A PROPOSED EVIDENTIARY PRIVILEGE FOR MEDICAL CHECKLISTS

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INTRODUCTION

Medical error is a serious problem in hospitals and the eighth-leading cause of death in the United States.[1] Recent

[1] INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 26–48 (1999) (finding that deaths resulting from preventable errors in hospitals each year exceed deaths from car accidents, breast cancer, and AIDS and that these errors also cost hospitals between $17 and $29 billion annually, cause loss of morale and frustration among healthcare professionals, and erode the general public's trust in healthcare providers and systems); *see also* Troyen A. Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study*, 324 NEW ENG. J. MED. 370, 370 (1991) (finding,

research indicates that medical checklists are one of the most promising emerging interventions to address medical error. One study found that the use of a surgical checklist caused complications from surgery to fall by more than a third and the rates of surgical site infections and post-surgical deaths to roughly halve.[2] In a different hospital setting, researchers found that "simply having the doctors and nurses in the ICU create their own checklists for what

ten years prior to the IOM study, that medical errors cause substantial injury to patients and that "many injuries are the result of substandard care"); E.J. Thomas et al., *Costs of Medical Injuries in Utah and Colorado*, 36 INQUIRY 255 (1999) (finding that the costs of adverse events in Utah and Colorado alone were equivalent to the national costs of caring for people with AIDS and accounted for 4.8% of per capita healthcare expenditures in those two states). The Institute of Medicine used the results of the Brennan and Thomas studies to reach its numerical predictions about medical error. *See* David Costa, *Human Error: An Inevitable Part of Healthcare, or a Better Future?*, RESPIRATORY THERAPY, June–July 2008, at 9 (noting that medical error is the eighth-leading cause of American deaths).

[2] *See* Alex B. Haynes et al., *A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population*, 360 NEW ENG. J. MED. 491 (2009) (discussing a study evaluating the efficacy of surgical checklists and finding that deaths of post-surgical patients fell by almost half); Peter J. Pronovost et al., *An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU*, 355 NEW ENG. J. MED. 2725, 2726 (2006) (finding that requiring healthcare providers to use a simple five-step checklist caused the rate of catheter-related bloodstream infections to decrease by up to 66% and that this decrease was sustained over an eighteen-month period); Eefje N. de Vries et al., *Effect of a Comprehensive Surgical Safety System on Patient Outcomes*, 363 NEW ENG. J. MED. 1928, 1928 (2010) (observing that after surgical checklist implementation, the proportion of post-surgical patients with one or more complications decreased from 15.4% to 10.6% and in-hospital mortality decreased from 1.5% to 0.8%); Kevin B. O'Reilly, *Central Line Infections Declining, CDC Reports*, AM. MED. NEWS Jun. 14, 2010 (reporting 18% fewer central-line associated bloodstream infections than projected). *But see* Kevin B. O'Reilly, *Infection Checklist Effort Expands, but National Rates Unchanged*, AM. MED. NEWS, Apr. 26, 2010 (summarizing findings from study by the Agency for Healthcare Research and Quality that, nationally, hospitals have not improved the rate of catheter-related bloodstream infections due to their failure to measure performance and implement changes, and concluding that their "fear of discussing missteps makes it difficult to improve care").

they thought should be done each day improved the consistency of care to the point that the average length of patient stay in intensive care dropped by half."[3] An evidentiary privilege that bars admissibility of checklists in court would encourage healthcare institutions to experiment with new policies that incentivize providers to develop and use checklists. Such a privilege would increase the willingness of providers to pool their knowledge to develop and use institutional checklists, thereby increasing the quality of patient care. Given that a similar evidentiary privilege has been instituted to protect the after-error data created in response to incidents that have already occurred,[4] an evidentiary privilege is certainly warranted to protect data tools that are used to prevent those incidents in the first place.

Since 1999, when the Institute of Medicine (IOM) released its seminal report, "To Err is Human,"[5] the growing "patient safety movement"[6] has encouraged systemic change to ensure that medical interventions are delivered correctly. Subsequent legislative responses enacted to protect patients and reduce systematic medical error include the Patient Safety and Quality Improvement Act (PSQIA),[7] mandatory

[3] ATUL GAWANDE, THE CHECKLIST MANIFESTO: HOW TO GET THINGS RIGHT 39 (2010).

[4] *See infra* Part I.A.

[5] INST. OF MED., *supra* note 1.

[6] Maxine M. Harrington, *Revisiting Medical Error: Five Years After the IOM Report, Have Reporting Systems Made a Measurable Difference?*, 15 HEALTH MATRIX 329, 331 (2005) (describing the IOM Report and the subsequent "patient safety movement").

[7] Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §§ 299b-21 to -26 (2005). The PSQIA creates an evidentiary privilege that protects information submitted to "patient safety organizations" (PSOs), which are specially defined groups (excluding health insurers) that compile information on medical errors. When providers—broadly defined to include hospitals, physicians, and others—create "patient safety work product" and submit it to a PSO, that work product is protected with an evidentiary privilege. The privilege therefore protects the reports created by a provider in the aftermath of an incident. However, the underlying facts of the incident are still open to discovery. The privilege is meant to encourage the creation of these after-incident analyses and reports. *See*

and voluntary error reporting systems adopted by numerous states, and the Centers for Medicare and Medicaid Services' (CMS) "never-event" reimbursement rule.[8] However, these policies only indirectly attempt to reduce medical error, and perhaps as a result, they have achieved only limited success and have been subject to criticism by academics[9] and

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Kristen MacIsaac, Note, *Medicare's August Rule: Necessary Step Toward Minimizing Federal Spending or Overbroad Decision Leading to Higher Malpractice Costs?*, 50 B.C. L. REV. 533, 539–40 (explaining that PSQIA was intended to give providers incentives to voluntarily report medical error date but that the reporting system, overall, is flawed).

[8] The Deficit Reduction Act of 2005 required the Secretary of Health and Human Services to select diagnosis codes that were either high cost or highly prevalent, and that "could reasonably be prevented through the application of evidence-based guidelines." 42 U.S.C. § 1395ww(d)(4)(D) (Supp. II 2008). The "never-event" rule promulgated by CMS in response to the statutory mandate specifies that care for certain conditions known as "hospital-acquired conditions" is non-reimbursable by the government if the conditions were not present on admission to the hospital. Effective October 1, 2008, the categories of these conditions include: (1) foreign object retained after surgery, (2) air embolism, (3) blood incompatibility, (4) pressure ulcers (stages III and IV), (5) falls, (6) manifestations of poor glycemic control, (7) catheter-associated urinary tract infection, (8) vascular catheter-associated infection, (9) deep vein thrombosis, and (10) surgical site infection associated with certain specified procedures. Final Inpatient Prospective Payment System Rule, 73 Fed. Reg. 48,434, 48,471 (Aug. 19, 2008). These conditions, also known as "never-events," are posited to be completely preventable so long as adequate care is delivered. The rationale behind the rule is that if such an event occurs during the patient's hospital stay, it is the provider's fault, and the provider, rather than the government, should pay to fix it. In other words, the event's but-for cause is the provider, so the provider should be held financially responsible. There is general consensus, however, that many of the events classified as non-reimbursable are not preventable in all cases. *See* Hudson T. Rowland, *When Never Happens: Implications of Medicare's Never-Event Policy*, 10 MARQ. ELDER'S ADVISOR 341, 378 (2009) (criticizing various conditions on the CMS list of "never-events" and noting that very few individuals agree that such conditions should never occur under a hospital's watch). If that is the case, providers are currently being unfairly financially penalized for the occurrence of medical events that, they cannot prevent, even with appropriate care.

[9] *See* Rowland, *supra* note 8, at 378; Stanton N. Smullens et al., *Regulating for Patient Safety: The Law's Response to Medical Errors*, 12

practitioners.[10] Critics observe that these policies simply reinforce existing incentives[11] on administrators to avoid medical error and provide no insight into the policies that can be implemented to stem the commission of errors by individual providers. In other words, they fail to provide a mechanism to translate the meta-incentive that exists at the institutional level into an incentive for individual healthcare providers at the level where care is actually delivered.[12] A

WIDENER L. REV. 39 (2005) (noting widespread concerns about under-reporting in both voluntary and mandatory reporting systems).

[10] *See* Pauline Chen, *Who Pays for Medical Complications?*, N.Y. TIMES, May 27, 2010, *available at* http://www.nytimes.com/2010/05/27/health/views/27chen.html (criticizing some aspects of the CMS "never-event" list for failing to reflect the fact that certain high-risk patients are far more likely to develop some of these conditions and cautioning that cherry-picking of patients may occur as a result); Donald E. Fry et al., *Patient Characteristics and the Occurrence of Never Events*, 145 ARCHIVES OF SURGERY 148, 148 (2010) ("[P]atient characteristics and type of operative procedure are important predictors of complications of surgical care . . . undermining the rationale for their current classification as 'never-events.'"). *But see* Meredith B. Rosenthal, *Nonpayment for Performance? Medicare's New Reimbursement Rule*, 357 NEW ENG. J. MED. 1573, 1575 (2007) (arguing that the 2007 CMS "never-event" reimbursement rule was largely symbolic and will not have a significant effect on reimbursement rates).

[11] Rachel Deutsch, Note, *The Federal Role in Reducing Hospital-Acquired Conditions: Are Medicare Reimbursement Incentives Enough?*, 42 COLUM. J.L. & SOC. PROBS. 1, 16–17 (2008) (evaluating the CMS "never-event" rule and concluding that it is based on the faulty assumption that sufficient financial incentives are not already in place, when indeed they are, but hospitals lack the resources and systems to effectively respond to these already existing incentives).

[12] The first and most obvious problem is that a financial disincentive for the hospital is not the same thing as a financial disincentive for the healthcare providers within that hospital. There must be a mechanism of transferring the disincentive to the individuals who actually provide care. Moreover, it is not clear that healthcare providers will always respond to financial incentives in the intended ways. *See* Stephanie S. Teleki et al., *Will Financial Incentives Stimulate Quality Improvement? Reactions from Frontline Physicians*, 21 AM. J. MED. QUAL. 367 (2006) (citing a study that found that physicians may respond adversely to programs that base compensation on their performance); Gloria Ramsey, *Nurses, Medical Errors, and the Culture of Blame*, NEONATAL INTENSIVE CARE, Jan.–Feb.

hospital must still find successful mechanisms to prevent the commission of medical error by the individuals responsible for providing care.

An alternative approach to error reduction utilizes direct action to prevent medical errors before they occur: the medical checklist. Rather than indirectly addressing medical errors by complex, attenuated, and mismatched incentive structures, checklists give providers a blueprint for preventing the commission of these errors. Unlike error reporting systems, checklists align incentives and deal with unrecognized error by improving recognition of improper care and would-be errors. Furthermore, unlike the CMS non-reimbursement rule, checklists provide an actual mechanism for reducing the number of medical errors at the level of the delivery of care. Checklists increase the likelihood that quality-optimizing precautions and

2007, at 53 ("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."). For example, a study by a Preferred Provider Organization found that physicians do not change their behavior in response to financial incentives, such as those in "pay-for-performance" programs, and reacted with "anger and suspicion to the health plan's use of financial incentives to improve quality." Teleki et al., *supra*, at 371. This finding may be controversial, as it is probably untrue at least in the context of providers who practice "defensive medicine" (such as ordering or not ordering certain tests or procedures primarily to avoid malpractice liability rather than to diagnose/treat a certain condition) out of a concern for their own potential legal liability. *See, e.g.*, Michelle Mello et al., *National Costs of the Medical Liability System*, 29 HEALTH AFFAIRS 1569, 1570 (2010) (estimating that defensive medicine spending costs $45.6 billion annually, which comprises about 80% of the total $55.6 billion annual cost of the medical liability system; the medical liability system, in turn, accounts for about 2.4% of the total costs of healthcare spending). In this respect, it may be useful to recognize that these two positions are not mutually exclusive. Physicians can be offended by and non-responsive to programs that imply that their provision of quality care is financially motivated, while at the same time practicing defensive medicine to prevent the possibility of their own future liability. Physicians may not need financial incentives to want to provide quality care, but they will respond to fear of perceived unfair liability by ordering tests that will not impact the quality of care.

procedures will be considered and followed by intervening in the delivery of care at the moment immediately preceding its improper provision.

Unlike the other policies that have been adopted in response to the IOM Report, the medical checklist bridges the gap between altering systems and altering individual behavior. Checklists are the ideal way to look at medical error on a broad-based, institutional level, to diagnose systematic problems, and to ensure that individual actors are incorporating the solutions into their everyday actions.

A major barrier to continued implementation and experimentation with checklist-use policies is that healthcare institutions and providers are extremely sensitive to litigation concerns.[13] They shape their policies and actions according to the perceived risks of litigation.[14] They may not

[13] *See* Katherine Mikk, Note, *Making the Plaintiff's Bar Earn Its Keep: Rethinking the Hospital Incident Report*, 53 N.Y.L. SCH. L. REV. 133, 156 (2008–09) (discussing hospitals' litigation concerns as they relate to the incident reporting process); Troyen A. Brennan, *The Institute of Medicine Report on Medical Errors—Could It Do Harm?*, 342 NEW ENG. J. MED. 1123, 1125 (2000) ("Any effort to prevent injury due to medical care is complicated by the dead weight of a litigation system that induces secrecy and silence."); Emily R. Carrier et al., *Physicians' Fears of Malpractice Lawsuits Are Not Assuaged by Tort Reforms*, 29 HEALTH AFFAIRS 1585 (2010) (finding high levels of malpractice concern among both generalists and specialists even in states where objective risk of malpractice was low).

