MEDICARE'S AUGUST RULE: NECESSARY STEP TOWARD MINIMIZING FEDERAL SPENDING OR OVERBROAD DECISION LEADING TO HIGHER MALPRACTICE COSTS?

Abstract: Recently, the federal agency that administers Medicare decided that, beginning in 2008, Medicare will no longer pay for certain patient conditions acquired in the hospital that are deemed preventable. Patient safety advocates support this pronouncement because it gives health care providers an additional reason to avoid the occurrence of these conditions. Some physicians, however, believe that the decision was too overbroad because of its inclusion of certain infections and bedsores that are not always preventable for all patients. Because some conditions involved are not preventable, the occurrence of a condition should be presented in the same manner as other evidence in a malpractice case, through expert testimony.

Introduction

On August 22, 2007, in response to congressional legislation, the Centers for Medicare and Medicaid Services ("CMS"), the federal agency that administers Medicare, decided that beginning in 2008, Medicare would no longer pay for certain preventable conditions acquired in a hospital (the "August Rule").[1] The legislation required that CMS select at least two conditions that are (a) high cost or high volume, (b) result in the assignment of a case to a diagnosis-related group ("DRG") that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the ap-

[1] *See* Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, 72 Fed. Reg. 47,130 (Aug. 22, 2007) (to be codified at 42 C.F.R. pts. 411, 412, 413, 489); Press Release, Ctrs. for Medicare & Medicaid Servs., CMS Announces Payment Reforms for Inpatient Hospital Services in 2008 (Aug. 1, 2007) (on file with author) [hereinafter Aug. Press Release]; *see also* Dayna C. Nicholson & Lynsey A. Mitchel, *Medical Error Happened: Now What? The Implications for Medical Errors Heat Up,* J. Health Care Compliance, Jan.–Feb. 2008, at 5, 11.

plication of evidence-based guidelines.[2] For hospital discharges occurring since October 1, 2008, hospitals do not receive additional payment for treating one of the selected conditions if it was not present on admission.[3] This legislation is a response to increasing concerns about the economic and personal cost of medical errors.[4]

In 2004, Margaret O'Neill had intestinal surgery at a Seattle hospital to have scar tissue removed.[5] Although the operation itself was successful, Ms. O'Neill died less than a week later because of an infection that the hospital staff failed to control.[6] Ms. O'Neill's daughter, Eileen O'Neill-Pardo, believes that her experience demonstrates the need for Medicare's August Rule.[7] Another quintessential example of a preventable medical error occurred after the birth of actor Dennis Quaid's twins, who nearly died from an accidental overdose of the blood-thinning drug Heparin.[8] Cedars-Sinai, the hospital responsible for giving the Quaid twins the overdose, described the event as a preventable error involving a failure to follow its standard policies and procedures.[9]

Richard Dustin Flagg was also a victim of preventable medical error.[10] Mr. Flagg was diagnosed with a benign bleeding tumor in one of his lungs and went into surgery to have the tumor removed.[11] The surgeon removed the wrong lung, which was healthy.[12] As a result, Mr. Flagg needed oxygen twenty-four hours a day and was permanently connected to oxygen tanks that he carried on an electric cart that he rode wherever he went.[13] In 2003, Mr. Flagg testified before a forum on

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[2] *See* Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 5001(c), 120 Stat. 4, 30 (codified at 42 U.S.C.A. § 1395ww (West Supp. 2008); Changes to the Hospital Inpatient Prospective Payment Systems, 72 Fed. Reg. at 47,135, 47,200.

[3] *See* 42 U.S.C.A. § 1395ww; Changes to the Hospital Inpatient Prospective Payment Systems, 72 Fed. Reg. at 47,135, 47,200.

[4] *See* Changes to the Hospital Inpatient Prospective Payment Systems, 72 Fed. Reg. at 47,135, 47,200; Aug. Press Release, *supra* note 1; *see also* Robert Pear, *Medicare Says It Won't Cover "Preventable" Hospital Errors*, N.Y. Times, Aug. 19, 2007, at A1; Dan Childs, *Medical Errors, Past and Present*, ABC News, Nov. 27, 2007, http://abcnews.go.com/Health/Story?id=3789868 &page=1; Ctr. for Justice & Democracy, In Memoriam: Richard Flagg, http://www.centerjd.org/archives/malpractice/stories/Flagg%20Obit.php (last visited Feb. 1, 2009).

[5] *See* Pear, *supra* note 4.

[6] *See id.*

[7] *See id.*; *see also* Nicholson & Mitchel, *supra* note 1, at 11. *See generally* Changes to the Hospital Inpatient Prospective Payment Systems, 72 Fed. Reg. 47,130.

[8] *See* Childs, *supra* note 4.

[9] *See id.*

[10] *See* Ctr. for Justice & Democracy, *supra* note 4.

[11] *See id.*

[12] *See id.*

[13] *See id.*

medical malpractice, organized by House Judiciary Committee Democrats, about his experience as the victim of a medical error.[14] Despite the deterioration of his health caused by medical error, Mr. Flagg seized the opportunity to fight anti-patient legislation in Congress.[15] In addition to traveling to Washington, D.C., twice to testify and speak with members of Congress, Mr. Flagg was an Internet activist, telling his story online so that others would understand the dangers of medical malpractice.[16] Mr. Flagg died as a result of complications caused by medical malpractice at age 63.[17]

Part I of this Note explains the August Rule, and Part II describes prior attempts at regulating patient safety and preventable conditions.[18] Part III discusses the potential effect of the August Rule on costs borne by health care providers, and Part IV examines the possible effect of the rule on a provider's malpractice liability.[19] Part V argues that the occurrence of a condition listed in the August Rule should not be conclusive evidence of physician or hospital malpractice.[20]

I. Introduction to the August Rule

In the aftermath of medical errors such as those experienced by Ms. O'Neill, the Quaid twins, and Mr. Flagg, CMS was prompted by congressional legislation to take action, and it promulgated the August Rule.[21] The August Rule prohibits Medicare from paying hospitals for the additional costs of treating patients who acquire preventable conditions during hospital stays.[22] The preamble to the August Rule provides that CMS is selecting only those conditions that, if hospital personnel are engaging in good medical practice, the additional treatment costs will, in most cases, be avoided, and the risk of selectively avoiding patients at high risk of complications will be minimized.[23] The August Rule's preamble goes on to explain that these costs should be elimi-

[14] *See id.*

[15] *See* Ctr. for Justice & Democracy, *supra* note 4.

[16] *See id.*

[17] *See id.*

[18] *See infra* notes 21–63 and accompanying text.

[19] *See infra* notes 64–149 and accompanying text.

[20] *See infra* notes 150–223 and accompanying text.

[21] *See* Aug. Press Release, *supra* note 1; *see also* Pear, *supra* note 4; Childs, *supra* note 4; Ctr. for Justice & Democracy, *supra* note 4.

[22] Aug. Press Release, *supra* note 1.

[23] Nicholson & Mitchel, *supra* note 1, at 11.

nated in most cases by providers engaging in good medical practice, but that not all of the conditions in the rule are always preventable.[24]

The August Rule identifies a total of eight conditions that are not reimbursed: (1) an object left behind in the body during surgery; (2) blood incompatibility; (3) air embolism; (4) hospital-acquired injuries; (5) mediastinitis (preventable surgical site infection); (6) catheter-associated urinary tract infections; (7) pressure ulcers; and (8) vascular catheter-associated infections.[25] Three of these conditions, an object left behind in the body during surgery, blood incompatibility, and air embolism, are serious preventable errors that are sometimes referred to as "never events."[26] Generally, a medical error can be defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.[27]

The August Rule has been criticized by some doctors and hospitals but applauded by quality care advocates and others concerned with minimizing hospital errors.[28] The heart of the debate is whether condi-

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[24] *See id.* Doctor Edward Rodriguez, an Instructor of Orthopedic Surgery of Harvard Medical School, who is on staff at Beth Israel Deaconess Medical Center, has stated that pre-existing conditions often predispose patients to higher infection rates. *See* Edward K. Rodriguez, Letter to the Editor, *An Imperfect Science: Hospitals Address Medical Errors*, Boston Globe, Sept. 19, 2007, at A14; *see also* Beth Israel Deaconess Med. Ctr., Find a Doctor, http://services.bidmc.org/Find_a_doc/default.asp (enter "Rodriguez" in last name field) (last visited Feb. 1, 2009). Specifically, some doctors argue that infections and bedsores can occur in susceptible patients with an underlying condition without error on the part of the health care provider. *See* Maxine M. Harrington, *Revisiting Medical Error: Five Years After the IOM Report, Have Reporting Systems Made a Measurable Difference?*, 15 Health Matrix 329, 340 (2005); Rodriguez, *supra.*

[25] *See* Nicholson & Mitchel, *supra* note 1, at 11; Fact Sheet, Ctrs. for Medicare & Medicaid Servs., FY 2008 Inpatient Prospective Payment System Final Rule (Aug. 1, 2007) (on file with author) [hereinafter Aug. Fact Sheet].

