NOTES

REGULATING YOUR MEDICAL HISTORY WITHOUT REGULATIONS: A PRIVATE REGULATORY FRAMEWORK TO ELECTRONIC HEALTH RECORD ADOPTION

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INTRODUCTION

The U.S. health care system is about to enter the modern age. Through the Health Information Technology for Economic and Clinical Health Act (HITECH),[1] a subset of the American Recovery and Reinvestment Act of 2009,[2] the federal government has committed twenty-seven billion dollars to

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[1] 42 U.S.C.A. § 201 (West 2010).

[2] 26 U.S.C.A. § 1 (West 2010).

invigorate medical technology.[3] Specifically, Congress seeks to encourage comprehensive utilization of electronic health record (EHR) systems by 2014.[4] EHR systems offer substantial benefits, including improved patient safety through reduced medical errors and cost savings due to increased system efficiencies.[5] Notwithstanding these benefits, serious concerns remain. In January 2009, the U.S. Department of Veterans Affairs (VA) announced that its EHR system exposed patients to potentially lethal levels of the blood thinner heparin over a five month period.[6] Other serious injuries have been attributed to complex user interfaces and to the failure of EHR systems to record hospital patients' locations.[7] In total, the Food and Drug Administration (FDA) has received reports of forty-four injuries and six deaths attributed to EHR systems.[8]

The true magnitude of EHR system failures is unknown. The FDA receives reports of malfunction errors on a purely voluntary basis,[9] since the agency historically refused to exercise regulatory authority over EHR systems.[10] Recently, however, the FDA has started to entertain the possibility of EHR regulation.[11] While FDA oversight might seem like an appropriate remedy to the current EHR system difficulties, it is unclear whether the FDA possesses

[3] Over the next ten years, Congress will make available incentive payments totaling $44,000 through Medicare and $63,750 through Medicaid per clinician to encourage the adoption of health information technology. David Blumenthal & Marilyn Tavenner, *The "Meaningful Use" Regulation for Electronic Health Records*, 363 NEW ENG. J. MED. 501, 501 (2010).

[4] *See* 42 U.S.C.A. § 300jj-11(c)(3)(A)(ii).

[5] *See* Steven Shea & George Hripcsak, *Accelerating the Use of Electronic Health Records in Physician Practices*, 362 NEW ENG. J. MED. 192, 193 (2010); Jane E. Brody, *Medical Paper Trail Takes Electronic Turn*, N.Y. TIMES, Feb. 23, 2010, at D7. For a more thorough discussion of the benefits of EHR systems, see Part I of this Note.

[6] *Veterans Given Wrong Drug Doses Due to Glitch*, 6 ADVERSE EVENT REP. NEWS 1, 1 (2009).

[7] For example, an incident report claimed that "extraneous and distractive" information on a hospital's computer system caused a "life threatening acute asthma attack in a patient given the wrong drug." Fred Schulte & Emma Schwartz, *Electronic Medical Record Shift: Signs of Harm Emerge as Doctors Move from Paper*, HUFFINGTON POST (June 20, 2010), http://www.huffingtonpost.com/2010/04/20/electronic-medical-record_n_545441.html. (internal quotation marks omitted). In another incident, a computer notification system failed to apprise medical providers that an intensive care patient was moved to their ward. *Id.*

[8] Jeffrey Shuren, Dir. of FDA's Ctr. for Devices and Radiological Health, Testimony at the Health Info. Tech. Policy Comm. Adoption/Certification Workgroup (Feb. 25, 2010) (acknowledging the receipt of 260 reports of malfunctioning EHR systems since 2008).

[9] *Id.*

[10] Sharona Hoffman & Andy Podgurski, *Finding a Cure: The Case for Regulation and Oversight of Electronic Health Record Systems*, 22 HARV. J.L. & TECH. 103, 134 (2008).

[11] *See* Shuren, *supra* note 8.

regulatory authority.[12] Although the Federal Food, Drug, and Cosmetic Act (FD&C Act) charges the FDA with regulating medical devices,[13] there is much debate over whether EHRs qualify as such.[14] Additionally, the FDA is encountering resistance from the Obama Administration, which views systematic regulation as an impediment to its goal of comprehensive EHR adoption by 2014.[15]

Leading the Administration's opposition to FDA regulation is the Office of the National Coordinator for Health Information Technology (ONC), which is responsible for expediting the adoption of EHR systems.[16] National Coordinator David Blumenthal has cast doubt upon the FDA's regulatory authority, suggesting that EHRs are not medical "devices" within the purview of the FDA.[17] Instead, the National Coordinator created a set of EHR standards and certification criteria which health care providers must meet to qualify for stimulus funding under the Medicare and Medicaid EHR Incentive Programs.[18] These standards, however, fall far short of comprehensive regulation. Not only are the standards voluntary, but they also do not begin to address one of the government's primary goals of achieving interoperable EHR systems.[19] Moreover, the ONC delegates the certification of EHR systems entirely to the health information technology (HIT) industry.[20] Not surprisingly, the HIT industry fully supports this certification structure and argues that comprehensive regulation would "stifle innovation" and delay EHR adoption.[21] One must question whether these industry-run certification bodies have sufficient incentives to enforce certification criteria. Further, in light of

[12] *See infra* Part II.B.2.

[13] For a definition of the term "device" under the FDA's jurisdiction, see 21 U.S.C. § 321(h) (2006).

[14] *See infra* Part II.B.1.

[15] *See* Fred Schulte & Emma Schwartz, *FDA, Obama Digital Medical Records Team at Odds over Safety Oversight*, HUFFINGTON POST INVESTIGATIVE FUND (Aug. 3, 2010), http://huffpostfund.org/print/2210.

[16] 42 U.S.C.A. § 300jj-11(c)(3)(A)(ii) (West 2010). Prior to the National Coordinator's statutory creation under HITECH, President George W. Bush established the position by executive order, charging the National Coordinator with advancing EHR technology. *See* Meghan Hamilton-Piercy, *Cybersurgery: Why the United States Should Embrace this Emerging Technology*, 7 J. HIGH TECH. L. 203, 220 (2007).

[17] *Hearing on Implementation of the Health Information Technology for Economic and Clinical Health (HITECH) Act Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 111th Cong. 85-87 (2010) [hereinafter *Hearing on Implementation of HITECH*] (statement of David Blumenthal, National Coordinator, Health Information Technology, U.S. Department of Health and Human Services).

[18] *Id.* at 63; *Id.* at 68-69 (statement of Anthony Trenkle, Director, Office of E-Health Standards and Services, Centers for Medicare and Medicaid Services).

[19] *See* Hoffman & Podgurski, *supra* note 10, at 109.

[20] *See infra* text accompanying notes 63-67.

[21] Schulte & Schwartz, *supra* note 15.

the limited scope of the standards and the technical complexity of EHR systems, the certification bodies have considerable discretion in certification and enforcement of procedures.[22]

Notwithstanding the questionable motivations of the certification bodies, the HIT industry raises valid concerns. The inherent complexity in regulating EHR systems and a sharp increase in demand due to the incentive payments impose a considerable burden on the ONC. It is also unlikely that the FDA, subject to budgetary constraints and criticism for inadequate regulation of complicated medical devices,[23] would be an ideal substitute for the ONC. Accordingly, this Note proposes a private regulatory framework that holds individual EHR system manufacturers liable for producing systems based on suboptimal standards and grants immunity to health care providers from malpractice suits resulting from harm caused by system malfunctions. Additionally, minimal federal legislation is necessary to compel certain standards, such as system interoperability. This proposed framework addresses the Obama Administration's twin goals of swift adoption and interoperability while simultaneously motivating the HIT industry to enhance patient safety.

Part I of this Note explains the benefits of EHR systems and the many ways that EHRs impact patient health. EHR system capabilities have evolved dramatically over the last several decades, explaining the FDA's initial reluctance to promulgate regulations addressing patient safety concerns. Further advancement in EHR technology is imminent, and regulatory bodies will have to adapt quickly to keep pace. Part II introduces the ONC's role in establishing guidelines for Medicare and Medicaid EHR Incentive Programs. It further examines the FDA's jurisdiction and the current debate over regulatory authority. Part III concludes by recommending a private regulatory framework that encourages HIT manufacturers to adopt optimal safety standards by requiring them to absorb the costs of medical malpractice lawsuits that result from faulty EHR systems.