[14] Significantly, in the healthcare context, individuals and entities appear to shape their behavior in response to perceived exposure to legal liability, regardless of actual exposure. *See* Carrier et al., *supra* note 13, at 1585. For example, the chance of a medical malpractice lawsuit being brought and ultimately resulting in payout for a legitimate medical error is thought to be quite low, at least in relation to the number of such errors that occur, and any settlement or trial award will frequently be covered by an insurer. *See, e.g.*, A. Russell Localio et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence*, 325 NEW ENG. J. MED. 245 (1991) (concluding that medical malpractice litigation infrequently compensates patient injury by medical negligence and rarely identifies and holds providers accountable for substandard care); *see also* Troyen A. Brennan et al., *Relation Between Negligent Adverse Events and the Outcomes of Medical-Malpractice Litigation*, 335 NEW ENG. J. MED. 1963 (1996) ("The severity of the patient's disability, not the occurrence of an adverse event or an adverse event due to negligence, was predictive of

want to use checklists because in the event of a lawsuit, an incomplete checklist could be entered as evidence by a plaintiff and viewed as overwhelmingly persuasive by a jury, regardless of the context of the injury.[15] Perhaps as a result of these concerns, they have failed to take full advantage of this opportunity to improve care.[16]

An evidentiary privilege that protects against discovery and admissibility of medical checklists used during patient

payment to plaintiff."). Fear of such lawsuits has generated billions of dollars in costs in the form of providers' practice of defensive medicine, indicating that even if the chance of litigation is minor and/or random, providers' behavior still assumes that the chance of legal liability can be lessened by ordering (or not ordering) additional tests. *See, e.g.*, Mello et al., *supra* note 12, at 1570 (finding that the practice of defensive medicine costs over $40 billion annually). In other words, this research shows that providers act on their fears of potential liability even if that liability is not great. This finding has particular relevance in the checklist context, where courts may not view checklists as being entitled to much substantive weight (*see* O'Leary v. Schweiker, 710 F.2d 1334, 1341 (8th Cir. 1983)), but providers' strong intuitive sense that checklists would be highly prejudicial to them in court accounts for their reluctance to utilize them.

[15] *See, e.g.*, Atul Gawande, Op-Ed., *A Lifesaving Checklist*, N.Y. TIMES, Dec. 30, 2007, § 4, at 48 (describing the Office of Human Research Protections decision to shut down a checklist efficacy study partially on the grounds that the study was too risky for doctors, whose poor job at following basic infection-prevention procedures would be exposed).

[16] For example, the Institute for Healthcare Improvement has an ongoing project in place to track hospitals that have tested surgical safety checklists and that have policies fully in place to implement the continuous use of those checklists. The Institute has found that while many hospitals across the country have tested checklists, the number that have actually implemented policies supporting their continuous use is surprisingly few. *See* INST. FOR HEALTHCARE IMPROVEMENT, http://www.ihi.org/ihi/gmaps/Surgical_Sprint_Map.aspx (last visited Dec. 1, 2010). Indeed, "[b]y the end of 2009, about ten percent of American hospitals had either adopted the checklist or taken steps to implement it . . . ." GAWANDE, *supra* note 3, at 159. *See also* KEVIN JEWELL & LISA MCGIFFERT, TO ERR IS HUMAN, TO DELAY IS DEADLY: TEN YEARS LATER 2 (2009) (concluding that it is unclear whether any real progress has been made since the release of the IOM report and criticizing the current efforts to reduce "the harm caused by our medical care system [as] few and fragmented . . .").

treatment should be created in order to incentivize healthcare institutions to establish policies that encourage their use. Given the potential patient safety improvements to be gained by more widespread use and development of checklists, failing to encourage their use by quelling liability fears is ultimately a disservice to patients and endangers their safety. An evidentiary privilege[17] similar to that instituted for patient safety work product created after-the-fact of an incident under the PSQIA should be extended to medical checklists as well.

It is unlikely that plaintiffs would be seriously disadvantaged by this privilege.[18] Due to the nature of many items on the checklist,[19] admitting the checklist would

[17] A person would not be permitted to testify as to whether the checklist indicated that a particular step was performed or not, or enter the checklist into evidence to show that a sponge count was not performed after the operation.

[18] While a checklist is very valuable to healthcare providers and patients who receive care, its use in litigation is more attenuated and prejudicial than probative. The Eighth Circuit has recognized this by admitting checklists as evidence but noting that they are not entitled to much substantive weight. *See* O'Leary v. Schweiker, 710 F.2d 1334, 1341 (8th Cir. 1983). The reality of checklist use is that they are often used in chaotic, hectic, and stressful circumstances; in an emergency room or any surgical setting, providers are not (and should not be) focused on making tick-marks on a piece of paper. They may forget to make marks even though they have performed each item, or the patient may be in such a precarious condition that providers do not have the time to complete each item on the checklist. *See* de Vries et al., *supra* note 2, at 1931 (finding that in a random sample of surgical checklists, a median of eighty percent of items per checklist were marked as completed). For further discussion, see *infra* Part IV.A.

[19] The Surgical Safety Checklist designed by Dr. Gawande for the World Health Organization (WHO) includes the following items: *Before induction of anesthesia* (has the patient confirmed his/her identity, site, procedure, and consent; is the site marked; is the anesthesia machine and medication check complete; is the pulse oximeter on the patient and functioning; does the patient have a known allergy, difficult airway or aspiration risk, or a risk of greater than 500 ml blood loss); *Before skin incision* (confirm all team members have introduced themselves by name and role; confirm the patient's name, procedure, and where the incision will be made; has antibiotic prophylaxis been given within the last sixty minutes; what are the critical or non-routine steps; how long will the case

typically be unnecessary to establish the cause of injury. Either the item would not be sufficient to establish causation of injury (i.e., introducing each team member by name and role) or the item could be established by looking at the underlying facts of the incident.[20]

Traditionally, hospital administrators have not regulated behavior that is considered to fall within the realm of clinical and safety measures.[21] However, hospitals are beginning to recognize that patient safety should be the foremost consideration of all hospital employees, not just those who actively deliver care.[22] Hospital administrators and hospital

take; what is the anticipated blood loss; are there any patient specific concerns (to anesthesiologist); has sterility been confirmed and are there equipment issues or any concerns (to nursing team); is essential imaging displayed); *Before patient leaves operating room* (nurse verbally confirms: the name of the procedure, completion of instrument, sponge, and needle counts, specimen labeling, whether there are any equipment problems to be addressed; all parties determine what are the key concerns for recovery and management of this patient). WORLD HEALTH ORG., *Surgical Safety Checklist*, http://www.safesurg.org/uploads/1/0/9/0/1090835/surgical_safety_checklist_production.pdf.

[20] For example, entering a checklist as evidence would be unnecessary to establish that a patient had a sponge left inside his body after surgery; there would be far more compelling evidence than a checklist to show that the care provided was negligent.

[21] *See* Sandra Yin, *Doctors and Hospitals Must Play Together or Risk Extinction*, FIERCEHEALTHCARE (Sept. 3, 2010, 10:37 AM), http://www.fiercehealthcare.com/story/dr-bob-wachter-doctors-and-hospitals-must-play-together-or-risk-extinction/2010-09-03 ("We're moving to a world where hospitals, more than doctors, are being held accountable for safety and quality . . . . [T]he hospital is under the gun to try to improve quality and safety.").

[22] Encouraging executives to take an active role in protecting patient safety is crucial. For example, in Dr. Pronovost's Keystone Initiative study, which implemented checklists in hospitals across Michigan, he insisted that each "participating hospital assign to each unit a senior hospital executive who would visit at least once a month, hear the staff's complaints, and help them solve problems." GAWANDE, *supra* note 3, at 43. While the executives were initially reluctant to get involved and shift from budgets to the realm of patient territory, "their involvement proved crucial. In the first month, the executives discovered that chlorhexidinie soap, shown to reduce line infections, was available in less than a third of

patient safety committees should work together to implement policies that encourage individual care providers to develop and use checklists tailored to their needs and institutional settings.[23]

Beyond their medical efficacy, checklists should also appeal to the cost sensitivity of hospital administrators.[24] Research demonstrates that checklist-use policies are inexpensive to adopt and save hospitals money.[25] Moreover,

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the ICUs. This was a problem only an executive could solve. Within weeks, every ICU in Michigan had a supply of soap." *Id.*

[23] *See infra* notes 179, 185, 188 and accompanying text. Various policies, some encouraging checklist use, and others requiring it, should be explored. In some situations, mandates may ultimately be counterproductive because they create a backlash from providers who feel that their autonomy is being infringed upon. *See* GAWANDE, *supra* note 3, at 151; *infra* note 159 and accompanying text. In instances where third parties have mandated that physicians use checklists, doctors have not embraced the concept with considerable enthusiasm. "The checklist has arrived in our operating rooms mostly from the outside in and from the top down. It has come from finger-wagging health officials, who are regarded by surgeons as more or less the enemy, or from jug-eared hospital safety officers . . . ." GAWANDE, *supra* note 3, at 160. Since "[j]ust ticking boxes is not the ultimate goal here" but rather "embracing a culture of teamwork and discipline[,]" rankling providers by mandating its use may sometimes not be the right way to proceed. *Id.* On the other hand, even tough critics of checklists have been converted once they recognize the utility of checklists. *Id.* at 152–53. Individual institutions are best suited for determining whether and when mandating use of the checklist is preferable to encouraging it. That determination depends greatly on the personalities of providers and administrators at an institution. In either instance, however, a commitment by administrators to increasing the use of checklists and encouraging their development is critical. *See infra* note 167 and accompanying text.

[24] *See* Yin, *supra* note 21; Christopher Rowland, *Hospitals Tie CEO Bonuses to Safety*, BOS. GLOBE, May 5, 2007, at A1 ("Hospitals have traditionally rewarded chief executives for their ability to attract patients and make money . . . [and they now increasingly] link[] a portion of executives' pay to a range of safety measures, from reducing medication errors to monitoring how often doctors wash their hands.").

[25] *See* Marcus E. Semel et al., *Adopting a Surgical Safety Checklist Could Save Money and Improve the Quality of Care in U.S. Hospitals*, 29 HEALTH AFFAIRS 1593 (finding that in a hospital with a baseline major complication rate after surgery of at least three percent, the checklist

the existing financial disincentives to commit medical error will likely become even more pronounced once Medicare begins tracking hospital medical error rates as required by the Patient Protection and Affordable Care Act (PPACA).[26] Medical error is costly to patients in terms of their health and reduced economic productivity and to providers in terms of financial liability. Furthermore, estimates indicate that half of surgical complications alone are preventable.[27] Identifying and implementing effective methods of reducing preventable medical error can critically affect the finances of healthcare providers, particularly in the current era of Inpatient Prospective Payment System (IPPS) reductions, schedule-based fee reductions, and high medical malpractice payouts. Therefore, the adoption of policies that encourage the use of checklists achieves financial and administrative objectives in addition to patient safety goals.

Alternatively, state legislatures could mandate that healthcare providers use certain medical checklists as an element of the providers' standard of care. However, such an action would be inconsistent with the legislature's traditional stance of deference to the medical profession in setting the accepted medical standard of care. It would also impede medical professionals from developing and using

generates cost savings once it prevents at least five major complications, and that using a checklist would both save money and improve the quality of care in U.S. hospitals).

[26] *See, e.g.*, Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), amended by Health Care and Education Reconciliation Act, Pub. L. No. 111-152, 124 Stat. 1029 (2010) § 3011 (to be codified at 42 U.S.C. § 280j) (requiring the Secretary to develop a national strategy for quality improvement in healthcare, including research on ways to improve patient safety and reduce medical errors and a mandate that the Secretary's strategy include ways to align public and private payors with regard to quality and patient safety efforts).

[27] GAWANDE, *supra* note 3, at 91; *see also* OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH AND HUMAN SERVS., ADVERSE EVENTS IN HOSPITALS: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES ii (2010) (finding that 44% of adverse and temporary harm events were clearly or likely preventable).

checklists that uniquely suit each hospital's peculiar environment.

For example, in 2005 the United Kingdom's National Patient Safety Agency (NPSA) required hospitals to implement a specific set of guidelines in order to reduce the frequency of wrong-site surgeries. It replaced the guidelines in 2010 with new ones adopting the WHO Surgical Safety standards.[28] In the interim, healthcare institutions were bound to the set of 2005 guidelines, which effectively prevented them from progressing to what is now largely recognized as a superior medical practice. Moreover, providers lacked incentives to develop their own wrong-site checklists that would be more appropriate for the unique patient populations at their own hospitals because they were already bound to using a particular set of guidelines to reduce wrong-site surgeries. Accordingly, although checklists may potentially improve care in many areas, the absence of an evidentiary privilege dissuades hospitals from maintaining policies that encourage innovation with new checklist formulations and applications to determine which will optimally suit a particular hospital environment. If hospitals and healthcare providers are not given the freedom to experiment and innovate with new checklists, we will never realize the full potential that checklists have to offer.[29]

Part I of this Note discusses the medical community's recognition of medical error as a widespread problem and the various legal interventions subsequently adopted to address it, including the PSQIA evidentiary privilege, state-level adoption of error reporting systems, and the CMS "never-event" reimbursement rule. Part II critiques each of these legal interventions as inadequate responses, and argues that they are fundamentally flawed because they lack a mechanism to translate overarching system changes to the level at which care is actually delivered. Part III proposes as an alternative the creation of a privilege protecting the

[28] NAT'L PATIENT SAFETY AGENCY, PATIENT SAFETY ALERT: UPDATE (2009), *available at* http://www.safesurg.org/uploads/1/0/9/0/1090835/npsa_checklist.pdf.

[29] *See infra* note 189 and accompanying text.

medical checklist from admissibility as evidence. This Part describes the nature of the medical checklist and why it is theoretically better capable of reducing the incidence of medical error. It also argues that an evidentiary privilege applied to medical checklists is analogous to other evidentiary privileges currently recognized by the Federal Rules of Evidence, and that such a privilege falls within the guidelines specified by the Supreme Court in *Jaffee v. Redmond*,[30] which govern the situations in which the creation of an evidentiary privilege is appropriate. This Note further argues that such a privilege is similar in structure and purpose to the evidentiary privilege already created for certain voluntary reporting systems under the PSQIA but that a checklist privilege is likely to more effectively achieve that same purpose of enhanced patient safety. Finally, Part IV addresses various objections to the creation of an evidentiary privilege for checklists. The section responds to these criticisms and argues that state legislative requirements mandating use of particular checklists would deter exploration of the full range of potential innovative uses for checklists. Part V concludes that establishing an evidentiary privilege for medical checklists is critical to reducing the frequency of preventable medical errors.

I. BACKGROUND: CURRENT LEGISLATIVE RESPONSES TO MEDICAL ERROR

The healthcare sector's role in the U.S. economy is significant, and will likely continue to grow faster than any other segment of the economy during the next decade.[31]

[30] 518 U.S. 1 (1996) (recognizing federal privilege protecting confidential communications between psychotherapist and patient).