[26] "Never events" are medical errors that are preventable and have serious consequences for patient well-being. *See* Aug. Press Release, *supra* note 1; Aug. Fact Sheet, *supra* note 25; Press Release, Ctrs. for Medicare & Medicaid Servs., Eliminating Serious, Preventable, and Costly Medical Errors—Never Events (May 18, 2006) (on file with author) [hereinafter May Press Release]. The National Quality Forum ("NQF"), an organization created to develop and implement a national strategy for health care quality measurement, has developed a list of these events with the support of CMS. *See* Aug. Press Release, *supra* note 1; Aug. Fact Sheet, *supra* note 25; May Press Release, *supra.*

[27] *See* Inst. of Med., To Err Is Human 1 (1999), *available at* http://www.iom.edu/File.aspx?ID=4117; *see also* John D. Blum, *Combating Those Ugly Medical Errors—It's Time for a Hospital Regulatory Makeover!*, 12 Widener L. Rev. 53, 60 (2005). The Institute of Medicine is a nonprofit organization created for the purpose of providing the nation with science-based advice on matters of biomedical science, medicine, and health. Inst. of Med., About, http://www.iom.edu/CMS/AboutIOM.aspx (last visited Feb. 1, 2009).

[28] *See* David A. Hyman & Charles Silver, *You Get What You Pay for: Result-Based Compensation for Health Care*, 58 Wash. & Lee L. Rev. 1427, 1429 (2001); Pear, *supra* note 4. *See generally* Kaiser Network, Kaiser Daily Health Policy Report, Medicare Will Not Pay for Prevent-

tions that are at least sometimes preventable, such as infections, bedsores, and ulcers, should be reimbursed by Medicare.[29] Generally, Medicare compensates hospitals and doctors for each incremental service that they provide.[30] This arrangement is referred to as a fee-for-service payment system.[31] Prior to the August Rule, payment was provided regardless of the outcome or whether the reason for treatment was medical error.[32] Some doctors and hospitals argue that the August Rule will result in higher costs to hospitals and physicians for conditions such as infections and bedsores that are sometimes uncontrollable, and therefore should be reimbursed.[33] The August Rule, however, is commended by consumer groups concerned with minimizing hospital errors, given the high rate and added health care costs generated by those errors.[34] One study, for example, concluded that medical errors could account for 2.4 million extra hospital days and $9.3 billion in excess charges.[35] At least 44,000, and possibly as many as 98,000, Americans die from medical errors every year, which is more than motor vehicle accident, breast cancer, or AIDS deaths.[36]

The federal government funds approximately 40% of the nation's health care costs, making significant health care providers financially obligated to participate in federally funded programs such as Medicare and Medicaid.[37] Thus, health care providers attempt to avoid any transaction that might pose even the slightest risk of retribution under the

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able Conditions Acquired at Hospitals (Aug. 20, 2007), http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=46979.

[29] *See* Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, 72 Fed. Reg. 47,130, 47,200 (Aug. 22, 2007) (to be codified at 42 C.F.R. pts. 411, 412, 413, 489) (noting that CMS has previously stated some pressure ulcers are "unavoidable"); Pear, *supra* note 4.

[30] *See* May Press Release, *supra* note 26.

[31] *See id.*

[32] *See id.*

[33] *See* Rodriguez, *supra* note 24.

[34] Pear, *supra* note 4.

[35] *See* May Press Release, *supra* note 26.

[36] *See* INST. OF MED., *supra* note 27, at 1; Hyman & Silver, *supra* note 28, at 1430, 1489.

[37] *See* KAISER FAMILY FOUND., MEDICARE: A PRIMER 1 (2009), *available at* http://www.kff.org/medicare/upload/7615-02.pdf; *see also* Amy Gremminger White, *Paying for Patients: Choice of Law, Conflicting Interests, and Evolving Standards of Health Care Remuneration*, 39 TEX. INT'L L.J. 327, 344 (2004). Providers are doctors, hospitals, and other institutions that deliver health care services. MARK A. HALL ET AL., HEALTH CARE LAW AND ETHICS 101 (6th ed. 2003). Because Medicare provides health insurance coverage to 45 million people, insurance payments from Medicare on behalf of the program's recipients are significant to health care providers. *See* KAISER FAMILY FOUND., *supra*, at 1; *see also* White, *supra*, at 344.

federal health care funding scheme.[38] Because hospitals depend heavily on federal funding, they will likely strive harder to avoid the conditions and errors listed in the August Rule.[39] Adding a cost incentive for hospitals to avoid these eight conditions should help reduce overall costs and improve care, assuming physicians and hospitals have control over the occurrence of the conditions in the August Rule.[40]

II. Laws Preceding the August Rule

In addition to the August Rule, other Medicare regulations, as well as congressional acts, are in effect to attempt to monitor hospital performance.[41] Unlike the August Rule, however, the prior laws in place do not prevent payment to physicians or hospitals based on poor performance.[42] Instead, the prior laws encourage the reporting of medical errors and provide for a lower Medicare payment update if a hospital fails to report quality measures in the required areas.[43] The preexisting statutes and regulations have not yet yielded sufficient improvements in the quality of patient care because of impediments and possibly a lack of adequate incentives to improve care.[44] Because the August Rule di-

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[38] White, *supra* note 37, at 344.

[39] *See* Editorial, *Medicare and Medical Mistakes*, Wash. Times, Aug. 28, 2007, at A18.

[40] *See id.* Awareness and concern over medical errors has grown since the 1999 release of a study by the Institute of Medicine ("IOM"). *See* Blum, *supra* note 27, at 54; *see also* Inst. of Med., *supra* note 27, at 1. The IOM study included a 1999 projection of up to 98,000 deaths per year and hundreds of thousands of avoidable injuries and extra days of hospitalization caused by medical errors. *See* Inst. of Med., *supra* note 27, at 1; Barry R. Furrow, *Regulating Patient Safety: Toward a Federal Model of Medical Error Reduction*, 12 Widener L. Rev. 1, 2 (2005). The Centers for Disease Control ("CDC") has estimated that medical errors, if ranked as a disease, would be the sixth leading cause of death in the United States. Furrow, *supra*, at 2.

Although hospitals are taking steps to improve patient safety, several problems still exist. Blum, *supra* note 27, at 61–62. Steps that hospitals have taken to improve patient safety include requiring workers to wash their hands with disinfectant before and after seeing patients and having procedures in place to prevent bed sores. *Id.*

[41] *See* Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (codified as amended at 42 U.S.C.A. §§ 299–299c-7 (West Supp. 2008)); Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 10, 21, 26, & 42 U.S.C.A.); *see also* Blum, *supra* note 27, at 64; Press Release, Ctrs. for Medicare & Medicaid Servs., CMS Announces Guidelines for Reporting Hospital Quality Data (Jan. 28, 2004) (on file with author) [hereinafter Jan. Press Release].

[42] *See* 42 U.S.C.A. §§ 299–299c-7; Medicare Prescription Drug, Improvement, and Modernization Act, 117 Stat. 2066; *see also* Blum, *supra* note 27, at 64; Jan. Press Release, *supra* note 41.

[43] *See* 42 U.S.C.A. § 1395w-4 (West Supp. 2008); *see also* Blum, *supra* note 27, at 64; Nicholson & Mitchel, *supra* note 1, at 6; Jan. Press Release, *supra* note 41.

[44] Furrow, *supra* note 40, at 5–6.

rectly prohibits payment for medical errors, it could result in a significant improvement in the quality of patient care that has so far been unattainable.[45]

State-based Medicare Quality Improvement Organizations ("QIOs") are required to collect institutional performance data and consult with hospitals to meet certain data reporting mandates.[46] Hospitals are required to submit performance data to QIOs in ten target areas.[47] Any hospital that fails to report quality measures in the specified areas receives a 0.4% lower Medicare payment update than reporting hospitals.[48] Unfortunately, a recent study evaluating hospitals that partnered with QIOs compared to those that did not concluded that the findings did not support a hypothesis that the QIO program improves the quality of care for Medicare beneficiaries in the inpatient setting.[49] The study's data, however, was several years old, and researchers noted that more recent QIO partnerships have had more success.[50]

Another federal response to the prevalence of medical errors is the Patient Safety and Quality Improvement Act of 2005 ("PSQIA"), which allows physicians and other providers to voluntarily report confidential and privileged patient safety information to federally certified regional entities.[51] To give providers incentives to voluntarily report this

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[45] *See* INST. OF MED., *supra* note 27, at 1; Nicholson & Mitchel, *supra* note 1, at 6; Aug. Press Release, *supra* note 1.

