sup> Lucian L. Leape & Donald M. Berwick, *Five Years After To Err Is Human: What Have We Learned?*, 293 JAMA 2384, 2388 (2005) (citation omitted).

<sup>155</sup> *See* E. HAIVI MORREIM, HOLDING HEALTH CARE ACCOUNTABLE: LAW AND THE NEW MEDICAL MARKETPLACE 3-12 (2001) (describing the relationship between tort suits and behavior change and explaining what needs to be altered to make health care providers more accountable).

This reliance on tort suits is changing. CMS has several outcome-based payment programs in place,<sup>156</sup> and PPACA supports this trend to dock providers who fall below quality standards and to award bonuses to those who exceed them. Such pay-for-performance concepts are already well underway in Medicare reimbursement, and it is not the most revolutionary feature of PPACA, as Part V will demonstrate.

#### A. “Never Events”

The original concept of “never events”<sup>157</sup> was to mandate that hospitals notify state officials of such events so that these bad outcomes could be tracked statewide. Indirectly, they serve as a source of modest regulatory pressure on hospitals to reduce the frequency of such events and avoid the public embarrassment that revelation of their performance might create. CMS has since adopted a nonpayment strategy that is based on the “never events” approach, recognizing the added costs to the Medicare program in treating the consequences of such events.<sup>158</sup> This CMS position on “never events” and payment represents a significant step toward pay for performance.

#### B. Hospital-Acquired Infections

Medicare began to adjust payments in 2008 for hospital-acquired infections.<sup>159</sup> If the diagnosis is not present on admission to the hospital, then payment for several hospital-acquired infections will be disallowed.<sup>160</sup> This payment initiative continually enlarges the list of disallowed conditions and represents real pressure on hospitals to reduce their level of infections to avoid reimbursement losses.

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<sup>156</sup> See, e.g., CTRS. FOR MEDICARE & MEDICAID SERVS., DEVELOPMENT OF A PLAN TO TRANSITION TO A MEDICARE VALUE-BASED PURCHASING PROGRAM FOR PHYSICIAN AND OTHER PROFESSIONAL SERVICES 9-24 (Dec. 9, 2008), available at <http://www.cms.gov/PhysicianFeeSched/downloads/PhysicianVBP-Plan-Issues-Paper.pdf> (discussing performance-based program designs for Medicare).

<sup>157</sup> For a definition of “never events,” see text accompanying *supra* note 104.

<sup>158</sup> *Fiscal Year 2009 Quality Measure Reporting for 2010 Payment Update*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <http://www.cms.gov/HospitalQualityInits/downloads/HospitalRHQDAPU200808.pdf> (last visited Mar. 15, 2011).

<sup>159</sup> *Id.*

<sup>160</sup> *Centers for Medicare & Medicaid—CMS, PREMIER*, <http://www.premierinc.com/quality-safety/tools-services/safety/topics/guidelines/cms-guidelines-4-infection.jsp> (last visited Mar. 15, 2011).

### C. Premier Hospital Quality Initiative

As early as 2002, CMS had launched a national Premier Quality Initiative in which hospitals are ranked in deciles by performance.<sup>161</sup> Those hospitals ranked within the top ten and twenty percent will receive a two-percent and a one-percent bonus payment, respectively.<sup>162</sup> If hospital performance falls below the payment adjustment threshold by year three, the hospital will receive reduced Medicare reimbursement—losing as much as one or two percent of its previous Medicare payment.<sup>163</sup> This is a small but effective pay-for-performance initiative that PPACA continues more aggressively.

### D. Reporting Hospital Quality Data for Annual Payment Update Program

CMS gives hospitals that successfully report designated quality measures a higher annual increase in their payment rates, while hospitals that do not participate or meet reporting requirements will have a two-percent reduction in their Medicare annual payment update. This information is available to consumers on the Hospital Compare website, continuing the movement to disclose performance to consumers while also linking reimbursement to performance.<sup>164</sup>

### E. Physician Quality Reporting System (PQRS)

The PQRS<sup>165</sup> is a voluntary reporting program that offers extra incentive payments to medical practices whose providers report data on

<sup>161</sup> See *Rewarding Superior Quality Care: The Premier Hospital Quality Incentive Demonstration Fact Sheet*, ALLIANCE FOR HEALTH REFORM (2006), <http://www.allhealth.org/BriefingMaterials/HospitalPremierFS200602-175.pdf> (explaining how hospitals will be scored and ranked based on quality measures); see also *Premier Hospital Quality Incentive Demonstration*, CENTERS FOR MEDICARE & MEDICAID SERVICES, [https://www.cms.gov/HospitalQualityInits/35\\_HospitalPremier.asp](https://www.cms.gov/HospitalQualityInits/35_HospitalPremier.asp) (last visited Mar. 15, 2011) (describing the initiative and linking to results of the project).

<sup>162</sup> *Rewarding Superior Quality Care*, *supra* note 161.

<sup>163</sup> *Id.*

<sup>164</sup> Press Release, Ctrs. for Medicare & Medicaid Servs., CMS Updates the National Hospital Quality Measure Acute Myocardial Infarction Set for Discharges as of April 1, 2009 (Dec. 31, 2008), *available at* [www.cms.gov/HospitalQualityInits/Downloads/HospitalAMI-6FactSheet.pdf](http://www.cms.gov/HospitalQualityInits/Downloads/HospitalAMI-6FactSheet.pdf).

<sup>165</sup> The Medicare Improvements and Extension Act of 2006, sec. 101(b), § 1848, 120 Stat. 2975, 2975-77, established PQRS. The PQRS was originally called the PQRI (Physician Quality Reporting Initiative). Press Release, Ctrs. for Medicare & Medicaid Servs., Physician Quality Reporting System and E-Prescribing Program (Nov. 3, 2010), *available at* <http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3858>.

quality measures for covered Physician Fee Schedule services under Medicare Part B.<sup>166</sup> For 2011, an incentive payment of one percent of total Medicare Part B allowed charges for a provider is possible.<sup>167</sup> CMS has expanded PQRS for 2011 and beyond, adding twenty new measures, including several involving reporting through electronic health records.<sup>168</sup> In addition to offering bonuses, the system will dock providers who do not satisfactorily report data on quality measures by one-and-a-half percent starting in 2015 and two percent in 2016 and after.<sup>169</sup> Providers who write prescriptions electronically starting in 2011 can earn an incentive payment of one percent of their total allowed Medicare Part B services during the reporting period.<sup>170</sup> Also, as of 2012, providers who are not “successful” e-prescribers will suffer a “program adjustment[]”; in other words, their reimbursement will be docked.<sup>171</sup>

#### F. General Quality Indicators

CMS has issued a proposed rule<sup>172</sup> that “would establish a new hospital value-based purchasing program to reward hospitals for providing high quality, safe care for patients.”<sup>173</sup> Hospitals that performed well under the program in both quality of care delivered to patients and patient experience of care would receive higher payments.<sup>174</sup>

#### G. Insurance Exchange Mandates

Quality-reimbursement incentives pervade PPACA. The Act focuses primarily on Medicare payment incentives, given the magnitude of such payments in the U.S. health care system. But PPACA’s central focus is reform of the private insurance market. Health Benefit Exchanges are a central feature of this insurance market reform. Such

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<sup>166</sup> Press Release, Ctrs. For Medicare & Medicaid Servs., *supra* note 165.