[31] Recent estimates from CMS actuaries indicate that, with the implementation of the PPACA, healthcare spending will grow from $2.6 trillion in 2010 to $4.57 trillion in 2019. Andrea M. Sisko et al., *National Health Spending Projections: The Estimated Impact of Reform Through 2019*, 29 HEALTH AFFAIRS 10 (2010), *available at* http://content.healthaffairs.org/cgi/content/full/hlthaff.2010.0788v1; *see also* BIPARTISAN POLICY CTR., RESTORING AMERICA'S FUTURE 11 (2010) (warning that "by 2025, federal revenues will be completely consumed by

Currently, the healthcare sector comprises 17.5% of the United States' GDP; by 2019, its relative share is predicted to increase to 19.6%.[32] At the same time, legislators are implementing various types of reimbursement rate cuts for hospitals and individual providers as one means of reducing the rate of ever-increasing healthcare spending.[33]

Healthcare companies in particular stand to gain or lose considerable profits depending on the care delivery policies they adopt over the next decade. For example, the PPACA requires Medicare to track the rates of medical error at hospitals, with rate cuts to disincentivize error presumably to follow.[34] Coupled with other measures to reduce reimbursement rates, such as penalties for failure to adopt and meaningfully use electronic medical records,[35] hospitals with high error rates could face severe cuts in their IPPS reimbursement over the next few years. Additionally, the Society of Actuaries has stated that medical errors cost almost $20 billion in 2008 alone.[36] Understanding the role of

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the combination of interest payments, Medicare, Medicaid, and Social Security").

[32] Sisko et al., *supra* note 31, at 2.

[33] For example, the meaningful use regulations released by CMS in July 2010 include financial incentives for eligible providers who adopt and meaningfully use electronic medical records; otherwise, eligible providers are penalized with schedule-based fee reductions. *See* Electronic Health Record Incentive Program Rule, 75 Fed. Reg. 44,313 (July 28, 2010) (to be codified at 42 C.F.R. § 495).

[34] PPACA § 3011.

[35] *See* 75 Fed. Reg. 44,573 (July 28, 2010) (to be codified at 42 C.F.R. § 495.104) (calculating payment adjustments to eligible hospitals).

[36] JON SHREVE ET AL., THE ECONOMIC MEASUREMENT OF MEDICAL ERRORS 5 (2010). Even using a conservative methodology, the study found that 1.5 million measureable medical errors occurred in 2008. This figure does not include those errors that were not identifiable through claims data, so the authors predict that the actual amount is even greater. *Id.* The report contained a number of interesting findings: the average total cost per error was $13,000; in an inpatient setting, seven percent of hospital admissions were estimated to result in some type of medical injury; and measurable medical errors resulted in more than 2,500 avoidable deaths in 2008 and more than ten million cumulative days of work missed that year due to short-term disability. *But see* INST. OF MED.,

medical error in ever-increasing healthcare costs is crucial to identifying the most effective methods of reducing them. Healthcare institutions and providers that successfully identify the causes of these errors will realize significant savings if they subsequently implement targeted policies to reduce their frequency.

Most serious attempts to reduce medical error are traceable to the release of the 1999 IOM Report, "To Err Is Human."[37] This report compellingly argued that medical error is a rampant problem in healthcare provision settings and estimated that 44,000 to 98,000 error-related hospital deaths occur each year.[38] One commentator described medical errors as the "eighth leading cause of death in the United States. The number of deaths [every day] due to errors is equivalent to a jet airliner crashing every day."[39] Scholars have criticized the IOM estimate on various grounds, pointing out that the upper and lower estimates span an unacceptably large range and that the report failed to properly delineate truly preventable events from those that occurred despite the best possible care.[40] However, even critics of the IOM Report agree that, regardless of the precise

supra note 1, at 1 (finding that the number of deaths attributable to medical error ranges from 44,000 to 98,000 per year). Note that the Society of Actuaries study estimate is far lower than this.

[37] INST. OF MED., *supra* note 1.

[38] *Id.* at 26.

[39] Costa, *supra* note 1 (discussing how the extensive use of checklists in the aviation industry has resulted in very significant safety gains and what healthcare leaders can learn from the aviation industry's use of checklists). *But see* Lucian L. Leape et al., *Error in Medicine*, 272 J. AM. MED. ASS'N 1851, 1851 (1994) (extrapolating from New York statistics and finding that iatrogenic injury rates are equivalent to three jumbo-jet crashes ever other day).

[40] Harrington, *supra* note 6 (claiming that IOM's 44,000 to 98,000 range of estimated annual deaths is far too large a range to be considered scientifically respectable and that the IOM report fails to define "medical error" in a clear way that properly excludes unpreventable deaths and adverse events).

statistical estimates, medical error is a major problem in hospitals today.[41]

The IOM Report has tremendously impacted the healthcare industry and shaped a new discourse that encourages innovations to maximize patient safety and the safe utilization of existing medical technologies.[42] The widespread consensus on this issue, popularly termed the "patient safety movement," has been the impetus behind the adoption of various legal measures intended to enhance the safety of care that patients receive from their healthcare providers.[43] These measures include the federal PSQIA,[44] various statewide schemes for reporting medical errors,[45] and CMS' "never-event" non-reimbursement rule.[46] Because much of this legislation is fairly recent, its impact is still uncertain. However, fairly extensive criticism of these policies already exists in the academic literature, and studies indicate that little progress has been made toward reducing the prevalence of medical error in the last decade.[47]

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[41] *Id.* at 331; Brennan, *supra* note 13 (listing numerous well-reasoned criticisms of the IOM report's methodology and assumptions, but recognizing that "[n]o one can disagree with the main point of the IOM report: we should be working to make hospitals safer . . . . The report will help us do better by encouraging research on the prevention of medical errors . . . .").

[42] "[M]any argue that the modern field of patient safety began with [the IOM] report's publication. . . . [I]t is clear that the IOM report was essential in placing the issue of medical mistakes on the public and professional agenda." AHRQ PATIENT SAFETY NETWORK, http://psnet.ahrq.gov/resource.aspx?resourceID=1579 (last visited Dec. 1, 2010).

[43] Harrington, *supra* note 6.

[44] 42 U.S.C. §§ 299b-21 to -26.

[45] *See* Smullens et al., *supra* note 9, at 46–47 (describing the Pennsylvania mandatory error reporting system); Natalie J. Kussart, Comment, *Reporting Medical Errors: The Good, the Bad, and the Ugly*, 31 S. ILL. U. L.J. 385, 393–95 (2007) (discussing the Illinois Adverse Health Care Events Reporting Law of 2005).

[46] 42 U.S.C. § 1395ww(d)(4)(D) (Supp. II 2008).

[47] *See* JEWELL & MCGIFFERT, *supra* note 16, at 2 ("Ten years later, we don't know if we've made any real progress, and efforts to reduce the harm caused by our medical care system are few and fragmented . . . ."); Rowland, *supra* note 8, at 344 (criticizing the CMS "never-event" rule);

A. The Patient Safety and Quality Improvement Act

The PSQIA aims to reduce the occurrence of medical error by encouraging voluntary reporting of medical errors to patient safety organizations (PSOs).[48] Certain information reported to PSOs is protected by an evidentiary privilege and confidential status.[49] The PSQIA privilege protects patient safety work product[50] from "subpoena by, or discovery and admission into evidence in connection with, any civil, criminal or administrative proceeding before any federal, state, local or tribal body, including disciplinary proceedings against a provider."[51] The PSQIA privilege does not preempt

Smullens et al., *supra* note 9, at 45 (noting widespread concerns about under-reporting in both voluntary and mandatory reporting systems); Chen, *supra* note 10 (criticizing 2008 additions to CMS' "never-event" rule).

[48] 42 U.S.C. §§ 299b-21 to -26 (2005); *see also* Leigh Ann Lauth, Note, *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, 152 (2007) (describing the PSQIA and exposing the potential for powerful doctors to exploit their competitors under "sham peer review" proceedings).

[49] Lauth, *supra* note 48, at 152.

[50] Patient safety work product, with some exceptions, is defined in the PSQIA as "data, reports, memoranda, analyses, (such as root cause analyses), or written or oral statements which are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or which identify or constitute the deliberations or analysis of, or identify the fact or reporting pursuant to, a patient safety evaluation system." 42 U.S.C. § 299b-21(7)(A). The patient's medical record, billing, and discharge information, and any other original patient or provider record are statutorily excluded from the definition. 42 U.S.C. § 299b-21(7)(B).

[51] David S. Ivill & Amy Hooper Kearbey, *The Rise of Patient Safety Organizations: Reporting and Sharing Without Fear of Liability*, N.Y.L.J., Nov. 2, 2009, at col. 1 (discussing the practical mechanics of the PSQIA).

state or local laws that afford more extensive legal protection than the PSQIA provides.[52]

The PSQIA assumes that providers will be more likely to report their medical errors to organizations that compile such data if doing so will not increase their exposure to malpractice litigation. Those organizations can then "analyze, review, and provide feedback concerning the reported medical errors, and eventually the rates of death due to medical mistakes will be lowered."[53] The evidentiary privilege applies only to data compiled as part of a patient safety evaluation system and subsequently reported to a PSO. The privilege is not intended to foreclose litigation of claims altogether. The underlying facts of the incident, medical records, billing information, and all other information not compiled as part of a patient safety evaluation system remain outside the scope of the evidentiary privilege and therefore open to discovery.[54] However, the hospital's patient safety information compiled in the aftermath of an incident and reported to a PSO is protected in order to encourage the reporting of errors.[55] Otherwise, hospitals might be unwilling to compile such information out of fear that an adversary may exploit it in a subsequent lawsuit.[56] The privilege is therefore narrowly tailored to facilitate the reporting of medical error incidents, while leaving enough information unprivileged for affected patients to obtain appropriate relief.

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[52] 42 U.S.C. § 299b-22(g)(1) (2005) (setting forth the rules of construction for the PSQIA).

[53] Lauth, *supra* note 48, at 156.

[54] *Id.* at 158–62.

[55] *Id.* at 158–61.

[56] In practice, this means that the adversary has access to all the original data, including records and statements, but must hire his own expert to interpret that data because the hospital's opinions on the matter are privileged. *See* Kathryn Leaman, Note, *Let's Give Them Something to Talk About: How the PSQIA May Provide Federal Privilege and Confidentiality Protections to the Medical Peer Review Process*, 11 MICH. ST. U. J. MED. & L. 177, 200–01 (2007) (discussing whether the medical peer review process falls under the protections of the PSQIA).

B. State Error Reporting Systems

Although reporting is voluntary under the PSQIA, the evidentiary privilege protecting information reported to a PSO nevertheless aims to incentivize providers to report errors.[57] Many states, however, have adopted mandatory error reporting systems for serious medical errors in accordance with the IOM Report's recommendation.[58] In fact, almost half of the states adopted mandatory systems at some point.[59] These systems were "plagued by under-reporting," and states typically accorded some form of legal protection to reported data in order to encourage compliance.[60] Voluntary error reporting systems, such as those made to private organizations like The Joint Commission, and mandatory systems that do not protect data continue to experience substantial under-reporting.[61]

Existing mandatory systems vary significantly from state to state. Pennsylvania,[62] for example, has a unique

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[57] Lauth, *supra* note 48, at 152.

[58] The IOM report "called for a nationwide, mandatory system administered by the states for reporting errors that cause serious harm or death, and voluntary, non-regulatory reporting programs for those errors that cause minor or no harm to patients." Harrington, *supra* note 6, at 330.

[59] *Id.* at 362.

[60] *See* Smullens et al., *supra* note 9, at 45 (discussing the twenty-one states that adopted mandatory error reporting systems with the goal of increasing provider accountability). These systems have largely resulted in severe under-reporting of errors. As a result, many states are now moving towards a system of establishing mandatory error reporting systems that release aggregate reports and give more confidentiality protection to the data received. *See* Harrington, *supra* note 6, at 352 ("Ultimately, professionals and organizations will not report under either voluntary or mandatory systems if it is not in their best interests.").

[61] *See* Harrington, *supra* note 6, at 360 (citing Bryan A. Liang & Steven D. Small, *Communicating About Care: Addressing Federal-State Issues in Peer Review and Mediation to Promote Patient Safety*, 3 HOUS. J. HEALTH & POL'Y 226–28 (2003)) ("Many experts acknowledge that there has been serious under-reporting to [The Joint Commission], which is directly tied to providers' fear of disclosure of the reports in litigation.").

[62] Medical Care Availability and Reduction of Error Act, 40 PA. STAT. ANN. § 1303 (West 2005); Smullens et al., *supra* note 9, at 46–47.

mandatory system that requires the reporting of both serious events and "near misses."[63] Pennsylvania law also requires full, written disclosure to patients in either scenario[64] and provides evidentiary protection to hospitals that do report, but levies monetary fines on those that do not.[65] In contrast, Illinois' more typical mandatory reporting system requires that hospitals report serious mistakes and protects those reports from discovery and admissibility in a subsequent legal or administrative proceeding against the hospital or provider.[66] The Illinois system is based on the IOM vision of having mandatory reporting systems that encourage the use of centralized reporting to a governmental department.[67] These systems were established with the intention of increasing the frequency of reporting, but even the systems that couple legal protections with a reporting mandate continue to experience serious under-reporting as well.[68]

C. The CMS "Never-Event" Reimbursement Rule

In 2007, Congress directed CMS to adopt a new rule changing reimbursement policy for the occurrence of Hospital Acquired Conditions (HACs).[69] HACs are medical events that, according to CMS, never occur if adequate care is rendered to patients.[70] HACs span a broad range of

[63] A "near miss" is typically understood as an error incident that occurs but does not have any adverse consequence for the patient. *See* Marieke Kessels-Habraken et al., *Defining Near Misses: Towards a Sharpened Definition Based on Empirical Data About Error Handling Processes*, 70 SOC. SCI. & MED. 1301, 1301 (2010).

[64] Smullens et al., *supra* note 9, at 46–47.

[65] *Id.* at 47.

[66] Kussart, *supra* note 45, at 392–95.

[67] *See supra* note 58 and accompanying text.

[68] *See* Smullens et al., *supra* note 9, at 45 ("All state systems are plagued by underreporting . . . .").

[69] 42 U.S.C. § 1395ww(d)(4)(D).

