

D.C. IN ACTION: AN EARLY LOOK AT MEANINGFUL USE,
THE GOVERNMENT PRACTICE OF MEDICINE, AND TORT
REFORM

I. INTRODUCTION	208
II. BACKGROUND: THE ROAD TO MEANINGFUL USE	209
<i>A. An Executive Order and the Market-Oriented Approach</i>	209
<i>B. HITECH and the Government-Oriented Approach</i>	211
III. MEANINGFUL USE.....	212
<i>A. The Statute</i>	212
1. <i>Certified EHR Technology</i>	213
2. <i>Meaningful Use</i>	214
3. <i>Exchange of Information</i>	215
4. <i>Reporting of Clinical Quality Measures</i>	215
<i>B. Interpreting the Statute</i>	216
1. <i>The Plain Meaning</i>	217
2. <i>Legislative Intent</i>	217
3. <i>Net Effect: An Enabling Principle</i>	218
<i>C. The Currently Proposed Rule</i>	219
1. <i>Priority One: Increasing Health Care Quality, Safety, and</i> <i>Efficiency</i>	220
2. <i>Priority Two: Provider Engagement with Families</i>	221
3. <i>Priority Three: Care Coordination</i>	221
4. <i>Priority Four: Improve Population Health</i>	221
5. <i>Priority Five: Privacy Assurance</i>	222
<i>D. The Future Direction of Meaningful Use</i>	222
IV. AN EARLY LOOK	224
<i>A. Time and Cost-Based Challenges to Provider HIT Adoption</i>	224
<i>B. The Government Practice of Medicine</i>	227
<i>C. Tort Reform and the Meaningful Defenses?</i>	229
1. <i>Federal Preemption</i>	230
<i>a. Impossibility Doctrine</i>	230
<i>b. Obstacle and Purposes Preemption</i>	231
2. <i>Uniform Standards of Care and Meaningful Use</i> <i>Safe Harbors</i>	232
3. <i>Liability Shifting</i>	234
V. CONCLUSION.....	235

I. INTRODUCTION

Increased use of information technology by health care providers can improve the quality of health care in the United States.¹ It has been used in many other industries, resulting in increased productivity and in overall quality gains.² Moreover, most developed countries already have substantial provider adoption of information technology through widespread use of electronic health records (EHR).³ In the United States, however, most medical records are still stored on paper.⁴ This is despite estimated cost savings from health care provider use of EHR reaching as high as \$513 billion over the next fifteen years, with numbers doubling that figure if the benefits attainable from the technology's chronic disease management and prevention capabilities are also reached.⁵ The leading reasons cited by U.S. providers for their failure to adopt EHR are the actual costs and a perceived lack of return on their investment.⁶

Tucked away in 2009's \$800 billion fiscal stimulus package, the American Recovery and Reinvestment Act (ARRA), is a provision that both attempts to address providers' cost concerns with EHR adoption and, at the same time, possesses the potential to transform the delivery of health care in the United States.⁷ The overarching goals of the ARRA provision, referred to as the Health Information Technology for Economic and Clinical Health Act (HITECH), are to improve health care quality, create a national electronic health record exchange, and establish the infrastructure necessary to measure providers' performance.⁸ The legislation will attempt to meet its goals by providing billions in incentive payments over the next five years to Medicare and Medicaid providers who demonstrate "meaningful use" of an EHR technology certified by the federal

1. See Richard Hillestad et al., *Can Electronic Medical Record Systems Transform Health care? Potential Health Benefits, Savings, and Costs*, 24 HEALTH AFF. 1103, 1103 (2005); see also David Blumenthal, *Launching HITECH*, 362 NEW ENG. J. MED. 382, 385 (2010) ("It is impossible to imagine a high-performing U.S. health system that does not take full advantage of the computing technology that has transformed virtually every other aspect of human endeavor.").

2. See generally KEVIN J. STIROH, FEDERAL RESERVE BANK OF NEW YORK, INFORMATION TECHNOLOGY AND THE U.S. PRODUCTIVITY REVIVAL: WHAT DO THE INDUSTRY DATA SAY? (2001), http://www.newyorkfed.org/research/staff_reports/sr115.pdf.