<sup>167</sup> *Id.*

<sup>168</sup> *Id.*

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

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

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

<sup>172</sup> Hospital Inpatient Value-Based Purchasing Program, 76 Fed. Reg. 2454 (proposed Jan. 13, 2011) (to be codified at 42 C.F.R. pts. 422 and 480).

<sup>173</sup> Press Release, Ctrs. for Medicare & Medicaid Servs., Affordable Care Act to Improve Hospital Care for Patients (Jan. 7, 2011), *available at* <http://www.cms.gov/apps/media/press/release.asp?Counter=3893>.

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

exchanges will promote transparency for consumers; they will also use reimbursement incentives to evaluate private insurers who seek to sell insurance through the exchanges, and to force them to evaluate hospitals by the same benchmarks.

Part II, Subtitle D of PPACA, “Consumer Choices and Insurance Competition Through Health Benefit Exchanges,” has an important quality component. Section 1311 spells out the form of the American Health Benefit Exchanges.<sup>175</sup> Subsection (c) specifies criteria for the certification of health plans, including marketing and provider choice provisions.<sup>176</sup> Subsection (c)(1)(D) addresses quality issues, requiring that accreditation of plans be based in part on

local performance on clinical quality measures such as the Healthcare Effectiveness Data and Information Set, patient experience ratings on a standardized Consumer Assessment of Healthcare Providers and Systems survey, as well as consumer access, utilization management, quality assurance, provider credentialing, complaints and appeals, network adequacy and access, and patient information programs . . . .<sup>177</sup>

Subsection (c)(1)(E) requires the plans to “implement a quality improvement strategy,”<sup>178</sup> and subsection (c)(1)(H) requires disclosure of quality measures to enrollees and prospective enrollees.<sup>179</sup>

PPACA’s section 1001 amends portions of the Public Health Service Act, including section 2717, “Ensuring the Quality of Care,” which requires that the HHS Secretary “develop reporting requirements for use by a group health plan, and a health insurance issuer offering group or individual health insurance coverage, with respect to plan or coverage benefits and health care provider reimbursement structures . . . .”<sup>180</sup> These reporting requirements require the insurer to:

(A) improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives, . . . for treatment or services under the plan or coverage;

(B) implement activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning,

<sup>175</sup> PPACA § 1311, 42 U.S.C.A. § 18031 (West Supp. 1B 2010).

<sup>176</sup> *Id.* § 1311(c), 42 U.S.C.A. § 18031(c).

<sup>177</sup> *Id.* § 1311(c)(1)(D), 42 U.S.C.A. § 18031(c)(1)(D).

<sup>178</sup> *Id.* § 1311(c)(1)(E), 42 U.S.C.A. § 18031(c)(1)(E).

<sup>179</sup> *Id.* § 1311(c)(1)(H), 42 U.S.C.A. § 18031(c)(1)(H).

<sup>180</sup> *Id.* sec. 1001, § 2717(a)(1), 42 U.S.C.A. § 300gg-17(a)(1) (West Supp. 1A 2010).

and post discharge reinforcement by an appropriate health care professional;

(C) implement activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage; and

(D) implement wellness and health promotion activities.<sup>181</sup>

Finally, subsection 1311(g) of PPACA, “Rewarding Quality Through Market-Based Incentives,” mandates a payment structure that is quality and health outcome based, providing increased reimbursement or other incentives for improvements in health outcomes through quality reporting and a range of other coordination initiatives found elsewhere in PPACA.<sup>182</sup> Its most relevant patient safety language can be found in subsection (1)(C), which mandates quality payments for “the implementation of activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage.”<sup>183</sup>

The second significant patient-safety component of the health exchanges is the relationship of qualified health plans to hospitals. Subsection 1311(h), “Quality Improvement,” specifies that a qualified health plan may contract with a hospital with more than fifty beds only if the hospital “utilizes a patient safety evaluation system” and has a mechanism in place “to ensure that each patient receives a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional.”<sup>184</sup> This provision links the health plans and hospitals through compliance with patient-safety systems of various kinds and uses both plan certification and reimbursement to drive patient-safety mechanisms in providers selected by health plans.

The cumulative effect of this intensifying patient safety regulation is to create powerful incentives for providers to achieve patient safety targets. The mandates imposed on insurers who want to sell insurance in the health exchanges moves them into a quasi-regulatory role, defined by federal rules, rather than by a range of largely unsuccessful

<sup>181</sup> *Id.* sec. 1001, § 2717(a)(1)(A)–(D), 42 U.S.C.A. § 300gg-17(a)(1)(A)–(D).

<sup>182</sup> *Id.* § 1311(g), 42 U.S.C.A. § 18031(g) (West Supp. 1B 2010).

<sup>183</sup> *Id.* § 1311(g)(1)(C), 42 U.S.C.A. § 18031(g)(1)(C).

<sup>184</sup> *Id.* § 1311(h)(1)(A), 42 U.S.C.A. § 18031(h)(1)(A).

cost control devices that proliferated during the heyday of health maintenance organizations.<sup>185</sup>

## V. COORDINATING AND INTEGRATING CARE

PPACA is perhaps most creative in its funding of innovations in delivery system models. The Act offers a range of models, coupled with financial incentives, to move health care delivery away from the fragmenting forces of fee-for-service medicine.<sup>186</sup> As David Hyman notes, “Compared to other industries that deal with comparably complex products, health care delivery is extremely fragmented.”<sup>187</sup> Hyman further observes, “Fragmentation manifests itself across every practice setting, in every state, for all types of patients—and where it occurs, it contributes to higher costs and lower quality.”<sup>188</sup> We pay providers for what they do, not what they accomplish in terms of good outcomes and patient improvement. PPACA offers provisions that promote both coordination of care and integration of care.<sup>189</sup> It moves Medicare from its traditional model of fee-for-service payment toward a model of incentivized and coordinated care. The Act offers funding for a range of demonstration projects and pilots on the theory that grassroots experimentation is needed to see which delivery model works best in different settings.<sup>190</sup> Several provisions illustrate the strategy underpinning PPACA’s quality provisions.

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<sup>185</sup> For a discussion of the full range of tools used by managed care plans in the 1980s and into the 1990s, see generally Barry R. Furrow, *Managed Care Organizations and Patient Injury: Rethinking Liability*, 31 GA. L. REV. 419 (1997).

<sup>186</sup> See generally THE FRAGMENTATION OF U.S. HEALTH CARE: CAUSES AND SOLUTIONS (Einer R. Elhauge ed., 2010) (collecting essays on health care fragmentation, a situation where multiple decisionmakers make health care decisions which would be better handled by unified decisionmaking).

<sup>187</sup> David A. Hyman, *Health Care Fragmentation: We Get What We Pay For*, in *id.* at 21, 21.

<sup>188</sup> *Id.* at 22.

<sup>189</sup> See generally Alain Enthoven, *Curing Fragmentation with Integrated Delivery Systems: What They Do, What Has Blocked Them, Why We Need Them, and How to Get There from Here* (defining and describing integration as the opposite of fragmentation and proposing ways to achieve greater integration), in THE FRAGMENTATION OF U.S. HEALTH CARE: CAUSES AND SOLUTIONS, *supra* note 186, at 61, 63-68, 77-85.