[70] Amy J. Chaho, Note, *To Pay or Not to Pay: Medicare and the Preventable Adverse Event: A Rational Decision or Dangerous Philosophical Change?*, 22 J.L. & HEALTH 91, 92 (2009) (criticizing the CMS "never-event" rule and its unintended consequences (such as

events, from a patient developing a pressure ulcer during a hospital stay to a surgeon removing the wrong limb during surgery. When one of these events occurs and further treatment is required to correct it, CMS will not reimburse the hospital[71] for the costs of care flowing from the incident.[72]

The rule's objective is to incentivize hospitals to prevent such events from occurring. This shifts costs from payors (e.g., the government or insurance companies that follow CMS billing procedures) to hospitals, thereby effectively rendering patients with HACs uninsured to the extent of the treatment costs for the HACs.[73] Some research indicates that federal costs will actually increase under this scheme.[74] Unlike the PSQIA, which rewards and encourages certain behavior by granting an evidentiary privilege, the CMS "never-event" policy punishes and discourages what it presumes to be improperly delivered medical care through the use of financial penalties.

II. CURRENT LEGISLATIVE RESPONSES TO MEDICAL ERROR ARE INCOMPLETE AND HAVE ONLY LIMITED POTENTIAL TO REDUCE MEDICAL ERROR

Each of the three major interventions taken in response to the IOM Report—the PSQIA privilege, the states' adoption of error reporting systems, and the CMS "never-event" rule—have been subject to considerable criticism.

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harming the patients who acquire HACs) and suggesting that Congress reconsider this policy and encourage cooperative solutions instead).

[71] Under the PPACA, the Secretary of Health and Human Services is directed to study whether this policy should be expanded to other facilities under the Medicare program as well, including but not limited to long-term care hospitals, hospital outpatient departments, skilled nursing facilities, ambulatory surgical centers, and health clinics. The Secretary's report and recommendation are due to Congress by January 1, 2012. PPACA § 3008(b). Therefore, the program may soon be expanded to facilities other than hospitals.

[72] Chaho, *supra* note 70, at 92.

[73] *Id.* at 93.

[74] *Id.* at 120.

A. The Patient Safety and Quality Improvement Act

Criticism of the PSQIA evidentiary privilege centers on its perceived inefficacy. It fails to adequately address the most basic problem inherent in medical error reporting: that all self-reporting systems entail a degree of voluntarism in that they require the cooperation of the reporters.[75] While removal of legal liability may encourage reporting in some instances, there are still many other disincentives to reporting that the PSQIA—or, realistically, any legislation—cannot address. Thus, it is not clear that an evidentiary privilege in this context is sufficient to overcome the broad array of disincentives to self-reporting that providers face. They may worry that reporting an error will damage their reputations or job security, or will potentially prompt internal disciplinary actions.[76]

Given the presence of these additional disincentives to reporting, a significant amount of errors will go unreported so long as the expected costs of reporting exceed the expected benefits, which limits the efficacy of the privilege and its potential to substantially reduce medical error. Therefore, while the PSQIA does address providers' concerns about liability, it is significantly flawed in that it relies on providers to act against their perceived self-interest to ultimately reduce the rate of medical error.

B. State Error Reporting Systems

State error reporting systems may rely on either voluntary or mandatory error reporting by providers.[77] Mandatory error reporting systems do not necessarily solve the problems that arise under voluntary reporting systems.[78]

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[75] Lauth, *supra* note 48, at 163–64; Harrington, *supra* note 6, at 352 ("Ultimately, professionals and organizations will not report under either voluntary or mandatory systems if it is not in their best interests.").

[76] Lauth, *supra* note 48, at 164.

[77] Smullens et al., *supra* note 9, at 44 (describing characteristics of mandatory and voluntary error reporting systems).

[78] This is not to say that well-designed mandatory or voluntary error reporting systems should be eliminated. To the contrary, these systems

Even when a system is mandatory, many errors will go unnoticed unless the provider steps forward to report them. In fact, it is not clear that making a system "mandatory" will better ensure that incidents are actually reported.[79] As the president of the American Hospital Association, Richard Davidson, explained, "[t]he idea that a mandatory reporting system is going to change behavior is naive at best. You need to focus on making a cultural change in hospitals, to promote open discussion of errors, and that's not possible if some plaintiff's attorney is climbing on your back."[80]

Rather than promote a cultural change, error reporting systems require effort, paperwork, and self-implication of a provider in potentially tortious conduct. If the provider does not report the error, especially in situations where little or no injury occurs, it is unlikely that anyone will ever find out about the error. Moreover, even the best-designed reporting systems will by their very nature miss the entire class of medical errors consisting of those errors that providers do not notice.

Many other problems with error reporting systems exist. Hospitals often receive severely adverse publicity when a government entity publicly disseminates reports with aggregate medical error information, which may reduce public confidence in the medical system and possibly discourage some individuals from going to the hospital when

represent a valuable means of gathering incident data so that policies can be formulated to combat medical error. However, they do not currently provide a complete (or even close-to-complete) picture of medical error, and even if they did, they do not on their own serve as a sufficient policy response to reduce medical error. Simply gathering incident data is not a solution to combating medical error; such information must be used in conjunction with other systems (such as checklists) to actually reduce error.

[79] *See* Smullens et al., *supra* note 9, at 43–45 (discussing problems with error reporting systems in general). *But see* Harrington, *supra* note 6, at 365 ("Although it is widely thought that mandatory reporting systems are unreliable, these systems may capture more patient-related injuries than voluntary systems.").

[80] Kussart, *supra* note 45, at 389.

they are ill.[81] There are also practical limits on the number of conditions for which a state or organization can feasibly gather and analyze data. Resource constraints in healthcare are notoriously tight, and gathering this data can be quite costly.[82] Finally, publication of these reports may raise privacy concerns under HIPAA.[83] The more detailed a report is, the more useful it is likely to be. However, the more detailed it is, the more likely it is to breach patient confidentiality rules. This paradox, along with the other problems plaguing reporting systems, limits the potential efficacy of these error reporting systems in substantially reducing medical errors.

C. The CMS "Never-Event" Reimbursement Rule

The CMS "never-event" rule has been harshly criticized.[84] Perhaps the most troublesome aspect of the rule is that, although it purports to penalize only HACs that are fully preventable by adequate care, in reality a number of the enumerated conditions for which CMS denies payment are not always preventable by the hospital. CMS' refusal to pay

[81] *See, e.g.*, Kussart, *supra* note 45, at 398–99; Harrington, *supra* note 6, at 352.

[82] New York, for example, mandates reporting of certain hospital infections. N.Y. PUB. HEALTH LAW § 2819 (McKinney 2008). The law only applies to thirteen infections, however, and many feel that the types of infections and, more generally, all medical error, should be reported. *See* Jay Jochnowitz, *Open the Window on Hospital Errors*, THE OBSERVATION DECK (Sept. 8, 2010, 6:00 AM), http://blog.timesunion.com/opinion/open-the-window-on-hospital-errors/6160. The reporting law demonstrates the twin difficulties inherent in any mandatory reporting system: first, it is challenging to devise an optimally effective list of exactly what infections should be reported (and such a list would likely become obsolete quite quickly, given the rapidly changing nature of healthcare technology and techniques), and second, there may not be enough resources available to gather and analyze that data even if an optimal list is created.

[83] *See* Kussart, *supra* note 45, at 400.

[84] *See, e.g.*, Deutsch, *supra* note 11, at 27–28 (evaluating the CMS "never-event" rule and concluding that it is based on the faulty assumption that sufficient financial incentives are not already in place, but that hospitals lack the resources and systems to effectively respond to these already existing incentives); Chaho, *supra* note 70, at 93.

in such circumstances seems unfair.[85] For example, CMS itself acknowledges that catheter-associated urinary tract infections are not always preventable when a catheter is in place for more than three days;[86] nevertheless, even though medical necessity sometimes requires long-term use of a catheter,[87] such a condition is non-reimbursable under the new payment scheme.

Another major criticism of the rule is that it assumes that hospitals and individual providers are not already motivated, both financially and otherwise, to avoid these conditions.[88] The lack of financial incentives likely does not cause these conditions; rather, they occur because the current system fails to identify and implement successful and effective means of preventing them.[89] One scholar observes, "[h]ospitals already have significant financial incentives to reduce preventable complications. What they lack, and urgently need, is proven models to implement the institutional change needed to consistently apply best treatment practices."[90] Because hospitals already absorb[91]

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[85] *See* Chaho, *supra* note 70, at 109–10.

[86] Deutsch, *supra* note 11, at 16.

[87] *See* Mary H. Wilde & Kathryn Getliffe, *Urinary Catheter Use for Older Adults*, Aug. 8, 2006, *available at* http://www.annalsoflong-termcare.com/article/6051 (finding that for older adults, long-term cathertization—lasting for a number of years—is sometimes medically necessary).

[88] *See* Deutsch, *supra* note 11, at 17.

[89] *See id.* at 21.

[90] *Id.*

[91] For example, the Medicaid program in New York already refuses to reimburse for specified never-events. *See* Press Release, N.Y. State Dep't of Health, Medicaid to Cease Reimbursement to Hospitals for "Never Events" and Avoidable Errors (June 5, 2008), http://www.health.state.ny.us/press/releases/2008/2008-06-05_medicaid_cease_paying_never_events.htm. Large insurers such as WellPoint have also adopted similar non-payment policies. *See* Press Release, WellPoint, WellPoint Announces Initiative Aimed at Preventing Serious Medical Errors (Apr. 2, 2008), http://phx.corporate-ir.net/phoenix.zhtml?c=130104&p=irol-newsArticle_general&t=Regular&id=1124709&. Because hospitals cannot discharge a patient who requires immediate emergency medical treatment without risking a later lawsuit, if payors refuse to pay, hospitals are left with the

many of the costs associated with HACs, the CMS rule does not "create a new financial incentive for hospitals to prevent infections, but only [amplifies] an existing one."[92]

One study of the CMS rule indicates that it is likely to be ineffective or counterproductive because it is based on the tenuous assumption that reimbursement policies directly affect quality of care.[93] This assumption cannot be generally applied to healthcare delivery because of the contradictory ways in which benefits and costs are aligned.[94] For example, in the IPPS reimbursement context, incentives are misaligned because the erring party is not the same as the financially penalized party. A nurse may cause a patient to develop a pressure ulcer because of the nurse's failure to turn the patient even though he knows the patient is at risk for developing a pressure ulcer. However, the hospital, rather than the nurse, suffers the financial penalty for such an error. Because nurses are in short supply[95] and may receive protection from punishment by virtue of union membership, a hospital may choose not to impose any significant punishment on a nurse for wrongful behavior. Additionally, professional licensure boards in some states are notoriously ineffective at regulating the industry even where

bill. *See* Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd (2006) (requiring that any individual requesting care at a hospital emergency department be screened to determine whether an emergency medical condition exists and, if the hospital's facilities are adequate, the hospital must deliver the treatment required to stabilize the medical condition); *see, e.g.*, Wickline v. California, 192 Cal. App. 3d 1630, 1645 (Cal. Ct. App. 1986) (holding that a "patient who requires treatment and who is harmed when care which should have been provided is not provided should recover for the injuries suffered from all those responsible for the deprivation of such care . . . .").

[92] Deutsch, *supra* note 11, at 22.

[93] *Id.* at 18.

[94] *See id.*

[95] *See, e.g.*, Tom Pelton, *Lack of Nurses Blamed for More Deaths*, L.A. TIMES, June 3, 2002, at S4, *available at* http://articles.latimes.com/2002/jun/03/health/he-nurses3 (reporting on nationwide nursing shortage).

a nurse has been fired for performance or safety related reasons.[96]

The CMS rule simply misses the point: hospital administrators, the actors most sensitive to changes in reimbursement rules, are already incentivized to prevent medical errors and HACs. The CMS rule still leaves administrators wondering what system-wide policies they can implement to stem the commission of errors by individual providers.

Rather than aligning incentives, the CMS rule creates an increased administrative workload by requiring hospitals to carefully code any conditions present on admission in order to ensure that they are reimbursed later for preexisting conditions.[97] The rule also increases unnecessary diagnostic testing at admission[98] and discourages hospitals from treating the elderly and other patients who are at high-risk for certain HACs. If these conditions later develop the hospital will not be reimbursed regardless of whether or not it was at fault.[99] Overall, the CMS reimbursement rule has only limited potential to reduce medical error rates because it does not successfully align incentives and may ultimately harm the patients that it seeks to protect by effectively rendering them uninsured for the cost of care stemming from medical errors.

[96] Charles Ornstein et al., *When Caregivers Harm: Problem Nurses Stay on the Job as Patients Suffer*, L.A. TIMES, July 12, 2009, at A1, *available at* http://articles.latimes.com/2009/jul/12/local/me-nurse12 (citing study finding that the Board of Registered Nursing took an average of three years to investigate reports and failed to keep current records of nurses with disciplinary actions on their record, thus allowing nurses who commit errors to simply start work at a new hospital after they quit at an old one).

[97] *See* Deutsch, *supra* note 11, at 14.

[98] Chaho, *supra* note 70, at 118.

[99] *See* Deutsch, *supra* note 11, at 16–17.

D. Present Interventions Have Not Significantly Reduced Medical Error Because They Fail to Align the Incentives of Individual Providers with the Overarching Goals of the Care Delivery System

The interventions undertaken in response to the IOM Report have not facilitated effective progress towards the IOM Report's recommendation of the creation of "a 'culture of safety' in which systems are designed to keep patients safe from harm . . . ."[100] Rather than moving toward a culture of safety, these interventions only address error through attenuated mechanisms and reinforce preexisting (and often misaligned) incentives. A culture of safety requires focusing on error prior to its commission, attempting to align incentives properly toward the common goal of patient safety, and making meaningful changes toward new systems that ensure that care is delivered properly in the first place. This requires direct intervention and a cultural shift in hospitals, instead of continued use of indirect interventions currently employed to reinforce the norms already in place.

In contrast to the uncertain results yielded by indirect mechanisms, direct interventions taken at the point of care can substantially reduce medical error. For example, the medical error rate at the VA Hospital in Topeka, Kansas dropped by 57% after the hospital began using bar-code technology to administer medications.[101] Until effective direct measures like this are identified and adopted as hospital policy, there will not be significant progress in reducing the rate of medical error.[102]

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[100] *Id.* at 6.

[101] David H. Johnson & David W. Shapiro, *The Institute of Medicine Report on Reducing Medical Error and Its Implications for Healthcare Providers and Attorneys*, HEALTH LAW., June 2000, at 1, 5 (examining successful attempts, both within and outside of the health industry, to reduce error rates).

