

The Federal Role in Reducing Hospital-Acquired Conditions: Are Medicare Reimbursement Incentives Enough?

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A new Medicare rule that will take effect October 2008 will prevent hospitals from receiving payment for the costs of treating certain hospital-acquired infections and conditions. This Note argues that the rule is unlikely to reduce the frequency of hospital-acquired conditions. The rule is based on the erroneous assumption that distorted financial incentives are responsible for the high rate of hospital-acquired conditions, and ignores the fact that hospitals lack the resources and data to tackle the systemic problems that endanger patients. This misguided approach could render the new CMS rule ineffectual, or worse, result in unintended consequences that undermine patient care. To significantly contribute to a reduction in hospital-acquired conditions, the federal government should increase funding for the Agency for Healthcare Research and Quality to develop proven strategies that hospitals can implement to reduce infection.

I. INTRODUCTION

A shocking number of Americans suffer from health problems caused by medical providers. As many as 1.7 million hospital-acquired infections occur annually in the United States, resulting in an estimated 99,000 deaths.¹ Over the past decade, the enor-

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1. R. Monina Klevens et al., *Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002*, 122 PUB. HEALTH REP. 160, 164 (2007); Lucian L. Leape & Donald M. Berwick, *Five Years After To Err Is Human: What Have We Learned?* 293 JAMA 2384 (2005).

mity and urgency of this problem has garnered increasing attention within the health policy community.² Yet, for all the technological sophistication of American health care, effective regulatory strategies for keeping patients safe within hospitals remain elusive.

In 2005, Congress directed the Centers for Medicare and Medicaid Services (“CMS”) to use its power as a health care purchaser to reduce hospital-acquired infections.³ The resulting rule, which takes effect in October 2008, will deny Medicare reimbursement for the costs of treating certain hospital-acquired conditions, in the hopes that the reduction in payment will spur hospitals to better safeguard patients. While the federal government’s willingness to play a larger role in addressing this intractable problem is welcome, several conceptual and technical flaws in the new reimbursement rule undermine its capacity to significantly contribute to patient safety.

In contrast to generalized efforts to improve health care “quality” — an amorphous term that encompasses preventive care, accurate medication dosage, and a warm bedside manner — the impending rule targets a specific problem. Preventable medical complications simply should not occur in hospitals, especially when tax dollars are paying for care. As the largest payer, Medicare has always played a prominent role in shaping health care delivery.⁴ It is now using that influence to direct hospital executives’ attention to the unacceptable level of hospital-acquired conditions. The rule, if successful, could represent an innovative use of Medicare spending to achieve important advances in public health.

Yet, contextual factors will determine whether the new reimbursement scheme can produce the desired outcome. The complexity of health care financing arrangements creates multiple pressures and incentives that shape the way health care providers respond to even the most specific rule. For example, reimbursement reductions from governmental payers may prompt hospitals to raise prices for private payers. Because the new

2. Leape & Berwick, *supra* note 1.

3. 42 U.S.C. § 1395ww(d)(4)(D) (2008), discussed *infra* Part III.A.

4. See, e.g., Chantal Worzala et al., *Challenges and Opportunities for Medicare’s Original Prospective Payment System*, 22 HEALTH AFF. 175 (2003) (discussing the tensions and unintended consequences of using Medicare to achieve health policy goals).

reimbursement rule assumes a direct causal role for Medicare payments and largely ignores the interplay of factors that influence provider behavior, it is unlikely to achieve substantial reductions in hospital-acquired conditions.

Part II briefly outlines the legislation, the sources of medical error and hospital-acquired conditions, and the origins of reimbursement-oriented approaches to patient safety. Part III describes CMS' rule-making process and the administrative and practical difficulties involved in implementing the legislation. Part IV disputes the central assumption of the new rule by demonstrating that financial incentives may not be solely or even primarily responsible for the high rate of hospital-acquired conditions. Adherents of law-and-economics theory have posited that altering financial incentives will force hospitals and physicians to change because providers are rational economic actors seeking to maximize profit.⁵ This assumes that providers have the capability to radically alter the way they treat patients and lack only the will to do so. In reality, hospitals lack the resources and data to tackle the systemic problems that endanger patients.

Therefore, in Part V, this Note argues that the federal government should supplement the new reimbursement rule with an infusion of funding for the Agency for Healthcare Research and Quality ("AHRQ") in order to pursue a three-pronged research agenda. With appropriate funding, AHRQ can expedite the development of a national database of patient safety information; standardize and validate evidence-based guidelines to be used at the physician level; and develop and test systems-based strategies to ensure those guidelines are consistently followed at the hospital level.

A recent intervention in Michigan intensive care units points the way toward promising innovations in reducing hospital-acquired infections. But replicating this project on a large scale will require significant and targeted research. Without additional funding to allow AHRQ to aggressively seek solutions to the multifaceted problem of medical error, the new Medicare rule

5. See, e.g., Joanna M. Shepherd, *Tort Reforms Winners and Losers: The Competing Effects of Care and Activity Levels*, 55 UCLA L. REV. 905, 922-23 (2008) (applying law and economics analysis to predict the results of tort reform on physicians incentives to provide quality care and to perform risky procedures).

may simply curtail hospital funding without triggering a meaningful decline in infection rates.

II. THE RULE'S CONCEPTUAL ROOTS

Under Medicare's prospective payment system, the Secretary of Health and Human Services has the authority to classify patients and the costs of their treatment according to diagnosis-related groups ("DRGs").⁶ These DRGs form the basis for Medicare payments to hospitals.⁷ If a complication occurs, the patient is assigned a secondary diagnosis that often results in a DRG with a higher payment than the original diagnosis; it may also generate more reimbursement by triggering outlier payments for unusually high treatment costs.⁸ As a result, hospitals can receive more money for treating patients with complications, even if those complications are the result of the hospital's own failure to adhere to proper treatment standards. This Part describes the legislation that sought to redress this pattern of Medicare payment for preventable complications. It traces the statute's conceptual roots to a systems-based approach to patient safety and the reimbursement-focused trend known as Pay-for-Performance ("P4P").

A. THE STATUTORY AUTHORIZATION OF THE RULE

Many have long regarded the higher payments associated with hospital-acquired conditions as an irrational incentive in Medicare reimbursement.⁹ In 2005, Congress addressed this by including a clause in the Deficit Reduction Act that required the

6. § 1395ww(d)(4)(A). This system is intended to group together patients whose care is expected to require similar resources. Worzala et al., *supra* note 4, at 176.

7. Actual payments are calculated by weighting the DRG with standardized amounts representing labor, non-labor, and capital costs, subject to other adjustments such as area wage index and outlier costs. See BARRY R. FURROW ET AL., *THE LAW OF HEALTH CARE ORGANIZATION AND FINANCE* 373–74 (2004).

8. Hospital-Acquired Conditions, Including Infections, 71 Fed. Reg. 24,100 (Apr. 25, 2006).

9. See, e.g., Barry R. Furrow, *Regulating Patient Safety: Toward a Federal Model of Medical Error Reduction*, 12 WIDENER L. REV. 1, 11–12 (2005); Meredith B. Rosenthal, *Nonpayment for Performance? Medicare's New Reimbursement Rule*, 357 NEW ENG. J. MED. 1573 (2007); David A. Hyman & Charles Silver, *You Get What You Pay For: Result-Based Compensation For Health Care*, 58 WASH. & LEE L. REV. 1427, 1480 (2001).

Secretary to select at least two preventable hospital-acquired conditions that would no longer be reimbursable by Medicare.¹⁰ The objective is not merely to make Medicare reimbursement more cost-effective, but to improve healthcare quality.¹¹ In August 2008, CMS issued a final rule executing — indeed, exceeding — this mandate, by selecting ten medical conditions that will be denied reimbursement if they were not present when the patient entered the hospital.¹²

To prevent adverse outcomes from generating higher payments, Congress instructed CMS to select at least two medical conditions that are (a) high cost, high volume or both, (b) result in higher Medicare reimbursements when present as a secondary diagnosis, and (c) are reasonably preventable through the use of evidence-based guidelines.¹³ Starting October 1, 2008, the selected conditions will no longer trigger assignment to the higher-paying DRG unless the patient presented the diagnosis at the time of admission (in other words, unless the condition is not attributable to the hospital's error).¹⁴ This requires hospitals to document, for the first time, which secondary diagnoses are present on admission.

B. UNDERSTANDING MEDICAL ERROR AS A SYSTEMS PROBLEM

The concept of forcing hospitals to take financial responsibility for preventable infections has its roots in the Institute of Medi-

10. § 1395ww(d)(4)(D).

11. See Reporting of Hospital Quality Data for Annual Hospital Payment Update, 73 Fed. Reg. 23,643 (Apr. 30, 2008) (“Linking a payment incentive to hospitals’ prevention of avoidable or preventable HACs [hospital-acquired conditions] is a strong approach for encouraging high quality care.”).

12. Preventable Hospital-Acquired Conditions (HACs), Including Infections, 73 Fed. Reg. 48,477 (Aug. 19, 2008). (publishing and discussing final CMS rule on Hospital-Acquired Condition reimbursement changes). Several of these conditions are infections, but the remaining are medical conditions such as pressure ulcers and injuries due to patients falling. The scope of the rule is thus “hospital-acquired conditions,” with hospital-acquired infections as a subset.

13. § 1395ww(d)(4)(D); Deficit Reduction Act of 2005, Pub. L. 109-171 § 5001(c), 120 Stat. 4, 30 (2006); Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47,200 (Aug. 22, 2007). Evidence-based guidelines are discussed *infra* Part IV. For a helpful comparison of the concept of evidence in the worlds of law and medicine, see John M. Eisenberg, *What Does Evidence Mean? Can the Law and Medicine be Reconciled?*, 26 J. HEALTH POL. POL'Y & L. 369 (2001).

14. § 1395ww(d)(4).

cine's ("IOM") groundbreaking 1999 report, *To Err Is Human: Building a Safer Health System*.¹⁵ The report challenged a complacent health care system in which negative patient care outcomes were considered an inevitable byproduct of the practice of medicine. The IOM concluded that between 44,000 and 98,000 hospital patients die annually as a result of preventable medical errors; more than the death toll of breast cancer or car crashes.¹⁶ These alarming numbers catalyzed a public debate about the extent of preventable medical errors and how to protect patients from unnecessary harm.¹⁷

To Err Is Human highlighted the failure of the medical malpractice framework, which is primarily designed to apportion blame to individual providers, to adequately address patient safety problems.¹⁸ The report argued that the root cause of medical error is poorly designed systems. The tremendous complexity of health care delivery systems makes hospitals highly susceptible to both technological and human error. The IOM argued that hospitals should strive to create a "culture of safety" in which systems are designed to keep patients safe from harm, rather than blaming individual clinicians for adverse outcomes.¹⁹ Faulting individuals for errors generated by systems only discourages providers from candidly identifying and addressing medical errors. Since its publication, *To Err Is Human* has produced a rough con-

15. COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., *TO ERR IS HUMAN* (Linda Kohn et al. eds., 2000) [hereinafter *IOM Report*]. The IOM is a branch of the National Academy of Sciences.

16. *Id.* at 26. The IOM report uses "error" to encompass both failures of execution and failure to choose an appropriate course of action for the problem at hand. *Id.* at 54. It is not synonymous with hospital acquired infection.