<sup>190</sup> See, e.g., Atul Gawande, *Testing, Testing*, NEW YORKER, Dec. 14, 2009, at 34, 35-36. Gawande uses the United States Department of Agriculture farm demonstration projects as an example of a productive government role in a highly fragmented industry and explains that “[t]he government never took over agriculture, but the government didn’t leave it alone, either. It shaped a feedback loop of experiment and learning and encouragement for farmers across the country.” *Id.* PPACA, as Gawande notes, adopts much the same strategy of testing virtually every idea in health services research and evaluating the results constantly. *Id.* at 38, 40. He writes, “Government

### A. Center for Medicare and Medicaid Innovation

Centers can fund research, disseminate findings, and create a powerful force for the diffusion of effective models. Section 3021 of PPACA establishes a new Center for Medicare and Medicaid Innovation (CMI) within CMS.<sup>191</sup> The CMI will test innovative payment and delivery service models within the Medicare and Medicaid programs that are to reduce program expenditures while simultaneously maintaining or improving quality of care for beneficiaries.<sup>192</sup> The HHS Secretary is charged with selecting models that not only reduce costs and enhance the quality of care, but also improve “the coordination, quality, and efficiency of health care services.”<sup>193</sup> The models will be selected by the HHS Secretary based on demonstrated evidence that “the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.”<sup>194</sup> PPACA lists a variety of potential models to be tested<sup>195</sup> that will vary in focus from improving the management and coordination of care for chronic care patients,<sup>196</sup> to implementing widespread use of evidence-based medicine,<sup>197</sup> to moving physician payments away from the fee-for-service paradigm.<sup>198</sup>

After the CMI has tested and evaluated the various models described in PPACA, the HHS Secretary will have the ability to extend successful models, including implementation on a nationwide basis, if they have demonstrated the ability to reduce spending while improving, or at least not reducing, the quality of care.<sup>199</sup>

The purpose of the CMI will be to research, develop, test, and expand innovative payment and delivery arrangements both to improve the quality and to reduce the cost of care provided to patients in each

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has a crucial role to play here—not running the system but guiding it, by looking for the best strategies and practices and finding ways to get them adopted, county by county.” *Id.* at 38.

<sup>191</sup> PPACA sec. 3021(a), § 1115A(a)(1), 42 U.S.C.A. § 1315a(a)(1) (West Supp. 1A 2010).

<sup>192</sup> *Id.*

<sup>193</sup> *Id.*

<sup>194</sup> *Id.*, § 1115A(b)(2)(A), 42 U.S.C.A. § 1315a(b)(2)(A).

<sup>195</sup> *Id.*, § 1115A(b)(2)(B)(i)–(xviii), 42 U.S.C.A. § 1315a(b)(2)(B)(i)–(xviii).

<sup>196</sup> *Id.*, § 1115A(b)(2)(B)(iii), (v), (viii), (xiv), 42 U.S.C.A. § 1315a(b)(2)(B)(iii), (v), (viii), (xiv).

<sup>197</sup> *Id.*, § 1115A(b)(2)(B)(iii), (xii), 42 U.S.C.A. § 1315a(b)(2)(B)(iii), (xii).

<sup>198</sup> *Id.*, § 1115A(b)(2)(B)(i), (vi), 42 U.S.C.A. § 1315a(b)(2)(B)(i)(vi).

<sup>199</sup> *Id.*, § 1115A(c)(1)(A)–(B), 42 U.S.C.A. § 1315a(c)(1)(A)–(B).

program.<sup>200</sup> Dedicated funding is provided to allow for testing of models that require benefits not currently covered by Medicare.<sup>201</sup> Because centers such as the CMI can channel millions of dollars toward research and expansion of payment and delivery reforms, their output is likely to be influential on the future of medical practice.

### B. Health Care Innovation Zones

Subsection 3021(a) aims to create such zones, comprised of “groups of providers that include a teaching hospital, physicians, and other clinical entities[] that . . . [can] deliver a full spectrum of integrated and comprehensive health care services to applicable individuals.”<sup>202</sup>

### C. Accountable Care Organizations

Accountable Care Organizations (ACOs) have been one of the most discussed features of PPACA. Section 3022, the “Medicare Shared Savings Program,” creates a program that “promotes accountability for a patient population and coordinates items and services under parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.”<sup>203</sup> As defined by PPACA, ACOs are “groups of providers of services and suppliers who work together to manage and coordinate care for Medicare fee-for-service beneficiaries.”<sup>204</sup> ACOs typically will be a

<sup>200</sup> *Id.*, § 1115A(a)(1), 42 U.S.C.A. § 1315a(a)(1).

<sup>201</sup> *Id.*, § 1115A(f), 42 U.S.C.A. § 1315a(f).

<sup>202</sup> *Id.*, § 1115A(b)(2)(B)(xviii), 42 U.S.C.A. § 1315a(b)(2)(B)(xviii).

<sup>203</sup> *Id.*, sec. 3022, § 1899(a)(1), 42 U.S.C. § 1395jjj(a)(1) (West Supp. 1B 2010).

<sup>204</sup> *Id.*, § 1899(a)(1)(A), 42 U.S.C.A. § 1395jjj(a)(1)(A). See generally Elliott S. Fisher et al., *Creating Accountable Care Organizations: The Extended Hospital Medical Staff*, 26 HEALTH AFF. w44, w51-w53 (2007), <http://content.healthaffairs.org/content/26/1/w44.full.pdf+html> (arguing for the use of ACOs at the level of “extended hospital medical staff” as a way to better coordinate patient care); Stephen M. Shortell & Lawrence P. Casalino, *Health Care Reform Requires Accountable Care Systems*, 300 JAMA 95, 97 (2008) (discussing the potential for ACOs to be designed to create value by improving patient outcomes while simultaneously reducing costs). Much of the formative work of ACOs can be traced to the Dartmouth Institute for Health Policy and Clinical Practice headed by Dr. Elliott Fisher and Dr. James Weinstein. See Elliott S. Fisher et al., *Fostering Accountable Health Care: Moving Forward in Medicare*, 28 HEALTH AFF. w219, w220, w227 (2009), <http://content.healthaffairs.org/content/28/2/w219.full.pdf+html> (proposing Medicare-payment reform through ACOs wherein coordination of patient care would be prioritized and financially rewarded); see also *The Brookings-Dartmouth Accountable Care Organization Learning Network*, ACCOUNTABLE CARE ORG. LEARNING NETWORK, <https://xteam.brookings.edu/bdacoln/Documents/Network%20Overview.pdf> (last visited Mar. 15, 2011) (providing resources on ACOs). The Medi-

collection of primary care physicians, specialists, and potentially other health professionals (and may include hospitals) who accept joint responsibility for the quality and cost of care provided to their patients.<sup>205</sup> If the ACO meets certain targets, its members receive a financial bonus.<sup>206</sup> At the heart of the ACO concept is the expectation that when groups of providers are collectively accountable for meeting cost and quality targets, internal peer review and peer pressure will drive the identification and implementation of best practices systematically, which in turn could lead to better cost controls and outcomes.<sup>207</sup> Models include more than five different types of practice arrangements, such as integrated or organized delivery systems, multispecialty group practices, physician-hospital organizations, independent-practice associations, and “virtual” physician organizations.<sup>208</sup>

ACOs will most likely operate as mini-health plans, building the infrastructure to manage utilization and ensure quality-care delivery. To establish targets, cost trends, and provider-payment and incentive-distribution models, ACOs will require sophisticated financial and actuarial analyses. To control demand and improve the quality of care delivery, ACOs will need to have the tools, processes, and reporting for chronic-disease management, complex-case management, and wellness-prevention services. To control medically unnecessary services, ACOs will need to have the tools, processes, and reporting for preauthorization, hospital utilization review, high-tech radiology management, specialty referral management, and pharmacy management.