[46] *See* 42 U.S.C.A. § 1395w-4; Blum, *supra* note 27; Jan. Press Release, *supra* note 41. The data reporting mandate was passed under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), which requires that most hospitals submit performance data to QIOs in ten target areas dealing with practices concerning heart attacks, heart failure, and pneumonia. *See* 42 U.S.C.A. § 1395w-4. Consumers will be able to view the results of the reported data and use those results to compare the performances of different hospitals. *See id.*; *see also* Blum, *supra* note 27, at 64.

[47] *See* Jan. Press Release, *supra* note 41; *see also* Blum, *supra* note 27, at 64. The ten quality measures that must be reported were chosen because they are related to three medical conditions that are common among people with Medicare and that result in hospitalization: heart attack, heart failure, and pneumonia. Jan. Press Release, *supra* note 41. Related to a heart attack, the quality measures are whether: aspirin was given to the patient upon arrival at the hospital; aspirin was prescribed when the patient was discharged; a beta-blocker was given to the patient upon arrival at the hospital; a beta-blocker was prescribed when the patient was discharged; and an ACE Inhibitor was given for the patient with heart failure. *Id.* For heart failure, the measures are whether the patient had an assessment of his or her heart function and whether an ACE Inhibitor was given to the patient. *Id.* Lastly, for a patient with pneumonia, the measures are whether an antibiotic was given to the patient in a timely way, whether the patient received a Pneumococcal vaccination, and whether the patient's oxygen level was assessed. *Id.*

[48] *See* Blum, *supra* note 27, at 64; Jan. Press Release, *supra* note 41.

[49] Furrow, *supra* note 40, at 8.

[50] *Id.*

[51] *See* 42 U.S.C.A. § 299b-22; *see also* Blum, *supra* note 27, at 64.

data, the PSQIA creates privilege and confidentiality protections for the reported information, as long as certain requirements are met.[52] Many critics believe that the PSQIA reporting system is flawed for two reasons.[53] First, reporting under the PSQIA system is voluntary.[54] Second, it is not clear that providers will choose to make reports because the conditions that must be met to obtain the attendant confidentiality protections are complex.[55] The PSQIA does not preempt more stringent state laws that mandate reporting, however, and as of November 2006, twenty-five states required licensed health care organizations to report adverse events.[56] Because the PSQIA system was implemented so recently, it is unclear whether that system will improve the quality of care for Medicare beneficiaries, and whether health care providers will choose to report their errors given the complex conditions required for the information provided to remain confidential.[57]

Notwithstanding these governmental attempts at quality improvement, a 2005 congressional report determined that Medicare patients experienced an increasingly high level of errors, and hospital-acquired infection rates worsened by approximately 20% from 2000 to 2003.[58] Although institutional short-staffing and long working hours are causes of medical errors, it appears that "system failures" account for most of them.[59] A system failure is the breakdown of a hospital's ability to ensure the best possible patient safety because of an approach or procedure that is archaic, poorly designed, or error prone.[60] Factors contrib-

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[52] Nicholson & Mitchel, *supra* note 1, at 6. In order for the system authorized by PSQIA to become operable, it needed to be created by the Agency for Healthcare Research and Quality ("AHRQ"). *Id.* The AHRQ is the health services research arm of the U.S. Department of Health and Human Services ("HHS"). *See* Agency for Healthcare Research & Quality, What Is AHRQ?, http://www.ahrq.gov/about/whatis.htm (last visited Feb. 10, 2009). HHS issued a final rule to implement the PSQIA that became effective on January 19, 2009. *See* Agency for Healthcare Research & Quality, Patient Safety Organizations, http://www.pso.ahrq.gov/regulations/regulations.htm (last visited Feb. 10, 2009).

[53] Nicholson & Mitchel, *supra* note 1, at 6.

[54] *Id.*

[55] *Id.*

[56] *Id.*

[57] *See* Furrow, *supra* note 40, at 8; Nicholson & Mitchel, *supra* note 1, at 6.

[58] 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; *see also* Furrow, *supra* note 40, at 3–4.

[59] *See* Donald Goldmann, *System Failure Versus Personal Accountability—The Case for Clean Hands*, 355 New Eng. J. Med. 121, 121 (2006); *see also* Furrow, *supra* note 40, at 5.

[60] *See* Goldmann, *supra* note 59, at 121; *see also* Furrow, *supra* note 40, at 5. For example, a system failure could include a hospital failing to ensure that physicians and nurses wash their hands before touching a new patient. *See* Goldmann, *supra* note 59, at 122; *see*

uting to system failures and delaying the recognition of medical errors include the complexity of determining an error's cause, attribution errors, trust in authority, wishful thinking, and defensiveness.[61] These impediments support a vigorous policy intervention to strengthen detection and correction of health care quality failures.[62] Given the unacceptably high rate of medical errors, the delay in instituting a national system of error reporting, and desire to lower expenses, one can easily understand the decision of CMS to issue the August Rule to provide a strong financial incentive for recipients to avoid medical errors.[63]

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also Furrow, *supra* note 40, at 5. To ensure this practice, a hospital could educate staff members on hand hygiene and monitor their performance in this area regularly. *See* Goldmann, *supra* note 59, at 122; *see also* Furrow, *supra* note 40, at 5.

[61] Furrow, *supra* note 40, at 5. An error's cause can be difficult to determine because we often lack the ability to confidently specify the best clinical interventions or expected outcomes, so it can be difficult to differentiate inevitable outcomes from the consequences of a quality failure. *See* Arnold Milstein & Nancy E. Adler, *Why Doesn't Widespread Clinical Quality Failure Command Our Attention?*, HEALTH AFF., Mar.–Apr. 2003, at 121. Attribution errors can occur because most people are biased in favor of individual, rather than situational or system-caused, attributions. *Id.* at 123. Attribution errors can drive mistargeted and therefore inadequate remedies, such as disciplinary actions, rather than reforming defective methods of work that account for most quality failures. *See id.*

Trustworthiness or familiarity contributes to delaying the recognition of medical errors because one may be less vigilant for quality failures at a local hospital where one works or has previously visited or been treated. *Id.* at 122. National surveys show that consumers estimate the likelihood of failure by physicians and hospitals they have used to be much lower than by other providers. *Id.*

Empirical research has documented widespread "optimistic bias," with the average person viewing himself as being at lower-than-average risk of bad outcomes. *Id.* The belief that one can individually prevent failures increases optimistic bias and, as a consequence, reduces one's vigilance in detecting and preventing failure. *Id.* Furthermore, wishful thinking may reduce clinicians' likelihood of perceiving imminent and past quality failure, in specific instances and in general. *Id.* at 124.

Defensiveness can contribute to system failure and delaying recognition of medical errors because it is painful for anyone to acknowledge that his actions have caused harm to others. *Id.* This may make it harder for doctors to acknowledge quality failure by themselves and others, and to accept appropriate responsibility for their contribution to failure. *Id.*

[62] Furrow, *supra* note 40, at 5–6.

[63] *See* INST. OF MED., *supra* note 27, at 1; Nicholson & Mitchel, *supra* note 1, at 6; Aug. Press Release, *supra* note 1.

III. Impact of the August Rule on Costs Borne by Health Care Providers

The August Rule was issued to prevent reimbursement for treating medical errors and hopefully to reduce their frequency.[64] Potential negative impacts of the rule exist, however, including implementation costs and the costs of treating conditions listed in the rule, regardless of whether the condition was caused by an error.[65] The August Rule forces health care providers to pay the costs of treating specified conditions, thereby providing them with a financial incentive to avoid errors.[66] A patient injury or infection can have multiple causes, however, and it can be difficult to differentiate among complications resulting from an underlying disease, treatment, or medical error.[67]

The August Rule gives health care providers an incentive to discover the real source of patient injuries.[68] The preamble to the August Rule states that conditions are selected such that if hospital personnel engage in good medical practice, the additional costs of the hospital-acquired condition will be avoided in most cases.[69] Of course, *most* cases is certainly not the same as *all* cases, and CMS thus appears to be declaring that in some instances, health care providers need to incur the cost of treatment even when no error was made.[70] CMS offers that providers still receive some reimbursement for the treatment of these conditions, even if acquired in the hospital, through inpatient prospective payment systems ("IPPS").[71] Through IPPS, the capital-related costs of hospital inpatient stays must be paid under a prospective payment system ("PPS").[72] Under PPSs, the Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge.[73] Discharges are classified according to a list of diagnosis-related groups.[74] Before the August

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[64] *See* Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, 72 Fed. Reg. 47,130 (Aug. 22, 2007) (to be codified at 42 C.F.R. pts. 411, 412, 413, 489); Aug. Press Release, *supra* note 1.

[65] Furrow, *supra* note 40, at 11; *see* Harrington, *supra* note 24, at 339–40.