3. See Denis Protti, *Comparison of Information Technology in General Practice in 10 Countries*, 10 HEALTHCARE Q. 107, 110 (2007).

4. See Catherine M. DesRoches et al., *Electronic Health Records in Ambulatory Care—A National Survey of Physicians*, 359 NEW ENG. J. MED. 50, 51 (2008).

5. See Hillestad, *supra* note 1, at 1114.

6. See DesRoches, *supra* note 4, at 54–56.

7. See Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 467 (2009).

8. See 42 U.S.C.A. § 1395w-4(o)(2) (West Supp. 2010).

government.⁹ HITECH, however, is not just an ordinary Congressional appropriation—providers who fail to satisfactorily demonstrate meaningful use after 2015 will be penalized with a reduction in their total government-based reimbursement.¹⁰

For the legislation to reach its desired potential, meaningful use will have to move beyond its current state, a vague Congressional delegation of authority, and actually operate to increase provider adoption of EHR. To do this, the Administration's implementing regulations will have to carefully balance HITECH's limited timeframe for incentives with the competing desire for the legislation to be more than just a government rebate for a provider's purchase of EHR technology.¹¹ The various interests involved—hospitals, physicians, software vendors, consumer groups, Congress, and a multitude of government agencies—will serve to only compound the difficulties in achieving the benefits of truly meaningful use from an integrated, uniform, and national health information technology (HIT) system.

This Note will first provide a brief background of the circumstances leading to the passage of HITECH, before reviewing the statute and its proposed regulations.¹² It will then consider some of the economic and psychological challenges facing HITECH and will conclude by discussing how potential changes in state tort law from widespread provider adoption of HIT could operate to increase the likelihood that HITECH meets its goal of transforming the delivery of health care in the United States.

II. BACKGROUND: THE ROAD TO MEANINGFUL USE

A. *An Executive Order and the Market-Oriented Approach*

Prior to 2004, the federal government had only minimal involvement in the introduction of information technology to the health care industry.¹³ This changed with the issuance of an executive order in 2004 that estab-

9. See *id.* § 1395w-4(o)(1).

10. See *id.* § 1395w-4(a).

11. Skeptics like former New York Lieutenant Governor Betsy McCaughey feel that this is the way the government will enforce rationing of health care and sterilize physicians. Betsy McCaughey, *Ruin Your Health With the Obama Stimulus Plan*, BLOOMBERG (Feb. 9, 2009), <http://www.bloomberg.com/apps/news?pid=20601039&sid=aLzfDxfbwhzs> (“Senators should read these provisions and vote against them because they are dangerous to your health.”).

12. Due to time constraints, it was not possible to incorporate the final regulations into this Note. For a comprehensive breakdown of the differences in the proposed and final regulations, see Centers for Medicare & Medicaid Services, Comparison of Meaningful Use Objectives Between the Proposed Rule to the Final Rule, (July, 13 2010) https://www.cms.gov/EHRIncentivePrograms/Downloads/NPRM_vs_FR_Table_Comparison_Final.pdf.

13. In 2003, Congress created financial incentives for provider use of electronic prescription technology. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

lished a federal mandate for the creation of a nationwide health information infrastructure that was to contain a portable EHR for every American by 2014.¹⁴ The order sought to reach its mandate through a volunteer, market-oriented approach towards health care provider adoption of HIT.¹⁵

The order created a position, the National Health Information Technology Coordinator (Coordinator), responsible for executing the order's vision.¹⁶ The Coordinator's work consisted of developing and directing the creation of the national health information infrastructure by coordinating the HIT adoptions efforts of the Department of Health and Human Services (HHS) and the private sector.¹⁷ The idea was to establish uniform technical standards for HIT by contracting with two groups: the Health Information Technology Standards Panel (Standards Panel) and the Certification Commission for Health Information Technology (CCHIT).¹⁸ The Standards Panel, a partnership of government and private interests, was responsible for creating the uniform standards necessary for HIT vendors to develop systems capable of communicating with each other, while the CCHIT, a partnership of purely private interests, was responsible for encouraging vendors to develop with uniform standards by certifying that HIT vendors' systems met the Standards Panel's requirements.¹⁹