I. DEFINING EHR SYSTEMS AND IDENTIFYING HEALTH AND ECONOMIC BENEFITS

While there is no standard definition of an EHR, the Institute of Medicine has identified several key attributes, including documentation of physician notes, display of laboratory test results, and electronic prescribing.[24] A more expansive understanding of the term "EHR systems," as used in this Note, includes clinical decision support services, such as best practices guidelines,

[22] *Cf. CCHIT Town Call: An EHR Alternative Certification for Hospitals*, CCHIT, http://www.cchit.org/category/cchit-events/town-call (last modified May 17, 2011) [hereinafter *CCHIT Town Call*] (advising HIT manufacturers seeking certification to adhere to the HIT trade association's toolkit to navigate vague technical standards).

[23] Hoffman & Podgurski, *supra* note 10, at 138.

[24] Ashish K. Jha et al., *How Common Are Electronic Health Records in the United States? A Summary of the Evidence*, 25 HEALTH AFF. w496, w497 (2006).

drug-drug and drug-allergy alerts, and system interoperability, as well as other attributes.[25] The term cannot, and should not, be tied to any rigid definition.[26] One of the difficulties that the ONC has encountered in enacting certification guidelines is compartmentalizing various EHR technologies into precise categories.[27] The definition is fluid and will take on new meanings as the technology advances. As such, the ONC's efforts to define "EHR" tend to frustrate the goal of swift EHR system adoption.

Regardless of the formal definition, substantial benefits abound from EHR systems. Chief among these benefits is the ease with which medical providers may access such systems.[28] This feature facilitates coordination among health care practitioners by reducing duplicative medical tests and procedures and by avoiding contraindicated medications, lowering costs, and increasing patient safety.[29] At a 2010 House hearing on the implementation of HITECH, Congressman Frank Pallone, Jr. recounted his frustration with non-interoperable EHR systems.[30] The Congressman's mother, who died of pancreatic cancer, was forced to redo multiple CAT scans because hospitals were unable to read her electronically stored CAT scan images.[31] The electronic transfer of medical records also obviates the need for medical and family history updates and assists the patient who may not recall or recognize the relevance of every past medical event.[32] Significantly, this technology

[25] *See, e.g.*, Hoffman & Podgurski, *supra* note 10, at 104 n.1; *see also* Jha et al., *supra* note 24, at w497-98 (explaining that features such as data exchanges and data collection for disease surveillance are part of the larger field of HIT). This Note also does not draw a distinction between EHRs and electronic medical records or any variation thereof.

[26] *See* Shuren, *supra* note 8 (observing that the "dynamic" nature of HIT software necessitates adaptability to respond to changes in needs).

[27] *See, e.g.*, 45 C.F.R. §§ 170.102, .205, .207, .210, .302 (2010) (creating and distinguishing various forms of EHRs and prescribing intricate standards and guidelines); *infra* note 58 and accompanying text.

[28] Patient privacy and security concerns are beyond the scope of this Note. The Health Insurance Portability and Accountability Act (HIPAA) was enacted to safeguard a patient's protected health information. For an overview of HIPAA's impact on EHR systems, see Hoffman & Podgurski, *supra* note 10, at 121-23.

[29] *See* Shea & Hripcsak, *supra* note 5, at 194; Brody, *supra* note 5, at D7 (observing that avoiding procedures that could be hazardous when repeated enhances patient safety). *But see* Frederick E. Lepore, Letter to the Editor, *Digitizing Patient Records*, N.Y. TIMES, Mar. 2, 2010, at D4 (arguing that EHRs inhibit doctor-patient contact and reduce patients' illnesses to boxes on a checklist).

[30] *Hearing on Implementation of HITECH*, *supra* note 17, at 6 (statement of Rep. Frank Pallone, Jr., Chairman, Subcomm. on Health of the H. Comm. on Energy & Commerce).

[31] *Id.*

[32] Brody, *supra* note 5, at D7; *see also* Hoffman & Podgurski, *supra* note 10, at 113 (considering how critical information is likely missed, since the average Medicare patient visits seven different physicians per year).

could prove invaluable to emergency room physicians faced with an incapacitated patient.

Nevertheless, this paramount benefit is underutilized because many EHR systems function on different computer codes and are thus non-interoperable.[33] The HIT industry – the primary impediment to interoperability – currently lacks an incentive to make their systems interoperable. National interoperability would likely increase competition among manufacturers by simplifying the transition to new vendors, thereby decreasing EHR system costs.[34] A reduction in cost would likely induce a largely untapped market of small physician groups and sole practitioners to invest in EHR systems.[35] New client demand, therefore, should equalize any loss that manufacturers incur as a result of increased competition.

Beyond facilitating access to medical records, EHR systems also have the potential to improve patient care.[36] Electronic prescribing, for example, can reduce the likelihood of pharmacists misreading a doctor's order and can conduct an automatic search for drug-drug and drug-allergy interactions.[37] One physician even learned from his EHR system that he had mistakenly prescribed ten times the recommended dose of a particular medication for twenty years.[38] Clinical decision support systems further enhance patient care by alerting doctors to schedule tests and recommending possible diagnoses and treatment options.[39]

Health care providers also stand to benefit from significant cost savings derived from EHR system utilization.[40] Many of the cost savings will come from eliminating inefficiencies, such as avoiding redundant services and

[33] *See* Shea & Hripcsak, *supra* note 5, at 194. The ONC does require EHR systems that qualify for Medicare and Medicaid EHR Incentive Programs to operate on the same computer language, which no doubt increases interoperability. *See* CONG. BUDGET OFFICE, EVIDENCE ON THE COSTS AND BENEFITS OF HEALTH INFORMATION TECHNOLOGY 2 (2008). Without complete interoperability, however, medical providers cannot realize the true benefits and cost savings of EHRs. Further, lacking certainty that systems are interoperable, medical providers will be dissuaded from exchanging information and investing in the technology.

[34] *See* Shea & Hripcsak, *supra* note 5, at 194.

[35] *Cf.* CONG. BUDGET OFFICE, *supra* note 33, at 17 (recognizing that small physician groups pay more for EHR systems than large hospitals).

[36] Hoffman & Podgurski, *supra* note 10, at 113-16; Brody, *supra* note 5, at D7.

[37] Brody, *supra* note 5, at D7.

[38] Ceci Connolly, *Cedars-Sinai Doctors Cling to Pen and Paper*, WASH. POST, Mar. 21, 2005, at A1 (stating that prior to the implementation of the EHR system, this physician's nurses had secretly corrected the dosages to prevent patient harm).

[39] *See* CONG. BUDGET OFFICE, *supra* note 33, at 13. *But cf.* Michael D. Cabana et al., *Why Don't Physicians Follow Clinical Practice Guidelines? A Framework for Improvement*, 282 J. AM. MED. ASS'N 1458, 1461-62 (1999) (summarizing why many physicians do not observe clinical practice guidelines that are not part of EHR systems).

[40] *See* CONG. BUDGET OFFICE, *supra* note 33, at 6.

tests,[41] as well as reducing defensive medicine.[42] EHR systems can also streamline the medical billing process by reducing administrative paperwork and ensuring that all procedures are appropriately submitted for payment. Moreover, a universally interoperable system would assist physicians in quickly identifying likely illnesses, reducing the length of patient visits,[43] and decreasing the probability of medical errors, thereby lowering malpractice costs over time.[44]

Although the many benefits of EHR systems make adoption desirable, substantial barriers still exist. The initial investment in comprehensive EHR systems is substantial. Practitioners and hospitals must acquire the appropriate hardware and software, pay licensing fees, and anticipate long-term system maintenance costs.[45] A 2005 study estimated that the typical EHR system requires a $33,000 capital investment per clinician and monthly maintenance costs of $1500 per clinician.[46] A steep learning curve also diverts time away from patients and discourages many doctors from relinquishing their paper charts. Additionally, individual health care practitioners cannot readily capture many of the aforementioned cost savings. Savings resulting from improved quality of patient care, reduced test duplication, and minimized defensive medicine provide incalculable benefits to the U.S. health care system as a whole, but not necessarily to the individual clinician. Patients, health insurance companies, and state and federal health care programs will realize instant gains from these cost reductions while health care providers are left to pay off their investments. Nevertheless, the qualitative benefits of EHR systems are evident,[47] and Medicare and Medicaid EHR Incentive Programs largely offset these costs.[48]

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[41] *Id.* at 11.