[66] Furrow, *supra* note 40, at 11.

[67] *See* Harrington, *supra* note 24, at 339–40.

[68] Furrow, *supra* note 40, at 11.

[69] Nicholson & Mitchel, *supra* note 1, at 11.

[70] *See id.*

[71] Changes to the Hospital Inpatient Prospective Payment Systems, 72 Fed. Reg. at 47,135.

[72] *Id.*

[73] *Id.*

[74] *Id.*

Rule, however, hospitals could bill Medicare for the entire cost of additional services needed when patients were injured by the hospital's errors, so presumably hospitals still will not receive the same amount of payment as before, even with IPPS payments based on predetermined rates for a discharge.[75]

Implementation of the August Rule will be costly to hospitals because providers will be denied reimbursement, even when there is no evidence of a medical error.[76] The August Rule's preamble states in part that CMS is selecting conditions that will be avoided in *most* cases and that the risk of selectively avoiding patients at high risk of complications will thus be minimized.[77] Minimizing the risk of selectively avoiding patients at high risk of complications is of course not the same as eliminating that risk.[78] CMS could eliminate or reduce that risk significantly by limiting the conditions listed in the August Rule to those that all patients would be equally medically likely to experience.[79] For example, it would be equally probable that a healthy or chronically ill person could be given an incompatible blood type, have an object left in after surgery, or have an operation on the incorrect body part.[80]

Critics of the August Rule argue that some events considered preventable, such as certain infections contracted in the hospital, can be complicated by patients' preexisting conditions.[81] By refusing reimbursement to providers who treat patients with conditions contained in the August Rule, hospitals could be discouraged from treating those patients who are more susceptible to, or are already suffering from, the conditions in the rule.[82] The argument is that a system that denies reimbursement for the care of a postoperative infection would only result in the decreased availability of surgical services to diabetics, the obese, the frail elderly, the severely injured, and

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[75] *See id.*; Furrow, *supra* note 40, at 11.

[76] Nicholson & Mitchel, *supra* note 1, at 11; *see* Aug. Fact Sheet, *supra* note 25.

[77] *See* Nicholson & Mitchel, *supra* note 1, at 11.

[78] *See id.*

[79] *See* Aug. Fact Sheet, *supra* note 25; Aug. Press Release, *supra* note 1; May Press Release, *supra* note 26.

[80] *See* Aug. Fact Sheet, *supra* note 25; Aug. Press Release, *supra* note 1; May Press Release, *supra* note 26.

[81] Rodriguez, *supra* note 24.

[82] *See id.* After surgery, patients who are diabetic, obese, frail, elderly, severely injured, or immunosuppressed have higher incidences of infections. *See id.* Because some infections are included in the August Rule as "preventable conditions," the concern is that health care providers may be more hesitant to treat people who may be more susceptible to infection. *See* Editorial, *supra* note 39; Rodriguez, *supra* note 24.

the immunosuppressed, all of whom have higher documented incidences of infections after elective and emergency surgery.[83]

When dealing with patients more likely to experience infections or injuries, physicians may disagree over whether a result was caused by the patient's underlying condition or a medical error.[84] If physicians have difficulty determining the cause of an infection or injury in susceptible patients, some argue that hospitals and physicians could prefer not to serve patients who are likely to develop these medical problems.[85] These critics assert that claims by some hospitals that they have achieved zero infection rates could be deceptive if care is refused to certain patients or patients are discharged quickly.[86] Some suggest that postoperative infections, a condition to which some could be more susceptible than others, should be reduced by developing standardized protocols and penalizing providers who refuse to implement them, rather than refusing payment in all cases regardless of the infection's cause.[87]

CMS specifically addressed the concern that hospitals will be hesitant to accept patients who have a greater risk of complications by claiming that the cost of treating these conditions should be avoided with good medical practice.[88] Despite CMS's assurances that these costs can be avoided, hospitals will be more inclined to test for infections when a patient is admitted to prove that the infection is not a result of substandard hospital care.[89] Most states currently do not require hospital records to indicate whether patients develop conditions before or after admission.[90] CMS's decision, therefore, will require hospitals to conduct additional tests to demonstrate that patient conditions were developed before admission, prior to receiving Medicare reimbursement.[91] Because Medicare generally pays a flat fee for each case, hospitals may have to absorb the costs of these extra tests.[92] Under the August Rule, hospitals are not permitted to bill family members or others for costs not covered by Medicare.[93] Even if hospitals test each admitted

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[83] Rodriguez, *supra* note 24.
[84] *See* Harrington, *supra* note 24, at 340; Rodriguez, *supra* note 24.
[85] *See* Harrington, *supra* note 24, at 340.
[86] Rodriguez, *supra* note 24.
[87] *Id.*
[88] Editorial, *supra* note 39.
[89] *Id.*
[90] *See* Kaiser Network, *supra* note 28.
[91] *Id.*
[92] *Id.*
[93] *Id.*

patient to ascertain whether an infection is present at the time of admission, certain patients, including those at the end of life, could be exceptionally prone to developing pressure ulcers, for example, despite receiving appropriate care.[94] The August Rule, then, could encourage unnecessary testing by hospitals wanting to show that infections were already present at the time of admission, and costly infections can occur even when all of the recommended precautions are taken.[95]

Because a patient injury or infection can have multiple causes, clinical judgment is required to distinguish among complications resulting from an underlying disease, those resulting from treatment, and medical error.[96] Physicians may have difficulty agreeing on whether a patient's underlying condition or a medical error caused an injury or death.[97] Physicians may further disagree on the type of conduct that constitutes an adverse event.[98] Reliability is not high among those retrospectively rating physician's charts to evaluate whether an error was made.[99]

For example, a team of investigators reviewed records from the Harvard Medical Practice Study ("HMPS"), which was relied on by the Institute of Medicine for numbers of deaths caused by medical errors, and found that cases in which paired physicians disagreed about the occurrence of an adverse event outnumbered cases in which they agreed.[100] The investigators noted that adverse events caused by a wrong

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[94] Pear, *supra* note 4.

[95] *Id.*

[96] *See* Harrington, *supra* note 24, at 339.

[97] *See id.* at 340.

[98] *See id.*

[99] A. Russell Localio et al., *Identifying Adverse Events Caused by Medical Care: Degree of Physician Agreement in a Retrospective Chart Review*, 125 ANNALS INTERNAL MED. 457, 457, 463–64 (1996). The study examining reliability among those retrospectively rating physician's charts consisted of 7533 pairs of "structured implicit" reviews (subjective opinions based on guidelines) of medical records done by 127 physicians working independently. *Id.* at 457; *see* Harrington, *supra* note 24, at 340. The physicians viewed a random sample of inpatient medical records from a random sample of fifty-one inpatient facilities in New York State. Localio et al., *supra*, at 457; *see* Harrington, *supra* note 24, at 340. In 12.9% of cases, the two physicians in a pair had an extreme disagreement about the occurrence of an adverse event. Localio et al., *supra*, at 457; *see* Harrington, *supra* note 24, at 340. Both reviewers found an adverse event in 10% of cases. Localio et al., *supra*, at 457; *see* Harrington, *supra* note 24, at 340. The level of agreement did tend to increase with the amount of experience of the physicians. Localio et al., *supra*, at 457; *see* Harrington, *supra* note 24, at 340. Agreement was highest for wound infections and lowest for adverse events attributed to failure to diagnose or lack of therapy. Localio et al., *supra*, at 457; *see* Harrington, *supra* note 24, at 340.

[100] Localio et al., *supra* note 99, at 457; *see* Harrington, *supra* note 24, at 340. In 12.9% of cases in the HMPS, paired physicians strongly disagreed about the occurrence of an

diagnosis, delay in diagnosis, or inappropriate treatment could be particularly susceptible to disagreement, and the more seriously ill the patient, the more difficult it is to assign a cause for a bad outcome.[101]

As a result of the difficulty in deciding whether an adverse event or medical error has occurred, the August Rule could withhold payment from health care providers when no error was made.[102] Some conditions covered by the August Rule, such as leaving a sponge or other object in a patient during surgery, or using incompatible blood products, are clearly the result of an error.[103] Yet, when a patient has an underlying condition, physicians can disagree as to whether a new complication was caused by a preexisting condition, prior treatment, or an error.[104] Infections and bedsores, two conditions listed in the August Rule, are particularly difficult to attribute to medical error, as they can occur frequently without fault.[105] Some maintain that it is unfair and detrimental to health care providers and patients to withhold payment for services performed without error because this could result in higher costs to patients and fewer treatment options for those with preexisting conditions.[106]

IV. Effect of August Rule on Malpractice Liability of Health Care Providers

In addition to the potential consequences of the August Rule, the rule's list of conditions deemed preventable could affect a provider's malpractice liability.[107] The August Rule could impact the result of a medical malpractice case because it could affect the determination of whether a provider was negligent and whether due care was used.[108] To establish a prima facie case of negligence in a medical malpractice action, four elements must be met: (1) the provider owed the patient a duty to conform his or her conduct to the standard of care necessary to

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adverse event. Localio et al., *supra* note 99, at 457; *see* Harrington, *supra* note 24, at 333, 340.