ACOs present a positive coordination model, but their success is hardly guaranteed. They look like a new and improved version of the best managed care organizations of old, based on the capitation mod-

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care Payment Advisory Commission (MedPAC) has also provided extensive analysis of the ACO concept. See MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO CONGRESS: IMPROVING INCENTIVES IN THE MEDICARE PROGRAM 39-56 (2009), available at [http://www.medpac.gov/documents/Jun09\\_EntireReport.pdf](http://www.medpac.gov/documents/Jun09_EntireReport.pdf) (developing an ACO model as a recommendation for reforming Medicare’s health care delivery system).

<sup>205</sup> See Timothy L. Greaney, *Accountable Care Organizations—The Fork in the Road*, 364 NEW ENG. J. MED. e1(1), e1(1)-(2) (2011), <http://www.nejm.org/doi/pdf/10.1056/NEJMp1013404> (discussing the benefits and concerns surrounding the implementation of ACO reform measures).

<sup>206</sup> See Mark McClellan et al., *A National Strategy to Put Accountable Care into Practice*, 29 HEALTH AFF. 982, 983 (2010) (discussing different ACO payment models).

<sup>207</sup> See Stephen M. Shortell et al., *How the Center for Medicare and Medicaid Innovation Should Test Accountable Care Organizations*, 29 HEALTH AFF. 1293, 1294 (2010) (arguing that ACOs could result in more cost-effective health care in large part because of the increased coordination among clinician teams that ACOs would induce).

<sup>208</sup> *Id.*

el. Risk-bearing, provider-sponsored organizations in the managed care era were poorly equipped to manage care or risk, and employers and consumers demonstrated a strong preference for unimpeded (i.e., “free”) choice of providers. The shared-savings model also provides only weak incentives to bring together hospitals and physicians that have a strong interest in preserving the status quo.<sup>209</sup>

#### D. *Performance-Based Care Coordination*

Section 3021 of PPACA provides a number of possible coordination reforms. These innovative payment and delivery arrangements include the promotion of various models of integration that reduce or eliminate fee-for-service payment systems; for example, patient-centered medical home models and other models “transition primary care practices away from fee-for-service based reimbursement and toward comprehensive payment or salary-based payment.”<sup>210</sup> Other models include direct contracting with groups of providers to promote new delivery models “through risk-based comprehensive payment or salary-based payment”<sup>211</sup> and coordinated-care models that “transition health care providers away from fee-for-service based reimbursement and toward salary-based payment.”<sup>212</sup> A particularly intriguing model explicitly allows for testing of “all-payer payment reform for the medical care of residents of the States.”<sup>213</sup> Physicians will earn a bonus for curtailing growth in the cost of health services by better managing treatment across care settings and by pursuing quality benchmark targets.<sup>214</sup> A care-coordination model may be structured differently from an ACO and may also use different methods to calculate shared savings.

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<sup>209</sup> See Jeff Goldsmith, *The Accountable Care Organization: Not Ready For Prime Time*, HEALTH AFF. BLOG (Aug. 17, 2009), <http://healthaffairs.org/blog/2009/08/17/the-accountable-care-organization-not-ready-for-prime-time> (arguing that ACOs would create huge problems similar to those in the wake of the Clinton-era health care mergers and consolidations).

<sup>210</sup> PPACA sec. 3021(a), § 1115A(b)(2)(B)(i), 42 U.S.C.A. § 1315a(b)(2)(B)(i) (West Supp. 1A 2010).

<sup>211</sup> *Id.*, § 1115A(b)(2)(B)(ii), 42 U.S.C.A. § 1315a(b)(2)(B)(ii).

<sup>212</sup> *Id.*, § 1115A(b)(2)(B)(iv), 42 U.S.C.A. § 1315a(b)(2)(B)(iv).

<sup>213</sup> *Id.*, § 1115A(b)(2)(B)(xi), 42 U.S.C.A. § 1315a(b)(2)(B)(xi).

<sup>214</sup> *Id.* sec. 3022, § 1899, 42 U.S.C.A. § 1395jjj (West Supp. 1B 2010).

### E. Payment Bundling

Section 2023, “Payment Bundling,” constitutes another essential piece of PPACA’s incentive program.<sup>215</sup> Under such a program, similar services are grouped together and are compensated using a single or global payment. Services can be grouped according to the care provided by a single doctor or multiple doctors. Section 3023 mandates a pilot program on payment bundling that integrates hospital care for a Medicare beneficiary based on episodes of care “in order to improve the coordination, quality, and efficiency of health care services.”<sup>216</sup> An episode of care is a period of time that includes three days prior to admission to a hospital for a condition, the length of stay in the hospital, and thirty days after discharge.<sup>217</sup> The nature of the conditions that can be bundled will be determined by the HHS Secretary.<sup>218</sup>

Bundled payments must include “payment for the furnishing of applicable services and other appropriate services, such as care coordination, medication reconciliation, discharge planning, transitional care services, and other patient-centered activities as determined appropriate by the Secretary”<sup>219</sup> and will cover comprehensively the costs of those services. Payments will be made to entities who participate in the pilot program when they provide these services to individuals during an episode of care.<sup>220</sup>

This bundling concept is similar to the Diagnostic-Related Group (DRG) payment model Medicare uses for hospital payments.<sup>221</sup> It is

<sup>215</sup> *Id.* sec. 3023, § 1866D, 42 U.S.C.A. § 1395cc-4.

<sup>216</sup> *Id.*, § 1866D(a) (1), 42 U.S.C.A. § 1395cc-4(a) (1).

<sup>217</sup> *Id.*, § 1866D(a) (2) (D) (i) (I)–(III), 42 U.S.C.A. § 1395cc-4(a) (2) (D) (i) (I)–(III).

<sup>218</sup> *Id.*, § 1866D(a) (2) (B), 42 U.S.C.A. § 1395cc-4(a) (2) (B). The factors the Secretary must consider when selecting these conditions include (1) “[w]hether the conditions selected include a mix of chronic and acute conditions”; (2) “[w]hether the conditions selected include a mix of surgical and medical conditions”; (3) whether the conditions provide “an opportunity for providers . . . and suppliers to improve the quality of care furnished[,] while reducing total expenditures”; (4) whether the conditions have sufficient variation in the number of readmissions and amount of post-acute care spending; and (5) which conditions are most amenable to bundling. *Id.*, § 1866D(a) (2) (B) (i)–(vi), 42 U.S.C.A. § 1395cc-4(a) (2) (B) (i)–(vi).

<sup>219</sup> *Id.*, § 1866D(c) (3) (B), 42 U.S.C.A. § 1395cc-4(c) (3) (B).

<sup>220</sup> *Id.*, § 1866D(c) (3) (C) (i) (I)–(II), 42 U.S.C.A. § 1395cc-4(c) (3) (C) (i) (I)–(II).