[42] Hoffman & Podgurski, *supra* note 10, at 114.

[43] *See* CONG. BUDGET OFFICE, *supra* note 33, at 12.

[44] Even with significant reductions in malpractice costs, skepticism exists over whether malpractice insurance companies will pass those savings along to physicians. *See, e.g.*, *New Data Shows Tort Law Changes Won't Reduce Malpractice Premium*, AM. ASS'N FOR JUST. (Oct. 29, 2009), http://georgiajustice.blogspot.com/2009/10/tort-law-changes-wont-reduce.html [hereinafter *New Data*]. *But cf.* PERRY BEIDER & STUART HAGEN, CONG. BUDGET OFFICE, LIMITING TORT LIABILITY FOR MEDICAL MALPRACTICE 5 (2004) (reporting that caps on malpractice damage awards resulted in decreased malpractice premiums).

[45] *See* CONG. BUDGET OFFICE, *supra* note 33, at 17.

[46] David Gans et al., *Medical Groups' Adoption of Electronic Health Records and Information Systems*, 24 HEALTH AFF. 1323, 1329 (2005). The average hospital spends two percent of its operating budget on HIT system maintenance. Hospitals with more advanced EHR systems can spend an exponentially higher percentage. *See* NAT'L CENTER FOR RESEARCH RES., NAT'L INSTS. OF HEALTH, ELECTRONIC HEALTH RECORDS OVERVIEW 18 (2006).

[47] *See* NAT'L CENTER FOR RESEARCH RES., *supra* note 46, at 18.

[48] The Medicare EHR Incentive Program will provide eligible professionals up to $44,000 over five years. *EHR Incentive Programs Overview*, CTRS. FOR MEDICARE &

II. THE REGULATION OF EHR SYSTEMS

A. *The Role of the Office of the National Coordinator for Health Information Technology*

EHR systems are not currently regulated, although the ONC plays a significant role in establishing standards and guidelines with which health care providers must comply in order to be eligible for Medicare and Medicaid EHR Incentive Programs. The ONC was a legislative mandate in HITECH as a division of the U.S. Department of Health and Human Services (HHS) and charged with promoting the adoption of EHR systems.[49] The ONC was also charged with promulgating regulations to ensure that incentive payment recipients are "meaningful users" of EHR systems.[50] That is, to qualify for incentive payments, the EHR systems must significantly advance patient care.[51] HITECH also created the HIT Policy Committee, which recommends a policy framework for HIT infrastructure to the ONC,[52] and the HIT Standards Committee, which advances standards and certification criteria based upon the Policy Committee's suggested framework.[53]

Based upon HIT Policy Committee and HIT Standards Committee recommendations, the ONC created a minimum set of standards that EHR systems must meet to satisfy the meaningful use requirement.[54] Among the

MEDICAID SERVS., https://www.cms.gov/EHRIncentivePrograms (last modified May 17, 2011). Health professionals are eligible for up to $63,750 over six years under the Medicaid EHR Incentive Program. *Id.* Hospital incentive payments are calculated on an individual basis under the Medicaid EHR Incentive Program, but hospitals can expect to receive an initial two million dollar payment. *Id.* Additionally, all EHR systems must comply with "meaningful use" regulations in order to qualify for these incentives. *See* infra notes 50-51 and accompanying text.

[49] 42 U.S.C.A. § 300jj-11(a) (West 2010); *see also About the Office of the National Coordinator for Health Information Technology*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__onc/1200 (last updated Dec. 8, 2010).

[50] *See Electronic Health Records and Meaningful Use*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__meaningful_use_announcement/2996 (last updated Feb. 9, 2011).

[51] *See* Blumenthal, *supra* note 3, at 501.

[52] 42 U.S.C.A. § 300jj-12; *see also Health IT Policy Committee*, U.S. DEPARTMENT OF HEALTH & HUM. SERVICES, http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__health_it_policy_committee/1269 (last updated Aug. 19, 2011).

[53] 42 U.S.C.A. § 300jj-13; *see also Health IT Standards Committee*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__health_it_standards_committee/1271 (last updated Aug. 19, 2011) (describing the HIT Standard Committee's role as a Federal Advisory Committee).

[54] *See Standards and Certification Criteria*, U.S. DEP'T OF HEALTH & HUMAN SERVS., http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__standards_ifr/1195 (last updated Mar. 31, 2011) (stating that the HHS developed a Final Rule "in an

standards are vocabulary codes, encryption requirements, notifications for drug-drug and drug-allergy interactions, and vital sign recording capabilities.[55] Certain enhanced standards apply to specific types of medical practices, such as ambulatory care.[56] Certified ambulatory care EHR systems must be able to record patients' medications, laboratory results, and demographic information, as well as offer clinical decision support services.[57] Additionally, the ONC attempts to define various forms of EHR technology by categorizing features into specific groups, such as Certified EHR Technology, Complete EHRs, EHR Modules, and Qualified EHRs.[58]

To ensure compliance with these standards, the ONC established a temporary certification program whereby private organizations apply to become ONC-authorized testing and certification bodies (ONC-ATCB).[59] Applicants must submit internal reports and manuals that comply with various procedures set forth by the International Organization for Standardization and pass a proficiency examination.[60] Once certified, ONC-ATCBs can verify that health care practitioners' EHR systems are technically capable of meeting meaningful use standards.[61] ONC-ATCBs can also grant certifications to developers of EHR systems to facilitate the direct sale of pre-certified EHR systems to health care practitioners.[62]

So far, the ONC has certified six ONC-ATCBs since the regulations have been in force: the Certification Commission for Health Information Technology (CCHIT), Drummond Group, Inc., InfoGard Laboratories, Inc., Surescripts LLC, ICSA Labs, and SLI Global Solutions.[63] CCHIT was active

incremental approach to adopting standards, implementation specifications, and certification criteria to enhance the interoperability, functionality, utility, and security of health IT and to support its meaningful use").

[55] *See* 45 C.F.R. §§ 170.205, .207, .210, .302 (2010).

[56] *See id.* § 170.304.

[57] *Id.*

[58] *Id.* § 170.102. Qualified EHRs, for example, must provide clinical decision support, facilitate prescription ordering, and record patient demographic information and medical history. *Id.* A Certified EHR must satisfy the same standards as a Qualified EHR and receive formal certification. *Id.* Complete EHRs must satisfy all "certification criteria," which is vaguely defined as "applicable standards" adopted by HHS. *Id.* EHR modules need only satisfy one certification criterion. *Id.*

[59] *Id.* § 170.401.

[60] *Id.* § 170.420.

[61] *See HITECH Temporary Certification Program for EHR Technology*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=2887&PageID=19630 (last updated Sept. 11, 2010).

[62] *See id.*

[63] *ONC-Authorized Testing and Certification Bodies*, U.S. DEPARTMENT HEALTH & HUM. SERVICES, http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__onc-authorized_testing_and_certification_bodies/3120 (last updated Dec. 28, 2010).

in the HIT certification field prior to the enactment of ONC regulations.[64] It was the first organization to develop standards for the HIT industry, and HHS awarded it a three-year contract in 2005 to develop certification and inspection criteria for EHR systems.[65] CCHIT is an industry-run organization, however, and critics claim that its certification and inspection criteria are "excessively favorable" to the HIT industry.[66] Although ONC regulations trump CCHIT's criteria with respect to EHR systems that are eligible for incentive payments, the ONC likely relied heavily upon CCHIT's questionable standards when drafting its regulations. Indeed, the ONC implicitly acknowledged that its standards are insufficient by recognizing the need for more detailed regulations in the permanent certification program,[67] which will replace the temporary program on January 1, 2012.[68]

Other inadequacies in the current regulatory system are manifold. First, the regulations do not provide guidance on how to administer the certification process. For example, CCHIT is free to conduct its standard one-day EHR system test to certify EHR systems. This is troubling because many EHR system malfunctions are not detectable in a single day.[69] In short, the regulatory bodies are ensuring compliance with certain minimum guidelines but failing to adequately ensure reliability and safety. The permanent certification program attempts to increase reliability by requiring ONC-ATCBs to occasionally interpret EHR systems.[70] Although continued inspections will help to ensure system reliability, ONC-ATCB's will only verify that systems continue to function as they did when originally inspected, without regard to updated safety requirements.[71] Second, there has been little discussion regarding the regulation of EHR systems following the expiration of the incentive programs. ONC-ATCBs cannot be expected to maintain defunct ONC standards. Besides, such standards might become obsolete as HIT advances. Finally, ONC regulations do not implicate all EHR systems but only those that seek certification. Indeed, HITECH expressly limits its mandate to

[64] *See* Hoffman & Podgurski, *supra* note 10, at 132-34.