17. Leape & Berwick, *supra* note 1, at 2384.

18. Medical malpractice suits allow patients to recover only if they can prove a causal connection between a physician's lapse in applying treatment protocols and their resulting injury. Some scholars advocate moving toward an enterprise liability model, in which financial liability is imposed on hospitals rather than doctors, although a physician's breach of duty remains a predicate for liability. See Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381 (1994). While malpractice suits provide remuneration and vindication for some patients, few consider malpractice liability alone to be an effective legal tool for preventing medical errors. See, e.g., Michelle M. Mello et al., *Fostering Rational Regulation of Patient Safety*, 30 J. HEALTH POL. POL'Y & L. 375, 386-89 (2005) (discussing the inadequacy of tort law to address patient safety because there is scant evidence that tort system sends effective deterrence signal to physicians and courts lack healthcare expertise).

19. *IOM report*, *supra* note 15, at 157.

sensus that bad systems, not careless doctors, are responsible for most medical errors.²⁰

The IOM followed up in 2001 with *Crossing the Quality Chasm*, which analyzed the multiple levels at which the health care system should be reconfigured to improve patient care.²¹ In response, Congress appropriated \$50 million annually for patient safety research to be conducted by AHRQ.²² AHRQ dedicated approximately \$20 million of its initial budget to research on medical errors.²³ As Part VI will discuss, this allocation is small relative to the magnitude of the problem and to governmental spending on other areas of medical research. Consequently, progress in solving systematic patient safety problems, and even the development of yardsticks to measure that progress, remains slow.

C. PAY-FOR-PERFORMANCE

The conceptual core of the new CMS rule is simple: punishing providers for poor outcomes can improve healthcare quality and save money. The corollary tenet is that “when providers are paid to deliver high quality care, they are more likely to do so.”²⁴ The

20. Leape & Berwick, *supra* note 1, at 2385; Lucian L. Leape, *Foreword: Preventing Medical Accidents: Is “Systems Analysis” the Answer?*, 27 AM. J.L. & MED. 145, 145–46 (2001).

21. COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., *CROSSING THE QUALITY CHASM* (2001) [hereinafter *Quality Chasm*]. The report contained a number of specific recommendations for changes at the microsystem level, where a small team of clinicians operates; but the suggestions for change at the level of the hospital itself were far less concrete. See Donald M. Berwick, *A User’s Manual for the IOM’s ‘Quality Chasm’ Report*, 21 HEALTH AFF. 80 (2002) (summarizing the key points, as well as the strengths and weaknesses, of the report).

22. Leape & Berwick, *supra* note 1, at 2385; *AHRQ Profile: Advancing Excellence in Healthcare*, AHRQ Publication No. 00-P005, March 2001. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/about/profile.htm> (last visited Sept. 6, 2008). The agency was initially created as the Agency for Health Care Policy and Research, but reauthorized in 1999 as AHRQ. Healthcare Research and Quality Act of 1999, Pub. L. No. 106-129 § 2(b)(2), 113 Stat. 1653, 1670 (1999). AHRQ is discussed in more detail *infra*, Part V.

23. *Patient Safety and Error Reduction Act: Hearing on S. 2738*, 106th Cong. 146 Cong. Rec. S5241-02 (2001) (statement of Sen. Jeffords) (predicting the need for additional funding for medical error reduction).

24. Hyman & Silver, *supra* note 9, at 1430 (2001). But see Bruce Vladeck, *If Paying for Quality is Such a Bad Idea, Why is Everyone for It?*, 60 WASH. & LEE L. REV. 1345, 1350 (2004) (arguing that frustration with the current payment system, coupled with the tendency to seek grand solutions to intractable health care problems, underpins the fervor for Pay-for-Performance).

seemingly indisputable logic of this proposition has given rise to a powerful new trend in healthcare. Pay-for-Performance refers to a spectrum of programs in which reimbursement is designed to reward high quality care and create incentives for quality improvement.²⁵ Over half of commercial HMOs incorporate financial incentives into their payment contracts, and Medicare is considering ways to incorporate P4P principles as well.²⁶

Existing P4P programs have deployed financial bonuses in a number of different ways. Financial incentives may operate at the physician or hospital level; providers may compete for funds; bonuses may reward quality improvement or achievement of a specified level of quality.²⁷ P4P may reward processes (such as application of clinical guidelines) or outcomes (such as a reduction of hospital-acquired infections).

Advocates of P4P note evidence confirming that compensation systems influence health care providers' behavior. For example, Medicare's switch to the prospective payment system triggered a decline in patients' length-of-stay, as hospitals were no longer paid on a per-diem basis.²⁸ Advocates argue that tying reimbursement to quality ought to have the same effect. Moreover, the contractual nature of P4P, whereby payers reward providers for delivering high quality care, appeals to those who prefer market-based initiatives to "top-down" regulatory schemes.²⁹ P4P shapes Medicare and HMO spending rather than seeking to in-

25. Meredith B. Rosenthal & R. Adams Dudley, *Pay-for-Performance: Will the Latest Payment Trend Improve Care?*, 297 JAMA 740 (2007).

26. *Id.* (acknowledging that most Pay-for-Performance programs currently fall short of expectations, and highlighting key factors to better align incentives with the goal of improving quality); Karen Milgate & Sharon Bee Cheng, *Pay-For-Performance: The Med-PAC Perspective*, 25 HEALTH AFF. 413, 415 (2006). MedPAC, which advises Congress on Medicare payment policy, has advocated incorporating Pay-for-Performance into Medicare reimbursement since 2003.

27. Charles N. Kahn III et al., *Snapshot of Hospital Quality Reporting and Pay-for-Performance Under Medicare*, 25 HEALTH AFF. 148, 151 (2006). In the Premier Hospital Quality Incentive Demonstration, a CMS project, hospitals that fall in the top ten percent on certain quality measures will receive 2% bonuses, while low performers are penalized. Hospitals in the bottom 10% are penalized by 2% while hospitals in the next lowest decile are penalized 1%. In a different model, the Medicare Payment Advisory Commission (MedPAC) has recommended setting aside 1-2% of total Medicare payments into a pool that is used to reward hospitals for both quality improvement and achievement. Milgate & Cheng, *supra* note 26, at 415. This represents an implicit penalty on lower performing hospitals because payment are reduced by 1-2% overall. Kahn et al., *supra* at 153.

28. Hyman & Silver, *supra* note 9, at 1448.

29. *Id.* at 1457-58.

fluence individual consumer choices. By harnessing the economic clout of larger payers, P4P could have a profound impact on quality. However, as will be discussed in Part IV, a closer examination of P4P reveals a number of theoretical and practical problems that have implications for the efficacy of the new CMS rule on hospital-acquired conditions.

III. FROM STATUTE TO RULE: ADMINISTRATIVE AND PRACTICAL SHORTCOMINGS

In crafting a rule to eliminate payment for hospital-acquired conditions, the Center for Medicare and Medicaid Services was obligated to select at least two medical conditions that are (a) high cost, high volume or both, (b) result in higher Medicare reimbursements when present as a secondary diagnosis, and (c) are reasonably preventable through the use of evidence-based guidelines.³⁰ This Part describes the rule-making process and considers the immediate practical difficulties the rule will create for providers. The statute granted CMS considerable discretion, but the criteria also constrained CMS to select some hospital-acquired conditions that are already rare and to omit others that have a larger impact on public health. The rule requires hospitals to overhaul their admissions process and documentation on a compressed, and perhaps unrealistic, timeline. Finally, the rule will halt reimbursement for conditions that research suggests are not entirely preventable.

A. AGENCY INTERPRETATION AND RULEMAKING

CMS collaborated with the Centers for Disease Control and Prevention (“CDC”) to develop an initial list of hospital-acquired conditions and engaged in extensive notice-and-comment rule-making to evaluate which conditions met the statutory criteria. After receiving hundreds of comments from health care providers and professional associations, CMS originally selected eight conditions, exceeding the statutory mandate to select two conditions.

30. 42 U.S.C. § 1395ww(d)(4)(D) (2008).

Catheter-associated urinary tract infections,³¹ vascular catheter infections,³² surgical site infections, and pressure ulcers³³ will no longer be reimbursable unless they are present on admission. In addition, Medicare will not reimburse for “serious preventable events,” including objects left in patients during surgery, air embolisms, incompatible blood transfusions, and hospital-acquired injuries such as fractures that occur as a result of patient falls.³⁴ Finally, in August 2008, less than two months before the new reimbursement rule is scheduled to take effect, CMS added additional hospital-acquired conditions. These include several conditions that reflect poor monitoring of blood sugar levels,³⁵ some surgical site infections,³⁶ and deep vein thrombosis/pulmonary embolism.³⁷

The hospital-acquired conditions that will become subject to the rule reflect Medicare’s struggle to address public health needs within the legislative and technical constraints established by Congress. The first of the three statutory criteria for selecting

31. Urinary tract infections often occur among patients with indwelling catheters. Indwelling urinary catheters account for 80% of hospital-acquired urinary tract infections, and up to 40% of all hospital-acquired infections. Heidi L. Wald & Andrew M. Kramer, *Nonpayment for Harms Resulting from Medical Care*, 298 JAMA 2782, 2783 (2007).

32. Vascular catheter infections occur when bacteria invades a patient’s bloodstream as a result of contamination of the site where an intravenous line has been inserted into the patient’s vein. See Michele L. Pearson et al., *Guideline for Prevention of Intravascular Device-Related Infections*, 24 AM. J. INFECTION CONTROL 262 (1996).

33. Pressure ulcers, also called decubitus ulcers, occur when patients remain in one position too long. The pressure reduces blood flow to the skin, causing the tissue to die and skin to break down. Courtney H. Lyder, *Pressure Ulcer Prevention and Management*, 289 JAMA 223 (2003). See Michael Stockham, “*This Might Sting a Bit*”: *Policing Skin Care in Nursing Facilities by Litigating Fraud*, 87 CORNELL L. REV. 1041 (2002) (advocating False Claims Act litigation to enforce appropriate skin care and pressure ulcer prevention in nursing homes).

34. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47,217 (Aug. 22, 2007).

35. Hypoglycemia (low blood glucose levels) and hyperglycemia (elevated blood glucose levels) may be complications of diabetes or side effects of certain medications. The CMS rule as finally published prohibits reimbursement of comas resulting from these conditions, which can be avoided by routine testing of blood glucose levels. Preventable Hospital-Acquired Conditions (HACs), Including Infections, 73 Fed. Reg. 48,475 (Aug. 19, 2008).

36. These include infections following (often elective) orthopedic surgeries to repair the spine, shoulder and elbow, and infections following coronary artery bypass graft surgery. Preventable Hospital-Acquired Conditions (HACs), Including Infections, 73 Fed. Reg. 48,477 (Aug. 19, 2008).

37. Deep vein thrombosis (DVT) occurs when a blood clot forms in a vein, usually in the leg. When the clot migrates to the lung, it is known as pulmonary embolism (PE), which can be fatal. 73 Fed. Reg. 48,480 (Aug. 19, 2008).

conditions, “high cost or volume or both,” turned out to be relatively meaningless due to the paucity of reliable data on the cost and volume of specific hospital-acquired conditions among the Medicare population.³⁸ In discussing this criterion, CMS cited the average charges for cases in which the condition was reported as a secondary diagnosis; rather than the difference between the cost of treating a primary condition with, or without, the hospital-acquired secondary condition.³⁹ For example, CMS noted that the average charge (for the entire hospital stay) for patients diagnosed with pressure ulcers was \$40,381.⁴⁰ However, a study that isolated the cost of hospital-acquired pressure ulcers found that they accounted for an average of \$735 in additional Medicare payments.⁴¹ In comparison, each case of postoperative sepsis was associated with an additional \$8,881 payment.⁴² While the frequency of pressure ulcers may justify its inclusion in the rule, it remains puzzling that CMS referenced no benchmark in asserting that a particular condition was high cost or high volume.