[101] Localio et al., *supra* note 99, at 457; *see* Harrington, *supra* note 24, at 341.

[102] *See* Harrington, *supra* note 24, at 339; Pear, *supra* note 4.

[103] Pear, *supra* note 4.

[104] *See* Harrington, *supra* note 24, at 339.

[105] *See* Rodriguez, *supra* note 24.

[106] *See id.*

[107] *See* 42 U.S.C. § 1320c-6(c)(1)–(2) (2000); Restatement (Second) of Torts § 328A (1965); *see also* Jodi M. Finder, *The Future of Practice Guidelines: Should They Constitute Conclusive Evidence of the Standard of Care?*, 10 Health Matrix 67, 76, 103 (2000).

[108] *See* 42 U.S.C. § 1320c-6(c)(1)–(2); Restatement (Second) of Torts § 328A; *see also* Finder, *supra* note 107, at 76, 103.

avoid an unreasonable risk of harm; (2) the provider's conduct, by act or omission, did not comport with the applicable standard of care; (3) the provider's failure to satisfy the standard of care was causally related to the harm suffered by the patient; and (4) the patient actually suffered harm.[109] If the August Rule's list of preventable conditions is considered to indicate that the standard of care necessary to avoid an unreasonable risk of harm to others was not met if a condition occurs, the rule could affect the elements of negligence.[110]

The imposition of medical malpractice liability also depends upon whether due care was used by the health care provider.[111] Due care is measured by the prevailing medical custom, which can be difficult to define.[112] CMS's designation of certain conditions as preventable in its rule could mean that the occurrence of one of the conditions implies that a physician did not exercise due care, even if he acted in compliance with professionally developed norms of care and treatment.[113] The presence of one of the conditions listed in the August Rule could imply that due care was not exercised or that the applicable standard of care was not met.[114]

A. *The August Rule's Effect on Standard of Care*

In order to establish a prima facie case of negligence in a medical malpractice action, four elements listed above must be proven, and the August Rule could affect the elements of negligence dealing with the applicable standard of care.[115] The standard of care applied in medical tort cases is usually based on input from leaders, conferences, and pro-

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[109] *See* RESTATEMENT (SECOND) OF TORTS § 328A; Finder, *supra* note 107, at 76.

[110] *See* RESTATEMENT (SECOND) OF TORTS § 328A; Finder, *supra* note 107, at 76; Aug. Press Release, *supra* note 1.

[111] *See* 42 U.S.C. § 1320c-6(c)(1)–(2); *see also* Finder, *supra* note 107, at 103.

[112] *See* CLARK C. HAVIGHURST ET AL., HEALTH CARE LAW AND POLICY 1001 (2d ed. 1998); James A. Henderson & John A. Siciliano, *Universal Health and the Continued Reliance on Custom in Determining Malpractice*, 79 CORNELL L. REV. 1382, 1390–91 (1994); *see also* Nichole Hines, *Why Technology Provides Compelling Reasons to Apply a* Daubert *Analysis to the Legal Standard of Care in Medical Malpractice Cases*, 2006 DUKE L. & TECH. REV. 18, ¶¶ 22, 28–29.

[113] *See* 42 U.S.C. § 1320c-6(c)(1)–(2); *see also* Finder, *supra* note 107, at 103.

[114] *See* RESTATEMENT (SECOND) OF TORTS § 328A; Finder, *supra* note 107, at 76; Aug. Press Release, *supra* note 1.

[115] *See* RESTATEMENT (SECOND) OF TORTS § 328A; Finder, *supra* note 107, at 76. This Note examines only the second and third elements of a negligence claim, which involve the standard of care that could be impacted by the August Rule. *See* RESTATEMENT (SECOND) OF TORTS § 328A; Finder, *supra* note 107, at 76.

fessional networks and journals.[116] Once an idea becomes generally accepted, it can be deemed a standard of care.[117] Although a health care professional is expected to act in accordance with his superior skills or knowledge, the jury is responsible for choosing the specific standard of care in each case.[118] Because each patient's medical situation is necessarily unique, a jury would weigh evidence on differing standards of care in light of that patient's circumstances.[119]

Because Medicare policies, medical journals, expert opinions, practice guidelines, and other sources provide information used when assessing provider performance, and because the August Rule could be considered a practice guideline, it could be used as evidence of the standard of care.[120] The U.S. Supreme Court has decided that similar Centers for Disease Control ("CDC") guidelines are "not definitive" evidence.[121] Because the CDC guidelines were nationally acclaimed, it appears likely that the August Rule's listing of certain conditions as preventable could also be regarded as not definitive by the courts.[122] Even if the August Rule were considered not to be definitive, it could be used as a guideline, and expert testimony could be offered as to the implications of a condition listed in the rule on a provider's malpractice case.[123]

Interestingly, under a federal statute, physicians who treat Medicare patients in compliance with or reliance upon professionally developed norms of care and treatment applied by a peer review organization are protected from civil liability.[124] To be protected under this statute, a physician must have "exercised due care in all professional conduct taken or directed by him and reasonably related to, and resulting from, the actions taken in compliance with or reliance upon professionally accepted norms of care and treatment."[125] This protection supports the August Rule's use as a piece of evidence in a medical

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[116] Finder, *supra* note 107, at 77.

[117] *Id.*

[118] *See* Finder, *supra* note 107, at 78; Edward B. Hirshfeld, *Practice Parameters and the Malpractice Liability of Physicians*, 263 J. Am. Med. Ass'n 1556, 1559 (1990).

[119] *See* Finder, *supra* note 107, at 78; Hirshfeld, *supra* note 118, at 1556.

[120] *See* Claudia A. Steiner et al., *The Review Process Used by U.S. Health Care Plans to Evaluate New Medical Technology for Coverage*, 11 J. Gen. Internal Med. 294, 294 (1996); *see also* Finder, *supra* note 107, at 71; Sara Rosenbaum et al., *Who Should Determine When Health Care Is Medically Necessary?*, 340 New Eng. J. Med. 229, 231 (1999).

[121] Bragdon v. Abbott, 524 U.S. 624, 651 (1998); *see also* Finder, *supra* note 107, at 101–02.

[122] *Bragdon*, 524 U.S. at 651; *see also* Finder, *supra* note 107, at 101–02.

[123] *See* Finder, *supra* note 107, at 78; Hirshfeld, *supra* note 118, at 1556.

[124] 42 U.S.C. § 1320c-6(c); *see also* Finder, *supra* note 107, at 103.

[125] 42 U.S.C. § 1320c-6(c)(1)–(2); *see also* Finder, *supra* note 107, at 103.

malpractice case, rather than as definitive proof of negligence.[126] If a provider demonstrates that due care was used and the action was taken in compliance with or reliance on a professionally accepted norm of care and treatment, that provider should be protected from civil liability even if the patient's condition was deemed preventable by the August Rule.[127]

A defendant's medical malpractice liability thus depends upon whether due care was used.[128] The exclusive measure of due care is typically the prevailing medical custom in medical malpractice cases.[129] The prevailing medical custom must be demonstrated by expert testimony at trial.[130] Because numerous methods are often used by different physicians to treat one medical condition, it could be difficult to identify a medical custom because it is unlikely that just one custom even exists.[131] CMS states in the preamble to the August Rule that conditions are selected where, if hospital personnel are engaging in good medical practice, the additional costs of the hospital-acquired condition will, in most cases, be avoided.[132] CMS is aware that all of these conditions will not be avoided in all cases by engaging in good medical practice.[133] Some physicians argue that conditions such as infections and bedsores, which are listed as preventable in the August Rule, can occur more frequently in some patients, without error on the part of a physician.[134] These conditions could seemingly occur if a physician chose one custom of care over another for the overall benefit of an individual patient.[135]

Given that conditions often occur as a result of many variables, a lack of due care might not necessarily have caused a condition labeled

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[126] *See* 42 U.S.C. § 1320c-6(c)(1)–(2); Hirshfeld, *supra* note 118, at 1556; *see also* Finder, *supra* note 107, at 78, 103.

[127] *See* 42 U.S.C. § 1320c-6(c)(1)–(2); Hirshfeld, *supra* note 118, at 1556; *see also* Finder, *supra* note 107, at 78, 103.

[128] *See* 42 U.S.C. § 1320c-6(c)(1)–(2); *see also* Finder, *supra* note 107, at 103.

[129] *See* HAVIGHURST ET AL., *supra* note 112, at 1001; *see also* Hines, *supra* note 112, ¶¶ 9, 12.