In addition to the Coordinator's work, the Administration also promulgated regulations that created Stark Law exceptions and Anti-Kickback Statute safe harbors for physician compensation in the form of electronic prescription software and EHR.²⁰ The regulations worked to encourage HIT adoption by allowing providers to avoid harsh civil and criminal penalties when potentially referral-based compensation was in the form of HIT.²¹ Moreover, the exceptions to the physician referral laws worked in concert with the Coordinator's plan, as the HIT system provided to the physician must have been certified by the CCHIT for the exceptions to apply.²²

14. See Exec. Order No. 13,335, 69 Fed. Reg. 24,059 (Apr. 27, 2004).

15. See Press Release, The White House, Office of Communications, Affordable, Accessible, and Flexible Health Coverage (Jan. 25, 2007), available at 2007 WL 185881.

16. See Exec. Order No. 13,335, *supra* note 13.

17. See Press Release, The White House, Office of Communications, *supra* note 14.

18. See ROB CUNNINGHAM, NATIONAL HEALTH POLICY FORUM, STIMULUS BILL IMPLEMENTATION: EXPANDING MEANINGFUL USE OF HEALTH IT 9-10 (2009), http://www.nhpf.org/library/issue-briefs/IB834_StimulusIT_08-25-09.pdf.

19. See *id.*

20. See 42 C.F.R. § 411.357 (2009) (the Stark exception) and 42 C.F.R. § 1001.952 (2009) (the Anti-Kickback Statute safe harbor); see also Daphne Lawrence, *Has HITECH Hijacked Stark?*, HEALTHCARE INFORMATICS, Sept. 2009, at 19, available at <http://www.healthcare-informatics.com/ME2/dirmod.asp?sid=&nm=&type=Publishing&mod=Publications%3A%3A Article&mid=8F3A7027421841978F18BE895F87F791&tier=4&id=5DDDF35F31B0E44A38FE2BB6FD AFCE1E5>.

21. See 42 C.F.R. § 411.357 (2009) (the Stark exception); 42 C.F.R. § 1001.952 (2009) (the Anti-Kickback Statute safe harbor).

22. See 42 C.F.R. § 411.357 (2009) (the Stark exception); 42 C.F.R. § 1001.952 (2009) (the Anti-

Despite those efforts, a 2008 New England Journal of Medicine study showed that only 4% of U.S. physicians had adopted an EHR, while a 2009 study by the Journal indicated that only 7.6% of U.S. hospitals had a basic system with only 1.5% possessing a “comprehensive electronic-records system.”²³ At the same point in time, another study showed that over 90% of health care practitioners in ten developed countries utilized EHR in their daily practices.²⁴

After issuing the executive order commanding a market-oriented approach, President Bush clairvoyantly warned that “[t]here’s always a bill out there in case the volunteerism is not quite as strong as it should be.”²⁵ And indeed, in 2008 Congress found the level of “volunteerism” for HIT adoption lacking; seven bills were introduced that year with the purpose of increasing the government’s role in provider adoption of HIT.²⁶

B. HITECH and the Government-Oriented Approach

The actual opportunity for Congress to accelerate adoption of HIT through a more government-oriented approach came in October 2008 when a severe recession created the political will necessary to place one of those seven bills into the ARRA, an enormous fiscal spending bill commonly referred to as the “Stimulus.”²⁷ The ARRA established financial incentives designed specifically to facilitate health care provider adoption

Kickback Statute safe harbor).

23. Ashish K. Jha et al., *Use of Electronic Health Records in U.S. Hospitals*, 360 NEW ENG. J. MED. 1628, 1628 (2009); see also DesRoches, *supra* note 4, at 54.

24. See Protti, *supra* note 3, at 110. The ten countries in the study were Australia, Austria, Denmark, England, Germany, the Netherlands, New Zealand, Norway, Scotland, and Sweden. *Id.* at 107.

25. See Press Release, The White House, Office of Communications, President Discusses Health care (Feb. 15 2006), available at 2006 WL 338662.