The second selection criterion reflects the requirement that CMS choose conditions that are identifiable by a specific code pursuant to the ICD-9-CM, the official system for classifying diagnoses and hospital treatments.⁴³ Many hospital-acquired con-

38. This is because, until now, CMS has not required hospitals to record whether secondary diagnoses are “present on admission” so there was no nationwide data to differentiate hospital-acquired from community-acquired infections. See Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 24,716, 24,718 (May 3, 2007) (inviting comment on a list of thirteen proposed hospital-acquired conditions).

39. See, e.g., Hospital-Acquired Conditions, Including Infections 72 Fed. Reg. at 24,719; Comment Letter, Medicare Payment Advisory Commission (“MedPAC”) (June 11, 2007) at 18. For example, conditions such as “object left in patient during surgery” is likely to be associated with a higher average charge simply because surgeries are high cost.

40. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47,205 (Aug. 22, 2007).

41. Chunliu Zhan et al., *Medicare Payment for Selected Adverse Events: Building the Business Case for Investing in Patient Safety*, 25 HEALTH AFF. 1386, 1388–89 (2006) (assessing how much Medicare pays, under the DRG prospective payment system, for five hospital-acquired conditions, and how much of the additional costs incurred by those conditions must be absorbed by the hospital).

42. *Id.* at 1389. Postoperative sepsis occurs when a patient contracts a bacterial infection during surgery and the immune system reacts by going into overdrive. It can lead to organ failure and death if not treated quickly. See Medline Plus: Sepsis, U.S. NAT’L LIB. OF MED. & NAT’L INST. OF HEALTH, <http://www.nlm.nih.gov/medlineplus/sepsis.html> (last visited Sept. 16, 2008).

43. 42 U.S.C. § 1395ww(d)(4)(D)(ii)(1); Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. at 24,718. ICD-9-CM (International Classification of Diseases, Clinical

ditions that pose significant public health risks could not be included on this basis, although the governmental bodies responsible for promulgating ICD-9-CM codes are working to develop new codes for hospital-acquired conditions. For example, as of August 2007, ventilator-associated pneumonia was not represented by a unique ICD-9-CM code, but was included in a list of new codes that will take effect October 1, 2008.⁴⁴ Development of additional specific codes may increase the rule's scope in the future, but revising the list of ICD-9-CM codes is a complex and laborious process.⁴⁵

CMS interpreted the statutory mandate to select "reasonably preventable" conditions with some latitude. While the term could be construed as directing CMS to select conditions that could be prevented through the use of reasonable (that is, cost-effective) precautions, CMS interpreted it as license to select conditions that, for some high-risk patients, are not preventable despite consistent application of evidence-based guidelines.⁴⁶ For example, it is considered impossible to prevent the development of urinary tract infections ("UTIs") among patients who have been cathete-

Modification) is the official system to assign codes to diagnoses and hospital treatments. Classification of Disease, Functioning, and Disability, NAT'L CTR. FOR HEALTH STATISTICS, <http://www.cdc.gov/nchs/icd9.htm> (last visited Sept. 16, 2008).

44. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47,209 (Aug. 22, 2007) (stating that ventilator-associated pneumonia is not represented by a unique ICD-9-CM code, although there are twenty-seven codes for pneumonia which in some cases may be hospital acquired); Changes to the ICD-9-CM Coding System, 73 Fed. Reg. 23,579 (Apr. 30, 2008) (including ventilator-associated pneumonia as a distinct code). The agencies also created a new code for vascular catheter-associated infections, allowing CMS to select that harmful and frequent infection for inclusion. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. at 47,211.

45. See Changes to the ICD-9-CM Coding System, 73 Fed. Reg. 23,579 (Apr. 30, 2008). The ICD-9-CM Coordination and Maintenance Committee is co-chaired by the National Center for Health Statistics ("NCHS") and the Centers for Medicare and Medicaid Services CMS. In the spring and fall of each year, the committee holds public meetings to discuss proposed coding changes, consulting with organizations such as the American Hospital Association and the American Health Information Management Association. Changes must be approved by the agencies and are published on the CMS and NCHS websites in May of each year, five months before they take effect.

46. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. at 47,201 ("We are only selecting those conditions where, if hospital personnel are engaging in good medical practice, the additional costs of the hospital-acquired condition will, in most cases, be avoided."); Preventable Hospital-Acquired Conditions (HACs), Including Infections, 73 Fed. Reg. 48,474 (Aug. 19, 2008) ("the statute does not require that a condition be "always preventable" . . . but rather that it be "reasonably preventable" which necessarily implies something less than 100 percent.").

rized for more than three days.⁴⁷ As will be discussed below, CMS's selection of criteria that are not completely preventable provoked considerable protests from hospitals and health care professionals.

This combination of statutory criteria resulted in a hodgepodge of excludable conditions that bears only a glancing relationship to public health priorities. The three "serious preventable events" that CMS selected — objects left inside patients during surgery, air embolism, and providing incompatible blood — were remarkably uncontroversial.⁴⁸ They are preventable, identifiable by specific codes, and very dangerous. However, they are extremely rare, indicating that hospitals are already adept at preventing these types of events.⁴⁹

On the other hand, CMS was unable to include staphylococcus aureus bloodstream infection or ventilator-associated pneumonia,⁵⁰ despite the fact that they affect far more patients, because of the absence of unique codes to identify preventable cases of the conditions.⁵¹ Methicillin-resistant staphylococcus aureus (MRSA) and other antibiotic-resistant infections are among the most alarming and widely-discussed hospital-acquired conditions.⁵²

47. Wald & Kramer, *supra* note 31, at 2783.

48. Comment Letter, Association for Professionals in Infection Control and Epidemiology ("APIC") (June 11, 2007) [hereinafter APIC Comment Letter]. APIC and a number of other health care organizations endorsed selection of these conditions while cautioning against immediate adoption of the other infections. All Comment Letters can be found at <http://www.cms.hhs.gov/eRulemaking/ECCMSR/itemdetail.asp?filterType=dual,%20date&filterValue=90%7Cd&filterByDID=&sortByDID=1&sortOrder=ascending&itemID=CMS1201453&intNumPerPage=10>.

49. In 2006, there were 764 reported cases of Medicare patients who had an object left inside them during surgery; 45 reported cases of air embolisms; and only 33 reported cases of incompatible blood transfusions. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47,206–07 (Aug. 22, 2007).

50. Staphylococcus aureus is a bacteria that can cause serious infection, especially those strains that are immune to treatment with antibiotics. *See infra* note 52. Ventilator-associated pneumonia refers to pneumonia that develops in patients who require mechanical assistance to breathe.

51. Staphylococcus aureus septicemia affected 29,500 Medicare patients in 2006; 92,586 Medicare patients developed pneumonia as a secondary diagnosis (although it is not clear that all were on ventilators). Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. at 24,721–22.

52. MRSA is the most frequent cause of skin and soft tissue infections reported at hospital emergency rooms in the United States. It can invade the tissue to become a severe, and sometimes fatal, condition. R. Monina Klevens et al., *Invasive Methicillin-Resistant Staphylococcus aureus Infections in the United States*, 298 JAMA 1763, 1763–64 (2007).

However, MRSA was never considered as an excludable condition because it is not classified as a complication or co-morbidity and therefore does not trigger a higher payment when reported as a secondary diagnosis.⁵³ The statutory conditions thus somewhat limit the public health impact of the reimbursement rule.

B. PRESENT ON ADMISSION CODING

The success of the new CMS rule depends in part on a tedious but crucial administrative detail: the mechanics of Medicare claims processing. Until now, Medicare did not require providers to document whether a complication resulting in a secondary diagnosis developed before or after the patient entered the hospital. The new rule requires hospitals to implement present on admission (“POA”) coding to differentiate between pre-existing complications, which Medicare will continue to reimburse, and conditions acquired in the hospital.⁵⁴

In addition to enabling Medicare to withhold payment pursuant to the new rule, the POA coding requirement will provide the first nationwide data about the frequency of these hospital-acquired conditions. Unfortunately, hospitals are unlikely to have successfully implemented POA coding by the time the rule takes effect. At least in the short term, this is almost certain to result in denials of Medicare reimbursement beyond those contemplated by the rule.

The original rule required hospitals to begin collecting POA data on October 1, 2007, one year before POA status would begin to trigger denials of payment. However, CMS postponed the start date for implementing POA coding until January 1, 2008 due to technical problems with the software.⁵⁵ This left only nine months for hospitals to fully implement POA coding before the rule takes effect. The experience of New York and California, which piloted POA coding programs in recent years, demonstrated that it takes at least two years to establish a reliable coding

53. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. at 24,718.

54. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47,201 (Aug. 22, 2007).

55. Comment Letter, Society for Healthcare Epidemiology of America (“SHEA”) (June 11, 2007) [hereinafter SHEA Comment Letter]; Comment Letter, American Hospital Association (“AHA”) (June 4, 2007) [hereinafter AHA Comment Letter].

process.⁵⁶ Successfully implementing POA coding requires intensive education of physicians and other clinicians, as well as claims-processing staff. There is no evidence that CMS has offered support for expedited training, despite a report by AHRQ emphasizing the need for training resources.⁵⁷

Hospitals will face the challenge of implementing a coding innovation in a brief time period, while they simultaneously develop systems to ensure physicians are consistently applying the clinical procedures that are known to prevent hospital-acquired infections. At least initially, hospitals are likely to face significant administrative costs in training clinicians for POA coding and appealing denials based on coding errors, causing frustration among providers about “unfunded mandates.”⁵⁸ The compressed timeline for implementing POA coding systems makes it highly likely that coding problems will expose hospitals to financial penalties even when the infection is present on admission and not hospital-acquired. Fearing this, many health care providers and professionals have urged CMS to delay implementation of the rule until POA coding could be successfully implemented.⁵⁹ They also requested a process by which providers could appeal reimbursement denial decisions that were made on the basis of coding inaccuracies.⁶⁰ However, CMS declined to either delay implementation or develop a specific appeals process, asserting that current procedures allow providers to challenge denials.⁶¹

C. THE SELECTED CONDITIONS ARE NOT ALWAYS PREVENTABLE

Many of the conditions selected for exclusion are sometimes unavoidable, even with consistent application of evidence-based

56. Comment Letter, Texas Hospital Association (June 4, 2007) at 2; SHEA Comment Letter, *supra* note 55, at 3; AHA Comment Letter, *supra* note 55, at 16; Comment Letter, Hospital and Health System Association of Pennsylvania (June 11, 2007) at 7.

57. SHEA Comment Letter, *supra* note 55, at 3.

58. Comment Letter, Ohio Hospital Association (June 8, 2007) at 4. “Unfunded mandate” refers to a regulatory scheme that requires hospitals to introduce expensive innovations without providing additional funds to offset that cost.

59. *See, e.g.*, Comment Letter, California Hospital Association (June 12, 2007) at 12; AHA Comment Letter, *supra* note 55, at 16.

60. SHEA Comment Letter, *supra* note 55, at 8; APIC Comment Letter, *supra* note 48, at 8; Comment Letter, Michigan Hospital Association (June 8, 2007) at 19.

61. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47,216 (Aug. 22, 2007).

guidelines. For example, CMS acknowledged that there is no way to prevent catheter-associated UTIs when the catheter has been in place for three days or more.⁶² Therefore, the primary prevention guideline is to remove catheters as quickly as possible; yet, many patients require ongoing catheterization.⁶³ CMS brushed aside this critique, asserting that its goal was to reduce “unnecessary and inappropriate use of indwelling urinary catheters,”⁶⁴ and that the high prevalence of catheter-associated UTIs in hospitalized Medicare patients made it a “public health goal to encourage practices that will reduce” UTIs.⁶⁵ In other words, hospitals must bear the costs of non-preventable, catheter-associated UTIs as well as those they could have prevented.

Pressure ulcers, another condition selected for exclusion, are also extremely difficult to prevent in some cases. Vulnerable patients, including the elderly and those in end-of-life stages, often develop pressure ulcers despite application of prevention guidelines.⁶⁶ Providers also expressed concern about the application of Medicare rules that require all POA coding to be based exclusively on physicians’ notes and diagnoses.⁶⁷ Nurses typically perform the comprehensive, full-body admissions assessments that would discover pre-existing pressure ulcers, but their documentation cannot be the basis for POA coding.⁶⁸ Although CMS acknowledged that some pressure ulcers are “unavoidable,” it included the condition in the rule on the rationale that “improved screening to identify pressure ulcers on admission . . . will increase the quality of care.”⁶⁹ Providers worry that CMS’s refusal to create exceptions for high-risk patients, like the elderly and those in

62. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. at 47,203.

63. See SHEA Comment Letter, *supra* note 55, at 3; APIC Comment Letter, *supra* note 48, at 3. These guidelines have not been updated since 1981. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47,204.

64. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47,204.

65. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 24,719.

66. Comment Letter, New Jersey Hospital Association (June 11, 2007) at 1; SHEA Comment Letter, *supra* note 55, at 4–5.

67. SHEA Comment Letter, *supra* note 55, at 4; APIC Comment Letter, *supra* note 48, at 4; AHA Comment Letter, *supra* note 55, at 16.

68. AHA Comment Letter, *supra* note 55, at 16.

69. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47,204 (Aug. 22, 2007). CMS acknowledged but did not respond to suggestions that CMS should continue to reimburse for patients whose diagnoses qualify them as high-risk for developing pressure ulcers (such as quadriplegia, wasting syndrome, and advanced AIDS).

end-of-life stages, may penalize hospitals for treating these patients.⁷⁰

If CMS's new rule prompts hospitals to take action to significantly reduce hospital-acquired conditions, requiring hospitals to absorb the costs in rare cases where the condition was not preventable would be justified from a policy perspective. The unwarranted financial penalty would represent a minor byproduct of implementing an important and life-saving regulation. However, even if the rule does achieve its crucial objective, it will also create an additional financial constraint that hinders cash-strapped hospitals from delivering high-quality care.

IV. THE DISCONNECT BETWEEN FINANCIAL PENALTIES AND IMPROVED PATIENT OUTCOMES

The CMS rule assumes that halting reimbursement for hospital-acquired conditions will cause hospitals to step up quality control in order to avoid providing uncompensated treatment. As this Part will explain, the rule was not predicated on a close examination of the features of the health care landscape that have prevented hospitals from adequately addressing the issue on their own. Since the CMS rule bears similarities to P4P, this Part first explores the objections to P4P and evaluates their relevance to the CMS rule. It then disputes the assumption that eliminating reimbursement for hospital-acquired conditions will significantly change hospitals' financial incentive structure. Hopefully, the new rule will help promote a "culture of safety" among hospital leaders. But even if the rule motivates hospital administrators to prioritize prevention of hospital-acquired infections, they will lack the organizational knowledge to efficiently and quickly change patient care practices. Hospitals may simply respond to the new Medicare reimbursement scheme by shifting costs to private insurers.

In *Crossing the Quality Chasm*, the IOM noted that "even among health professionals motivated to provide the best care possible, the structure of payment incentives may not facilitate

70. Rosenthal, *supra* note 9, at 1574–75. The Greater New York Hospital Association urged CMS to "develop a risk-adjusted model for evaluating hospital ulcer rates." See Comment Letter, Greater New York Hospital Association (June 11, 2007) at 14.

the actions needed to systematically improve the quality of care, and may even prevent such actions.”⁷¹ The IOM encouraged the federal government to explore and evaluate payment mechanisms that recognize and reward quality and support quality improvement.⁷² Recognizing the complexity of current payment systems, the IOM urged federal healthcare agencies to consider a host of incremental policy changes that could better align reimbursement with quality.⁷³

Unfortunately, many policymakers have adopted the central premise — healthcare quality is affected by payment — without the IOM’s nuanced approach to implementing reforms. Payment and quality intersect not on a theoretical, generalizable basis, but in contradictory ways across the spectrum of healthcare delivery. The assumption that payment affects quality directly, via an invisible on-off switch, could render the new CMS rule ineffectual or even counterproductive.

A. PAY FOR PERFORMANCE: A HEALTH CARE QUALITY PANACEA?

P4P and the new CMS rule on hospital-acquired conditions share a common premise: healthcare providers will be motivated to pursue quality improvements if their payment depends on it. Yet, a number of scholars have contested the theoretical and practical validity of P4P. P4P is promoted as a groundbreaking new way to align incentives and outcomes, but it may be nothing more than re-branding of an old idea.⁷⁴ Some HMOs have been using financial bonuses and penalties for years, with uninspiring

71. *Quality Chasm*, *supra* note 21, at 181.

72. *Id.* at 182.

73. *Id.* These include blended or bundled methods of payment for providers (covering multiple providers so that some elements of care can efficiently substitute for others, e.g. home care for office visits, *id.* at 188), multiyear contracts (providing longer relationships between payers and providers to encourage collaborative investments in quality), risk adjustment (so that providers and payers benefit financially from improved quality), and alternative approaches for addressing the capital requirements necessary to improve quality.

74. Robert A. Berenson, *Separating Fact From Fiction: A New Role for Health Affairs*, 26 HEALTH AFF. 1528, 1529 (2007) (urging *Health Affairs* to lead in ensuring health policy debates are not based on misuse or distortion of evidence, and citing Pay-for-Performance as an example of marketing an old and unsuccessful idea as the newest innovation).

results.⁷⁵ This suggests that competition on quality metrics, particularly in health care, simply does not operate the way that economic theory would predict.⁷⁶

In the Premier Hospital Quality Incentive Demonstration, a CMS-funded project, P4P was not associated with a statistically significantly greater rate of improvement, in either process measures or health outcomes, when compared to the control group.⁷⁷ It is not clear whether this disappointing result reflects shortcomings in the design of the Premier model or more fundamental flaws in P4P's underlying assumptions. However, it implies that P4P's contribution to the quest for quality improvement may be limited.

There are several obstacles to translating P4P from enticing theory into effective practice. How should "performance" and "quality" be measured? There are very few nationally uniform performance measures on which incentives can plausibly be based.⁷⁸ Some health care leaders point out that even developing such measures, much less incorporating them into payment schemes, is likely to be complex.⁷⁹

The optimal level of financial incentives is also unclear.⁸⁰ Delivering excessive amounts of reimbursement in the form of incentives could lead providers to focus resources only on measurements of care that are targeted by the incentive, to the detriment of other health care needs.⁸¹ Yet, smaller incentives may be drowned out by the other economic signals embodied in the

75. *Id.*

76. See William M. Sage, *Pay-for-Performance: Will It Work in Theory?*, 3 IND. HEALTH L. REV. 305, 311 (2006) (arguing that the Pay-for-Performance "movement" lacks a coherent theory or purpose beyond frustration with current payment systems and a quality improvement objective); Vladeck, *supra* note 24, at 1351.

77. Seth W. Glickman et al., *Pay-for-Performance, Quality of Care, and Outcomes in Acute Myocardial Infarction*, 297 JAMA 2373 (2007). Researchers analyzed the differences in treatment of acute myocardial infarction (heart attack) between hospitals that applied financial incentives and a control group. They found improvement in both groups, but no greater improvement in the P4P group. This has not stopped P4P advocates and CMS officials from characterizing the Premier demonstration as a success. See Berenson, *supra* note 74.

78. Rosenthal & Dudley, *supra* note 25, at 742.

79. See Mark R. Laret, UCSF MED. CTR., Letter to the Editor, 25 HEALTH AFF. 287 (2004); Dennis S. O'Leary, JOINT COMM'N ON THE ACCREDITATION OF HEALTHCARE ORGS., Letter to the Editor, 25 HEALTH AFF. 288 (2004).

80. Milgate & Cheng, *supra* note 26, at 415.

81. For example, if bonuses are tied to surgical outcomes, it may shift attention away from nonsurgical interventions oriented towards prevention.

complex health care pricing scheme.⁸² If incentives are funded out of the general reimbursement pool rather than as additional funds, they transfer resources from low-performing hospitals, which arguably need the money most, to the hospitals that have already achieved success.

More fundamentally, the assertion that financial incentives can change physician behavior assumes that physicians will respond positively to P4P programs. This assumption may not be warranted.⁸³ Maximizing profit is only one motivation for health care providers, alongside prestige and the genuine desire to improve patients' well-being. The assumption that physicians will vary their commitment to patient care depending on the presence of a financial incentive attributes an essentially unprofessional, and indeed mercenary, quality to the entire profession.⁸⁴ This undermines another promising strategy in quality improvement: appealing to physicians' professional pride and competitiveness.⁸⁵

The CMS rule is more targeted and defined than P4P, so it avoids some of these problems. "Quality" is defined as the absence of a hospital-acquired condition. The amount of the incentive — or in this case, penalty — is the cost incurred by the hospital in treating that condition. It is not clear that amount will be enough to inspire major changes in hospitals, particularly if

82. Vladeck, *supra* note 24, at 1357–58.

83. Stephanie S. Teleki et al., *Will Financial Incentives Stimulate Quality Improvement? Reactions from Frontline Physicians*, 21 AM. J. MED. QUAL. 367, 371 (2006). An assessment of a Pay-for-Performance program launched by a private PPO (preferred provider organization) found no modification of physician practice in response to financial incentives. Many physicians perceive financial incentives as a "take-away and give-back masquerading as a bonus" since the bonuses do not add to the health plan's total payments for care. Physicians reacted with anger and suspicion to the health plan's use of financial incentives to improve quality.

84. Vladeck, *supra* note 24, at 1370.

85. *Id.* at 1365; *Quality Chasm*, *supra* note 21, at 181 ("Recognition of professional accomplishment and innovation is a strong motivator of improvement."). Vladeck, who led the Health Care Financing Administration (the predecessor of the Centers for Medicare and Medicaid Services) during the Clinton Administration, also identifies ethical problems with Pay-for-Performance. If Medicare identifies a level of quality care that is high enough to justify additional incentive payments, it seems morally indefensible to continue *any* payments to those hospitals that fail to meet that threshold. Yet, excluding hospitals from participation because they fall below certain (possibly disputed) indicators of quality could have a negative impact on Medicare beneficiaries' access to care. *Id.* at 1361–62. In contrast, Vladeck considers the binary nature of the new CMS rule on hospital-acquired conditions to be a virtue. Interview with Bruce Vladeck, Interim President, Univ. of Medicine and Dentistry of N.J., (Nov. 29, 2007).

the condition occurs infrequently, which is true for objects left inside patients during surgery, air embolism, and incompatible blood transfusions. But like P4P, the rule assumes that changing one aspect of reimbursement, while leaving the remainder of the complex healthcare financing system in place, can produce the quality improvements that have eluded healthcare providers.