[65] *Id.*

[66] *Id.* at 132.

[67] *See Standards and Certification Criteria*, *supra* note 54 (stating that current ONC regulations "represent[] the first step in an incremental approach to adopting standards, implementation specifications, and certification criteria to enhance the interoperability, functionality, utility, and security of health IT").

[68] Establishment of the Permanent Certification Program for Health Information Technology, 76 Fed. Reg. 1262, 1265 (Jan. 7, 2011). This final rule is more comprehensive than the temporary program. It appears that the HIT industry will nevertheless continue to play a dominant role under the permanent system.

[69] Hoffman & Podgurski, *supra* note 10, at 133.

[70] Establishment of the Permanent Certification Program for Health Information Technology, 76 Fed. Reg. at 1282-83.

[71] *Id.*

entities seeking incentive payments.[72] As a result, the ultimate goal of universal interoperability will not be achieved.

B. *Proposed Regulatory Authority of the FDA*

1. FDA's Jurisdiction and Past Denial of EHR Regulatory Authority

The FD&C Act empowers the FDA to regulate medical devices. A medical device is defined as

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease . . . .[73]

The FD&C Act further categorizes devices into three classes, depending upon the regulatory controls that the FDA deems necessary to assure the safety and effectiveness of a device.[74] "Class I devices" do not support or sustain human life and do not pose an unreasonable risk of injury.[75] Such devices are subject to "general controls," or minimal FDA oversight, which include the regulation of misbranded or adulterated devices and company registration requirements.[76] "Class II devices" support or sustain human life and pose some risk of injury.[77] These devices must comply with "special controls," which include general controls and enhanced labeling requirements, performance standards, and post-market evaluations.[78] "Class III devices" are subject to the most stringent FDA controls because they support or sustain human life and present an unreasonable risk of injury.[79] Class III devices must attain pre-market approval by the FDA.[80] This process is lengthy and may cost manufacturers as much as one million dollars.[81] Manufacturers can, however, avoid the pre-

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[72] 42 U.S.C.A. § 300jj-16(a) (West 2010) ("[N]othing in [HITECH] . . . shall be construed to require a private entity to adopt or comply with a standard or implementation specification . . . .").

[73] 21 U.S.C. § 321(h) (2006).

[74] *Id.* § 360c; Devices: General Hospital and Personal Use Devices; Reclassification of Medical Device Data System, 73 Fed. Reg. 7498 (proposed Feb. 8, 2008).

[75] *See* 21 U.S.C. § 360c(a)(1)(A).

[76] *Id.*; JAMES T. O'REILLY, FOOD AND DRUG ADMINISTRATION § 18:76 (3d ed. 2010); *Medical Devices: General and Special Controls*, U.S. FOOD & DRUG ADMIN. (Apr. 23, 2009), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm.

[77] 21 U.S.C. § 360c(a)(1)(B); O'REILLY, *supra* note 76, at § 18:76.

[78] O'REILLY, *supra* note 76, at § 18:76.

[79] *See* 21 U.S.C. § 360c(a)(1)(C).

[80] *Id.*

[81] Devices: General Hospital and Personal Use Devices; Reclassification of Medical Device Data System, 73 Fed. Reg. 7498, 7501 (proposed Feb. 8, 2008).

market approval process by demonstrating that their products are "substantially equivalent" to an existing FDA-approved device.[82]

The definition of "device" clearly encompasses software that is essential to the functioning of devices that one traditionally associates with medical procedures, such as the MRI and x-ray.[83] It is less clear, however, whether this definition extends to "stand-alone" devices, such as EHRs.[84] In 1989, the FDA issued draft guidance concluding that it lacked regulatory authority over "computer products intended only for use as traditional 'library' functions, such as storage, retrieval, and dissemination of medical information," and software that functioned primarily for accounting or communications purposes.[85] EHR systems do function as library, storage, and retrieval devices and assist in accounting and billing, although these are not their sole functions.[86] Though the meaning of EHR has certainly evolved since the issuance of the FDA's draft guidance, identifying core EHR functions is problematic for the reasons outlined above.[87]

The FDA draft guidance further denied authority over computer products "that are intended to involve competent human intervention before any impact on human health occurs."[88] Defining "competent human intervention" presents difficulties similar to identifying core EHR functions. EHR systems can alert physicians to potentially life-threatening drug interactions, effectively intervening in the doctor's treatment of patients. EHRs containing clinical decision support services present further complications, since questions remain as to whether a physician that relies heavily upon such support services sufficiently intervenes before the device influences human health. The issue of physician reliance should figure significantly into the analysis of human intervention. Physicians likely will rely heavily on all aspects of EHR systems because they assume reliability. For example, a physician may presume that an EHR system's electronic prescribing function accurately converted the physician's handwritten prescription into a digital format. Despite the physician's intervention in the device's performance, the EHR system might

[82] 21 U.S.C. § 360c(f)(1).

[83] Arnold J. Rosoff, *On Being a Physician in the Electronic Age: Peering into the Mists at Point-&-Click Medicine*, 46 ST. LOUIS U. L.J., 111, 121 (2002).

[84] *Id.* "Stand-alone" devices can refer to EHRs that serve a purely recordkeeping function or EHRs that contain more complex functions. An EHR system, as used in this Note, is not a stand-alone device by definition.

[85] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., FDA POLICY FOR THE REGULATION OF COMPUTER PRODUCTS (proposed draft 1989), *available at* http://www.janosko.com/documents/FDA%20Policy%20Computer%20Products/FDAPolicyComputers1989.htm.

[86] *See* Shuren, *supra* note 8.

[87] *See supra* Part I.

[88] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., *supra* note 85.

misinterpret the order and, should the physician rely on this, result in patient harm.

2. FDA's Renewed Interest in EHR Regulation

The 1989 draft guidance[89] unofficially established the FDA's noninterference policy toward EHR regulation, which lasted for nearly two decades.[90] Recently, however, the FDA has taken steps toward the regulation of select EHR systems[91] and has explored more comprehensive regulatory measures.[92] In 2008, the FDA proposed a rule to "reclassify" medical device data systems (MDDSs) from Class III to Class I devices (Proposed Rule).[93] A MDDS, as defined in the Proposed Rule, is "a device that electronically stores, transfers, displays, or reformats patient medical data" but "does not provide any diagnostic or clinical decision making functions."[94] Such devices would include, for example, software that stores historical blood pressure information or converts digital medical data into a readable format.[95] MDDSs do not encompass EHRs that merely store patient information entered by a physician.[96]

The FDA's use of the term "reclassify" with respect to MDDSs is rather bold. It presupposes FDA authority over devices similar – or possibly identical – to devices for which it renounced regulatory authority in the 1989 draft guidance. While the Proposed Rule is somewhat limited in scope, it is reasonable to assume that the FDA would contend that its authority extends to virtually all EHR systems, given the simple function capabilities described in the MDDS definition. Perhaps most striking, however, is the FDA's presumption that MDDSs qualify as Class III devices within the meaning of the FD&C Act.[97] The Proposed Rule justifies this "deregulation" on the grounds that a change to Class I classification will provide adequate safety assurances and reduce pre-market approval costs associated with Class III

[89] The FDA withdrew the 1989 draft guidance from its website in 2005. Letter from Bernie Liebler, Dir., Tech. & Regulatory Affairs, AdvaMed, to Div. of Dockets Mgmt., U.S. Food & Drug Admin. (Aug. 5, 2008), *available at* http://www.fda.gov/ohrms/dockets/dailys/02/Dec02/120402/02d-0325-c000015-vol1.pdf.