[130] *See* John W. Ely et al., *Determining the Standard of Care in Medical Malpractice: The Physician's Perspective*, 37 WAKE FOREST L. REV. 861, 864–65 (2002); Hines, *supra* note 112, ¶ 9.

[131] *See* Henderson & Siciliano, *supra* note 112, at 1390–91; *see also* Hines, *supra* note 112, ¶¶ 22, 28–29.

[132] Nicholson & Mitchel, *supra* note 1, at 11.

[133] *Id.*

[134] *See* Rodriguez, *supra* note 24.

[135] *See* Henderson & Siciliano, *supra* note 112, at 1390–91; *see also* Hines, *supra* note 112, ¶¶ 9–10.

preventable.[136] For example, even if a preventable condition could be avoided by the use of a particular treatment, that treatment could have adverse affects on other medical conditions that the patient could have.[137] Therefore, a preventable condition could be so only for some patients, or under certain circumstances.[138] Of course, some conditions deemed preventable by Medicare, such as performing an operation on an incorrect body part, could be prevented by performing due care.[139] Others, however, such as infections, might not be preventable if a patient is more susceptible than the average person to developing that condition.[140]

B. *The August Rule's Effect on Liability Under a Strict Liability or Due Care Standard*

The doctrine of negligence per se provides that a defendant's conduct is categorically negligent if a statute or regulation intended to address the type of injury involved was violated by the defendant.[141] It is

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[136] *See* John D. Ayers, *The Use and Abuse of Medical Practice Guidelines*, 15 J. Legal Med. 421, 428 (1994) (citing David M. Eddy, *The Individual vs. Society: Is There a Conflict?*, 265 J. Am. Med. Ass'n 1446 (1991)); *see also* Finder, *supra* note 107, at 110.

[137] *See* Ayers, *supra* note 136, at 428; *see also* Finder, *supra* note 107, at 110.

[138] *See* Ayers, *supra* note 136, at 428; *see also* Finder, *supra* note 107, at 110.

[139] *See* 42 U.S.C. § 1320c-6(c)(1)–(2); Nicholson & Mitchel, *supra* note 1, at 11; *see also* Finder, *supra* note 107, at 103.

[140] *See* Rodriguez, *supra* note 24.

[141] Restatement (Third) of Torts § 14 (2005). Under the doctrine of negligence per se, an actor (e.g., a health care provider) is negligent if, without excuse, the actor violates a statute designed to protect against the type of accident the actor's conduct causes, and if the accident victim is within the class of persons the statute is designed to protect. *See id.* Section 14 of the *Restatement (Third) of Torts* most frequently applies to statutes adopted by state legislatures, but it also applies to regulations adopted by state administrative bodies, federal statutes, and regulations promulgated by federal agencies. *Id.*

Many statutes create a public-law penalty, but they are silent as to private liability for a statutory violation. *Id.* A court may infer from the statute a cause of action for damages in appropriate cases. *Id.* In cases involving conduct that causes physical harm, however, as a medical malpractice case would, courts have not often exercised the authority to infer a cause of action for damages, probably because the common-law rule affirmed in section 14 reduces the significance of an implied statutory cause of action. *Id.*

Still, section 14 concludes that courts may exercise their authority to develop tort doctrine, and they should regard an actor's statutory violation as evidence admissible against the actor and should treat it as determining the actor's negligence. *Id.* The violation of federal statutes and regulations is commonly given negligence per se effect in state tort proceedings. *Id.*; *see, e.g.*, DiRosa v. Showa Denko K.K., 52 Cal. Rptr. 2d. 128, 133 (Cal. Ct. App. 1996) (stating that a federal regulation may be adopted as a standard of care and affirming the use of the negligence per se instruction in the lower court for a federal statute violation); Femrite v. Abbott Nw. Hosp., 568 N.W.2d 535, 538–39 (Minn. Ct. App. 1997) (discussing negligence per se claims of patients, but ultimately rejecting the claims

not clear that this doctrine could be applied to the occurrence of a condition deemed preventable by the August Rule because the presence of a condition listed does not necessarily indicate a rule violation.[142] As each patient's circumstance is unique, this doctrine may not be appropriate for determining negligence when an infection or bedsore, conditions covered by the August Rule, occurs.[143]

The concept of liability without fault can result in an institution's liability, as well as that of individual health care providers.[144] Institutional liability can be asserted under a theory of vicarious or direct liability.[145] Under the theory of vicarious liability, a hospital could be held strictly liable for acts of negligence by "member physicians."[146] Member physicians are those who have a relationship with the hospital.[147] Under the theory of direct liability, a plaintiff would need to prove some wrongdoing by the institution's management with respect to physician competence and patient care.[148] Liability for hospitals thus appears to be possible if a member physician, or the hospital itself, fails to exercise appropriate due care.[149]

V. Effects of the August Rule on Malpractice Evidence

The August Rule, which denies reimbursement to hospitals for treatment of specific conditions, was implemented to avoid compensating health care providers for the costs of medical errors, and to address increased concern about these errors.[150] All of the conditions included in the August Rule may not be preventable in all patients and situations.[151] Implementation of the August Rule has increased concerns of

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because the patients did not belong to the class of persons that the regulation was intended to protect).

[142] *See* Hirshfeld, *supra* note 118, at 606; *see also* Finder, *supra* note 107, at 102.

[143] *See* Hirshfeld, *supra* note 118, at 606; Rodriguez, *supra* note 24; *see also* Finder, *supra* note 107, at 102.

[144] *See* Hall et al., *supra* note 37, at 355.

[145] *Id.* at 418. The term "institution" in this context refers to a hospital or insurer. *See id.*

[146] *See id.* Strict liability is liability without fault on the part of the defendant. *See id.* at 355.

[147] *See id.*

[148] *See id.*

[149] *See* 42 U.S.C.A. § 1320c-6(c)(1)–(2); *see also* Hall et al., *supra* note 37, at 418; Finder, *supra* note 107, at 103.

[150] *See* Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, 72 Fed. Reg. 47,130 (Aug. 22, 2007) (to be codified at 42 C.F.R. pts. 411, 412, 413, 489); Aug. Press Release, *supra* note 1.

[151] *See supra* note 24 and accompanying text.

health care costs unintentionally being raised by discouraging treatment of some patients and also by increasing the frequency of unnecessary testing.[152] The August Rule's operation has further created apprehension concerning whether the rule will impact medical malpractice cases.[153]

A. *Medicare's Decision Not to Reimburse a Provider Should Not Be Considered Conclusive Evidence of Malpractice*

The occurrence of one of the conditions in the August Rule should not be considered conclusive evidence of medical malpractice because some conditions in the rule are alleged to be preventable only some of the time.[154] The August Rule identifies eight conditions for which CMS will not pay providers to treat.[155] At least two of these conditions, infections and bedsores, are not viewed by many as errors in all cases.[156] The August Rule's stated purpose is to stop reimbursing hospitals for the additional costs of treating patients who acquire preventable conditions during hospital stays.[157] Given the August Rule's stated purpose, CMS probably did not intend for the August Rule to affect health care providers' due care standard and their malpractice liability.[158] Because conditions can occur as a result of many variables, a lack of due care may not always be the cause of a condition deemed preventable by Medicare.[159] Although the August Rule could be helpful in determining whether a condition's occurrence could indicate a failure to use due care, the presence of one of the conditions in the rule should not be considered conclusive evidence.[160] Instead, the presence of a condition listed in Medicare's August Rule should be considered in a similar manner to other evidence often considered in evaluating whether a health care provider acted with due care.[161]

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[152] Pear, *supra* note 4.

[153] *See* Restatement (Second) of Torts § 328A (1965); Finder, *supra* note 107, at 76; Aug. Press Release, *supra* note 1.

[154] *See* Ayers, *supra* note 136, at 428; *see also* Finder, *supra* note 107, at 110; Rodriguez, *supra* note 24.

[155] Nicholson & Mitchel, *supra* note 1, at 11; *see* Aug. Fact Sheet, *supra* note 25.

[156] *See* Harrington, *supra* note 24, at 340; Rodriguez, *supra* note 24.

[157] *See* Aug. Press Release, *supra* note 1.

[158] *See id.*

[159] *See* Ayers, *supra* note 136, at 428; *see also* Finder, *supra* note 107, at 110.

[160] *See* Ayers, *supra* note 136, at 428; *see also* Finder, *supra* note 107, at 110; Rodriguez, *supra* note 24.

[161] *See* Comm. to Advise the Pub. Health Serv. on Clinical Practice Guidelines, Inst. of Med., Clinical Practice Guidelines 2–3, 8 (Marilyn J. Field & Kathleen N.