26. See, e.g., Wired for Health care Quality Act, S. 1693, 110th Cong. (2008); Ensuring the Future Physician Workforce Act of 2008, S. 2729, 110th Cong. (2008); PRO(TECH)T Act, H.R. 6357, 110th Cong. (2008); Patient-Controlled Health IT Act, H.R. 6345, 110th Cong. (2008); Health Information Technology Act, H.R. 6898, 110th Cong. (2008); Promoting Health Information Technology Act, H.R. 6179, 110th Cong. (2008); Health Information Technology Promotion Act, H.R. 5885, 110th Cong. (2008).

27. As Rahm Emanuel said, “Never allow a crisis to go to waste . . . They [sic] are opportunities to do big things.” Jeff Zeleny, *Obama Weighs Quick Undoing of Bush Policy*, N.Y. TIMES, Nov. 10, 2008, at A19. In fairness, investing fifty million dollars into the adoption of health information technology was part of President Obama’s health care plan’s campaign platform. KAISER FAMILY FOUNDATION, 2008 PRESIDENTIAL HEALTH CARE PROPOSALS: SIDE-BY-SIDE SUMMARY (2008), http://www.health08.org/sidebyside_results.cfm?c=5&c=16.

of HIT.²⁸ That specific portion of the ARRA is called HITECH and forms the subject of this Note.²⁹

Initially, HITECH provides financial incentives in the form of cash payments to eligible providers of Medicare and Medicaid services who satisfactorily demonstrate meaningful use of government-certified EHR technology.³⁰ The incentive period begins in 2011 when a Medicare physician can begin receiving \$44,000, a Medicaid physician can begin receiving \$63,750, and eligible hospitals can begin receiving millions.³¹ After 2015, however, HITECH's incentives turn into penalties, as providers who fail to meet its meaningful use requirements will no longer receive full reimbursement from Medicare or Medicaid for their services.³² The reduction may be anywhere from 3% to 5% of the provider's total government-based compensation.³³

III. MEANINGFUL USE

A. The Statute

To qualify as a "meaningful user" under the statute, Congress requires health care providers to meet the following three requirements: (1) make meaningful use of certified EHR technology, (2) exchange information using certified EHR technology, and (3) report clinical quality measures using certified EHR technology.³⁴ The statute's stated purpose is to "improve the use of electronic health records and health care quality."³⁵ This

28. Press Release, President Barack Obama, Remarks by the President on the Economy (April 14, 2009), available at 2009 WL 993055. The American Recovery and Reinvestment Act was not the product of a bipartisan vote. See GovTrack, H.R. 1: American Recovery and Reinvestment Act of 2009, <http://www.govtrack.us/congress/bill.xpd?bill=h111-1> (last visited Oct. 11, 2010) (providing "Vote Details" showing that zero Republicans in the House of Representatives and two Republicans in the Senate supported the legislation).

29. See Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 115 (2009).

30. This is not a small number of providers: CMS estimates there will be approximately 404,400 individual providers, 10,000 hospitals, and 12 Medicare Advantage organizations, which add an additional 28,000 physicians, and 29 more hospitals to the total eligible to receive the incentive payments. See Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844, 1,976 (Jan. 13, 2010) (to be codified at 42 C.F.R. pt. 412, 413, 422, & 495).

31. See 42 U.S.C.A. § 1395w-4 (West Supp. 2009).

32. See *id.* § 1395w-4(a)(7). The physicians' fee schedule will receive a downward adjustment of 1% in 2015, 2% in 2016, and cap at 97% percent in 2017 and beyond. *Id.* If the number of eligible physicians who are meaningful users of EHR in 2017 is less than 75%, Congress has allowed the Secretary to use his discretion and adjust payments downward to 95%. *Id.* Physicians may also qualify for a "hardship exemption" if they can adequately demonstrate their complete inability to meet the requirements. *Id.* § 1395w-4(a)(7)(B).

33. See 42 U.S.C. § 1395w-4(a)(7)(B).

34. See *id.* § 1395w-4(o)(2). The requirements constitute the elements of a meaningful EHR user. Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,870 ("[T]here are three elements of meaningful use.").