[102] *See* HEALTHGRADES, HEALTHGRADES QUALITY STUDY: SECOND ANNUAL PATIENT SAFETY IN AMERICAN HOSPITALS REPORT 3 (2005), *available at* http://www.healthgrades.com/media/dms/pdf/patientsafetyinamericanhospitalsreportfinal42905post.pdf (determining that hospital-acquired infection rates worsened by 20% from 2000 to 2003 and that error

III. THE MEDICAL CHECKLIST APPROPRIATELY RECOGNIZES THE CRUCIAL ROLE OF INDIVIDUAL PROVIDERS WITHIN THE CARE DELIVERY SYSTEM

A. The Medical Checklist, Coupled with an Evidentiary Privilege, Aligns Providers' Incentives with the Overarching Goals of the System

The medical checklist is the type of system-wide intervention envisioned by the IOM. Unlike the other policies that have been adopted in response to the IOM Report thus far, the medical checklist bridges the gap between altering systems and altering individual behavior. A medical checklist outlines a series of standardized[103] steps

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rates have worsened over time since the IOM Report); JEWELL & MCGIFFERT, *supra* note 16, at 2 ("Ten years later, we don't know if we've made any real progress, and efforts to reduce the harm caused by our medical care system are few and fragmented . . . . Based on our review of the scant evidence, we believe that preventable medical harm still accounts for more than 100,000 deaths each year . . . ."). Even though much energy has been focused on the problem of medical error, it is still not enough to avoid fairly shocking instances of repeat error. For example, in 2007, the esteemed Rhode Island Hospital reported that *three* different brain surgeons operated on the wrong parts of heads of *three* different patients. Mark Bello, *Rhode Island Hospital Medical Errors—The Case Against Tort Reform*, LAWSUIT FIN. BLOG (Nov. 5, 2009), http://www.lawsuitfinanceblog.com/2009/11/rhode_island_hospital_medical_1.html.

[103] Having a checklist with rigid requirements is not appropriate in all situations. While the "forcing function" of checklists is desirable for simple and routine problems, it is not appropriate for complex, nonroutine problems where conditions are fluid and unpredictable. GAWANDE, *supra* note 3, at 72–73. In such situations, however, communication items on checklists or separate communication checklists are highly valuable. A communication item reminds providers to pause at a defined moment to communicate about any potential problems they are aware of and to propose solutions; this ensures that everybody is on the same page and that all team members are made aware of any unexpected issues and given an opportunity to respond to them. A separate communication checklist, often used by builders in the construction industry, expands this concept further to deal with complex situations where it is important that

for healthcare providers to follow in each instance where a specific procedure is performed.[104] Often, one of the steps is a defined point at which a team of healthcare providers communicates to ensure that all members are aware of any potential problems that may arise with the patient.

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parties with different fields of expertise check-in with each other at defined intervals. The expectation is that they will benefit from hearing each other's input and identify the sorts of potential problems that inevitably arise in complex undertakings where no one person has the expertise to understand each individual component of the project. *See infra* note 107 and accompanying text. "The philosophy is that you push the power of decision making out of the periphery and away from the center. You give people the room to adapt, based on their experience and expertise." GAWANDE, *supra* note 3, at 72–73. Of course, there are situations where any use of checklists is simply too cumbersome, ineffective, or impractical. It is just as important to identify those situations where checklist use is inappropriate as it is to identify those situations where using a checklist enhances the quality of care. *See, e.g.*, *id.* at 48. The paucity of research on these subjects indicates the need for providers to have the freedom to experiment and innovate with checklists to explore where checklists are valuable and where they are not.

[104] Checklist design is a highly complex mix of science and art. Boeing issues over one hundred new checklists each year and has devised a number of guidelines for their design. GAWANDE, *supra* note 3, at 120. Checklists should be specific. They should be short and practical. Importantly, they should be designed by those who have awareness of the situations in which the checklists will be used; they should not be designed by "desk jockeys with no awareness of the situations in which they are to be deployed." *Id.* They should not "treat the people using the tools as dumb and try to spell out every single step." *Id.* To the contrary, a good checklist reminds people "of only the most critical and important steps—the ones that even the highly skilled professionals using them could miss. Good checklists are, above all, practical." *Id.* In other words, designing a checklist is a complicated task that involves a significant degree of experimentation, testing, and design input from those who use them. The mere fact that a step is critical does not necessitate its inclusion on the checklist if experience shows that actors never fail to perform it. In fact, some checklist experts argue that it is detrimental for such items to appear on the checklist. *Id.* at 128. Checklist development is complicated and highly dependent on the characteristics and tendencies of the providers who will be utilizing the checklist. Checklists are, above all, not one-size-fits-all. "[A]n item critical to one expert might not be critical to another." *Id.* at 138. This explains why healthcare provider input and customization of checklists to local practice environments is critical.

Healthcare professionals often use a combination of verbal confirmation[105] and written notations[106] to ensure the performance of each item on the checklist.

Checklists serve two critical functions. First, they address medical error across institutions by setting out a standardized format by which to perform a given procedure, which promotes uniformity and consistency in the delivery of care. Second, they improve communication among members of the healthcare team. Thus, checklists are useful in circumstances where uniformity and consistency translate into safety and quality and where improved communication results in improved care.[107]

Empirical studies indicate that checklists offer remarkable potential to stop medical errors before they occur and to have a direct and significant impact on the safety of

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[105] The verbal element is crucial. It ensures that the checklist serves its function of pulling the team together and improving communication. "It's supposed to be a *verbal* checklist, a *team* checklist." GAWANDE, *supra* note 3, at 112.

[106] Written notations are not necessarily a component of every checklist. For example, Dr. Gawande's surgical safety checklist for the WHO does not require written check marks (although providers may still choose, of course, to make marks as they proceed). *Id.* at 137. Many other checklists do utilize written notations such as check boxes. *Id.* at 100.

[107] Checklists sometimes serve as "'forcing functions': relatively straightforward solutions that force the necessary behavior." *Id.* at 50. The utility of checklists is not limited to these circumstances, however. Communication tasks may also be specified by means of a checklist. For example, in the construction industry, two types of checklists are used. For every new building, a first checklist is drawn up by representatives of sixteen trades and sent to subcontractors and independent experts so they can double-check everything. *Id.* at 62. A second checklist specifies communication tasks. Project managers deal with unexpected and uncertain tasks by making sure the experts speak to each other about specific issues on specific dates. *Id.* at 65. "[I]f you got the right people together and had them take a moment to talk things over as a team rather than as individuals, serious problems could be identified and averted." *Id.* Thus, the construction industry relies on "one set of checklists to make sure that simple steps are not missed or skipped and another set to make sure that everyone talks through and resolves all the hard and unexpected problems." *Id.* at 70.

patients. These benefits also come at a minimal cost.[108] The concept of a basic checklist to be used during routine medical procedures was pioneered by Dr. Peter Pronovost in 2001.[109] Dr. Pronovost listed the steps that needed to be completed during the routine procedure of line insertion and asked nurses to observe how frequently doctors failed to complete each step. After observation, he discovered that doctors skipped at least one of the required steps in more than 30% of patients.[110]

Building on this research, Dr. Atul Gawande partnered with the WHO in 2007 to develop a checklist for the basic safeguards to be employed during surgical procedures.[111] The list included many of the most basic precautions, such as confirming the patient's identity and counting sponges post-procedure to ensure that none were left in the patient. Providers were instructed to verbally confirm completion of each step at specified points during the surgery.[112] In October 2007, Dr. Gawande and his colleagues implemented use of the checklist in eight hospitals around the world, ranging from an American institution with a billion-dollar budget to a hospital in Ifakara, Tanzania with minimal resources and staff.[113] After a year, the checklist yielded rather stunning results: complications from surgery fell by more than a third, the rate of surgical site infections halved,

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[108] *See* Semel et al., *supra* note 25, at 1593. In Dr. Gawande's study, use of the checklist was fully introduced within one month. *See* Haynes et al., *supra* note 2, at 493–98. The checklist only had two items that involved significant cost. *Id.* at 498. Both items were available at all sites, including the low-income ones, prior to the study. *Id.*

[109] *See* Jeff Borrink, *Checklists, Specialization, Safety, and Automation in the Intensive Care Unit*, RESPIRATORY THERAPY, Apr.–May 2008, at 15, *available at* www.respiratorytherapy.ca/pdf/RT-03-02-AM08-web.pdf (discussing the history of medical checklists).

[110] *Id.*

[111] *See* Elizabeth Gudrais, *The Unlikely Writer*, HARV. MAG., Sept.–Oct. 2009, at 30, 32 (describing Dr. Gawande's checklist study).

[112] Haynes et al., *supra* note 2 (finding that the use of a simple surgical checklist can reduce deaths among post-surgical patients by almost half).

[113] GAWANDE, *supra* note 3, at 143.

and deaths of post-surgical patients decreased by almost half.[114] Moreover, the results were observed at both high-income and low-income sites.[115]

B. An Evidentiary Privilege for Medical Checklists Fits Comfortably Within Existing Frameworks for Other Policy-Based Evidentiary Privileges

The straightforward way in which checklists record whether certain crucial aspects of a medical procedure are performed could cause healthcare institutions and providers to worry about their potential for use in litigation.[116] A provider might fear that if a step is not checked off the list, a jury would take the omission as overwhelming evidence that the step was not performed, and that injury resulted from the omission. Of course, the step may simply have been inadvertently left unchecked in the chaos of an emergency procedure, or the subsequent injury may not have resulted from the particular omission. Nevertheless, a provider might legitimately fear that the simplicity of the checklist format or the intuitive sense that a missed step must have caused the injury would ultimately bias a jury. Even in cases that do not reach trial, the balance of power in settlement negotiations could be greatly altered. Hospitals and providers may therefore be hesitant to adopt and use checklists out of concern that ultimately these checklists will be used against them.[117]

Despite the demonstrated life-saving potential of checklists, there has been no attempt to encourage their use

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[114] Haynes et al., *supra* note 2, at 495.

[115] *Id.* at 496.

[116] For purely oral checklists where no notation is made, this may not be an issue. However, it is likely that some sort of notation-tracking progression is made on many checklists that are designed to be primarily oral. Furthermore, many checklists are designed to be written, so the liability concern would certainly be an issue in that context.

[117] *See supra* notes 12–13 and accompanying text.

through legal mechanisms like an evidentiary privilege.[118] There is ample precedent for the creation of such a privilege, however. For example, the Federal Rules of Evidence and many state codes recognize a privilege protecting evidence of subsequent remedial measures from being used against the party who made the repair.[119] Similarly, rape shield laws privilege otherwise admissible evidence in the interest of protecting the victim's privacy.[120] A pending bill in the New York State Assembly proposes, in the interest of public health, to block the use of condoms as evidence in prostitution cases in order to ensure that sex workers are not discouraged from using condoms.[121] Furthermore, the PSQIA

[118] In order to properly incentivize the desired behavior, an evidentiary privilege would also need to attach to oral testimony and communications regarding the *contents* of the checklists. However, in line with the notion that the underlying facts of the incident still remain subject to discovery, verbal testimony as to what happened would, of course, remain admissible. In other words, evidence offered to prove what actually happened is always admissible, but what the checklist said (whether presented as written or oral evidence) is not. Analogously, the attorney-client privilege protects communication between an attorney and his client. However, it does not privilege the underlying content of the communications. A person is not immunized from testifying about an occurrence simply because he talked to his attorney about those facts. The client cannot be forced to testify about the communication with the attorney (and the attorney cannot be called to testify about the communication), but the facts shared with the attorney remain admissible through other means. Similarly, the contents of the checklist itself would be privileged, but the facts of the incident would remain admissible through other means.

[119] *See* FED. R. EVID. 407 ("When, after an injury or harm allegedly caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction. This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment.").

[120] *See* FED. R. EVID. 412.

[121] Assemb. B. A10893, 233d Legis. Sess. (N.Y. 2009), *available at* http://public.leginfo.state.ny.us/menugetf.cgi (proposing amendment to

itself creates this privilege for materials generated by the hospital as part of a patient safety evaluation system when reported to a PSO.[122] Evidence law is replete with provisions for the exclusion of relevant evidence where doing so serves a greater policy goal.[123] Promoting the safety of hospital patients is one such goal, and medical checklists should thus receive a similar protective evidentiary privilege.

1. Creation of an Evidentiary Privilege for Medical Checklists is Consistent with Supreme Court Jurisprudence and the Federal Rules of Evidence

An evidentiary privilege protecting medical checklists from discovery or admissibility is justified by the same rationales that support the existence of currently recognized evidentiary privileges. Rule 407 of the Federal Rules of Evidence protects against the admissibility of evidence of subsequent remedial measures.[124] Rule 407 is motivated by the "social policy of encouraging people to take, or at least not discouraging them from taking, steps in furtherance of added safety."[125] It would, of course, be relevant in some instances to know that a property owner has made safety improvements after an accident occurs on his property, just as it would be relevant in some instances to know that a step on a checklist was not crossed off. However, in both cases, an extrinsic policy objective supersedes the goal of admitting relevant evidence into court.[126]

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state evidence code rendering condoms inadmissible as evidence of prostitution).

[122] 42 U.S.C. §§ 299b-21 to -22 (2005).

[123] *See* FED. R. EVID. 403.

[124] *See* FED. R. EVID. 407.

[125] FED. R. EVID. 407 advisory committee's note.

[126] The principal motivation for the exception is a concern that defendants should not be disincentivized from adopting safety measures that may prevent future harm. *See* FED. R. EVID. 407. Evidence that the defendant has taken subsequent remedial measures should not be admissible to prove liability because doing so may discourage other defendants from taking similar safety precautions. Likewise, a checklist

Admitting evidence of the subsequent remedial measures would discourage the owner from undertaking those measures, leaving the safety hazard in place and endangering the public's safety. Similarly, admitting the checklist as evidence would discourage the hospital from promoting the use of checklists in the future. Given the improvements in patient safety that can result from the use of checklists, not using checklists would ultimately be a disservice to patients.[127] Furthermore, such evidence is highly prejudicial because it is likely to be subject to the jury's hindsight bias. As such, Rule 407 is a wise policy choice that encourages good behavior and reduces the prejudicial effect of hindsight bias: "The fact of the accident cannot realistically be suppressed, but evidence that would aggravate the bias can be. Courts' response to the problem of subsequent remedial measures reveals a good understanding of the hindsight bias and the judicial ability to respond to it."[128]

One major criticism of Rule 407's efficacy is that the rule may not actually affect behavior because the majority of the population is unaware of and unresponsive to the intricacies of the rules of evidence. However, this concern is not persuasive as applied to hospital institutions and individual providers. While the typical application of Rule 407 may involve actors who are unfamiliar with the intricacies of the rules of evidence,[129] the same cannot be said of healthcare

adopted to improve patient safety should not be admissible as evidence if doing so would discourage adoption of that safety measure in the first place by that provider or others.