[90] *See* Hoffman & Podgurski, *supra* note 10, at 134 (observing that the FDA has not attempted to regulate EHR systems as of 2008).

[91] Devices: General Hospital and Personal Use Devices; Reclassification of Medical Device Data System, 73 Fed. Reg. 7498, 7498-7503 (proposed Feb. 8, 2008).

[92] Shuren, *supra* note 8.

[93] Devices: General Hospital and Personal Use Devices, 73 Fed. Reg. at 7500 (stating that MDDSs "are deemed to be class III devices by operation of . . . 21 U.S.C. 360c(f)").

[94] *Id.* at 7501.

[95] *Id.* at 7500.

[96] *Id.*

[97] *See id.*

devices.[98] The FDA impliedly acknowledged, however, that it has been reluctant to take action against MDDS manufacturers that have neglected to register.[99]

Not surprisingly, the FDA received considerable resistance from the HIT industry following the Proposed Rule. Dozens of the nation's leading HIT device manufacturers and trade associations commented on the Proposed Rule, condemning it as "irrationally broad"[100] and having the potential to create "tremendous confusion" regarding whether particular products are MDDSs.[101] Others beseeched the FDA to clarify that, since EHR systems do not satisfy the definition of a "medical device" under the FD&C Act, EHR systems do not qualify as MDDSs.[102] Of course, if the FDA acquiesced to such a request, the Proposed Rule would be rendered null.

So why did the FDA announce this Proposed Rule, and why did it define MDDS to include many of the characteristics traditionally associated with EHR systems? The FDA acknowledged that use of HIT has "grown exponentially" since it issued the 1989 draft guidance.[103] Recent reports of patient deaths and injuries attributable to EHR system failures also surely heightened the Agency's interest.[104] Why the FDA chose to use the term "MDDS" rather than "EHR" is less clear. The FDA likely has no interest in regulating EHR systems that only store patient data manually entered by physicians, so it might have avoided the term to exclude such devices. Still, the FDA could have used a variant of the term "EHR system" and articulated a definition similar to "MDDS." Importantly, based on the definition of MDDS and the FDA's explanation of the Proposed Rule, the Agency believes that more advanced EHR systems are subject to Class III regulation – the most stringent standard. By deliberately evading use of the term "EHR," the Agency likely avoided attracting intense scrutiny from the entire HIT community.

Perhaps the FDA designed the Proposed Rule solely to gauge the HIT industry's reaction to the possibility of regulation. The FDA did not finalize the regulation and has yet to propose a similar rule, although the Agency, as of

[98] *Id.* at 7500-01.

[99] *See id.* at 7500 ("Assuming that continued enforcement discretion is not a viable long-term regulatory alternative, the proposed rule would reduce the regulatory burden for manufacturers of MDDS devices.").

[100] Letter from Anthony A. Barrueta, Vice President of Gov't Relations, Kaiser Permanente, to Div. of Dockets Mgmt., U.S. Food & Drug Admin. (May 8, 2008) (on file with author).

[101] Letter from Jeffrey C. Schneider, Digital Health Grp. Counsel, Intel Corp., to Div. of Dockets Mgmt., U.S. Food & Drug Admin. (May 8, 2008) (on file with author).

[102] Letter from Donald Schoen, Chair, & Hugh Zettel, Vice Chair, HIMSS Elec. Health Record Vendors Ass'n, to Div. of Dockets Mgmt., U.S. Food & Drug Admin. (May 8, 2008) (on file with author).

[103] Devices: General Hospital and Personal Use Devices, 73 Fed. Reg. at 7500.

[104] *See supra* notes 6-8 and accompanying text.

January 2011, is developing responses to the comments.[105] Nevertheless, the FDA's cursory allusion to the fact that EHR systems with features more advanced than those contained in the definition of "MDDS" are Class III devices postulates that the technology comes within the meaning of "device."[106] The FDA has avoided addressing the issue directly, and legal commentators have questioned the agency's authority.[107] Health Canada, the FDA's Canadian counterpart,[108] concluded that it does have authority over medical software that shares EHR system characteristics[109] based on a definition of "device" which closely tracks the FD&C Act's language.[110] Additionally, the European Union is actively investigating HIT oversight possibilities through similar device regulations.[111] Despite the FDA's reluctance, it has continued to assert itself as a prospective figure in HIT regulation.

Jeffrey Shuren, Director of the FDA's Center for Devices and Radiological Health, announced at a HIT Policy Committee workgroup session that the FDA could, at a minimum, "play an important role in preventing and addressing HIT-related safety issues."[112] Shuren outlined three possible approaches to FDA regulation of HIT devices. The first approach would entail manufacturers registering their products with the FDA and submitting Medical Device Reports (MDRs) to the FDA.[113] Currently, device manufacturers and user facilities submit MDRs to report adverse events attributed to a given device.[114] While mandatory reporting of errors through MDRs would apprise

[105] E-mail from Anthony Watson, Ctr. for Devices & Radiological Health, Food & Drug Admin., to author (Jan. 16, 2011, 11:38 EST) (on file with author).

[106] *See* Devices: General Hospital and Personal Use Devices, 73 Fed. Reg. at 7500. Since the Proposed Rule was not promulgated, the FDA presumably considers devices featuring the basic characteristics of MDDSs to be Class III devices.

[107] *See, e.g.*, Hoffman & Podgurski, *supra* note 10, at 136; Rosoff, *supra* note 83, at 121.

[108] *About FDA: Office of International Programs Overview*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofGlobalRegulatoryOperationsandPolicy/OfficeofInternationalPrograms/ucm236581.htm (last updated Aug. 17, 2011).

[109] The characteristics similar to EHR systems include data analysis and editing, as well as alarm or alert functions. Notice from Health Canada to Manufacturers, Importers, and Distributors of Medical Device Software 3 (Dec. 3, 2010) (on file with author).

[110] Canada's Food and Drugs Act states that "device" means "any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in . . . the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals." Food and Drugs Act, R.S.C. 1985, c. F-27, s. 2.

[111] Alaina Busch, *Lack of Interoperability, Human Factors Could Complicate HIT Expansion*, INSIDE HEALTH REFORM, Dec. 29, 2010 (LEXIS).

[112] Shuren, *supra* note 8.

[113] *Id.*

[114] *See* 21 C.F.R §§ 803.3, .10 (2011).

EHR system users of known errors, this approach fails to hold manufacturers liable for neglecting to take corrective action.

The second approach builds upon the first by demanding compliance with the FDA's Quality Systems Regulation, which requires manufacturers to follow certain minimum quality guidelines in producing their products.[115] While these guidelines might create some uniformity among manufacturers, the manufacturers would determine the ultimate quality procedures. The final approach outlined by Shuren would involve the FDA enforcing its "traditional regulatory framework," subjecting manufacturers to premarket review.[116]

III. PROPOSED REGULATORY FRAMEWORK

A. *The Case for Private Regulation*

The Obama Administration's goal to have an EHR for every American by 2014[117] is laudable, and the U.S. health care system will undoubtedly benefit tremendously from this accomplishment. Nevertheless, swift adoption poses serious safety concerns that our current regulatory system does not sufficiently address. The VA, which maintains comprehensive EHR safety systems and tracks device errors,[118] has identified many types of EHR system defects within its own infrastructure.[119] The VA categorizes errors into quality defects, design-induced errors, defects in software programming logic, and data storage problems.[120] One software programming defect, for example, caused a previous patient's medical information to be displayed on a subsequent patient's EHR.[121]

Considering the VA's extensive experience with HIT, device errors are likely more pervasive nationwide. Yet, with no mandatory reporting system[122] and a lack of communication among EHR systems users,[123] these errors go

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[115] Shuren, *supra* note 8.

[116] *Id.*

[117] *See supra* text accompanying notes 15-16.

[118] The VA supports multiple avenues for reporting EHR system errors or concerns, including root cause analysis of adverse events, data entry fields in EHR systems, and web portal reporting. Jean M. Scott, Dir., Info. Tech. Patient Safety Office, U.S. Dep't of Veterans Affairs, Remarks at the Health Information Technology Policy Committee Adoption/Certification Workgroup (Feb. 25, 2010).