<sup>221</sup> Congress mandated the DRG prospective payment system in 1982 to control Medicare costs. This system changes payment from a highly inflationary fee-for-service approach to an individual reimbursement mechanism, which divides inpatient admission cases into categories called diagnostic-related groups (DRGs). DRG Classification and Weighting Factors, 42 C.F.R. § 412.60 (2010). Medicare then pays hospitals a flat per-case charge based on the particular DRG. The goal is to reward efficient hospitals

more expansive, however, in including all services provided to a patient during the episode of care. As with other coordination initiatives in PPACA, bundling payments for specific procedures is supposed to encourage providers to work together, reduce duplication of services and procedures, and incentivize hospitals, physicians, and other providers to improve the quality and efficiency of care.

#### F. Patient-Centered Medical Homes (PCMHs)

The medical home concept centers on primary care physicians and the comprehensive improvement of primary care delivery. PPACA carries forward this idea where physicians receive additional monthly payments for effectively using health information technology and other innovations to monitor, coordinate, and manage care.<sup>222</sup> The “medical home” is generally understood to combine services of health care providers with care delivery in a form that is accessible and coordinated in a community context. Medical homes thus help the patient (and physician) navigate the confusing and fragmented delivery system.<sup>223</sup> The medical home concept has a long history, going back to experiments in coordinating care in the 1970s and pediatric medical home demonstrations in more recent years.<sup>224</sup> Its lineage also includes the experience of primary care case management approaches undertaken by many managed care organizations in the 1990s.<sup>225</sup> Although proponents claim that the PCMH can be a vital tool in establishing a true “system” for health delivery while using an individualized, patient-focused approach to care, doubts persist about how they may evolve. Robert Berenson and his coauthors question small primary care practices’ capacity to undertake responsibility for comprehensive care

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and create incentives for inefficient hospitals to improve. See generally Office of Inspector Gen., OEI-09-00-00200, MEDICARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM: HOW DRG RATES ARE CALCULATED AND UPDATED (2001), available at <http://oig.hhs.gov/oei/reports/oei-09-00-00200.pdf>.

<sup>222</sup> See *Health Policy Brief: Patient-Centered Medical Homes*, HEALTH AFF., 1 (Sept. 14, 2010), [http://www.healthaffairs.org/healthpolicybriefs/brief\\_pdfs/healthpolicybrief\\_25.pdf](http://www.healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_25.pdf) (“Supporters [of health care reform] hope patient-centered medical homes will help refocus the U.S. health care system on the benefits of primary care.”).

<sup>223</sup> *Id.*

<sup>224</sup> Robert A. Berenson et al., *A House Is Not a Home: Keeping Patients at the Center of Practice Redesign*, 27 HEALTH AFF. 1219, 1223 (2008). For more information about the implementation of medical homes and related national initiatives, see generally *National Initiatives Overview*, NAT’L CENTER FOR MED. HOME IMPLEMENTATION, <http://www.medicalhomeinfo.org/national> (last visited Mar. 15, 2011).

<sup>225</sup> Berenson, *supra* note 224, at 1223.

management pointing out that new responsibilities for risk assessment and coordination across specialties and facilities might derogate their “patient centeredness” in delivering primary care.<sup>226</sup>

## VI. EXPANDING PROVIDER RESPONSIBILITY

PPACA has several sections that will significantly expand provider responsibility and affect their liability exposure, even though the only two provisions in the Act that explicitly have a liability dimension deal with decision aids for patient decisionmaking<sup>227</sup> and the tort demonstration project section.<sup>228</sup>

### A. *Explicit Liability Provisions in PPACA*

#### 1. Decision Aids

PPACA adopts the use of decision aids for “preference-sensitive care.”<sup>229</sup> Preference-sensitive care refers to care situations in which the clinical evidence does not clearly support one treatment option over another, confronting the patient and provider with significant tradeoffs among different outcomes for each treatment.<sup>230</sup> The goal is to give patients full information about treatment tradeoffs and ensure that patient preferences are incorporated into the treatment plan.<sup>231</sup> “Decision

<sup>226</sup> *Id.* at 1226. “Health homes” consist of a designated health care provider and a team of health care professionals working with designated caregivers to provide Medicaid beneficiaries with a comprehensive array of health services including care coordination and referral services. PPACA sec. 2703(a), § 1945(a), 42 U.S.C.A. § 1396w-4(a) (West Supp. 1B 2010). The Act also provides grants and other funding for “health teams” transitioning to become medical homes (meeting an extensive list of requirements). *Id.* § 3502(c)(2), 42 U.S.C.A. § 256a-1 (West Supp. 1A 2010).

<sup>227</sup> PPACA sec. 3506, § 936, 42 U.S.C.A. § 299b-36.

<sup>228</sup> *Id.* sec. 10607, § 399V-4, 42 U.S.C.A. § 280g-15.

<sup>229</sup> *Id.* sec. 3506, § 936, 42 U.S.C.A. § 299b-36.

<sup>230</sup> John E. Wennberg & Philip G. Peters, Jr., *Unwarranted Variations in the Quality of Health Care: Can the Law Help Medicine Provide a Remedy/Remedies?*, 37 WAKE FOREST L. REV. 925, 928-30 (2002). PPACA defines “preference-sensitive care” as

medical care for which the clinical evidence does not clearly support one treatment option such that the appropriate course of treatment depends on the values of the patient or the preferences of the patient, caregivers or authorized representatives regarding the benefits, harms and scientific evidence for each treatment option, the use of such care should depend on the informed patient choice among clinically appropriate treatment options.

*Id.* sec. 3506, § 936(b)(2), 42 U.S.C.A. § 299b-36(b)(2).

<sup>231</sup> See Wennberg & Peters, *supra* note 230, at 934-95.

aids are decision support tools that provide patients with detailed and specific information on options and outcomes, help them clarify their values, and guide them through the decision making process.”<sup>232</sup>

Such decision aids are intended to inform decisionmaking with regard to preference-sensitive care. Advocates contend that decision aids improve patient knowledge and generate realistic expectations of the benefits and harms of options; lower patient feelings of being uninformed; and reduce patient passivity in decision making.<sup>233</sup> They also help patients with chronic diseases feel socially supported and potentially improve their behavioral and clinical outcomes.<sup>234</sup> Decision aid examples include treatments for prostate surgery or treatments for heart disease, for which several clinical approaches are possible (e.g., medication, surgery, or watchful waiting).<sup>235</sup> Decision aid tools typically include DVDs that explain clinical choices, brochures, and other methods of presenting useful information to patients.<sup>236</sup>

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<sup>232</sup> Elie A. Akl et al., *A Decision Aid for COPD patients Considering Inhaled Steroid Therapy: Development and Before and After Pilot Testing*, BMC MED. INFORMATICS & DECISION MAKING 2 (May 15, 2007), <http://www.biomedcentral.com/1472-6947/7/12>. PPACA defines “patient decision aid” as “an educational tool that helps patients, caregivers or authorized representatives understand and communicate their beliefs and preferences related to their treatment options, and to decide with their health care provider what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences.” PPACA sec. 3506, § 936(b)(1), 42 U.S.C.A. § 299b-36(b)(1). Under PPACA, patient decision aids:

(A) shall be designed to engage patients, caregivers, and authorized representatives in informed decisionmaking with health care providers;

(B) shall present up-to-date clinical evidence about the risks and benefits of treatment options in a form and manner that is age-appropriate and can be adapted for patients, caregivers, and authorized representatives from a variety of cultural and educational backgrounds to reflect the varying needs of consumers and diverse levels of health literacy;

(C) shall, where appropriate, explain why there is a lack of evidence to support one treatment option over another; and

(D) shall address health care decisions across the age span, including those affecting vulnerable populations including children.