[127] *See* Gudrais, *supra* note 111, at 32.

[128] Jeffrey J. Rachlinski, *A Positive Psychological Theory of Judging in Hindsight*, 65 U. CHI. L. REV. 571, 618 (1998) (concluding that Rule 407 appropriately attempts to protect defendants from hindsight bias, particularly where evidence of subsequent remedial measures has limited probative value); *see also* FED. R. EVID. 407 advisory committee's note.

[129] For example, Rule 407 may apply where a homeowner subsequently repairs an uneven stretch of sidewalk in front of his residence after a pedestrian accidentally trips and injures himself.

providers and administrators. A hospital administrator[130] who considers implementing a checklist-use policy, for example, likely understands the law and its implications for the policies the hospital adopts. Hospital administrators have access to legal counsel and advice that may shape their decisions.[131] If anything, administrators may be over-sensitive to litigation concerns[132] and will be far more likely to adopt policies encouraging the development and use of institutional checklists if the administrator can be certain that checklists cannot be used as evidence of tortious conduct.

Rape shield laws operate on the same premise as Rule 407.[133] Rule 412 excludes from trial otherwise relevant evidence of a victim's past sexual history on the basis of the extrinsic policy concerns of protecting the privacy of victims and encouraging them to come forward with their claims.[134] Likewise, statements made during settlement negotiations (or plea negotiations in criminal cases) are inadmissible in order to further the policy interest of encouraging settlements and avoiding lengthy trials.[135] A privilege for medical checklists carries similar virtues to these existing evidentiary exemptions.

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[130] A hospital's success depends on having an administrator who drives initiatives that will save lives and emphasize patient safety goals. Costa, *supra* note 1, at 9.

[131] Mikk, *supra* note 13, at 136 (discussing hospital administrators' awareness of and responsiveness to litigation trends).

[132] *Id.* at 156 (discussing litigation concerns among healthcare providers more generally); Brennan, *supra* note 13, at 1125 (finding that fear of malpractice litigation counteracts physicians' ethical duty to report injuries); Carrier, *supra* note 13, at 1585 ("physicians consistently report that they often engage in defensive practices and that they feel intense pressure to do so out of fear of becoming the subject of a malpractice lawsuit."). *See supra* note 14 and accompanying text.

[133] FED. R. EVID. 412.

[134] *See* FED. R. EVID. 412 advisory committee's note.

[135] *See* FED. R. EVID. 408 advisory committee's note; FED. R. EVID. 410.

The Supreme Court has provided some guidance as to when courts should recognize an evidentiary privilege.[136] In *Jaffee v. Redmond*,[137] the Court considered the "significant public and private interests supporting recognition of the privilege, [and] the likely evidentiary benefit that would result from the denial of the privilege . . . ."[138] In balancing these interests, the Court recognized a federal privilege that protects confidential communications between psychotherapists and their patients.[139] The Court specifically held that statements made by a police officer during counseling sessions after she shot a man were protected from compelled disclosure in a subsequent suit by the man's survivors.

Further, the Court in *Jaffee* rejected the argument that the privilege should be determined on a case-by-case basis, noting that the privilege would be ineffective if it depended on a trial judge's determination: "Making the promise of confidentiality contingent upon a trial judge's later evaluation of the relative importance of the patient's interest in privacy and the evidentiary need for disclosure would eviscerate the effectiveness of the privilege."[140] This is likewise true for medical checklists. Any uncertainty as to

[136] An evidentiary privilege may be created by either judicial recognition or statutory codification. A judicially recognized evidentiary privilege for checklists, however, would be difficult to develop because there is no discernable consensus among the states on the issue. *See* Adkins v. Christie, 488 F.3d 1324, 1328 (11th Cir. 2007) (citing the four factors outlined by the Supreme Court relevant to the question of whether a judicial evidentiary privilege should be adopted, one of which is "consensus among the states."). Moreover, some courts are hesitant to recognize privileges in the medical malpractice arena altogether, such that a strong statement by the legislature recognizing such a privilege is likely necessary. *See* Brennan, *supra* note 13, at 1125 (noting that because "judges [are] increasingly hostile to claims of confidentiality" by physicians, the establishment of such a privilege likely requires legislative action).

[137] 518 U.S. 1, 11 (1996) (recognizing federal privilege protecting confidential communications between psychotherapist and patient).

[138] *Id.*

[139] *Id.* at 2.

[140] *Id.* at 17.

the admissibility of the checklists would undermine the purpose of the privilege by failing to provide an environment of legal certainty.

Relying on the Court's opinion in *Jaffee*, lower courts have considered four factors in determining whether the creation of an evidentiary privilege is appropriate: (1) the needs of the public good, (2) whether the privilege is rooted in the imperative need for confidence and trust, (3) the evidentiary benefit of the denial of the privilege, and (4) consensus among the states.[141] Application of these factors here supports the creation of an evidentiary privilege for medical checklists. The magnitude of the medical error problem and the immense potential of checklists to save lives indicate that the public good would be enhanced by the increased use of checklists. The privilege would not be rooted in the imperative need for confidence and trust in the same way that the Court in *Jaffee* understood psychotherapy to be imperative in order to satisfy a person's need to confide. However, there still is an imperative need for those using checklists to be confident that the checklists will not be used against them in court. Additionally, potentially prejudicial, and often only marginally relevant, information will be blocked from admissibility under the privilege.[142] Concededly, however, there is little consensus (or even discussion) among the states about this privilege. The *Jaffee* factors therefore support the creation of the privilege given the gains in public safety that would result from encouraging the use of checklists, the strong need for providers to be confident that their own checklists will not be used against

[141] *See, e.g.*, *Adkins*, 488 F.3d at 1328 (describing the factors cited by the Supreme Court as relevant to whether an evidentiary privilege should be created).

[142] *See* O'Leary v. Schweiker, 710 F.2d 1334, 1341 (8th Cir. 1983) (noting that the Eighth Circuit allows introduction of checklists, although they may not be entitled to much substantive weight).

them, and the fact that checklists are rarely very probative and often very prejudicial.[143]

2. Compared to the PSQIA Privilege, an Evidentiary Privilege for Medical Checklists is More Likely to Effectively Reduce Medical Error

An evidentiary privilege similar to the PSQIA should be extended to medical checklists used to prevent incidents in the first place, not only to the after-error data created in response to incidents that have already occurred. Research demonstrates that hospitals and individual providers are concerned about compelled discovery of incident reports and other memoranda and that this fear prevents them from reporting their errors to medical error data banks.[144] In response, the PSQIA sought to privilege this information in order to encourage reporting, recognizing that the overall gain from a reduction in medical errors outweighs the benefits to potential plaintiffs who might use a particular document or report in a lawsuit.[145] It is likely that fear of litigation influences a hospital administrator's choice of whether to implement policies encouraging the use of checklists, just as "the mere fear of litigation due to disclosure of data is the greatest barrier to reporting" medical errors.[146]

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[143] Rape shield laws protect similar information: evidence that policy-makers have decided is potentially extremely prejudicial but only marginally relevant.

[144] Mikk, *supra* note 13, at 136.

[145] Lauth, *supra* note 48, at 152.

[146] Mikk, *supra* note 13, at 136; *see also* Brennan, *supra* note 13, at 1125 ("No matter how much we insist that physicians have an ethical duty to report injuries resulting from medical care or to work on their prevention, fear of malpractice litigation drags us back to the status quo."). Fear of litigation is a major concern for both healthcare providers and administrators. Consider, for example, the ever-decreasing rate of VBAC (vaginal birth after caesarean section) deliveries in the United States. In 1996, VBACs occurred at a rate of 28%, but after a handful of highly publicized lawsuits alleging uterine rupture (avoidable with a caesarean), the rate plummeted to 8.5% just ten years later in 2006. Many healthcare

In fact, an evidentiary privilege for checklists would likely be far more effective at achieving tangible patient safety gains than the current PSQIA privilege. The PSQIA privilege is problematic because fear of liability is not the sole factor contributing to the under-reporting of errors. Healthcare providers may not even recognize when they have committed an error, particularly when a patient does not suffer an adverse effect or when the provider who committed the error sees the patient only briefly. More problematic are healthcare providers' perverse incentives to under-report: providers legitimately fear reputational harm or on-the-job discipline if they comply and report, whereas they will likely suffer no harm if they do not report. As such, error reporting systems will always have difficulty ensuring that such errors are actually reported by the provider who erred because of misplaced incentives. On the other hand, the use of checklists designed by providers to address the issues they recognize as important is an intervention with which providers actually have good reason to comply. Thus, if an evidentiary privilege is justified for information compiled under the PSQIA, it is certainly justified for checklists.

3. Hospital Administrators and Medical Staff Have a Crucial Role to Play in Implementing Checklist-Use Policies

Given the demonstrated efficacy of medical checklists, hospitals should be encouraged to adopt policies that encourage the use of checklists. A hospital administrator committed to safety[147] can push to implement hospital-wide

commentators have expressed concern over the already high rate of caesareans in the U.S.; this surgical procedure is typically significantly riskier than a vaginal birth. *See* News, NEONATAL INTENSIVE CARE, Nov.–Dec. 2010, at 9–10. Nevertheless, due to perception of litigation risk, VBACs and vaginal birth deliveries in general continue to decrease in prevalence across the country. *Id.*

[147] Costa, *supra* note 1, at 9. Hospital administrative and medical leaders need to be involved in safety initiatives to ensure their success. Dr. Gawande's study chose participating pilot hospitals partially based on

guidelines on the use of checklists. Because checklists are most effective when tailored to a particular hospital setting,[148] an administrator who encourages the development of such checklists does a great service to patient safety at his institution.[149] An evidentiary privilege protecting medical checklists from discovery and admissibility (similar to the PSQIA privilege) would catalyze robust hospital implementation and experimentation with checklist policies,[150] which may be the most promising means of significantly reducing medical error.

Currently, checklists are part of a patient's medical record, which is discoverable and admissible under state and federal law.[151] If an evidentiary privilege existed,[152] a

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the hospital leadership's willingness to commit to the concept of the surgical safety checklist. "We knew better than to think that just dumping a pile of copies in their operating rooms was going to change anything. The hospital leaders committed to introducing the concept systematically." GAWANDE, *supra* note 3, at 145.

[148] *See infra* notes 185, 191 and accompanying text.

[149] Smullens et al., *supra* note 9, at 42.

[150] At a conference that discussed the implementation of a hand washing program under which patients would remind healthcare workers to comply, the primary concern of attendees was that "admission [to patients] of failure to comply with hand washing protocols could lead to legal action." Dan Bowman, *Doctors, Nurses Don't Want Patients to Bug Them About Hand Washing*, FIERCEHEALTHCARE (Sept. 14, 2010), http://www.fiercehealthcare.com/story/doctors-nurses-dont-want-patient-reminders-about-hand-washing/2010-09-14.

[151] Mikk, *supra* note 13, at 159. Alternatively, checklists could be excluded from federal court and some state courts on the ground that they are inadmissible hearsay. This is unlikely to succeed (particularly when hospitals systematically support their use) because they fall quite comfortably under the business records exception to the hearsay rule. *See* FED. R. EVID. 803(6). This exception makes admissible records of acts made at the time of an event if kept within the regular course of business, unless there is reason to think the records are untrustworthy. *See id.* Notations on checklists are obviously made simultaneously with the performance of the corresponding action, and institutional guidelines on the use of checklists would indicate that they are kept within the regular course of business. Even if the argument is made that they are untrustworthy and therefore should not be admissible, such a determination would have to be made on a case-by-case basis, with

hospital's administrators and patient safety committee could start by adopting a hospital-wide checklist policy that would be binding on all employees, including nurses and pharmacists.[153] However, nursing practice has already taken steps to incorporate checklist usage into its daily work;[154] where change is really needed is on the physician level.

Most physicians are independent contractors, and hospitals have traditionally only weakly enforced physician compliance with hospital-wide clinical standards.[155] Nevertheless, some administrators may believe that their hospital's physicians would be amenable to policies that require the development and use of checklists.[156] In such

reference to the particular institution's checklist policies and means of recording and utilizing checklists. Given that checklists are at least *sometimes* admissible, *see, e.g.*, *O'Leary v. Schweiker*, 710 F.2d 1334, 1341 (8th Cir. 1983) (noting that the Eighth Circuit allows introduction of checklists), the uncertain legal environment would likely preclude hospitals from experimenting with checklist adoption policies.

[152] Ideally, such a privilege would be adopted at both the federal and the state levels. Lawsuits potentially involving checklists might be heard in either state or federal court, so inconsistent adoption of such a privilege would almost certainly result in gaming by both parties to get into the more favorable venue, diluting the effect of the privilege. If, for example, a few states adopted the privilege but the federal government did not, hospitals' incentives to adopt checklist policies would be diminished because of the uncertain legal environment and the chance that the checklist would still be admissible in the federal venue under the business records exception.

[153] Robert M. Wachter & Peter J. Pronovost, *Balancing "No Blame" with Accountability in Patient Safety*, 361 NEW ENG. J. MED. 1401, 1402 (2009) (discussing hospital employment structure).

[154] *See* GAWANDE, *supra* note 3, at 37 ("[Checklists] have been welcomed by nursing but haven't quite carried over into doctoring.").

[155] Deutsch, *supra* note 11, at 28. Note that the resurgence of the trend towards direct hospital employment of physicians, which failed in the 1990s, would render employee-physicians subject to binding policies initiated by the hospital as well, subject to the terms of their employment contracts.