[119] *Id.*

[120] *Id.*

[121] *Id.*

[122] Director Scott suggests that HIT manufacturers define "device" too narrowly, allowing such manufacturers to justify their failure to report safety concerns on the ground that their products are not regulated by the FDA. *See id.*

[123] *See ICA Director of Interoperability Services, Tim Dunnington, to Attend IHE 2011 North American Connectathon*, BUS. WIRE, Jan. 13, 2011, [hereinafter *Connectathon*] *available at* http://ww2.icainformatics.com/2011/01/18/ica-director-of-interoperability-

largely unreported. As a result of several layers of device error reporting at the VA, all clinicians were put on notice of the software programming defect mentioned above.[124] Within three days of this notice, the VA received over twenty additional reports.[125] Beyond these traditional software defects, the VA has identified user interface design flaws that tend to induce human error.[126] For example, the VA's former electronic prescribing software auto-highlighted commonly-used prescriptions after a physician entered the first three letters of the medication's name.[127] The physician could then quickly select the medication by tapping the "Enter" key, which the VA claims predisposed physicians to select the highlighted entry.[128] While the HIT industry dismissed the problem as "user error" and correctable through "re-training," the VA's data collection revealed a systemic problem that demanded redesigning the software (mal)function.[129]

In addition to software malfunctions, usability difficulties, and lack of reporting requirements, universal interoperability will remain unachieved without legislative or regulatory action.[130] Although the HIT industry generally rejects mandatory government efforts to compel interoperability, some industry groups have come together to test interoperable software designs.[131] While these groups are well-intentioned, the problem is that there are many such groups working to create their own interoperable systems.[132] Even if the largest EHR system manufacturers agreed upon interoperable standards, individual hospitals or physician groups that design their own software would not necessarily utilize comparable clinical or technical formats.[133] Moreover, individual states are striving to create interoperable EHR systems within their own borders.[134] All of these efforts are further layered upon the ONC's standards, creating a complicated mix of unrelated, discretely interoperable systems. Should the current method of integration

services-tim-dunnington-to-attend-ihe-2011-north-american-connectathon/ (proposing data sharing among HIT users to overcome obstacles to health care modernization).

[124] Scott, *supra* note 118.

[125] *Id.*

[126] *Id.*

[127] *Id.*

[128] *Id.*

[129] *Id.*

[130] *See supra* notes 19, 33-35 and accompanying text.

[131] *Connectathon*, *supra* note 123.

[132] *See id.*

[133] *See* William B. Munier, Report to Health Information Technology Policy Committee Adoption/Certification Workgroup (Feb. 25, 2010) (on file with author).

[134] Daniel F. Shay, *A Primer on Electronic Health Record License Agreements*, *in* 2006 HEALTH LAW HANDBOOK § 9:2 (Alice G. Gosfield ed., 2010) (explaining Virginia's goal to create EHRs capable of sharing information among health care providers). The Massachusetts eHealth Collaborative, a private organization, is also fostering interoperability efforts within the state. *Id.*

persist, mandatory interoperability will be necessary to realize fully the benefits of EHR systems.

B. *Private Regulatory Framework*

1. Minimal Mandatory Guidelines

Regardless of the broader regulatory regime, two elements are critical to ensuring system efficiency and patient safety: interoperability and adverse event reporting. Interoperability is a cornerstone of the Obama Administration's HIT effort[135] and is regarded as a primary goal for many HIT industry members.[136] As discussed above, however, unification efforts are disjointed and mandatory regulations are inadequate.[137] Currently, the ONC's guidelines do not require interoperability for devices to qualify for Medicare and Medicaid EHR Incentive Programs, although the ONC anticipates that this will change.[138] The HIT industry is well aware that the ONC may promulgate such a regulation and has been provided with sufficient time to investigate interoperable standards. Accordingly, the ONC's permanent certification program should require interoperability.

Regulations predicated on the receipt of incentive payments will nevertheless fail to reach manufacturers and users that do not seek, or are not eligible for, the federal benefits. To overcome this obstacle, statutory or regulatory action may be necessary. Federalism concerns may threaten to derail congressionally mandated interoperability, but such arguments are unlikely to succeed.[139] The federal government's extensive authority under the Commerce Clause to regulate interstate health care likely extends to nationwide interoperability standards.[140] The more pressing issue is who should design the standards.[141] The ONC is best situated to undertake the task

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[135] *See supra* note 19 and accompanying text.

[136] *Interoperability*, CCHIT, http://www.cchit.org/workgroups/interoperability (last visited Jan. 20, 2011) ("Ensuring that EHR products and networks can share data compatibly is one of the primary goals of certification – and the public and private health IT communities.").

[137] *See supra* notes 131-134 and accompanying text.

[138] Health Information Technology: Initial Set of Standards, 75 Fed. Reg. 44599 (July 28, 2010) (to be codified at 45 C.F.R. pt. 170) ("We believe this final rule correctly balances at this stage of EHR adoption our goal of promoting interoperability with the HIT industry's . . . need for flexibility. Consistent with our long-term goals for interoperability, we anticipate that this balance will need to change . . . .").

[139] *See* Benjamin J. Beaton, Note, *Walking the Federalist Tightrope: A National Policy of State Experimentation for Health Information Technology*, 108 COLUM. L. REV. 1670, 1710 & n.276 (2008) (noting that congressionally mandated interoperability standards are probably permissible in light of Congress's vast power to regulate health care under the Commerce and Spending Clauses).

[140] *Id.*

[141] *See id.* at 1710.

of designing interoperable standards because of its experience in the technical aspects of HIT and its relationships with the HIT industry. The ONC should continue to collaborate with the HIT industry and involve states that have adopted their own information-sharing systems. Following such collaborations and investigations, the ONC should promulgate regulations requiring that all EHR systems comply with its interoperability standards.

In addition to interoperability regulations, device manufacturers and users should be required to report all adverse events that are attributable, or possibly attributable, to EHR systems. Error reporting should be a continuous process throughout the life of a product to address new issues that arise as HIT users discover system vulnerabilities.[142] A reporting system will foster collaboration between manufacturers and end users, leading to safer and more usable, reliable products.[143] Ideally, interoperable systems would compliment mandatory error reporting to instantly communicate concerns to users of the same HIT technology.

The FDA already oversees error reporting through MDRs,[144] so mandatory reporting of adverse EHR events should simply adhere to the current system. If the FDA's contention that it currently possesses regulatory authority over EHR systems is correct,[145] then the only issue is one of enforcement. To test its theory, the FDA should commence enforcement efforts against members of the HIT community that do not submit MDRs subsequent to adverse events. If the FDA can successfully demonstrate a connection between patient harm and an EHR system error, it will likely survive challenges from the HIT manufacturers.

Alternatively, Congress could amend the definition of "device" to specifically include EHR systems. At a minimum, EHR systems could be statutorily classified as Class I devices so that the FDA's control is strictly defined. Such a compromise should appease the HIT industry, which presently must deal with a fairly zealous agency contemplating Class III pre-market approval status for EHR systems.[146]

2. The Legal Infrastructure of Private Regulation

The most effective EHR regulatory framework will need to respond to changes in technology, encourage innovation by the HIT industry, and stimulate the adoption of EHR systems by health care providers. The HIT industry argues that only self-regulation can satisfy these objectives.[147] Self-regulation, however, does nothing to ensure patient safety. Moreover, a self-

[142] *See* Scott, *supra* note 118 (urging continuous mandatory reporting of HIT concerns so that users may report flaws before harm results).

[143] *Id.*

[144] *See supra* text accompanying notes 113-114.

[145] *See* discussion *supra* Part II.B.2.

[146] *See supra* text accompanying notes 97, 116.

[147] *See supra* text accompanying note 21.

regulatory system is, by definition, purely voluntary.[148] Even if industry-produced standards did ensure patient safety, a self-regulatory system would therefore fail to guarantee compliance with those standards.