*Id.*, § 936(d)(2)(A)–(D), 42 U.S.C.A. § 299b-36(d)(2)(A)–(D).

<sup>233</sup> Elie A. Akl et al., *supra* note 232, at 2.

<sup>234</sup> *Id.*

<sup>235</sup> For examples of decision aids for such diseases with treatment options, see *Decision Aid Library*, DARTMOUTH-HITCHCOCK, [http://patients.dartmouth-hitchcock.org/shared\\_decision\\_making/decision\\_aid\\_library.html](http://patients.dartmouth-hitchcock.org/shared_decision_making/decision_aid_library.html) (last visited Mar. 15, 2011); see also *Patient Decision Aids*, FOUND. FOR INFORMED MED. DECISION MAKING, [http://www.informedmedicaldecisions.org/patient\\_decision\\_aids.html](http://www.informedmedicaldecisions.org/patient_decision_aids.html) (last visited Mar. 15, 2011) (describing and listing patient decision aids).

<sup>236</sup> See Michael J. Barry, *Health Decision Aids to Facilitate Shared Decision Making in*

Washington State has already amended its informed consent statute to fund demonstration projects and to incorporate decision aids into state informed consent law.<sup>237</sup> The legislation requires the state health care authority to implement a shared-decisionmaking demonstration project, to be conducted at one or more multi-specialty group practices.<sup>238</sup> The demonstration project will incorporate decision aids into clinical practice to assess the effect of shared decisionmaking on health care quality and cost.<sup>239</sup>

The PPACA mandate to use such certified decision aids introduces a federal requirement that overlays the common law of informed consent. Such decision aids must replace the normal process of informed consent disclosure, at first in Medicare health plans, but realistically in most settings as providers strive for consistency in their informed consent approaches. PPACA therefore sets the standard of care for disclosure of risks and benefits of procedures and requires use of the decision aid in order to satisfy this informational standard. If the provider does not use available decision aids, and a patient suffers injury, the patient has a legal claim that the provider breached the standard of care by failing to follow the statutory requirement. Decision aids would then become the community standard for information disclosure.<sup>240</sup>

## 2. Liability-Reform Demonstration Projects

PPACA promotes state demonstration programs that are limited in their scope by the terms of grants to the states. Tort reform was never seriously considered as a central part of health care reform, in part because cost savings from reform were not expected to be sub-

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*Office Practice*, 136 ANNALS INTERNAL MED. 127, 127 (2002) (“Health decision aids are designed to facilitate shared decision making by helping patients and their physicians choose among reasonable clinical options.” (citations omitted)).

<sup>237</sup> Wash. Rev. Code. §§ 7.70.060, 41.05.033 (West, Westlaw through 2011 legislation effective through April 19, 2011).

<sup>238</sup> *Id.* § 41.05.033(2).

<sup>239</sup> *Id.* While provisions of PPACA do not describe how the burden of proof might be altered, if at all, by requirements that such aids be used, Washington State requires that such aids be used, once developed and certified. *Id.* § 7.70.060. This creates a presumption of informed consent if a practitioner uses decision aids, and the presumption can only be rebutted by clear and convincing evidence. *Id.*

<sup>240</sup> Failure to follow the statutory requirement may even give rise to the argument of negligence per se.

stantial.<sup>241</sup> The Senate defined the parameters of tort reform as bounded by a search for effective alternative dispute resolution systems. Section 6801 of PPACA states that

[i]t is the sense of the Senate that—

(1) health care reform presents an opportunity to address issues related to medical malpractice and medical liability insurance;

(2) States should be encouraged to develop and test alternatives to the existing civil litigation system as a way of improving patient safety, reducing medical errors, encouraging the efficient resolution of disputes, increasing the availability of prompt and fair resolution of disputes, and improving access to liability insurance, while preserving an individual's right to seek redress in court; and

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<sup>241</sup> See Letter from Douglas W. Elmendorf, Dir., Cong. Budget Office, to Orrin G. Hatch, U.S. Senator (Oct. 9, 2009), available at <http://www.cbo.gov/ftpdocs/106xx/doc10641>. The letter represented the CBO's official response to Senator Hatch's "request for an updated analysis of the effects of proposals to limit costs related to medical malpractice ('tort reform')." *Id.* at 1. The CBO began with the assumption that "[t]ort reform could affect costs for health care both directly and indirectly: directly, by lowering premiums for medical liability insurance; and indirectly, by reducing the use of diagnostic tests and other health care services when providers recommend those services principally to reduce their potential exposure to lawsuits." *Id.* The CBO estimated costs savings from various tort reforms, such as caps on noneconomic damages; caps on punitive damages; modification of the "collateral source" rule; more restrictive statutes of limitations; and replacement of joint-and-several liability with a fair-share rule limiting a defendant's liability to the percentage of the final award that was equal to his or her share of responsibility for the injury. *Id.* at 1-2. The CBO also estimated that such reforms would reduce medical malpractice premiums by about ten percent. *Id.* at 2. The CBO further calculated that in 2009 the direct costs to providers for medical malpractice liability, including premiums, awards, settlements, and administrative costs, would be around \$35 billion, or roughly two percent of total health care expenditures. *Id.* A savings of ten percent in premiums plus costs would therefore, in the CBO's words, "reduce total national health care expenditures by about 0.2 percent." *Id.* at 2-3. This is hardly a significant savings.

In addition, the CBO noted the possibility of measurable indirect savings from "reduced utilization of health care services," although particular reforms might have different effects on physician incentives. *Id.* at 3. Adding these savings to the reform savings would reduce total national health care spending by about half a percent, or approximately \$11 billion in 2009. *Id.*

Finally, the CBO noted that much uncertainty remains about the possible negative effect on health outcomes of limiting the rights of injured patients to sue for injuries from medical errors. *Id.* at 5. It noted that the studies are in conflict, ranging from an estimate that a 10% reduction in costs would increase the overall mortality rate by 0.2%, to an estimate of no serious adverse outcomes for patient health. *Id.* The tort reformers' hope that extensive reforms could be sold as cost reduction, as part of the overall PPACA package, was limited by this CBO analysis.

(3) Congress should consider establishing a State demonstration program to evaluate alternatives to the existing civil litigation system with respect to the resolution of medical malpractice claims.<sup>242</sup>

The primary liability reform provision in PPACA is section 10607.<sup>243</sup> Under it, the HHS Secretary may award demonstration grants for up to five years to states to explore alternatives to tort litigation for resolving claims filed against health care providers or organizations.<sup>244</sup> PPACA specifies that the programs should resolve disputes over patient injuries and promote a reduction in medical errors “by encouraging the collection and analysis of patient safety data related to disputes resolved under subparagraph (A) by organizations that engage in efforts to improve patient safety and the quality of health care.”<sup>245</sup>

States seeking grants must demonstrate how their model

(A) makes the medical liability system more reliable by increasing the availability of prompt and fair resolution of disputes;

(B) encourages the efficient resolution of disputes;

(C) encourages the disclosure of health care errors;

(D) enhances patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events;

(E) improves access to liability insurance;

(F) fully informs patients about the differences in the alternative and current tort litigation;

(G) provides patients the ability to opt out of or voluntarily withdraw from participating in the alternative at any time and to pursue other options, including litigation, outside the alternative;

(H) would not conflict with State law at the time of the application in a way that would prohibit the adoption of an alternative to current tort litigation; and

(I) would not limit or curtail a patient’s existing legal rights, ability to file a claim in or access a State’s legal system, or otherwise abrogate a patient’s ability to file a medical malpractice claim.<sup>246</sup>

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<sup>242</sup> PPACA, Pub. L. No. 111-148, § 6801, 124 Stat. 119, 804 (2010).