B. A CLOSER LOOK AT EXISTING FINANCIAL INCENTIVES

There are reasons to be skeptical that denying payment for the costs of treating hospital-acquired conditions will quickly and effectively translate into improved treatment practices and health outcomes. Hospitals already have significant financial incentives to reduce preventable complications. What they lack, and urgently need, is proven models to implement the organizational change needed to consistently apply best treatment practices.

The theory that curtailing reimbursement for preventable hospital-acquired conditions will result in a reduction of these conditions rests on the assumption that the existing practice of reimbursement is causally related to hospitals' currently inadequate approach to patient safety. One patient safety scholar, deploring the fact that the costs of treating medical errors are not fully internalized by providers, states: "Feeling no extra financial pain, [providers] lack the incentive to track down the source of the patient injury."⁸⁶

Contrary to this belief, data suggests that hospitals do experience financial repercussions for hospital-acquired conditions. A recent study examined the costs incurred in treating Medicare patients for five preventable adverse events (including pressure ulcers, one of the conditions selected by the CMS rule).⁸⁷ Analyzing 2.5 million hospital discharges and claims data, researchers compared costs for cases with adverse events to simulated cases in which the patient was assigned to a diagnosis-related group ("DRG") as if the event had not happened, and the charge was recalculated accordingly.⁸⁸ The study found that Medicare cur-

86. Furrow, *supra* note 9, at 11.

87. Zhan et al., *supra* note 41.

88. *Id.* at 1388.

rently compensates hospitals for only 15% to 34% (depending on the type of adverse event) of additional costs.⁸⁹ Another study compared patients with central-line associated bloodstream infection (“CLAB”) to patients with identical primary diagnoses who did not develop infections.⁹⁰ Despite increased payment, hospitals suffered a net operating loss of \$26,885 for each patient that developed CLAB.⁹¹

These studies indicate that hospitals already absorb the large majority of costs generated by their failure to prevent hospital-acquired conditions, resulting in significant net losses. Therefore, the CMS rule will not create a new financial incentive for hospitals to prevent infections, but only amplify an existing one. The fact that hospitals are already subject to fiscal pressure (in addition to an organizational mission) to keep patients safe suggests that other problems, discussed below, may cause or contribute to the unacceptable rate of hospital-acquired conditions. It also raises the possibility that, rather than redoubling their efforts to keep patients safe, hospitals may resort to other mechanisms to minimize the rule’s impact.⁹²

C. CHALLENGES TO CONSISTENTLY IMPLEMENTING EVIDENCE-BASED GUIDELINES

Another reason for pessimism about the rule’s potential to significantly improve patient safety is that even where there are clinical guidelines that have been scientifically shown to prevent hospital-acquired conditions, hospital administrators face an uphill battle in ensuring that clinicians adhere to those guidelines every time they treat a patient. This may explain why hospital-acquired infections persist at unacceptable rates despite the fact that they hurt hospitals’ operating margins.

89. *Id.* at 1391.

90. Central-line infections are a subset of vascular catheter-associated infections, which are listed in the new CMS rule. Vascular catheters are inserted into blood vessels; central lines are catheters inserted into one of the major veins.

91. Richard P. Shannon et al., *Economics of Central-Line Associated Bloodstream Infections*, 21 AM. J. MED. QUALITY 7S, 14S (Supp.) (2006). The study examined government and private payers; it found no significant distinction in magnitude of financial loss when comparing Medicare and other payers. *Id.* at 15S.

92. *See infra* Part IV.D.

1. *Clinician Resistance to Clinical Guidelines*

Evidence-based medicine refers to treatment procedures that have been scientifically proven to improve health outcomes.⁹³ Each hospital-acquired condition covered by the CMS rule can be prevented, at least in most instances, by the application of an evidence-based guideline. But doctors and other medical staff often fail to follow those guidelines. Researchers have only recently begun to understand why health care practitioners, who are committed to their patients' well-being, fail to consistently execute steps that have been proven to reduce infection.⁹⁴

Physicians may disregard clinical guidelines if they are skeptical of their evidentiary foundations.⁹⁵ Studies on which clinical guidelines are based often vary widely in methodological approach, and quickly become outdated when new studies are published.⁹⁶ Other factors may subconsciously deter physicians from honoring guidelines even if they do not doubt their efficacy. Hand-washing is a straightforward and indisputably important part of infection control. Yet, one study showed poor adherence levels even though the vast majority of doctors and nurses were aware of the hand-washing guideline.⁹⁷ Clinicians' attitudes towards the hand-washing guideline were correlated with their reported compliance levels. For example, those that believed that repeated washing would chap their skin reported lower rates of compliance.⁹⁸

93. Kaveh G. Shojania & Jeremy M. Grimshaw, *Evidence-Based Quality Improvement: The State of the Science*, 24 HEALTH AFF. 138 (2005) (arguing that not only clinical decisions but also quality improvement efforts should be based on scientific evidence of effectiveness). Clinical guidelines are the mechanism for diffusing evidence-based knowledge about best treatment practices.

94. *Id.* at 141.

95. See Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 422 (2002) (noting that conflicts of interest may taint clinical guidelines, which may be authored by specialty medical societies or insurance companies).

96. *Id.* at 397 ("[P]eer review in the publication process cannot guarantee the accuracy or validity of the reported research.").

97. Dave Quiros et al., *Attitudes Toward Practice Guidelines Among Intensive Care Unit Personnel*, 36 HEART & LUNG: J. OF ACUTE & CRITICAL CARE 287 (2007).

98. *Id.* Hospitals struggle, often unsuccessfully, to ensure that clinicians wash their hands before touching patients. See Atul Gawande, *On Washing Hands*, 350 NEW ENG. J. MED. 1283 (2004) (describing the ongoing, unsuccessful, efforts of his hospital's infection control staff to promote consistent hand-washing by clinical staff); Didier Pittet et al., *Hand Hygiene Among Physicians: Performance, Beliefs, and Perceptions*, 141 ANN.

The obstacles to consistently implementing evidence-based treatment guidelines may operate at both the physician and hospital level, and are likely to vary depending on the guideline and the context. While the factors — economic, organizational, or social — that hinder efforts to change clinician behavior have been studied, researchers are still far from understanding which interventions have the most impact on specific settings and types of clinicians.⁹⁹ Most studies document only moderate, incremental improvements in care following each intervention.¹⁰⁰ Further, the literature is dominated by descriptions of improvement efforts in single institutions using before-and-after study design, making it difficult to attribute improvements to the intervention.¹⁰¹

2. *Common-Sense vs. Evidence-Based Solutions to Medical Error*

Some patient safety experts contend that a medical system which requires evidence-based protocols for medical treatment should also base systems-level strategies on proven efficacy.¹⁰² Interventions based on untested assumptions may waste scarce resources on ineffective programs or produce unintended harmful consequences.¹⁰³ Others counter that the level of preventable medical errors has reached a crisis that requires immediate adoption of common sense solutions, despite the lack of data evaluating those approaches.¹⁰⁴ These advocates argue that studies evaluating prevention of medical errors are costly and difficult; surely a study is not needed to confirm that standardization and simplification of processes, for example, will reduce error.¹⁰⁵

INTERNAL MED. 1 (2004) (finding a 57% hand-washing compliance rate and noting factors that were associated with adherence and nonadherence).

99. Richard Grol & Michel Wensing, *What Drives Change? Barriers to and Incentives for Achieving Evidence-Based Practice*, 180 MED. J. AUSTL. S57, S59 (2004) (proposing that barriers and incentives affecting absorption of clinical guidelines be analyzed at the level of the patient, physician, and innovation itself, with reference to the organizational, social, political and economic context).

100. Jeremy M. Grimshaw and Martin P. Eccles, *Is Evidence-Based Implementation of Evidence-Based Care Possible?*, 180 MED. J. AUSTL. S50 (2004).

101. Shojania & Grimshaw, *supra* note 93, at 141.

102. *See id.*

103. Andrew D. Auerbach et al., *The Tension Between Needing to Improve Care and Knowing How to Do It*, 357 NEW ENG. J. MED. 608 (2007).

104. Lucian L Leape et al., *What Practices Will Most Improve Safety?*, 288 JAMA 501, 505–06 (2002).

105. *Id.*

One illustration of this debate is the recent reduction in work hours for medical residents. This reduction was based on restrictions on work hours in other occupations, such as aviation, where errors can be fatal.¹⁰⁶ There is only tentative evidence indicating that the work hour reduction has improved patient care outcomes.¹⁰⁷ The urgency of reducing medical error, coupled with the obvious premise that exhaustion and fatigue increase error rates, compelled reform despite the absence of incontrovertible proof of efficacy. Yet, where the impetus for reform must come from an individual hospital, rather than occurring at a national level, the lack of evidence-based solutions undermines the ability of patient safety advocates and infection control specialists to gain approval for costly interventions.¹⁰⁸

3. *Inadequate Resources at the Hospital Level*

The new CMS rule applies financial pressure to force hospitals to quickly increase clinician compliance with clinical guidelines despite a dearth of reliable data to inform their strategy. The Ohio Hospital Association protested this discrepancy in a letter to CMS: “CMS is setting a wrong precedent by establishing a system that is punitive . . . without any clear indication about how the decisions will be translated into proactive, educational activities to ensure a problem is not repeated.”¹⁰⁹

Hospital financial and organizational constraints virtually guarantee that hospitals will not discover effective implementation strategies on their own. Because infection control efforts cost

106. *Id.* at 506; see Thomas R. McLean, *The 80-Hour Week*, 26 J. LEGAL MED. 339 (2005) (concluding that one implication of reduced physician hours will be greater reliance on “physician extenders” — healthcare workers with less training, such as respiratory therapists, physical therapists, and physician assistants); Jennifer F. Whetsell, *Changing the Law, Changing the Culture: Rethinking the “Sleepy Resident” Problem*, 12 ANNALS HEALTH L. 23 (2003) (analyzing New York’s restrictions on resident hours); Dori Page Antonetti, *A Dose of Their Own Medicine: Why the Federal Government Must Ensure Healthy Working Conditions for Medical Residents and How Reform Should Be Accomplished*, 15 CATH. U. L. REV. 875 (2002).

107. Auerbach et al., *supra* note 103, at 608.

108. See Eli N. Perencevich et al., *Raising Standards While Watching The Bottom Line: Making a Business Case for Infection Control*, 28 INFECTION CONTROL & HOSP. EPIDEMIOLOGY 1121 (2007) (discussing the need to make a “business case” to hospital administrators to gain approval for new infection control programs; including cost-benefit analysis to project future savings to be gained by introducing effective programs).