35. 42 U.S.C.A. § 1395w-4.

improvement is envisioned as a continuous process, with its requirements becoming more stringent over time.³⁶ Despite the statutory provision of only three requirements, this Note will construe the statute as containing four, as the use of certified technology is a separate component that is necessary to meet each of the statute's three requirements.

1. Certified EHR Technology

HITECH defines "EHR technology" as an electronic record of an individual's health information.³⁷ The statute also adds that the technology must include the capacity to capture patient demographics and clinical health information, provide clinical decision support, support physician order entry, capture health care quality information, and exchange and integrate the information with other sources.³⁸

HITECH's "Certified EHR Technology" requirement serves to provide a uniform blueprint that HIT vendors must follow to achieve certification from the federal government for their EHR products.³⁹ Its implementing rule requires that any application on a health information network be able to communicate with any other application; this changes the prior CCHIT approach by allowing a modular, or component, approach that aims to give providers the ability to mix and match products from various vendors when creating and designing their network.⁴⁰ Therefore, a provider may use a combination of different EHR modules from different HIT vendors as long as the modules together meet the definition of a qualified EHR that has been tested and certified by the government.⁴¹

The necessity of establishing a government certification program was intentional and due to the deemed failure of the prior market-based, CCHIT certification program.⁴² An HIT vendor's prior CCHIT certification for its HIT system is, therefore, irrelevant for purposes of HITECH.⁴³ In addition, the Office of the National Coordinator (ONC) was given the authority to promulgate the regulations that define what constitutes a "certified EHR" on an interim final basis.⁴⁴ This was deemed necessary be-

36. *See id.*

37. *See id.* §§ 300jj(13), 3004(b)(1).

38. *See id.*

39. *See* Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 2,014, 2,022 (Jan. 13, 2010) (to be codified at 45 C.F.R. pt. 170).

40. *See id.* at 2,022–23.

41. *See id.* at 2,015.

42. *See* David Kibbe, EHR Redux, http://www.thehealthcareblog.com/the_health_care_blog/2010/02/ehr-redux.html (last visited Oct. 12, 2010).

43. *See id.*

44. *See* Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. at 2,022–23. Generally, the Administrative Procedures Act requires public notice prior to promulgation of regulations;

cause of the short period of time between the enactment of HITECH and the start of the limited time period where providers are eligible to receive cash payments.⁴⁵ Government-certified EHR technology did not exist prior to the ONC's interim final rule, and HIT vendors will need the time provided by the rule's quick implementation to meet the new certification program's requirements.

The requirements for certified EHR technology were written so they would enable provider purchasers of the technology to meet each of the statute's requirements.⁴⁶ The certification requirements, like the meaningful use regulations discussed in more detail below, also take an incremental, or stage-based, approach.⁴⁷ Certification requires no act by providers—"[b]y being tested and certified, a Complete EHR or EHR Module will have demonstrated that this capability is available for an eligible professional or eligible hospital to use."⁴⁸ Therefore, to meet this requirement, and any of the other three requirements necessary to qualify as a meaningful user, providers must possess certified EHR technology.

2. *Meaningful Use*

Once the provider has a certified EHR, the first requirement the provider must meet to qualify as a "meaningful user" is to demonstrate to the satisfaction of the Secretary of the Department of Health and Human Services (Secretary) that they are using the certified technology in a "meaningful manner."⁴⁹ As to what constitutes meaningful, the only explicit guidance provided by the statute is that the requirements for meeting this element must at least include the use of electronic prescription technology.⁵⁰ The Secretary's interpretation of what else meaningful use should entail is discussed in more detail below.⁵¹

HITECH allows demonstration of the meaningful use requirement by any means the Secretary decides. In 2011, proof of meeting the requirement will be made by attestation.⁵² The implementing regulations indicate that the Centers for Medicare and Medicaid Services (CMS) do not "believe that HIT will advance enough from its current state to allow for more

however, when good cause is shown, an agency may promulgate regulations without meeting the public notice requirement. 5 U.S.C. § 553(b) (West Supp. 2010).

45. See Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. at 2,016.

46. See *id.*

47. See *id.* at 2,014.

48. *Id.* at 2,028–29.

49. 42 U.S.C.A. § 1395w-4(o)(2)(A)(i) (West Supp. 2010).