<sup>243</sup> *Id.* sec. 10607, § 399V-4, 42 U.S.C.A. § 280g-15.

<sup>244</sup> *Id.*, § 399V-4(a)–(b), 42 U.S.C.A. § 280g-15(a)–(b).

<sup>245</sup> *Id.*, § 399V-4(c) (1) (A)–(B), 42 U.S.C.A. § 280g-15(c) (1) (A)–(B).

<sup>246</sup> *Id.*, § 399V-4(c) (2) (A)–(I), 42 U.S.C.A. § 280g-15(c) (2) (A)–(I).

### B. *Streams of Liability Risk Under PPACA*

PPACA creates four streams of pressure that converge toward measurable and specific standards of care in practice. First, outcome measures will be researched, developed, and disseminated.<sup>247</sup> Second, under Subtitle F, PPACA mandates the AHRQ director—in collaboration with other federal agencies—to develop “innovative methodologies and strategies” for improving patient safety and health care outcomes.<sup>248</sup> AHRQ’s Center for Quality Improvement and Patient Safety will disseminate best practices<sup>249</sup> and develop mechanisms for delivering health care reliably, safely, and efficiently; translate evidence into widely applicable practice recommendations; and identify and mitigate hazards by analyzing and responding to patient safety data.<sup>250</sup> This is quite a list, and it is likely to force hospital patient safety and compliance officers into overtime as they struggle to absorb new findings. The use of “practice recommendations” approximates standard-setting for physicians and puts a heavier burden of justification on them to deviate from what lawyers will argue is a standard of care.

Third, research on outcome measures and best practices will be used to create clinical practice guidelines.<sup>251</sup> Fourth, outcomes, best practices, and guidelines will be rapidly disseminated to practice settings. Physician performance information will be available to consumers through website information,<sup>252</sup> just as hospital and nursing home comparative data are now. Such information will include measures collected under the Physician Quality Reporting Initiative and also assessments of such factors as efficiency, safety, and effectiveness.<sup>253</sup>

The Center for Quality Improvement and Patient Safety will push for adoption of best practices to improve the quality, safety, and efficiency of health care delivery services.<sup>254</sup> Findings will be disseminated through multiple media—linked with the Office of the National Coordinator of Health Information Technology—and used to “inform the activities of the health information technology extension pro-

<sup>247</sup> *Id.* sec. 10303(a), § 931(f), 42 U.S.C.A. § 299b-31(f); *see also supra* Section I.B (discussing PPACA’s provisions relating to outcome measures in greater depth).

<sup>248</sup> *Id.* sec. 3501, § 933(a), 42 U.S.C.A. § 299b-33(a).

<sup>249</sup> *Id.*, § 933(d), 42 U.S.C.A. § 299b-33(d).

<sup>250</sup> *Id.*, § 933(c)(2)(E)–(F), (H)–(I), 42 U.S.C.A. § 299b-33(c)(2)(E)–(F), (H)–(I).

<sup>251</sup> PPACA requires the HHS Secretary to identify existing and new clinical practice guidelines. *Id.* sec. 10303(c), § 304(b)(4), 42 U.S.C.A. § 299b-33.

<sup>252</sup> *Id.* § 10331(a), § 42 U.S.C.A. § 1395w-5(a) (West Supp. 1B 2010).

<sup>253</sup> *Id.*

<sup>254</sup> *Id.* sec. 3501, § 933(b)(8), 42 U.S.C.A. § 299b-33(b)(8) (West Supp. 1A 2010).

gram . . . as well as any relevant standards, certification criteria, or implementation specifications.”<sup>255</sup> A Patient-Centered Outcomes Research Institute will provide information to patients, providers, purchasers, and policymakers regarding disease management and recent research findings.<sup>256</sup>

The effect of the cumulative PPACA requirements will be to force the rapid diffusion of new standards into practice. First, millions of federal dollars are pouring into the research world to analyze the practice-outcome linkage for most medical practices and what best practices should be.<sup>257</sup> Second, PPACA mandates dissemination in a variety of ways, including websites, pay-for-performance reforms, and models of integrated practice. New payment reforms in particular will tie physician performance to these measures, particularly in ACOs, medical homes, and other new integrated modes of practice whose creation PPACA incentivizes. Best practices—grounded in research and made accessible and transparent to providers, patients, and payers—will start to squeeze out medical practice variation in clinical practice.

### 1. Physician Liability

The liability effect of reducing variations in medical practice is clear: defenses under existing state liability rules (e.g., respectable minority defenses, variations in practice, and proximate causation) will narrow as practice choices also narrow.<sup>258</sup> The physician who does not keep up with new research will not only suffer income loss; she will also suffer a higher risk of liability for failing to conform to what becomes the new standard of care.<sup>259</sup> Such practice guidelines and best practices will be used in malpractice suits, in spite of PPACA’s modest attempts to limit their use. The section of PPACA that creates the PCOR Institute specifies that its findings must be rapidly dissemi-

<sup>255</sup> *Id.*, § 933(d), 42 U.S.C.A. § 299b-33(d).

<sup>256</sup> *Id.* sec. 6301, § 1181(c), 42 U.S.C.A. § 1320e(c).

<sup>257</sup> American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, tit. VIII, 123 Stat. 115, 176-77.

<sup>258</sup> *See generally* FURROW ET AL., *supra* note 18, at 381-425 (surveying various defenses to medical malpractice suits).

<sup>259</sup> Mello and others argue that there are a variety of reasons why physicians resist adhering to suggested guidelines. *See, e.g.*, Mello, *supra* note 43, at 680-83 (explaining that physicians are not aware of best practices, do not like them, do not feel they are applicable in a particular case, and/or lack the resources to implement them). But findings generated by CER are likely to take the wind out of physician resistance, given better scientific underpinnings for medical practice.

nated to clinicians, presumably so that they can adopt them.<sup>260</sup> While PPACA specifies that such research findings do not include “practice guidelines, coverage recommendations, payment, or policy recommendations,”<sup>261</sup> this is hardly sufficient to keep such findings out of litigation over medical errors. Plaintiffs’ lawyers will use the findings as at least some evidence of a standard of care, and potentially powerful evidence at that. This is one of the costs of improving medical practice by narrowing practice variation and medical uncertainty. And as American physicians move more and more into integrated systems and hospitals and away from small private practices, their liability is likely to be shared with the health care systems.<sup>262</sup>

## 2. Institutional Liability

If we assume that health reform will achieve some reorganization of health care delivery, then within a few years ACOs will be formed, comprehensive patient bundling will be implemented in many hospitals, and salary-based payment systems will proliferate. These reforms will accomplish several objectives simultaneously: they will move more physicians from solo or small-group practice into salaried positions in a group model or hospitals; they will shift power toward enterprises that can buy and coordinate the technologies—from electronic health records to case management strategies—to meet the demands of the federal government; and they will therefore turn more providers into employee-agents of institutional providers instead of independent contractors. While the payment-reform measures in PPACA begin with physicians, it will primarily be institutional providers that will create systems.