The denial of reimbursement under the August Rule should be considered only as evidence of potential negligence, as is customary in the legal field when a professional rule is violated.[162] Costs for the health care industry will be lower if the lack of reimbursement under the August Rule is treated only as evidence of potential negligence, and not as conclusive proof that the standard of due care has been violated, because higher medical malpractice costs will be avoided.[163]

1. Comparison of the August Rule with Professional Standards as Evidence of Attorney Malpractice

The measure of due care in the medical profession is analogous to that of a lawyer, who must exercise the competence and diligence exercised by lawyers in similar circumstances.[164] In the medical malpractice setting, a prima facie case of negligence requires one to show that the applicable standard of care was not met.[165] A hospital could be liable if a member physician, or the hospital itself, failed to use due care.[166] In most jurisdictions, violation of a rule regulating the conduct of lawyers may be considered as an aid in understanding the competence and diligence exercised by lawyers in similar circumstances, but it does not alone result in a finding of malpractice.[167] The August Rule should be considered evidence of potential negligence or malpractice because this application of the rule would be consistent with the proof required for attorney negligence.[168]

Lohr eds., 1990); Steiner et al., *supra* note 120, at 294; *see also* Finder, *supra* note 107, at 70, 72.

[162] *See* Miami Int'l Realty Co. v. Paynter, 841 F.2d 348, 353 (10th Cir. 1988) (holding that testimony regarding the Colorado Code of Professional Responsibility was not error partly because the Code was not presented as having the force and effect of law and the testimony did not state that deviations from the Code constituted negligence per se); *see also* RESTATEMENT (THIRD) OF THE LAW GOVERNING LAWYERS § 52 (2000).

[163] *See* Julie Appleby, *Hospital Care Is Biggest Piece of Medical-Costs Pie: A Third,* USA TODAY, Aug. 31, 2005, at A5.

[164] *See* Smith v. Lewis, 530 P.2d 589, 593 (Cal. 1975) (stating that crucial inquiry is whether attorney failed to use such skill, prudence, and diligence as lawyers of ordinary skill and capacity commonly possess and exercise); Mayol v. Summers, Watson & Kimpel, 585 N.E.2d 1176, 1184 (Ill. App. Ct. 1992) (stating that malpractice liability may be imposed when the combined wisdom of the bar is that a reasonably competent attorney would not have exercised his or her judgment in that manner); *see also* RESTATEMENT (THIRD) OF THE LAW GOVERNING LAWYERS § 52.

[165] *See* RESTATEMENT (SECOND) OF TORTS § 328A; Finder, *supra* note 107, at 76.

[166] *See* 42 U.S.C.A. § 1320c-6(c)(1)–(2); *see also* HALL ET AL., *supra* note 37, at 418; Finder, *supra* note 107, at 103.

[167] *See supra* note 164 and accompanying text.

[168] *See supra* note 164 and accompanying text.

In most jurisdictions, proof of a violation of a rule or statute regulating the conduct of lawyers does not alone result in a finding of negligence or malpractice.[169] Violation of a rule does not give rise to an implied cause of action against a lawyer for professional negligence or breach of duty.[170] Instead, violation of a rule can be considered by a trier of fact as an aid in understanding the competence and diligence exercised by lawyers in similar circumstances.[171] Proof of a violation also can be considered to the extent that the rule was designed for the protection of persons in the position of the claimant and proof of the content and construction of the rule is relevant to the claim against the lawyer.[172]

A trier of fact applying the standard of competence and diligence exercised by lawyers in similar circumstances can consider the varying means by which different competent lawyers seek to accomplish the same client goal and the impossibility that all clients will reach their goals.[173] Thus, far from being considered an absolute indication of malpractice, proof of violation of a rule can be considered as an aid in understanding the standard of practice used to evaluate lawyers.[174]

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[169] *See* Model Rules of Prof'l Conduct R. 18 (1983) (stating that violation of a rule should not give rise to a cause of action or create a presumption that a legal duty has been breached); Restatement (Third) of the Law Governing Lawyers § 52; *see also Miami Int'l Realty*, 841 F.2d at 353 (holding that admission of testimony on the Code of Professional Responsibility was not error because the Code was not presented as having the force and effect of a law or that deviations from it constitute negligence per se); Allen v. Lefkoff, Duncan, Grimes & Dermer, P.C., 453 S.E.2d 719, 720 (Ga. 1995) (holding that an alleged violation of the Code of Professional Responsibility or Standards of Conduct, standing alone, cannot serve as the legal basis for a legal malpractice action); Lazy Seven Coal Sales, Inc. v. Stone & Hinds, P.C., 813 S.W.2d 400, 404 (Tenn. 1991) (stating that it is clear that the purpose of the Code of Professional Responsibility is not to define standards whereby a lawyer may be held civilly liable for damages).

[170] *See supra* note 169 and accompanying text.

[171] *See Allen*, 453 S.E.2d at 722 (stating that failure to comply with general rules of conduct can be considered along with other facts and circumstances in determining whether defendant acted with due care); Restatement (Third) of the Law Governing Lawyers § 52.

[172] *See Allen*, 453 S.E.2d at 721–22 (holding that a rule must be intended to protect a person in plaintiff's position or be addressed to the particular harm suffered by plaintiff to relate to the standard of care in a particular case); Restatement (Third) of the Law Governing Lawyers § 52.

[173] *See* Rosner v. Paley, 481 N.E.2d 553, 555 (N.Y. 1985) (stating that selection of one among several reasonable courses of action does not constitute malpractice); Restatement (Third) of the Law Governing Lawyers § 52.

[174] *See supra* notes 169–173 and accompanying text; Restatement (Third) of the Law Governing Lawyers § 52.

Expert testimony by those knowledgeable about the legal subject matter in question is also relevant in applying the standard.[175]

Similarly, although CMS has deemed the conditions included in its August Rule to be preventable, an occurrence of one of the conditions should not be conclusive evidence of negligence.[176] The occurrence of a condition in the August Rule should be viewed as a single piece of evidence relevant to the determination of negligence or malpractice.[177] Factors such as time pressures, varying means by which different competent health care providers can seek to treat a patient, and the unlikelihood that no patients will experience infections or bedsores, should be considered when deciding how the August Rule will relate to negligence and due care standards as well.[178] Because some patients could be more susceptible to certain infections and bedsores, a health care provider's decision regarding how to treat such a patient should be reviewed in connection with all of the surrounding circumstances and individual patient risks.[179]

2. How the August Rule's Legal Use Only as Evidence Could Keep Industry Costs Down

Treatment of the denial of benefits under the August Rule as evidence only of possible negligence will result in lower costs to the medical industry.[180] If some conditions on Medicare's list are not actually preventable, it is not fair to force hospitals to incur extra pre-admission testing costs, the expenses required to treat these conditions, and higher medical malpractice liability costs.[181] It has been recommended that hospitals should consider developing screening protocols to determine whether patients have any of the hospital-acquired conditions listed at the time they are admitted.[182] It is specified that the protocols

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[175] *See* Geiserman v. MacDonald, 893 F.2d 787, 793 (5th Cir. 1990) (stating that in most legal malpractice cases, expert testimony is necessary to establish the standard of care because only an attorney can competently testify to whether a defendant comported to the prevailing legal standard); RESTATEMENT (THIRD) OF THE LAW GOVERNING LAWYERS § 52.

[176] *See* RESTATEMENT (THIRD) OF THE LAW GOVERNING LAWYERS § 52; Aug. Press Release, *supra* note 1.

[177] *See* RESTATEMENT (THIRD) OF LAW GOVERNING LAWYERS § 52 (2000); Aug. Press Release, *supra* note 1.

[178] *See* RESTATEMENT (THIRD) OF LAW GOVERNING LAWYERS § 52 (2000); RESTATEMENT (SECOND) OF TORTS § 328A (1965); Aug. Press Release, *supra* note 1.

[179] *See* Editorial, *supra* note 39; Rodriguez, *supra* note 24.

[180] *See* Appleby, *supra* note 163.

[181] *See* Editorial, *supra* note 39; Rodriguez, *supra* note 24.

[182] Nicholson & Mitchel, *supra* note 1, at 11.

should address who will perform the initial assessment and how an effective initial assessment will be performed because not all of the current conditions in the August Rule are obvious at the time of admission.[183] Preadmission testing costs for some conditions in the August Rule will be incurred not for the purpose of helping patients, but for the purpose of ensuring that providers can receive payment for their services.[184] Additional unnecessary preadmission testing could be done in response to the heightened threat of a malpractice claim that could follow the occurrence of a condition in the August Rule.[185]

Ultimately, requiring health care providers to absorb the costs of ensuring that patients do not already have conditions listed in the August Rule upon admission could result in higher health care costs for patients generally because hospitals and physicians need to cover these costs somehow.[186] Hospitals have already raised prices in recent years, and hospital services contribute the largest share of the growth of health spending.[187] Under the August Rule, health care providers are not permitted to bill patients or their families directly for the cost of treating conditions included in the rule, but these costs can still be passed on indirectly to patients as a group through higher costs.[188]

Given the potential result of higher costs in the health care system and the uncertainty regarding whether conditions in the August Rule are preventable, it makes sense to consider the occurrence of a condition in the rule as a piece of evidence related to a claim of negligence or a lack of due care.[189] The presence of one of the August Rule's conditions should be considered one of many relevant pieces of evidence in a case claiming a lack of due care or a breach of a standard of care.[190] If the presence of one of the rule's conditions is considered conclusive evidence that the provider did not meet the level of care required, patients could be more likely to sue providers be-

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[183] *Id.* at 11–12.