[156] For example, at the University of California, San Francisco Medical Center, it is considered a violation of Medicare Conditions of Participation and Joint Commission standards if not all verbal orders are signed or if doctors do not dictate their operating room summaries quickly enough. Sandra Yin, *Pushing Patient Safety Takes More Guts Than We've*

cases, the hospital could enforce the mandated use of checklists by conditioning privileges, such as the use of operating rooms, on compliance with hospital policies.[157] Even for a hospital that is hesitant to enforce sanctions against physicians for fear of alienating them or losing their business,[158] policies that encourage the formation of hospital committees to collaborate and gather provider input on developing checklists would be very valuable. Paving the way for this provider involvement is crucial because it ensures that individual providers do not feel that their autonomy is being infringed upon and encourages them to become psychologically invested in the checklist and its success.[159]

Seen, FIERCEHEALTHCARE (Sept. 10, 2010, 9:20 AM), http://www.fiercehealthcare.com/story/how-pushing-patient-safety-takes-more-guts-weve-seen/2010-09-10?utm_medium=nl&utm_source=internal. Physicians may be suspended from the medical staff if they fail to comply with these rules. *Id.* Dr. Robert Wachter, chief of the Division of Hospital Medicine and chief of the Medical Service at UCSF, has stated (in the context of hospital policies mandating hand washing) that approaches that have consequences for doctors would improve statistics on hand hygiene nationally, because part of the reason that hospitals have gotten doctors to comply with other mandated standards is that "there is skin in the game." *Id.* Similarly, hospitals with employee-physicians may be more open to requiring checklist use by physicians. After all, the types of physicians who are willing to enter into employment contracts with hospitals may also be those who will be least resistant to hospital checklist policies.

[157] *See* Wachter, *supra* note 153, at 1402–03 (2009) (distinguishing between perceived "administrative" transgressions and "safety" transgressions and the disparate disciplinary approaches taken by hospitals to deal with them).

[158] Wachter, *supra* note 153, at 1403.

[159] Consider the reactions of providers in two different scenarios. In one, providers are forced to use universal, generalized checklists that are imposed on them by either legislators or administrators and that are untailored to their situations, with possibly irrelevant items. In a second scenario, providers play an important role in developing checklists for use at their own institutions, and the checklists are carefully tailored to the particular circumstances of their work environments (such as the patient population) and include the most relevant considerations to their practice. The reaction of providers is critical, because checklists must ultimately be meaningfully used by providers in order to be of any benefit to patients. In Dr. Gawande's study implementing surgical checklists at hospitals

IV. OBJECTIONS TO AN EVIDENTIARY PRIVILEGE FOR MEDICAL CHECKLISTS: CRITICISMS AND ALTERNATE APPROACHES

A. Criticisms of an Evidentiary Privilege for Checklists Fail to Acknowledge Checklists' Demonstrated Capacity to Significantly Reduce Medical Error

The criticisms of an evidentiary privilege for checklists are misplaced and fail to recognize their enormous potential to reduce medical errors.[160] Perhaps the most compelling argument against an evidentiary privilege is that it unfairly prevents an injured patient from using evidence that shows

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across the world, when hospital leaders wanted to force checklist use, the study authors "discouraged it. Forcing the obstinate few to adopt the checklist might cause a backlash that would sour others on participating. We asked the leaders to present the checklist as simply a tool for people to try in hopes of improving their results." GAWANDE, *supra* note 3, at 151.

[160] One concern that can be quickly addressed is whether the use of checklists violates the requirement of informed consent. The Office for Human Research Protections (OHRP) shut down Dr. Pronovost's initial study implementing the use of line insertion checklists in Michigan hospitals on the grounds that the study lacked informed consent. Atul Gawande, Op-Ed., *A Lifesaving Checklist*, N.Y. TIMES, Dec. 30, 2007, § 4, at 48 (criticizing the OHRP's decision to shut down the Michigan study). Ironically, part of the OHRP ruling was that a checklist might require even stricter oversight than normal because healthcare providers were also put at risk by "exposing how poorly some of them follow basic infection-preventing procedures." *Id.* However, after a great deal of publicity ensued, the OHRP clarified its position on its website, stating that the ruling was applicable specifically to Dr. Pronovost's study examining the effects of checklists, not to the use of checklists themselves. Jon Merz, *OHRP Responds to 'A Lifesaving Checklist'*, INS. REVIEW BD. FORUM (Jan. 15, 2008, 4:38 PM), http://www.irbforum.org/forum/read/2/161/161 (responding to Dr. Gawande's *New York Times* editorial). The OHRP determined that thereafter, "[i]f any hospital or intensive care unit decides to implement the use of checklists or other measures only for the reason that they believe those measures will improve the quality of care provided, they may do so without consideration of . . . regulations for the protection of human research subjects." *Id.* Therefore, the OHRP's initial ruling does not pose any barriers to hospitals that wish to adopt checklists as safety measures.

that he was negligently treated. After all, if a step is left unchecked from the list, the omission may be relevant and persuasive evidence that a care provider negligently provided medical care. Indeed, a checklist would create an apparent paper trail as to what transpired during the course of a patient's treatment.

Concededly, if an evidentiary privilege is adopted, there will no doubt be instances in which evidence is excluded that would otherwise be very useful to a patient's case. However, like the PSQIA privilege which similarly excludes relevant information, the evidentiary privilege is not a bar on liability, but simply a bar on the introduction of one single piece of evidence.[161] All of the underlying facts of the suit would still be subject to discovery and admissibility. The only product protected under the privilege would be the contents of the checklist itself. Both the written checklist and oral testimony as to its contents would be inadmissible. However, oral testimony as to what actually happened would still be admissible because it goes to the underlying facts of the incident that remain discoverable and admissible. Thus, the fact that a step on the checklist was not performed could still be established by asking witnesses what transpired.[162]

Moreover, because of the nature of many items on the checklist, it is unlikely that evidentiary use of a checklist would ever be necessary to establish the cause of a patient's

[161] Lauth, *supra* note 48, at 158.

[162] A discerning lawyer could, of course, read through a copy of the checklist steps and inquire during discovery as to whether each step was performed, thus effectively gathering the practical equivalent of the checklist's contents. This would not defeat the purpose of creating the evidentiary privilege. A lawyer could ask these questions regardless of whether a checklist was utilized. The privilege protects the piece of paper itself, which could otherwise be highly prejudicial. Further, knowledge of the checklist's protection will mitigate the sense of healthcare providers and administrators that its use represents a potential danger. Indeed, the fear of liability is often cited as the principal cause of the practice of defensive medicine. *See, e.g.*, Carrier et al., *supra* note 13, at 1585. Therefore, policies that reduce providers' perceived risks of liability can facilitate the desired changes in the behavior.

injury.[163] Some of the items cannot indicate what went wrong during a procedure, and entering an incomplete checklist would in many instances only serve to prejudice the fact-finder.[164] For example, the items that detail each team member's name and role, or that ask the surgeon to anticipate how long the case will take, are not sufficient to establish causation of injury even if they are left unmarked. Additionally, standard hospital practice combined with diagnosis of a patient's subsequent injury will likely yield the necessary knowledge to constitute evidence of what happened. For example, one of the items on Dr. Gawande's checklist requires that a provider count the number of sponges at the end of an operation to ensure that none are left inside the patient. However, if a surgical sponge is left inside the patient's body, subsequent infection and x-rays will indicate that fact; the checklist itself is not necessary to prove this in court. By contrast, checklists are particularly useful to the healthcare providers who must carry out the procedure. A provider who notices, after an operation, that the instruction to verify how many sponges the provider possesses is unmarked can pinpoint the problem quickly and accurately. Accordingly, checklists enhance a patient's safety, but a restriction on their admission in court would not hamper the patient's ability to prove negligence.

Other standard surgical checklist items include confirming the procedure to be performed, ensuring the correct site of surgery, and double-checking the patient's identity. For failures to perform these types of checklist items, the outcome of the procedure will make the omission quite obvious, and there will be far more compelling evidence than a checklist to show that the care provided was negligent. The intuitive nature of these items renders them provable by easily obtainable and admissible non-checklist

[163] *See supra* note 17 (listing the items included on the Surgical Safety Checklist designed by Dr. Gawande for the WHO).

[164] Of course, the defendant can object that the evidence is substantially more prejudicial than probative and should be excluded under Rule 403, but this requires an individual, case-by-case determination, which leads to an environment of legal uncertainty.

evidence. Because the most useful checklists are often largely comprised of highly intuitive items, privileging checklists may, in many instances, not have much of an impact on a plaintiff's case.[165]

Another criticism of an evidentiary privilege for checklists is that checklist-use policies will be ineffective because individual providers will either refuse to use checklists because they may feel checklists infringe on their autonomy,[166] or because each step will be mindlessly checked

[165] The airline industry, which utilizes checklists for every conceivable flight situation, has long recognized that the simplest checklists with the most intuitive items are often the most effective. GAWANDE, *supra* note 3, at 114-35. This is true whether the aircraft is flown by a commercial airline or the military. For example, when the Army Air Corps held a flight competition for airplane manufacturers in 1935, the clear frontrunner was the Boeing 299. To everyone's shock, however, the plane stalled and exploded during the test flight. Investigation later revealed that nothing mechanical had gone wrong. Rather, the highly experienced pilot, Major Hill, had forgotten to release a new locking mechanism. Instead of foregoing the use of the plane altogether, the Army purchased a few planes and decided to create a pilot's checklist. The checklist was simple and brief, and filled with the "kind of stuff that all pilots know to do. They check that the brakes are released, that the instruments are set, that the door and windows are closed, that the elevators controls are unlocked—dumb stuff. You wouldn't think it would make that much difference." *Id.* at 33–34. Nevertheless, pilots went on to fly the Model 299 1.8 million miles without a single accident, and the US gained a decisive air advantage in World War II by utilizing the aircraft. *Id.* at 34. Checklists are filled with intuitive, simple items. The idea is to allow the person using the checklist to concentrate on the complex issues that deserve mental attention rather than the mechanical, simple ones.

[166] Along these lines, it should be noted that improving quality and safety of care can be done along many dimensions. For example, there are quality and safety concerns in many aspects of care, including whether a diagnosis is correct, whether the right treatment is selected, whether treatment is performed in a technically competent manner, whether service quality is adequate, and whether consumers can access the care they desire. FED. TRADE COMM'N & DEP'T OF JUST., IMPROVING HEALTH CARE: A DOSE OF COMPETITION 3 (2004). The level to which autonomy concerns are implicated varies greatly in these different areas. In other words, autonomy concerns need to be viewed in light of the particular area of quality being targeted by a given safety measure. Ensuring that treatment is performed in a technically competent manner seems to be

off and no meaningful attempt made to correctly comply with the checklist.[167] These concerns are powerful. Despite the

relatively unoffensive to physicians' autonomy when viewed in this light. Like other professionals, physicians have a large degree of discretion and their autonomy should be respected, but not to the extent that they may go about performing accepted procedures incorrectly. Just as an attorney can be liable for malpractice for failing to follow the right procedure for filing a legal document, physicians can be held liable for failing to perform a widely accepted medical procedure correctly. Professional autonomy concerns are not implicated by insisting that professionals perform those aspects of their duties that are standardized according to the accepted procedures. The autonomy fear is misplaced because checklists actually free providers to concentrate on the truly discretionary and innovative aspects of care, where their creativity and ingenuity are required. "The fear people have about the idea of adherence to protocol is rigidity. They imagine mindless automatons, heads down in a checklist, incapable of looking out their windshield and coping with the real world in front of them. But what you find, when a checklist is well made, is exactly the opposite. The checklist gets the dumb stuff out of the way, the routines your brain shouldn't have to occupy itself with . . . and lets it rise above to focus on the hard stuff." GAWANDE, *supra* note 3, at 177.

[167] For example, use of pre-surgical checklists was mandated at the Rhode Island hospital where three wrong-site brain surgeries took place in 2007. The incidents would not have occurred had the checklists been followed correctly. *See* Bello, *supra* note 102. This demonstrates how important it is for hospital administrators to take a role in implementing checklist policies to which providers will actually respond. While hospitals traditionally separate medical and administrative responsibilities, this is no longer always the case because hospitals are now frequently held responsible for the safety errors of medical staff. *Id.* For example, the Rhode Island hospital was fined $150,000 for a string of 2007 wrong-site surgeries. *Id.* The hospital itself was also held responsible for implementing the surgical safety checklist. *Id.* Hospital administrators no longer have the luxury of leaving safety decisions to medical personnel only. As entities, hospitals are often held legally accountable for the mistakes that occur within their walls, regardless of the employment status of the individual who made the mistake. "We are going through a transition . . . . The phase we're leaving is one in which the doctor was king and professional autonomy was the dominant value for physicians and hospitals were places they worked. Hospital administrators were there partly to keep the doctors who bring in the patients happy. We're moving to a world where hospitals, more than doctors, are being held accountable for safety and quality. . . . [T]he hospital is under the gun to try to improve quality and safety. With The Joint Commission, Medicare, and other stakeholders holding them accountable, the hospitals have to

published empirical research demonstrating the potential value of checklists, many physicians have resisted using checklists because they view checklists as strict protocols that limit their professional autonomy and discretion.[168] Hospital administrators have largely been unwilling to challenge this attitude.[169]

One reason individual healthcare providers may refuse to use checklists is their concern about potential liability if a patient later develops complications. Thus, adoption of an evidentiary privilege would reduce some of this resistance to using checklists. Other providers may be more willing to use checklists once they see further research demonstrating their efficacy. Still others might be informally encouraged or pressured by physician colleagues and nursing staff to do so. Finally, many providers may be willing to use checklists if they are given an opportunity to actively shape the content of such checklists.[170] By setting forth a formal structure for developing institutional checklists, administrators can help ensure that providers are given an opportunity for meaningful input. Hopefully, this will translate into superior checklists and greater use of checklists by providers.

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figure out how to get everyone to play together or risk getting dinged on a Leapfrog report card or fail to pass a Joint Commission survey." Sandra Yin, *Doctors and Hospitals Must Play Together or Risk Extinction*, FIERCEHEALTHCARE (Sept. 3, 2010, 10:37 AM), http://www.fiercehealthcare.com/story/dr-bob-wachter-doctors-and-hospitals-must-play-together-or-risk-extinction/2010-09-03. This is even true on a personal level. About half of nonprofit hospital chief executives do not receive full annual salary bonuses unless they meet incentive goals related to safety. Christopher Rowland, *Hospitals Tie CEO Bonuses to Safety*, BOS. GLOBE, May 5, 2007, at A1 ("Hospitals have traditionally rewarded chief executives for their ability to attract patients and make money . . . now more are linking a portion of executives' pay to a range of safety measures, from reducing medication errors to monitoring how often doctors wash their hands.").

[168] Deutsch, *supra* note 11, at 28.

[169] *Id.*

[170] *See supra* note 159.