If these various reforms, incentives, and forces converge, institutional providers will become directly liable for patient injury as well as vicariously liable for injuries caused by physicians, since agency law will carry liability upstream from agent to principal. Physicians will be much more integrated in the system, whether or not they are salaried, and any argument that they are independent contractors will evaporate.<sup>263</sup>

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<sup>260</sup> PPACA sec. 6301, § 1181(d)(8), 42 U.S.C.A. § 1320e(d)(8).

<sup>261</sup> *Id.*, § 1181(d)(8)(A)(iv), 42 U.S.C.A. § 1320e(d)(8)(A)(iv).

<sup>262</sup> I do not address the problem of physician resistance to patient safety initiatives. For background on this problem, see *Behaviors That Undermine a Culture of Safety*, SENTINEL EVENT ALERT (The Joint Comm’n, Oakbrook Terrace, Ill.), July 9, 2008, available at [http://www.jointcommission.org/assets/1/18/SEA\\_40.pdf](http://www.jointcommission.org/assets/1/18/SEA_40.pdf).

<sup>263</sup> For a discussion of PPACA’s failure to legislate any liability reforms, see Thomas L. Hafemeister & Joshua Hinckley-Porter, *The Health Care Reform Act of 2010 and Medical*

Second, even if ACOs and other entities operate without a hospital as part of the organization, they are now health care providers, subject to liability just as a hospital or managed care organization, on both vicarious liability and direct negligence principles. Corporate negligence principles will likely apply to integrated organizations that manage care, whether a patient home, an ACO, or some other delivery form that PPACA creates. American courts have proved willing to look beyond the hospital form in deciding whether a health care entity might be liable for corporate negligence. For example, in *Gianquitti v. Atwood Medical Associates, Ltd.*, the court held that a professional medical group practice that provides on-call medical care to its patients if and when they are hospitalized could be liable for corporate negligence if it lacked a formal backup system.<sup>264</sup> In another case, *Davis v. Gish*, the court noted the kinds of activities that would turn a professional group or a physicians' practice group into an entity subject to corporate negligence.<sup>265</sup> The entity would, like an HMO, "involve [itself] daily in decisions affecting [its] subscriber's medical care. These decisions may, among others, limit the length of hospital stays, restrict the use of specialists, prohibit or limit post-hospital care, restrict access to therapy, or prevent rendering of emergency room care."<sup>266</sup> The entity must have general responsibility for "arranging and coordinating the total health care of its patients."<sup>267</sup> It must take "an active role in patients' care."<sup>268</sup>

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*Malpractice Liability: Worlds in Collision?*, 64 SMU L. REV. (forthcoming Aug. 2011), available at <http://ssrn.com/abstract=1755028>. Hafemeister and Hickley-Porter explain,

[S]ome have argued that because the PPACA does so little to directly address malpractice and malpractice litigation-related concerns, its enactment will actually result in an increase in the number of malpractice cases and related costs as its provisions come into effect. As more patient encounters occur per year as a result of more insured people seeking medical attention, as a matter of course the total number of adverse events may increase, resulting in a greater number of medical malpractice suits. In addition, because the number of available physicians will remain constant while the number of patients able to obtain medical care will increase, this may result in the time and energy of doctors being stretched to cover more patients, possibly resulting in an increased number of mistakes on the part of physicians.

*Id.* (manuscript at 21) (citations omitted).

<sup>264</sup> 973 A.2d 580, 591-92 (R.I. 2009).

<sup>265</sup> 2 Pa. D. & C.5th 154, 157-59 (Pa. Ct. Com. Pl. 2007).

<sup>266</sup> *Id.* at 158 (quoting *Shannon v. McNulty*, 718 A.2d 828, 835 (Pa. Super. Ct. 1998)).

<sup>267</sup> *Id.* at 159.

<sup>268</sup> *Id.*

Today most physician groups or physician office-based practices would not be said to possess such responsibility. PPACA—with its millions of dollars in demonstration grants and its new mandates—will foster new entities that are far more likely to coordinate care than are current health care providers. These new entities will take on new responsibilities that will make them appropriate defendants in tort litigation. Once liability is accepted, then institutions might willingly take the next step of responsibility for bad outcomes experienced by their patients. They might consider the warranty of care model offered by the Geisinger Clinic. The Geisinger Clinic, an integrated health care delivery system in northeastern Pennsylvania, has a “warranty” program which promises patients that forty key processes will be completed when they undergo elective coronary-artery bypass graft surgery (CABG).<sup>269</sup> Geisinger does not guarantee results, but it will cover care for post-surgery complications during the first ninety days.<sup>270</sup> This is a contract counterpart to enterprise liability for hospitals, a proposal often discussed but never adopted.<sup>271</sup> It may be that finally enterprise liability will make sense as integration and coordination intensify, and outcomes and performance data are generally available to all.

#### CONCLUSION

PPACA will change American health care in many ways, providing insurance coverage for many more Americans, expanding Medicaid coverage for low-income citizens, and improving the practice of medicine generally. Practice guidelines and best practices will be developed, outcomes measured, and tolerance of medical errors and pa-

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<sup>269</sup> Lee, *supra* note 19, at 531.

<sup>270</sup> *Id.*

<sup>271</sup> Pure outcome-based enterprise liability proposals have existed in the legal literature since the 1970s. See, e.g., Clark C. Havighurst & Laurence R. Tancredi, “*Medical Adversity Insurance*”—A No-Fault Approach to Medical Malpractice and Quality Assurance, 51 MILBANK MEMORIAL FUND Q. HEALTH & SOC’Y 125, 125-26 (1973) (proposing a no-fault system for handling unfavorable results of medical care); Clark C. Havighurst, “*Medical Adversity Insurance*”—Has Its Time Come?, 1975 DUKE L.J. 1233, 1253-55 (1975) (describing a system that would create a schedule of compensable medical injuries in advance, regardless of fault, as opposed to a system with case-by-case adjudications for medical injuries); Laurence R. Tancredi, *Designing a No-Fault Alternative*, 49 LAW & CONTEMP. PROBS. 277, 277 (1986) (“A no-fault compensation scheme should rank at the very top of a list of long-term solutions to the perceived crisis in medical malpractice.”). For more recent scholarship, see Philip G. Peters, Jr., *Resuscitating Hospital Enterprise Liability*, 73 MO. L. REV. 369, 369 (2008) (“No tort reform has more potential to improve the quality of medical care and to reduce the frequency of patient injuries than exclusive hospital enterprise liability.”).

tient harms reduced. The result will be a change in practice patterns for individual physicians and health care systems as both adapt to what is hoped to be a new and improved practice of medicine in the United States. The path to a new efficient health care system will be bumpy: physician cooperation is uncertain unless incentives are powerful enough; guidelines and effectiveness research may meet resistance; the promised coordination innovations may prove to be less successful than hoped as providers and insurers struggle to divide up the health care pie. PPACA, for all its many provisions, may lack sufficient regulatory muscle, relying on dissemination of research and modest incentives and disincentives to alter provider behavior. However, while many initiatives are still modest in scope, they are likely to intensify pressure on both physicians and institutional providers as more and more reimbursement is at risk. If the incentives are properly designed and good medical research begins to tell us more about what works and what is wasted, then American medicine may become both more effective and safer for patients.