109. Comment Letter, Ohio Hospital Association (June 8, 2007) at 3.

money but do not generate direct reimbursement, many hospitals have downsized infection control programs in recent years.¹¹⁰ One survey of nonprofit hospitals found that 30% had less than the recommended level of one full-time infection control professional per 100 patient beds, and only one out of thirty-one provided the data management support necessary for effective surveillance and monitoring of infection.¹¹¹ The most frequently cited obstacle to success was lack of resources.¹¹² In addition, the lack of data assessing the cost-effectiveness of different infection-control strategies may discourage hospitals from investing in innovative measures.¹¹³

D. UNINTENDED CONSEQUENCES: COST SHIFTING

Hospitals must already find ways to balance the operating losses that result from systematic Medicare underpayments, and they may use those strategies to blunt the effect of the new reimbursement rule. Medicare paid only 95 cents for every dollar of incurred hospital costs in 2002.¹¹⁴ To maintain positive operating margins that allow them to invest in new technology and maintain infrastructure, hospitals must increase the prices charged to private payers (which pass them on to patients as premium increases), in a phenomenon known as cost-shifting.¹¹⁵ The ability to shift costs to private insurers depends on hospitals' market power. Hospitals absorb some of their Medicare losses by becom-

110. Perencevich et al., *supra* note 108, at 1121; Marly Christenson et al., *Improving Patient Safety: Resource Availability and Application for Reducing the Incidence of Health care-Associated Infection*, 27 INFECTION CONTROL & HOSP. EPIDEMIOLOGY 245 (2006) (reporting a descriptive study of the resources, infrastructure, and procedures used by infection control departments to combat hospital-acquired conditions, within a network of nonprofit community-based hospitals).

111. Christenson et al., *supra* note 110, at 248.

112. *Id.* at 247.

113. Perencevich et al., *supra* note 108, at 1129. Grimshaw & Eccles, *supra* note 100, at S50 (indicating that less than one-third of studies report the costs of the implementation program).

114. Allen Dobson et al., *The Cost-Shift Payment 'Hydraulic': Foundation, History, and Implications*, 25 HEALTH AFF. 22, 25 (2006) (positing cost-shifting as an integral part of the health care financing system).

115. *Id.*; Paul B. Ginsburg, *Can Hospitals and Physicians Shift the Effects of Cuts in Medicare Reimbursement to Private Payers?*, HEALTH AFF. W3-472 (2003) (web exclusive) (explaining the economic basis for cost shifting and how it fluctuates under different market conditions).

ing more efficient or reducing services, but they have a limited and diminishing ability to absorb losses associated with treating Medicare patients, and tend to shift the remaining costs to private payers whenever possible.¹¹⁶ This raises insurance premiums, pricing some consumers out of the private market for health care. The growth of managed care in the 1990s undermined hospitals' market power, but recent consolidation in the hospital industry has renewed hospitals' ability to shift costs to private insurers.¹¹⁷

The hospital-acquired conditions rule is far narrower than the major Medicare payment modifications that have, in the past, corresponded with significant declines in hospital operating margins. Perhaps this will limit the degree to which hospitals respond by shifting costs. If practical steps to reduce hospital-acquired conditions are well-known and straightforward, the incentives may work as intended. Yet, if the current market supports cost-shifting, this strategy may appear more effective than struggling to reduce infections. If the reimbursement rule results only in cost-shifting, it will fail to improve patient care.

A number of private insurers, following in Medicare's footsteps, are renegotiating their contracts with providers to preclude payment for costs related to hospital-acquired conditions.¹¹⁸ This raises the prospect that individual patients will be billed for those costs. Medicare regulations prevent hospitals from billing any beneficiaries for the non-reimbursable costs of hospital-acquired conditions,¹¹⁹ but privately-insured patients may not be similarly protected. Insurers say they are structuring contracts with hospitals to include similar patient protections, but the prevalence of billing errors have led some patient advocates to be wary of these assurances.¹²⁰ If the sudden halt in reimbursement prompts renewed and successful patient safety efforts, private insurers' adoption of the CMS rule could be productive, but if individual patients end up shouldering the cost of their preventable compli-

116. Dobson et al., *supra* note 114, at 26.

117. *Id.* at 27–28; Ginsburg, *supra* note 115, at W3-478.

118. Vanessa Fuhrmans, *Insurers Stop Paying for Care Linked to Errors; Health Plans Say New Rules Improve Safety and Cut Costs; Hospitals Can't Dun Patients*, WALL ST. J., Jan. 15, 2008, at D1.

119. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47,201 (Aug. 22, 2007).

120. Fuhrmans, *supra* note 118.

cations, the rule will exacerbate the burden on those it is intended to protect.

E. HOSPITAL CULTURE AND THE WILL TO CHANGE

Despite the ample grounds for pessimism about the real-life impact of the new rule on hospital-acquired condition reimbursement, it may help surmount an important barrier to implementing patient safety protocols: the culture of hospitals. Physicians' fierce commitment to maintaining their professional autonomy has posed a challenge for those who would limit their individual discretion by requiring adherence to strict protocols.¹²¹ Few hospital executives have displayed bold leadership in pioneering the systems changes that are needed for patient safety.¹²² The new rule, by specifically targeting hospital-acquired conditions, alerts executives to the possibility that Medicare funding may be imperiled unless they focus on this problem. It could, therefore, play an incremental role in prompting hospital leaders to take more aggressive action to implement systems redesigns, overcoming physician resistance if necessary. Unfortunately, that impulse to act may be less fruitful if executives are left to grope blindly for effective interventions.

V. PROPOSAL: A COMPREHENSIVE FEDERAL PATIENT SAFETY RESEARCH AGENDA

The CMS rule prohibiting reimbursement for hospital-acquired conditions is likely to fail as an incentive because it is based on the erroneous assumption that providers are insufficiently motivated to prevent infection. In fact, the financial and professional incentives to keep patients safe already exist. Even if the rule enhances that incentive, relying on hospitals to find their own path toward improved patient safety is unlikely to be effective due to the scarcity of proven implementation models for consistent application of clinical guidelines. Thus, if Congress is truly committed to reducing hospital-acquired conditions, it must supplement the new CMS rule's financial incentives with re-

121. Leape & Berwick, *supra* note 1, at 2387.

122. *Id.* at 2388.

sources to guide hospitals in responding to the rule. This can be accomplished through an existing governmental resource: AHRQ.

As a preliminary matter, the agency's funding must be substantially increased. With adequate resources, AHRQ can provide needed leadership on three essential projects: data collection on a nation-wide scale that can be used to analyze the root causes of, and most promising approaches to, medical error; standardization and validation of clinical guidelines used by physicians; and evaluation of strategies to boost systematic application of these guidelines at the hospital level. If the federal government is serious about preventing hospital-acquired conditions and other patient safety problems, it must change AHRQ's orientation and resources to advance a more aggressive research agenda.

A. AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

The AHRQ's mission is to "enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health system practices" ¹²³ In its original incarnation, as the Agency for Healthcare Policy and Research, the agency promulgated clinical guidelines. ¹²⁴ However, at the behest of then-administrator John Eisenberg, the 1999 reauthorization deleted these provisions and launched AHRQ's new role as a "science partner" to the medical community. ¹²⁵ In that capacity, AHRQ grants funding for research into patient safety, health information technology, care management, pharmaceutical outcomes, and other topics. ¹²⁶ Just as the National Institutes of Health ("NIH") steers national research on the best ways to treat specific illnesses, AHRQ's role is to identify prescriptions for health care processes.

123. 42 U.S.C. § 299 (1999).

124. See Stockham, *supra* note 33, at 1057.

125. See § 299a-1 (noting deletion of prior provision "related to dissemination of research, demonstration projects, and evaluations"); *Reauthorization of the Agency for Health Care Policy and Research: Hearing before the Subcomm. on Health and Env't of the H. Comm. on Commerce*, 106th Cong. 24 (1999) (testimony of John M. Eisenberg, Administrator, Agency for Health Care Policy and Research).

126. Agency for Health Care Research and Quality, *AHRQ Portfolios of Research* (2005), <http://www.ahrq.gov/fund/portfolio.htm>.

B. NATIONAL DATABASE FOR PATIENT SAFETY RESEARCH

A national database of patient safety information would allow healthcare researchers to assess the frequency of medical errors, analyze their root causes, and identify the providers who have been most successful in improving patient safety so their strategies can be replicated.¹²⁷ In 2001, the IOM advocated a nationwide system for reporting errors that lead to death and serious injury.¹²⁸ Instead, multiple medical error disclosure regimes, with competing objectives, have developed.

The Joint Commission on the Accreditation of Health Care Organizations (“JCAHO”) is in the strongest position to implement an effective regime for reporting medical errors. Hospitals that do not comply with JCAHO requirements risk losing Medicare funding, so JCAHO could enforce mandatory, confidential reporting as a condition of accreditation.¹²⁹ However, JCAHO’s existing policy is widely regarded as ineffective and has not resulted in the aggregation of national patient safety data.¹³⁰

127. Joel L. Weissman et al., *Error Reporting and Disclosure Systems: Views from Hospital Leaders*, 293 JAMA 1359, 1365 (2005).

128. *IOM Report*, *supra* note 15, at 86–88.

129. Compliance with JCAHO accreditation requirements satisfies Medicare’s conditions for participation.

130. JCAHO requires reporting of “sentinel events,” and the reporting system is hindered by the broad definition of “sentinel events,” which is not coextensive with that of preventable medical error. A sentinel event is defined as “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.” Joint Commission on the Accreditation of Health Care Organizations, *Sentinel Event Policy and Procedures*, http://www.jointcommission.org/SentinelEvents/PolicyandProcedures/se_pp.htm (last visited Sept. 16, 2008). JCAHO is also notoriously reluctant to actually withdraw accreditation, making its “requirements” somewhat toothless. Of 3,000 sentinel events reported between 1995 and 2004, only 63% were reported by the accredited organizations, with the remainder reported by the media or other sources. Leigh Ann Lauth, *The Patient Safety and Quality Improvement Act of 2005: An Invitation for Sham Peer Review in the Health Care Setting*, 4 IND. HEALTH L. REV. 151 (2007); *see also* Maxine M. Harrington, *Revisiting Medical Error: Five Years After the IOM Report, Have Reporting Systems Made A Measurable Difference?*, 15 HEALTH MATRIX 329, 360 (2005) (discussing the lack of a uniform definition of medical error, and the disincentives for disclosure embedded in many reporting systems); Furrow, *supra* note 9, at 13–14. *But see* Michelle M. Mello et al., *Fostering Rational Regulation of Patient Safety*, 30 J. HEALTH POL. POL’Y & L. 375 (2005) (discussing the pluralistic regulatory environment for patient safety, and crediting JCAHO with becoming interested in patient safety before *To Err Is Human* was published and surmising that the standards are at least somewhat helpful).

Several states have stepped in to legislate mandatory disclosure of medical errors.¹³¹ Mandatory reporting statutes have been critiqued as ineffective, and research has shown that underreporting is the norm.¹³² Disclosure statutes are based on a theory that consumer choice drives competition between providers to improve quality.¹³³ This premise — which assumes that health care consumers will consult available information about rates of hospital-acquired infections and use the information in choosing providers — is fatally flawed.¹³⁴ There is little empirical data showing that disclosure statutes actually drive down medical error rates or make healthcare markets more efficient.¹³⁵ The den-

131. Harrington, *supra* note 130, at 362. As of November 2006, twenty-five states had some form of mandatory disclosure law. Dayna C. Nicholson & Lynsey A. Mitchel, *A Medical Error Happened: Now What? The Implications for Medical Errors Heat Up*, 1 J. HEALTH CARE COMPLIANCE 5 (2008). For example, Pennsylvania's statute requires reporting of serious events to both the state and to patients, and imposes penalties for failures to report medical errors. It also requires hospitals to disclose specific hospital-acquired infections and publishes each hospital's rate of infection; includes whistleblower protection that allows health care workers to anonymously report events; and immunizes documents provided to the state's health care authority from discovery in most litigation. Medical Care Availability and Reduction of Error Act, 40 PA. STAT. ANN. § 1303 (2002); see Barry R. Furrow, *Medical Mistakes: Tiptoeing Towards Safety*, 3 HOUS. J. HEALTH L. & POL'Y 181, 213–216 (2003) (discussing Pennsylvania's law). PENNSYLVANIA HEALTH CARE COST CONTAINMENT COUNCIL, HOSPITAL-ACQUIRED INFECTIONS IN PENNSYLVANIA (2006), <http://www.phc4.org/reports/hai/05/docs/hai2005report.pdf>; see also Michael M. Peng et al, *Adverse Outcomes From Hospital-Acquired Infection in Pennsylvania Cannot Be Attributed to Increased Risk on Admission*, 21 AM. J. MED. QUALITY 17S (2006).