Professor Ronen Avraham proposes a unique solution to rectify the inherent deficiencies in self-regulation: private regulation.[149] Within the context of medical malpractice, Professor Avraham suggests a system "where 'private regulators' set the gold standard of patient care by developing [clinical practice] guidelines" to sell to hospitals and doctors.[150] Firms that create the guidelines would absolve medical providers who comply with the standards from medical malpractice liability.[151] Insulating physicians from malpractice liability further requires recognition of the "private regulatory compliance defense."[152] This is similar to the regulatory compliance defense doctrine, in which a manufacturer avoids liability for defective products if it produced those products in accordance with state or federal regulations.[153] Under the private-regulatory compliance defense, doctors that comply with clinical practice guidelines are immunized against medical malpractice lawsuits.[154] Doctors that do not comply with the guidelines are liable under traditional negligence standards.[155]

Under this private regulation regime, the firms that produce the guidelines would only be subject to liability for writing suboptimal guidelines, taking into account both patient safety and efficiency.[156] In other words, firms that produce guidelines would not be liable for writing standards that do not provide the highest standard of care.[157] Additionally, medical providers would be required to disclose information on guideline compliance and effectiveness

[148] Michael J. Lenox, *The Role of Private Decentralized Institutions in Sustaining Industry Self-Regulation*, 17 ORG. SCI. 677, 677 (2006) ("Industry self-regulation is the voluntary association of firms to control their collective behavior." (citation omitted)). While certain prominent industry players may strictly conform to a self-regulatory system, other opportunistic industry members will neglect to follow the industry standards. *Id.* at 687.

[149] Ronen Avraham, *Private Regulation – A New Approach to the US Healthcare Crisis* 7, 48 (Univ. of Tex. Sch. of Law, Pub. Law & Legal Theory Research Paper Series No. 162, 2009), *available at* http://ssrn.com/abstract=1480982.

[150] *Id.* at 7.

[151] *Id.* at 7-8.

[152] *Id.* at 41-42, 46.

[153] *Id.* at 41. *See generally* Carl Tobias, *FDA Regulatory Compliance Reconsidered*, 93 CORNELL L. REV. 1003 (2008) (analyzing the FDA regulatory compliance defense).

[154] Avraham, *supra* note 149, at 41.

[155] *Id.*

[156] *Id.* at 40.

[157] *Id.*

to receive immunity.[158] The only cause of action under such a regime is "negligence regulation," judged from the ex ante perspective.[159]

Professor Avraham argues that granting medical malpractice immunity to providers is justified because "the financial incentives behind the guidelines are perfectly aligned with the social goals of minimizing healthcare costs while maximizing patient safety."[160] The threat of malpractice litigation will also cause firms that produce guidelines to "internalize the costs of their decisions and provide incentives" to create effective and efficient guidelines.[161] Nevertheless, Professor Avraham observes that the overwhelming belief among doctors that medical discretion is central to optimal care prevents the adoption of this private regulation regime.[162] Strictly following a checklist for patient care seems to undermine the complexity of medical practice and could cause physicians to forgo potentially more effective treatments not within the guidelines in order to avoid relinquishing malpractice immunity.

The impediments to a private regulation regime within the context of clinical practice guidelines are not applicable to EHR systems. Indeed, doctors would likely welcome the prospect of immunity from medical malpractice litigation that stems from patient harm caused by EHR system malfunctions.[163] Immunity would also encourage physicians to adopt EHR systems without fear that technological malfunctions beyond their control could lead to liability. This private regulation framework would also encourage HIT manufacturers to design EHR systems with an eye toward patient safety and respond swiftly to reports of glitches and user interface design flaws, rather than dismiss such problems as "user error."[164] Further, a private regulation system acquiesces to the demands of the HIT industry in that the federal government refrains from enacting its own regulations vis-à-vis the FDA.[165]

Currently, to prevail in a medical malpractice claim, a plaintiff must establish the four traditional elements of negligence: (1) a duty of care owed by the defendant to the injured party; (2) a breach of that duty by failing to

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[158] *Id.* at 48.

[159] *Id.* at 40.

[160] *Id.* at 8.

[161] *Id.* at 40.

[162] *Id.* at 55-60.

[163] Immunizing physicians from medical malpractice liability that results from EHR system malfunctions may decrease malpractice premiums. Even if immunity is not granted, however, certain HIT industry leaders argue that insurance companies could reduce malpractice premiums to providers who simply adopt an EHR system or increase premiums for physicians who do not adopt the technology. Elisabeth Belmont & Adele A. Waller, *The Role of Information Technology in Reducing Medical Errors*, 36 J. HEALTH L. 615, 619 (2003). Nevertheless, the notion that insurance companies will pass along savings to physicians as a result of decreased malpractice costs is highly contested. *New Data*, *supra* note 44.

[164] *See supra* text accompanying notes 126-129.

[165] *See supra* text accompanying note 21.

conform to the applicable standard of care; (3) a causal connection between the breach and the resulting injury; and (4) actual damages resulting to the injured party.[166] The standard of care in medical malpractice cases is "the generally recognized and accepted practices" in the medical profession.[167]

Physician negligence surrounding EHR systems could be established on a variety of grounds.[168] For example, a patient may be harmed as a result of erroneous data entries.[169] Physicians may also be liable for failure to heed EHR system alerts and warnings.[170] Courts have already applied this theory of negligence against pharmacies.[171] In *Happel v. Wal-Mart Stores, Inc.*, the court held that a pharmacy with a computerized drug interaction warning system had a duty to notify its customer's physician of contraindicated prescription medications and that failure to do so constituted negligence.[172] Conversely, inappropriate reliance on an EHR system might lead to liability if the system prompted the physician to respond in a fashion that deviated from the standard of care. Finally, system defects, such as those experienced with the VA's EHR system, can lead to significant injury or death and may be attributed to physician negligence.[173]

EHR system manufacturers should be held accountable for system defects that cause harm to patients. Defects in software quality, programming logic, and data storage may be exclusively attributed to the manufacturer. Where manufacturers are or should be aware of dangerous software defects and it is economically reasonable to correct those defects, courts should find negligence. Additionally, once manufacturers are put on notice of user interface design flaws, such manufacturers should also investigate the practicability of remedying those errors.

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[166] W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 30, at 164-65 (5th ed. 1984); Sharona Hoffman & Andy Podgurski, *E-Health Hazards: Provider Liability and Electronic Health Record Systems*, 24 BERKELEY TECH. L.J. 1523, 1533-34 (2009). Plaintiffs may also assert claims against health care organizations, such as hospitals, under the theories of corporate negligence and vicarious liability. Hoffman & Podgurski, *supra* note 166, at 1535. Hospitals have four primary duties: (1) the duty to reasonably maintain safe facilities and equipment; (2) the duty to hire and retain competent medical professionals; (3) the duty to supervise; and (4) the duty to create and enforce reasonable policies designed to ensure effective patient care. *Id.*

[167] Hoffman & Podgurski, *supra* note 166, at 1534 (quoting Doe v. Am. Red Cross Blood Servs., 377 S.E.2d 323, 326 (S.C. 1989)).

[168] *See id.* at 1537.

[169] *Id.*

[170] *Id.*

[171] Happel v. Wal-Mart Stores, Inc., 766 N.E.2d 1118, 1121, 1125 (Ill. 2002); Hoffman & Podgurski, *supra* note 166, at 1548.

[172] *Happel*, 766 N.E.2d at 1121, 1125.

[173] *See supra* note 6 and accompanying text.

Nevertheless, EHR system manufacturers contractually shift liability risks to medical providers.[174] Most manufacturers disclaim express and implied warranties and require purchasers to sign indemnity agreements.[175] Warranty disclaimers are exculpatory provisions inserted into contracts for sales of goods by manufacturers.[176] Indemnity agreements require one party to reimburse a second party for losses incurred by a third party,[177] such as damages stemming from a negligence lawsuit. These liability-shifting agreements thrust full liability upon medical providers even where the manufacturer's negligence caused the adverse event.[178] Courts may invalidate these agreements as violating public policy if the manufacturer has unfair bargaining power or if the agreements would encourage negligent behavior.[179] It seems clear that most manufacturers hold significantly greater bargaining power than the average hospital and certainly possess greater leverage than individual physicians. Further, such agreements undoubtedly encourage EHR system manufacturers to act negligently by removing economic incentives to produce safer systems and investigate system defects.[180]

Even where warranty disclaimer and indemnity agreements are not imposed, manufacturers rely upon the "learned intermediaries" doctrine to avoid liability.[181] According to this doctrine, EHR system manufacturers are not liable for system errors resulting in patient harm because medical professionals are responsible for identifying and correcting errors generated by EHR systems.[182] In light of their medical expertise and special knowledge of the patient's condition, physicians (in theory) intervene between the device manufacturer and the patient, relieving the manufacturer of liability that may result from harm caused by its product.[183]

Warranty disclaimer and indemnity agreements, as well as the learned intermediaries doctrine, encourage manufacturer negligence and endanger

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[174] Belmont & Waller, *supra* note 163, at 620-21; Hoffman & Podgurski, *supra* note 166, at 1554.