Regarding the concern that checklists are ineffective[171] because providers are not committed to their use, the research indicates precisely the opposite. In the two studies of their efficacy, checklists saved a substantial amount of money and many lives.[172] It seems overly pessimistic to suggest that providers would purposely falsify information on these checklists by simply checking steps off without making an effort to perform them. If providers are indeed so unmotivated to abide by protocols and ensure proper care, going to a hospital may not be a wise choice after all. Overall, research indicates that checklists are very effective over time and will be properly used when appropriately adopted.[173]

Moreover, checklists are still a relatively new innovation in many areas of medicine, and once providers recognize their efficacy, they will likely appreciate the need to use them. In his recent book, Dr. Gawande describes a study at a hospital where he implemented a checklist policy.[174] At the end of the study, Dr. Gawande asked healthcare providers whether they would want their doctor to use a checklist if they were admitted for treatment in a hospital. Ninety-three

[171] These criticisms specifically target checklists and the checklist efficacy studies rather than the evidentiary privilege. However, because the justification for the evidentiary privilege lies almost entirely in the perceived efficacy of checklists, they simultaneously implicate the argument that public policy should encourage the use of checklists with an evidentiary privilege.

[172] Haynes et al., *supra* note 2, at 491–96; Wachter, *supra* note 153, at 1401.

[173] One study offers powerful evidence that, once implemented, checklist policies result in significant, long-term safety gains even after the initial period of implementation. Lindsay Tanner, *Big VA Study Shows Surgery Checklist Saves Lives*, YAHOO NEWS (Oct. 19, 2010, 4:02 PM), http://news.yahoo.com/s/ap/20101019/ap_on_he_me/us_med_surgery_checklist. In 2003, VA hospitals adopted a surgery protocol whereby team members create and discuss checklists in briefings before, during, and after surgery. *Id.* Mortality rates in 2003 were 17 per 1,000 surgeries; by 2010, this dropped to 14 per 1,000 surgeries in hospitals implementing these checklist procedures. *Id.*

[174] GAWANDE, *supra* note 3, at 156–57.

percent answered "yes."[175] Dr. Gawande himself maintains that by using surgical checklists he avoids one or two mistakes each week.[176] Accordingly, resistance to checklists will likely decline as the body of empirical research continues to grow, checklists become more prevalently used, and a larger portion of the medical profession appreciates the safety gains checklists afford.

B. Legislating the Use of Checklists Would Destroy Much of Their Value by Preventing Providers from Utilizing Their Experience and Knowledge to Create Innovative and Relevant Checklists

An alternative to creating an evidentiary privilege for checklists is for states to simply mandate their use.[177] The United Kingdom has taken this approach. The National Patient Safety Agency (NPSA) requires that the WHO checklist be used in hospitals in England and Wales.[178] While this approach may have intuitive appeal, it carries the cost of excessive rigidity, particularly as applied across a broad spectrum of diverse institutions. Mandating the use of a particular checklist—or any medical technique—is simply not a feasible approach to implementing successful, evolving checklist policies.[179] "To be sure, checklists must not become

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[175] *Id.* at 157.

[176] *Id.* at 187.

[177] Another alternative is for courts to adopt the use of different types of checklists as a requisite element of the standard of care. It would be very unusual for a court to interpret reasonable medical care as requiring more than the care currently practiced by the majority of doctors, but not entirely unprecedented. *But see, e.g.*, Helling v. Carey, 519 P.2d 981 (Wash. 1974) (holding that glaucoma test must be performed for all patients, even those under forty, despite the fact that the profession had adopted a standard of care which required such a test only for patients over forty years of age).

[178] NAT'L PATIENT SAFETY AGENCY, PATIENT SAFETY ALERT: UPDATE (2009), *available at* http://www.safesurg.org/uploads/1/0/9/0/1090835/npsa_checklist.pdf.

[179] Coercive regulatory strategies "invariably trigger provider opposition, lobbying, and a full range of inefficiencies and unanticipated consequences." David A. Hyman & Charles Silver, *You Get What You Pay*

ossified mandates that hinder rather than help. Even the simplest requires frequent revisitation and ongoing refinement."[180]

The UK's approach illustrates this problem. In 2005, the NPSA issued a set of guidelines to hospitals to prevent wrong-site surgeries.[181] These guidelines were replaced with the WHO surgical checklist in 2010.[182] In the UK from 2005 until 2010, providers were bound to use what is now recognized as an incomplete mechanism for combating medical error. British providers were not able to experiment with, contribute to, or adopt policies in accordance with evolving standards of medicine. As a result of the evolving nature of medical standards of care, legislators should be, and typically are, hesitant to impose particular requirements

For: Result-Based Compensation for Health Care, 58 WASH. & LEE L. REV. 1427, 1457–58 (2001). On the other hand, localizing the process and giving providers input recognizes that providers are significantly better-situated to improve quality than regulators. "[Providers] have access to the information and skills that are needed to ensure the consistent delivery of high quality care. The trick is to create incentives for providers to gather this information and to develop systems for assuring quality. Regulators have great difficulty in accomplishing this goal because they must gather information and monitor quality using top-down mechanisms." *Id.* at 1458. Since regulators typically use disciplinary sanctions to accomplish their goals, they end up offending some providers, doing little to motivate non-sanctioned providers, and, on occasion, triggering "a profession-wide backlash." *Id.*

[180] GAWANDE, *supra* note 3, at 183. Dr. Gawande also notes that airline manufacturers put a publication date on all their checklists because they are *expected* to change with time. *Id.* at 184.

[181] Sally J. Giles et al., *Experience of Wrong Site Surgery and Surgical Marking Practices Among Clinicians in the UK*, 15 QUALITY & SAFETY IN HEALTH CARE 363, 365 (2006) (describing a study that showed the marking practices prior to the NPSA 2005 Correct Site Surgery Alert).

[182] *See* NAT'L PATIENT SAFETY AGENCY, *supra* note 178, at 1 (stating that the 2010 guidelines replace the 2005 Correct Site Surgery Alert). Recent research illustrates the problem with mandating the use of a specific checklist. The Surgical Patient Safety System (SURPASS), a surgical checklist that focuses on the entire surgical pathway (prior, during, and after surgery), evidently has the potential for a "more substantial improvement in safety" than the WHO checklist. de Vries et al., *supra* note 2, at 1929.

in the form of the standard of care.[183] It is not only impractical and outside the legislature's expertise to impose such standards, but it poses the risk of potentially stifling the creative development of checklists that fight medical error.

Furthermore, the legal imposition of a medical standard of care disrupts local systems that have adapted to their particular circumstances.[184] Checklists derive much of their utility from the way that they impose uniformity on medical procedures, but the process of developing the ideal uniform procedure for a given hospital environment is complex and not identical for every institution.[185] For example, the U.S. Centers for Disease Control and Prevention website includes a version of the surgical safety checklist for hospitals, but prefaces all of its checklists intended for use by hospitals with the disclaimer that they should be adjusted to the hospital's unique patient environment as necessary.[186]

In fact, checklists are most useful when they are developed by local healthcare providers to respond to local circumstances and problems. For example, Dr. Gawande describes the story of an emergency response team in a small Austrian town in the Alps. In a widely publicized case, a three-year-old girl was lost beneath the surface of an icy

[183] In the United States, much discretion has been afforded to physicians by the use of "standard of care" guidelines in medical malpractice lawsuits. Rather than judging whether a physician was negligent by pre-set, objective medical guidelines, a court looks to what other medical professionals would have done in the same context. *See, e.g.*, Zechmann v. Thigpen, 437 S.E.2d 475, 476 (Ga. Ct. App. 1993).

[184] *See* Giles et al., *supra* note 181, at 368.

[185] Significantly, in Dr. Gawande's study introducing the surgical checklist in hospitals across the world, each hospital made its own adjustments to the checklist. For checklists to be effective, they must be carefully crafted to fit the needs of their users. "Each hospital would have to adjust the order and wording of the checklist to suit its particular practices and terminology . . . . A few had already indicated they wanted to add extra checks." GAWANDE, *supra* note 3, at 146.

[186] *See, e.g.*, CTRS. FOR DISEASE CONTROL & PREVENTION, HEALTH PROFESSIONAL PANDEMIC PLANNING CHECKLISTS, http://www.flu.gov/professional/hospital/index.html (last visited Dec. 1, 2010).

fishpond for thirty minutes. When authorities finally retrieved her, she had no blood pressure or pulse. Her brain appeared to have ceased functioning, and she was ostensibly dead. However, through a series of stunning medical interventions over a period of weeks, doctors slowly brought the girl back to life. Dr. Markus Thalmann, a cardiac surgeon who operated on the girl, explained to Dr. Gawande his understanding of why they were able to achieve this remarkable outcome:

> [Dr. Thalmann] had been working in Klagenfurt for six years when the girl came in. She had not been the first person whom he and his colleagues had tried to revive from cardiac arrest after hypothermia and suffocation. His hospital received between three and five such patients a year, he estimated .... For a long time, he said, no matter how hard the hospital's medical staff tried, they had no survivors. Most of the victims had been without a pulse and oxygen for too long when they were found. But some, he was convinced, still had a flicker of viability in them, yet he and his colleagues had always failed to sustain it. He took a close look at the case records. Preparation, he determined, was the chief difficulty. Success required having an array of people and equipment at the ready .... Almost routinely, someone or something was missing. He tried the usual surgical approach to remedy this—yelling at everyone to get their act together. But still they had no saves. So he and a couple of colleagues decided to try something new. They made a checklist. They gave the checklist to the people with the least power in the whole process—the rescue squads and the hospital telephone operator—and walked them through the details. In cases like these, the checklist said, rescue teams were to tell the hospital to prepare for possible cardiac bypass and rewarming. They were to call, when possible, even before they arrived on the scene, as the preparation time would be significant. The telephone operator would then work down a list of people to notify them to have everything set up and standing by. With the checklist in place, the team

> had its first success—the rescue of the three-year old girl.[187]

The team has had two other such rescues, even after Dr. Thalmann's departure to a different hospital. This story illustrates the adaptability of checklists to a wide array of situations and the importance of providers' freedom to develop new uses for checklists. No legislator in a state capitol would be able to identify the need for a checklist in this circumstance and create one perfectly suited to it; the innovative role of providers should be preserved and encouraged, not minimized by implementation of rigid, centralized checklist policies. Doubtless other unique circumstances exist in which physicians and patients would benefit from the development of checklists adapted to their unique circumstances.[188] By incentivizing their production

[187] GAWANDE, *supra* note 3, at 44–46.

[188] Other instances of checklists developed within institutions to meet particular institutional needs abound. For example, in one hospital, the director of surgical administration (who also happened to be a pilot) decided to utilize the aviation approach to checklists by designing a whiteboard to be placed in each operating room that would provide check boxes for nurses to verbally confirm with the team that they had the correct patient and correct surgery site. He also designed a special tent to be set over the scalpel that could only be removed by the nurse once the checklist was completed. The tent served the dual purpose of reminding the team to perform the checklist but also to subtly empower the nurse to ensure that the checklist was completed. *Id.* at 100. In another hospital, the chairman of surgery explained how his institution had devised a broader, twenty-one-item list to catch a span of potential errors. This checklist was implemented alongside a mandatory team briefing prior to surgery. *Id.* at 100–01. A Johns Hopkins surgeon devised an eighteen-item checklist that he and eleven surgeons implemented at their institution. *Id.* at 101. A group of Kaiser hospitals in Southern California adopted a thirty-item checklist also premised on aviation checklist principles. *Id.* The considerable diversity of institutional checklists indicates the need to ensure institutional autonomy in their development. "[N]o one checklist [can] anticipate all the pitfalls a team must guard against." *Id.*

with an evidentiary privilege, the potential for such safety gains is enormous.[189]

Checklists can improve care in many areas, but without according them an evidentiary privilege hospitals and providers remain discouraged from using them and discovering innovative applications. Dr. Pronovost's original checklist dealt with the simple procedure of line insertion.[190] In just a year and a half, the hospitals involved in his project saved $175 million in costs and more than 1,500 lives. However, before this study, it was unlikely that anybody would have thought using a checklist for line insertion could produce such great benefits. In order to achieve the full array of safety gains that checklists have to offer, hospitals and healthcare providers need the freedom to experiment with new checklist policies.[191]

V. CONCLUSION

The statistics measuring the cost and frequency of medical error in the United States today are chilling. The

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[189] Dr. Gawande describes how surgeons could adopt specialized checklists for all types of major procedures and emergency checklists for nonroutine situations. Further, outside of the operating room, "there are hundreds, perhaps thousands, of things doctors do that are as dangerous and prone to error as surgery. . . . All involve risk, uncertainty, and complexity—and therefore steps that are worth committing to a checklist and testing in routine care. Good checklists could become as important for doctors and nurses as good stethoscopes . . . . The hard question—still unanswered—is whether medical culture can seize the opportunity." *Id.* at 161.

[190] Borrink, *supra* note 109, at 15.

[191] Each institution has to make a number of key decisions in checklist design. Checklists become too cumbersome when they are too long and induce people to take shortcuts. "So you want to keep the list short by focusing on . . . the steps that are most dangerous to skip and sometimes overlooked nonetheless." GAWANDE, *supra* note 3, at 124. The exact wording, look, and even font of the checklist are also important decisions to be made in checklist design. Overall, experimentation is critical: "[A] checklist has to be tested in the real world, which is inevitably more complicated than expected. First drafts always fall apart . . . and one needs to study how, make changes, and keep testing until the checklist works consistently." *Id.* at 123–24.

number of deaths caused by medical error annually roughly equals the number of deaths that would occur if a commercial jet airplane crashed each day of the year.[192] The IOM Report is invaluable for having brought this problem to the attention of the medical community and public. Unfortunately, the policies adopted in response to the report have not made significant inroads in reducing medical error.[193] This is likely because these policies do not aim to directly modify provider behavior. Medical checklists, however, have the demonstrated power to prevent medical errors from occurring. Checklists improve communication among members of teams of healthcare providers and aid with increased compliance with evidence-based standards of care.[194] These qualities are desirable in all aspects of medical care and have the potential to improve medicine in many ways.

If post-error reports merit an evidentiary privilege (such as those accorded by the PSQIA and state law), pre-error prevention efforts should as well. The creation of a new drug that could reduce the deaths of surgical patients by nearly half and which posed virtually no risk of harm to any surgical patient would likely be hailed as a miracle. Research demonstrates that checklists have the potential to do just that.[195] Even if checklists work half as well as research suggests they will, they are still likely the most effective medical innovation of the decade. Accordingly, the law should be structured to encourage their use by means of an evidentiary privilege.

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[192] *Id.*

[193] Harrington, *supra* note 6, at 381.

[194] Haynes et al., *supra* note 2, at 492.

[195] Haynes et al., *supra* note 2, at 491; Wachter, *supra* note 153, at 1401.