132. Harrington, *supra* note 130, at 364–66; Furrow, *supra* note 131, at 204; Weissman et al., *supra* note 127, at 1369 (discussing a recent survey of hospital administrators finding that over two-thirds believed that mandatory, non-confidential reporting systems discouraged honest reporting of errors and led to a greater number of lawsuits; twenty-three percent thought the reporting requirements in their state were unclear).

133. The “report card” that the Pennsylvania Health Care Containment Council publishes, based on the information hospitals are required to disclose, is one example. See PENNSYLVANIA HEALTH CARE COST CONTAINMENT COUNCIL, *supra* note 131; Kristin Madison, *Regulating Health Care Quality In an Information Age*, 40 U.C. DAVIS L. REV. 1557, 1590–91 (2007) (discussing information imperfections in the health care market, and citing Pennsylvania's statute as an example of a market-facilitating regulatory approach, in contrast to market-displacing or market-channeling regulations).

134. A national public-private partnership aimed at increasing voluntary hospital reporting of quality data is also premised on consumer use of healthcare data. See Voluntary Hospital Quality Data Reporting, 73 Fed. Reg. 23,643 (Apr. 30 2008) (describing a partnership between a plethora of acronym-identified agencies and organizations including CMS, AHRQ, AARP, AMA, AFL-CIO, to make data available on the *Hospital Compare* website, to be used by consumers selecting hospitals).

135. The Health Care Infection Control Practices Advisory Committee (HICPAC), which advises HHS and the CDC on infection control, recently evaluated mandatory reporting statutes. HICPAC found no evidence that public disclosure of infection rates were effective in reducing hospital-acquired infections. HICPAC declined to recommend for or

sity and complexity of healthcare quality data, combined with prevalent cognitive biases that distort health care decision-making, defeat consumer-oriented reporting regimes.¹³⁶

Rather than providing information to consumers, medical error reporting should be designed to collect information for analysis. The federal government took a step toward this goal in 2005, with the Patient Safety and Quality Improvement Act (“PSQIA”).¹³⁷ PSQIA encourages voluntary reporting by shielding providers from legal liability related to patient safety data.¹³⁸ But PSQIA is entirely voluntary — it merely encourages hospitals to release patient safety data to licensed Patient Safety Organiza-

against public reporting, but established best-practice guidelines for states choosing to implement disclosure statutes (such as selecting appropriate patient populations for monitoring; choosing process and outcomes measures; risk adjustment; and validation of data). Linda McKibben et al., *Guidance on Public Reporting of Health care-Associated Infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee*, 33 AM. J. INFECT. CONTROL 217 (2005). As for market efficiency, a few informed consumers who diligently shop for quality can theoretically influence the market even if most remain uninformed. But health care is hardly a conventional product. The health care market’s segregation along geographic, diagnosis-related, and demographic lines reduces the spillover effect of a minority of sophisticated quality-shoppers. Madison, *supra* note 133, at 1620–21.

136. Judith H. Hibbard & Jacquelyn J. Jewett, *Will Quality Report Cards Help Consumers?*, 16 HEALTH AFF. 218, 220–21, 225 (1997). The quality information that consumers describe as most salient in the abstract is not always the information they actually consider when choosing health plans. Consumers appear to rely more on patient satisfaction rates, which they can comprehend, than they do on more objective (but often baffling) clinically-based data. Although this research analyzes report cards for helping consumers choose insurers, rather than medical providers, cognitive biases are likely to similarly undermine the utility of provider report cards. See William Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701, 1728–30 (1999) (citing studies showing that large proportions of English-speaking patients are unable to comprehend standard health-related materials; that Medicare beneficiaries mostly lack the knowledge to make informed decisions between coverage options; and that people dismiss health information when they are healthy but over-emphasize it when they are ill).

137. 42 U.S.C. § 299b-21 *et. seq.*; see, e.g., 151 Cong. Rec. H6673, H6677 (daily ed. July 27, 2005) (statement of Rep. Brown) (“The consequences of reporting medical errors can be onerous, which deters some who commit or witness medical errors from documenting them. This legislation is intended to overcome that obstacle. To reduce the number of medical errors, we need to understand what causes them and address those causes. Accurate and complete information on medical errors is the first step.”).

138. Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (2005); § 299b-21 *et. seq.*; see Charles M. Key, *A Review of the Patient Safety and Quality Improvement Act of 2005*, 18 J. Health L. 20 (2005); Robert A. Kerr, *The Patient Safety and Quality Improvement Act of 2005: Who Should Pay for Improved Outcomes?*, 17 HEALTH MATRIX 319, 329–31 (2007) (noting that the PSQIA does not provide funding for PSOs, and prevents HMOs from sponsoring PSOs; the author argues that pharmaceutical companies should fund PSOs).

tions (“PSOs”) by immunizing such data from discovery.¹³⁹ Absent mandated disclosure, information is under-produced because the cost of producing it falls on one hospital while the benefits of the information are available to the public, and the structural peculiarities of health care aggravate this tendency.¹⁴⁰ Disclosure laws can rectify this asymmetry and produce reliable, consistent data from which to construct effective interventions to reduce hospital-acquired infections. To do so, however, disclosure must be mandatory.

The PSQIA appears primarily designed to encourage individual providers to work with the PSO of their choice to tackle their particular patient safety improvement objectives, and to allow PSOs to analyze the data they receive from providers. A deeper understanding of medical errors depends on collecting *all* the data from the various PSOs.¹⁴¹ To that end, the PSQIA also calls for the creation of a Network of Patient Safety Databases to aggregate patient safety information from PSOs.¹⁴² By providing researchers with a single, comprehensive data source on medical error, this national data depository has the capacity to be the federal government’s greatest contribution to patient safety.

Unfortunately, this achievement remains merely theoretical. As of this writing, the Secretary of Health and Human Services

139. § 299b-22. With a few exceptions, patient safety work product is not subject to discovery or subpoena in state, federal, civil or criminal proceedings; nor is it admissible in disciplinary proceedings conducted by state professional bodies. For further discussion on how legal liability deters health care providers from sharing quality and safety information, and the function of the PSQIA, see Bryan A. Liang, *Collaborating on Patient Safety: Legal Concerns and Policy Requirements*, 12 WIDENER L. REV. 83 (2005).

140. Sage, *supra* note 136, at 1771 (citing a lag in communications and data management in healthcare compared to other industries, regulatory interventions that discourage innovation, and “competitively sheltered hegemony of the medical profession”).

141. The government has estimated that 100 PSOs will apply for certification over an initial three year period. See Agency Information Collection Activities, 73 Fed. Reg. 9337 (Feb. 20, 2008) (inviting comment on AHRQ’s proposed request to the Office of Management and Budget to begin collecting information from PSOs in order to certify them pursuant to PSQIA).

142. § 299b-23. This statute states,

The Secretary shall facilitate the creation of, and maintain, a network of patient safety databases that provides an interactive evidence-based management resource for providers, patient safety organizations, and other entities. The network of databases shall have the capacity to accept, aggregate across the network, and analyze nonidentifiable patient safety work product voluntarily reported by patient safety organizations, providers, or other entities.

This information “shall be used to analyze national and regional statistics, including trends and patterns of health care errors.” *Id.*

has yet to finally establish the process for certifying PSOs.¹⁴³ Although the PSQIA was passed in 2005, no PSO has been certified and the data collection process has yet to begin. Moreover, the legislation gives the Secretary full discretion to determine whether the national database may be used for research purposes.¹⁴⁴ The advent of a national database for medical error information, and its use for extensive research by healthcare experts, is urgently needed to identify and surmount the barriers hospitals face in preventing hospital-acquired conditions. The federal government should expedite the certification of PSOs and reach out to providers to encourage their participation. AHRQ should be granted enough resources to establish the national database as quickly as possible and allow qualified experts to access the information for much-needed research.

C. STANDARDIZING CLINICAL GUIDELINES

The lack of standardized, universally accepted treatment guidelines, firmly supported by scientific evidence, is a significant obstacle to the prevention of hospital-acquired conditions and other medical errors.¹⁴⁵ The IOM turned its attention to this problem in a recent report, *Knowing What Works in Health Care*.¹⁴⁶ The report recognized that physicians' individual expertise should be applied in a manner consistent with information from scientific research. The report further found that processes supporting more accurate identification of what treatment is appropriate for each patient can have profound implications for containing the escalating costs of health care.¹⁴⁷

Developing a process to ensure that clinical guidelines are rooted in reputable evidence would also have implications for hospital-acquired infections. For reasons discussed above, hos-

143. On April 21, 2008, the AHRQ extended the period for members of the public to comment on its proposal regarding the forms by which PSOs could apply for certification. Agency Information Collection Activities, 73 Fed. Reg. 21349 (Apr. 21, 2008).

144. § 299b-23 ("The Secretary shall assess the feasibility of providing for a single point of access to the network for qualified researchers for information aggregated across the network and, if feasible, provide for implementation.")

145. See *supra* Part IV.C.

146. COMM. ON REVIEWING EVIDENCE TO IDENTIFY HIGHLY EFFECTIVE CLINICAL SERVICES, INST. OF MED., *KNOWING WHAT WORKS IN HEALTH CARE* (Jill Eden et al. eds., 2000).

147. *Id.* at 3, 33.

pitals' efforts to ensure that physicians consistently adhere to clinical guidelines, such as those that are proven to reduce catheter-associated UTIs or pressure ulcers, are undermined by clinicians' skepticism of guidelines generally. Physicians cannot assume that the underlying studies were conducted with rigorous methodologies or represent the most current data available.

The IOM called for establishing a national clinical effectiveness program to prioritize competing evidence assessment projects, conduct methodical reviews of available evidence, and endorse the resulting clinical guidelines.¹⁴⁸ The report emphasizes the need to systematically analyze the body of evidence regarding clinical effectiveness and to interpret the strength of the findings with reference to the quality of the individual studies that comprise it.¹⁴⁹ A national system for creating and updating clinical guidelines, along the lines suggested by the IOM, is a needed component of a long-term strategy to improve health care quality.

D. INTERVENTIONS TO REDUCE HOSPITAL-ACQUIRED CONDITIONS: THE KEYSTONE PROJECT

As discussed above, even when clinical guidelines are supported by rigorous science, ensuring that they are applied every day, with every patient, remains extremely difficult. Hospitals, then, need *operational* guidelines — systems proven to increase clinicians' compliance with the treatment processes that reduce infections. AHRQ has already played a supporting role in the most promising research to date in this area by providing a matching grant to the Keystone: ICU project.¹⁵⁰ This innovative collaboration between the Michigan Health and Hospital Association ("MHA") and Johns Hopkins University has achieved remarkable reductions in central line-associated infections in over

148. *Id.*

149. *Id.* at 6–7.