[175] Belmont & Waller, *supra* note 163, at 620-21; Hoffman & Podgurski, *supra* note 166, at 1554.

[176] 67A AM. JUR. 2D *Sales* § 843 (2011).

[177] 41 AM. JUR. 2D *Indemnity* § 1 (2011); *see also* BLACK'S LAW DICTIONARY 837-38 (9th ed. 2009).

[178] Belmont & Waller, *supra* note 163, at 621.

[179] Hoffman & Podgurski, *supra* note 166, at 1554. *See generally* AM. JUR. 2D *supra* note 176, at 2 (stating that warranty disclaimers are void if found to be unconscionable).

[180] *See* Belmont & Waller, *supra* note 163, at 621 (reporting that legal experts advocate for accountability among HIT manufacturers and recommend economic incentives to encourage manufacturers to ensure product safety).

[181] Ross Koppel & David Kreda, *Health Care Information Technology Vendors' "Hold Harmless" Clause: Implications for Patients and Clinicians*, 301 J. AM. MED. ASS'N 1276, 1276 (2009).

[182] *Id.*

[183] *See* 63A AM. JUR. 2D *Products Liability* § 1101 (2011).

patient safety. Courts of equity should refuse to enforce these agreements and decline to apply the learned intermediaries doctrine in light of the same safety considerations. Moreover, Congress should statutorily declare such agreements within the HIT industry invalid, much as Congress did with seat belt laws.[184] Congressional action is warranted not only because patient safety is at risk but also because Congress and the Obama Administration have committed significant resources to facilitate the widespread adoption of EHR systems.[185] The government should therefore encourage patient safety along with EHR system adoption and refuse to submit to HIT industry requests to stand down.[186]

By drawing upon the ideas discussed above, it is possible to design an effective private regulatory framework for EHR systems that is contingent on the satisfaction of four conditions. First, the federal and state governments must permit each HIT manufacturer to set its own standards. Eliminating government oversight of EHR system standards will encourage innovation, avoid bureaucratic delays, and accommodate the HIT community's desire to retain control over HIT standards.[187]

Second, courts must refuse to enforce warranty disclaimers and indemnity agreements imposed by EHR system manufacturers upon medical providers. Courts must also abandon the learned intermediaries doctrine with respect to EHR systems. Doctors will undoubtedly increase their reliance upon EHR systems as such systems become commonplace in the medical profession. It is unrealistic to require doctors to continually check input data for faulty information that could occur at any time due to a system malfunction. Indeed, it would be factually impossible for a doctor to conduct such a query without reliance upon paper records that are destroyed for the purpose of adopting a paperless system. Allowing manufacturers to avoid liability resulting from inherent software and storage defects thus significantly undermines the advantages of EHR systems and casts doubt upon federal funding for such technology. Alternatively, and as discussed above, Congress could statutorily prohibit such agreements and the learned intermediaries doctrine between EHR manufacturers and medical providers.

Third, courts must recognize the private regulatory compliance defense as applied to physicians using EHR systems. Because manufacturers are responsible for creating their own standards when developing an EHR system, and because the standards are written into the actual system, a physician will generally be deemed to follow the guidelines simply by using the EHR system as prescribed. In addition to physicians following EHR system guidelines, manufacturers should require that physicians receive sufficient training in the systems, install system updates when required, and report all concerns that the

[184] Koppel & Kreda, s*upra* note 181, at 1277-78.

[185] *See supra* text accompanying notes 3-4.

[186] *See supra* text accompanying notes 21, 131.

[187] *See supra* text accompanying notes 21, 68, 69.

physician may have regarding system safety. The satisfaction of these standards should serve as an affirmative defense to any malpractice claim attributable to an EHR system. A plaintiff's malpractice claim resulting from EHR system malfunctions will therefore only be actionable against the system manufacturer. The availability of this defense will instill confidence in EHR systems and encourage system adoption.

Finally, courts must evaluate the safety standards upon which the EHR system was created from the ex ante perspective in a negligence action against a manufacturer. Manufacturers would only be liable for designing suboptimal EHR systems that do not consider sufficiently patient safety, system efficiency, and generally accepted industry standards. The factfinder will determine whether a manufacturer should have corrected a software defect upon gaining knowledge of the issue and further resolve whether manufacturers or medical providers are liable for harm resulting from user interface design flaws. This condition should enhance the most critical concern underlying any regulatory framework: patient safety. Exposing manufacturers to actions for negligence aligns financial incentives with safety concerns and forces manufacturers to internalize the costs of decisions to sacrifice patient safety.

These four conditions – privately designed EHR system standards, the rejection of warranty disclaimers and the learned intermediaries doctrine, the recognition of the private regulatory compliance defense, and the evaluation of EHR system safety from the ex ante perspective – will help to ensure that every American citizen has an EHR by the year 2014 and will enhance patient safety and decrease health care costs. These conditions, coupled with minimal federal regulations mandating system interoperability and adverse event reporting, will bring the U.S. health care system to the forefront of medical technological innovation.

CONCLUSION

The U.S. health care system stands to reap considerable benefits from EHR systems. The technology can improve patient safety, reduce costs by increasing efficiency, and facilitate communication between patients' health care providers. Significantly, congressional incentive payments will make EHR systems more readily available to both large hospitals and sole practitioners and will help the Obama Administration reach its goal of having an EHR for every American citizen by the year 2014.

Swift adoption coupled with virtually no governmental oversight, however, undermines the stability and efficacy of HIT. Voluntary ONC guidelines are inadequate and are unduly influenced by the HIT industry. Similarly, the FDA's past denial of regulatory authority over EHR systems frustrates current efforts to exert FDA control. The FDA's renewed affirmation of EHR system authority without any concrete regulatory plan is unproductive and confusing for HIT industry members. Moreover, HIT industry resistance to any regulatory authority stymies the adoption of interoperable standards and puts patient safety in jeopardy.

This Note has proposed a private regulation framework that encourages innovation, responds to change, stimulates EHR system adoption, and ensures patient safety. This framework satisfies the demands of the HIT industry regarding minimal government involvement yet aligns the financial incentives of EHR system manufacturers with societal goals of safety and governmental ambitions to achieve comprehensive interoperability.

The private regulation framework is predicated on two sets of minimal government guidelines. First, Congress must empower the ONC to create mandatory interoperability standards for all EHR systems. Second, the FDA must formally recognize EHR systems as Class I devices and enforce adverse event reporting requirements against all HIT manufacturers. These two oversight mechanisms will ensure comprehensive interoperability and apprise the government and the public of potential safety concerns surrounding EHR systems.

Additionally, the private regulation framework relies upon the satisfaction of four conditions. First, the federal and state governments must permit EHR system manufacturers to develop their own standards independently. Second, Congress or the courts must invalidate warranty disclaimers and indemnity agreements imposed by system manufacturers upon medical providers. The government must also abandon the learned intermediaries doctrine. Third, courts must recognize the private regulatory compliance defense with respect to physicians that reasonably rely upon EHR systems. Finally, courts must evaluate the negligence of HIT manufacturers in developing suboptimal EHR systems from the ex ante perspective.

The advancement of medical technology poses unique concerns that necessitate innovative solutions. This Note adds a new regulatory option to this constantly evolving field that warrants careful consideration by government and HIT industry players.

ABBREVIATIONS

CCHIT	Certification Commission for Health Information Technology
EHR	electronic health record
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration
HHS	U.S. Department of Health and Human Services
HIT	health information technology
HITECH	Health Information Technology for Economic and Clinical Health Act
MDDS	medical device data system
MDR	medical device report
ONC	Office of the National Coordinator for Health Information Technology
ONC-ATCB	ONC authorized testing and certification body
VA	U.S. Department of Veterans Affairs