[184] *See* Mimi Marchev, The Medical Malpractice Insurance Crisis 1, 7–8 (2002), *available at* http://www.nashp.org/Files/gnl48_medical_malpractice.pdf; Kaiser Network, *supra* note 28.

[185] *See* Restatement (Second) of Torts § 328A; Finder, *supra* note 107, at 76; Aug. Press Release, *supra* note 1.

[186] *See* Appleby, *supra* note 163.

[187] *See id.*

[188] Editorial, *supra* note 39.

[189] *See* Kaiser Family Found., Trends in Health Care Costs and Spending 1 (2007), http://www.kff.org/insurance/upload/7692.pdf; Rodriguez, *supra* note 24.

[190] Rodriguez, *supra* note 24; *see* Kaiser Family Found., *supra* note 189, at 1.

cause they could foresee a greater chance of winning in court.[191] If more patients bring claims against health care providers and are successful, physicians and hospitals will experience more expensive liability insurance costs.[192] In turn, these higher liability insurance costs will be passed on to patients in the form of higher medical bills and more expensive insurance.[193] Although the practice of defensive medicine could contribute to the rising cost of health care, it is unclear whether the fear of malpractice is currently causing physicians to practice defensive medicine.[194] Consumers might be willing to pay higher costs for better health care, but if the higher costs do not necessarily lead to better health care, the result might not be worth the cost.[195]

Failing to reimburse hospitals for conditions contained in the August Rule could cause negative consequences beyond higher economic costs.[196] The preamble to the August Rule specifically states that CMS is selecting conditions that will be avoided in *most* cases and that the risk of selectively avoiding patients at high risk of complications will be minimized.[197] CMS thus appears to admit that in *some* cases these conditions will not be avoided, even when hospital personnel engage in good medical practice.[198] Therefore, health care providers could attempt to selectively avoid patients at high risk of complications, because the providers cannot always prevent conditions in the August Rule from occurring.[199] Certainly, a system providing incentives to providers to avoid conditions that are truly results of

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[191] *See* Amy Johnson, Medical Liability Reform: A Three-State Comparison (May 2003), http://www.washingtonpolicy.org/Centers/healthcare/policynote/05_johnson_medicalliability.html.

[192] *See id.*

[193] *See id.* The public experiences the cost of health care primarily through the premiums they pay for health insurance and the cost sharing that they pay at the time that they receive care. KAISER FAMILY FOUND., *supra* note 189, at 1. Between 2002 and 2007, the cumulative growth in health insurance premiums was 78%, demonstrating that the public is already experiencing rising health care costs. *Id.* An effect of the August Rule could be higher health care costs for the public because health care providers will not be directly reimbursed for the cost of treating conditions included in the rule. *See* Aug. Press Release, *supra* note 1; KAISER FAMILY FOUND., *supra* note 189, at 1.

[194] *See* MARCHEV, *supra* note 184; *see also* CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUMAN SERVS., YOUR GUIDE TO MEDICARE'S PREVENTIVE SERVICES 2 (Jan. 2009), *available at* http://www.medicare.gov/Publications/Pubs/pdf/10110.pdf.

[195] *See* Rodriguez, *supra* note 24.

[196] MARCHEV, *supra* note 184; Nicholson & Mitchel, *supra* note 1, at 11.

[197] Nicholson & Mitchel, *supra* note 1, at 11.

[198] *Id.*

[199] *Id.*

error, such as operating on the incorrect body part, leaving an object in a patient during surgery, or providing a patient with the incorrect blood type, seems desirable.[200] Patient safety and the avoidance of expenses for health care providers treating preventable errors are important goals for our health care system.[201] This reasoning evaporates, however, in the context of conditions that are not truly preventable, such as some infections and bedsores.[202] Health care providers might prefer not to treat patients who could be more susceptible to some of the conditions in the August Rule, such as infections and bedsores, because in order to do so, the provider itself would need to fund the associated expenses.[203] Decisions that result in an easier lawsuit to prove could also lead to more physicians choosing to leave the practice of medicine sooner than they would otherwise.[204]

Health care providers' apprehension about being sued for malpractice appears to affect their perceptions about the actual risk of being sued.[205] The perceived risk of being sued can be much greater than the actual risk.[206] The anxiety and concern on the part of physicians due to rising malpractice premiums could cause them to avoid high risk patients and procedures.[207] If physicians or hospitals believe that some patients could be more susceptible to infections or bedsores that would not be reimbursed by Medicare under the August Rule, providers could prefer not to treat those individuals.[208] For instance, some argue that denying reimbursement for the care of a postoperative infection would only result in the decreased availability of surgical services to diabetics, the obese, the frail elderly, the severely injured, and the immunosuppressed, all of whom have higher documented incidences of infections after elective and emergency surgery.[209] The possibility of discharging patients quickly to avoid the costs of these condi-

[200] Hyman & Silver, *supra* note 28, at 1430, 1489; Pear, *supra* note 4. *See generally* Inst. of Med., *supra* note 27.

[201] Aug. Press Release, *supra* note 1.

[202] Rodriguez, *supra* note 24; *see* Marchev, *supra* note 184.

[203] Editorial, *supra* note 39; Rodriguez, *supra* note 24; *see* Marchev, *supra* note 184.

[204] *See* Marchev, *supra* note 184 (noting that it is not clear that malpractice crises cause physicians to move to other states or to leave the practice of medicine in significant numbers).

[205] *See id.*

[206] *See id.*

[207] *See id.*

[208] *See* Harrington, *supra* note 24, at 340; Rodriguez, *supra* note 24.

[209] *See* Rodriguez, *supra* note 24.

tions also exists, and could even be an unconscious result of the August Rule's inclusion of some conditions that are not entirely preventable.[210]

Furthermore, there is an ongoing problem with a shortage of physicians in certain areas.[211] The potential exists for the August Rule to discourage some physicians from continuing to practice as a result of insurance costs.[212] If even one physician decided to leave an underserved area because of rising malpractice liability costs, the loss of that provider could have a disproportionate impact as compared with the loss of a physician in a well-served area.[213] The August Rule's inclusion of conditions that may or may not be preventable could also have the undesirable effect of health care providers hesitating to treat patients who could be more susceptible to the conditions, or discharging those patients more quickly.[214]

Conclusion

Medicare's August Rule is commendable in its purpose of improving patient care and ceasing payment to health care providers for errors. Certainly, health care providers should not be compensated for egregious errors such as providing a patient with an incompatible blood type transfusion, leaving a sponge or other object in a patient during surgery, operating on the wrong body part, or providing a patient with the incorrect medication. Because some conditions in the August Rule, such as bedsores and some infections, do not appear to always be the result of medical error, however, this rule could have unintended results.

Given that conditions often occur as a result of many variables, and that some patients could be more susceptible to bedsores and infections than others, the occurrence of a condition in the August Rule should only be considered evidence of a lack of due care or a failure to meet the standard of care required. The denial of reimbursement under the August Rule should not be considered conclusive evidence of medical malpractice. If the occurrence of a condition in the August Rule is considered conclusive evidence of malpractice or negligence, malpractice insurance costs will rise unnecessarily. The

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[210] *Id.*

[211] Marchev, *supra* note 184, at 7. This could have more to do with other factors, such as the concentration of hospitals in some areas, rather than malpractice claims or one state policy decision. *See id.*

[212] *See id.*

[213] *See id.*

[214] Rodriguez, *supra* note 24.

higher cost of insurance would then be indirectly passed on to patients through higher insurance premium costs and co-payments. Further, because most states currently do not require hospital records to indicate whether patients develop conditions before or after admission, the August Rule could also lead to excessive pre-admission testing. If this pre-admission testing assisted providers in ensuring patient safety, this result would be welcomed. If pre-admission testing does not actually serve to make patients safer, however, it could lead to higher health care costs without much benefit.

To the extent that the August Rule results in fewer errors, it is a significant step toward improving patient safety. The August Rule should be praised for lowering Medicare expenses and providing physicians and hospitals with a cost incentive to avoid inexcusable errors. By including conditions that are not always preventable in the August Rule, however, Medicare risks raising health care costs for all without a corresponding improvement in patient care.

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