150. This is one of six grants AHRQ has provided to evaluate systems-related best practices. See Dwight McNeill et al., *Beyond the Dusty Shelf: Shifting Paradigms and Effecting Change*, in *ADVANCES IN PATIENT SAFETY: FROM RESEARCH TO IMPLEMENTATION*, Vol. 3, at 384. Agency for Health care Research and Quality, AHRQ Publication No. 05-0021-3, 2005.

one hundred intensive care units (“ICUs”) across Michigan.¹⁵¹ The Keystone intervention targeted clinician adherence to five evidence-based processes that reduce vascular catheter-related infections, focusing on the processes that have the highest impact and are the easiest to implement.¹⁵²

One of the most obvious reasons that clinicians fail to consistently apply procedures proven to prevent hospital-acquired conditions is that they are busy and overwhelmed with seemingly more pressing tasks. The Keystone team deployed several strategies to keep clinicians focused: education about the harm that results from catheter-associated infections; a checklist where staff must note compliance with each guideline when a central line is inserted; a practice whereby nurses and physicians intervened if they observed a colleague violating a guideline; discussion at daily rounds of whether patients’ catheters were ready for removal; and monthly feedback on each ICU’s rates of infection.¹⁵³

The checklist, a technique adapted from aviation safety, reminds physicians to take steps that could be forgotten in the face of more urgent clinical tasks. It also reinforces clinicians’ recognition that seemingly mundane steps, such as draping a patient’s entire body with a sterile barrier, are minimum expectations in the treatment procedure.¹⁵⁴ The intervention succeeded in dramatically reducing the average rate of central line infections, from 7.7 per 1000 catheter-days to 1.4.¹⁵⁵ Both teaching and non-teaching hospitals, large and small, saw up to 66% reductions in

151. See Michigan Health & Hospital Association, KeyStone: ICU, http://www.mha.org/mha_app/keystone/icu_overview.jsp (last visited Aug. 27, 2008). CMS rule covers central-line infections, which are a subset of vascular catheter infections.

152. See Peter Provonost et al., *An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU*, 355 NEW ENG. J. MED. 2725, 2726 (2006) (describing the Keystone intervention and its clinical results). The five procedures are hand-washing, using full barrier precautions when inserting catheters into central lines, cleaning the skin with chlorhexidine, avoiding the femoral vein, and removing catheters as soon as they became clinically unnecessary.

153. *Id.* at 2726–27.

154. Atul Gawande, *The Checklist*, THE NEW YORKER, Dec. 10, 2007, at 91–92. The Keystone intervention prompted systems-level changes even before it was fully implemented. When the study was initiated, only 19% of Michigan ICUs stocked the antiseptic that clinical guidelines recommend using to disinfect the skin before inserting the catheter, in their central line kits. Within six weeks of the letter inviting hospitals to participate in the project and detailing the clinical guidelines, 64% of ICUs included the antiseptic, chlorhexidine, in the kits. Provonost et al., *supra* note 152, at 2729.

155. Provonost et al., *supra* note 152, at 2725. This reduction refers to the mean rate. The reduction in the median rate of infection was from 2.7 to 0.

infections.¹⁵⁶ Most importantly, this improvement was sustained over the eighteen month period after the intervention began.¹⁵⁷

This is an exciting development, although further research is needed to strengthen the Keystone findings. The lack of a randomized study design makes it slightly more difficult to confidently attribute the reduction in infection rates to the intervention, although the steep decline in infection rates was not observed in nonparticipating hospitals.¹⁵⁸ The study also does not shed light on which aspects of the multifaceted intervention were most effective, a question that could be explored in randomized trials.¹⁵⁹ Finally, the cost of the intervention was subsidized by AHRQ and MHA, and the study provides no estimated per-hospital implementation costs.¹⁶⁰ Individual hospitals might be more willing to replicate this intervention without financial assistance if they could predict its cost.¹⁶¹ While further research is required, the Keystone project has already demonstrated an evidence-based approach for reducing vascular-catheter infections that has saved lives across the state of Michigan. The federal government should take steps to extend the model and apply it to the prevention of other hospital-acquired conditions.

E. ADJUSTING AHRQ'S ROLE TO GENERATE IMPLEMENTATION SOLUTIONS

The Keystone project, which is expanding to also focus on hand hygiene and reduction of catheter-associated UTIs (also a target of the CMS rule), provides an exciting model for large-scale evaluation and implementation of interventions to reduce hospital-acquired infections. Keystone was spearheaded by Peter Pro-

156. *Id.* at 2729–31.

157. *Id.* at 2729.

158. *Id.* at 2730.

159. *Id.* at 2731.

160. *Id.* at 2730.

161. Unfortunately, plans by Johns Hopkins researchers to extend the Keystone project to hospitals in New Jersey and Rhode Island were recently halted by the Office for Human Research Protections. The agency determined that recording the results of the intervention amounted to a modification in medical care that, without informed consent from patients, violated research ethics. Atul Gawande, *A Lifesaving Checklist*, N.Y. TIMES, Dec. 30, 2007, at 8. Protecting the dignity and privacy of individuals involved in research is vital; hopefully the project can quickly adapt and receive authorization to proceed in additional states.

vonost, a Johns Hopkins researcher, and the MHA,¹⁶² but AHRQ could be a driving force in replicating this model in other states and with respect to other hospital-acquired conditions. The MHA played a key facilitating role in convening a large number of hospitals, enabling researchers to collect more reliable, transferable data than the results generated by single-site studies. By offering substantial funding for organizations that focus on reducing targeted hospital-acquired conditions, AHRQ could stimulate other state hospital associations, health departments, or private employer groups to emulate MHA in launching large-scale projects.

Sadly, AHRQ's current funding and orientation do not allow it to play this kind of leadership role in reducing hospital-acquired conditions. AHRQ's budget is neither large enough nor focused on the systems-level challenges that result in hospital-acquired conditions.¹⁶³ AHRQ receives a little over \$300 million dollars, compared to the \$28 billion that the NIH receives annually to fund traditional biomedical research.¹⁶⁴ Funding for "general patient safety" research, which includes implementation strategies for improving clinical guideline adherence and reducing hospital-acquired infections, is miniscule, especially in light of the morbidity and mortality rates attributed to medical error.¹⁶⁵

Most of the \$94 million requested for patient safety research in fiscal year 2008 was designated for specific initiatives, which do not include implementation strategies.¹⁶⁶ Since 2004, AHRQ funding for patient safety research has been almost exclusively focused on health information technology.¹⁶⁷ This may reflect a tendency to search for magic bullets, rather than incremental but

162. See Gawande, *supra* note 154, at 92.

163. Donald Berwick, a leading authority on patient safety, has called for AHRQ's budget to be "billionized." See, e.g., Berwick, *supra* note 21, at 88.

164. See AHRQ Justification of Estimates for Appropriations Committees, FY 2008, available at <http://ahrq.gov/about/cj2008/cj2008.pdf>; National Institutes of Health, NIH Budget, <http://www.nih.gov/about/budget.htm> (last visited Aug. 27, 2008).

165. The budget request for FY 2007 included less than six million dollars for general patient safety research. FY 2008 includes a fifteen million dollar increase in this section of the budget, but it is entirely earmarked for a Personalized Health Care Initiative. AHRQ, *supra* note 164.

166. AHRQ, *supra* note 164.

167. Leape & Berwick, *supra* note 1, at 2385.

ultimately more profound improvements.¹⁶⁸ Innovations such as computerized physician order entry are intended to harness cutting-edge technologies to reduce physician error. IT-based solutions that promise to radically modernize health care generate tremendous excitement, but often fail to deliver.¹⁶⁹ Even successful IT programs cannot solve every systems challenge that leads to unnecessary infections.¹⁷⁰

The few AHRQ grants that fund studies of systems-level changes to implement clinical guidelines have focused on disseminating new evidence-based knowledge, rather than the challenges of incorporating that knowledge into practice.¹⁷¹ If AHRQ is to galvanize patient safety research, its role must change. AHRQ is a traditional research institution: scientists develop and test hypotheses and publish the results, but their work only indirectly influences health outcomes if referenced by end users such as health care providers.¹⁷² Research priorities that are driven by the information needs of health care providers will be most effective in improving patient safety. Targeting grants to find implementation strategies for preventing hospital-acquired conditions represents a shift to this kind of demand-side model. If the federal government genuinely wants to reduce hospital-acquired infections, Congress should not rely on reimbursement penalties alone, but also provide financial support for capacity-building that will ensure hospitals respond appropriately to the new incentive structure.

168. See Nicolas P. Terry, *To HIPAA, a Son: Assessing the Technical, Conceptual, and Legal Frameworks for Patient Safety Information*, 12 WIDENER L. REV. 133 (2005) (hypothesizing that patient safety advocates may be drawn to solutions that can be implemented quickly, and noting that health information technology initiatives are the only health care reform proposals to gain bipartisan support in recent years).

169. Shojania & Grimshaw, *supra* note 93, at 141, 149 n.8; see J.D. Kleinke, *Release 0.0: Clinical Information Technology in the Real World*, 17 HEALTH AFF. 23 (1998); Ross Koppel et al., *Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors*, 293 JAMA 1197 (2005) (finding that a leading CPOE system frequently increased the risks of medication errors).

170. See Robert L. Wears & Marc Berg, *Computer Technology and Clinical Work: Still Waiting for Godot*, 293 JAMA 1261 (2005) (arguing that because technology does not stand alone but rather interacts with people and routines in the health care environment, health information technology must be integrated into a larger organizational change framework).

171. McNeill et al., *supra* note 150, at 392.

172. *Id.* at 384.

VI. CONCLUSION

The Hippocratic oath requires doctors to “first, do no harm.” The American health care system can, and must, deliver care without exposing patients to unnecessary injury and death. The new rule banning reimbursement for treatment of hospital-acquired conditions represents an important recognition of the federal government’s duty to confront this grave problem.

The history of Medicare payment reform demonstrates that reimbursement changes can have profound effects on the delivery of health care, not only for Medicare recipients, but for all patients. Yet, it also reminds us that Medicare does not operate in a vacuum, but rather at the center of a complex and interrelated web of hospitals, physicians, patient-consumers, and health care finance organizations. Developing responsible and effective reimbursement rules requires close attention to the competing financial and organizational pressures that shape health care delivery not merely in theory, but in the ICU.

Using Medicare’s purchasing power to specifically target hospital-acquired conditions is a promising approach, but it is unlikely to be a sufficient independent force to overcome the substantial barriers to systematic change. Punishing individual hospitals for lapses in quality care may be morally defensible and financially justifiable. However, if it does not save real people from suffering and dying as a result of hospital-acquired infections, the policy will fail. The human cost of these daily hospital tragedies is too high for a shortsighted focus on whether hospitals or taxpayers should bear the financial expense.

Real progress will require reconsidering the relationships between the different regulatory bodies and government entities that drive change in health care. Congress must supplement financial incentives with support for research that directly addresses health care providers’ need for guidance on implementation strategies. CMS and AHRQ have both evolved as Congress, presidents, and administrators have advanced competing ideas of the best way to achieve these agencies’ statutory missions. Yet, Medicare’s success in driving quality will depend on AHRQ’s ability to guide hospital responses to Medicare’s payment signals. As the federal government seeks to become a more selective purchaser of health care services for Medicare beneficiaries, it must

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invest in making AHRQ a more viable partner in the quest for patient safety.