50. See *id.*

51. See *infra* Part III.C.

52. See § 1395w-4(o)(2)(C).

automated and/or documented options of demonstrating meaningful use.”⁵³ The current plan is for mandatory electronic submission to begin in 2012.⁵⁴ At that point, the electronic submission will contain the “health IT functionality” measures necessary for the Secretary to qualify the submitting health care provider as a meaningful user of certified EHR.⁵⁵

3. *Exchange of Information*

Meaningful use also requires health care providers’ EHR to have the capability to electronically exchange information.⁵⁶ The statute requires that “such certified EHR technology is connected in a manner that provides . . . for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.”⁵⁷ The actual exchange of information is planned to take place on a national health information network, with the ultimate goal of creating a national network that allows providers to exchange patients’ personal health records among themselves and with the government both to increase care coordination and to improve population health.⁵⁸ At this point, because the necessary infrastructure is still lacking to exchange the records, providers must only demonstrate by a one-time test that they possess the capability to transmit clinical information.⁵⁹

4. *Reporting of Clinical Quality Measures*

The statute’s final requirement demands that providers report clinical quality measures using their certified EHR technology.⁶⁰ These measures are different than the “health IT functionality” measures required to meet HITECH’s meaningful use requirement.⁶¹ Clinical quality measures are defined “to consist of measures of processes, experience and/or outcomes of patient care, observations or treatment that relate to one or more quality aims for health care.”⁶² It was deemed unnecessary to subject these measures to public notice and comment rulemaking due to the consensus process used by the National Quality Forum (NQF).⁶³

53. Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844, 1,903 (Jan. 13, 2010) (to be codified at 42 C.F.R. pt. 412, 413, 422 & 495).

54. *See id.*

55. *Id.* at 1,858.

56. *See* § 1395w-4(o)(2)(A)(ii).

57. *Id.*

58. Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,864–65.

59. *Id.* at 1,865.

60. *See* § 1395w-4(o)(2).

61. Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,858.

62. *Id.* at 1,871.

63. *See id.* at 1,873.

In selecting clinical quality measures, HITECH requires the Secretary to give preference to measures that have been approved by an entity with a contract with HHS.⁶⁴ That entity is the NQF.⁶⁵ The NQF is a nonprofit organization controlled by industry stakeholders formed with the stated goal of improving the U.S. health care system by “[s]etting national priorities and goals for performance improvement; [e]ndorsing national consensus standards for measuring and publicly reporting on performance; and [p]romoting the attainment of national goals through education and outreach programs.”⁶⁶ The reporting of the clinical quality measures will both allow CMS to meet its goal of tracking improvements in patient care over time and aid its use of quality benchmarking to compare health care providers against their peers.⁶⁷ The ultimate goal of the requirement for tracking the measures is to transform the current physician payment system from one based on a fee-for-services model to one based on paying physicians for performance.⁶⁸

HITECH says electronic reporting of the clinical quality measures cannot be required until HHS has the capability to receive them electronically.⁶⁹ CMS does not think that HHS will have the capability to accept the measures electronically in 2011, but expects HHS to possess the ability to electronically accept the measures in 2012.⁷⁰ Therefore, in 2011 a provider must only attest to its capability to electronically submit the required clinical quality measures.⁷¹

B. Interpreting the Statute

The statutory requirements discussed above provide little detailed guidance on the intended operation of HITECH’s meaningful use requirement.⁷² The text of the statute only clearly provides that Congress envisions health care providers using government-certified EHR technology to report clinical quality measures endorsed by the NQF and to exchange patient health information. This would be sufficient, but HITECH also

64. See § 1395w-4; see also Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), 122 Stat. 2494 (2008); The National Quality Forum, *HHS Performance Measurement*, http://www.qualityforum.org/About_NQF/HHS_Performance_Measurement.aspx.

65. See Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,872.

66. The National Quality Forum, *About NQF*, http://www.qualityforum.org/About_NQF/About_NQF.aspx.

67. See Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,872.

68. See DEPARTMENT OF HEALTH & HUMAN SERVICES, OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, MEANINGFUL USE WORKGROUP PRESENTATION, at 5 (July 16, 2009), http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10741_876941_0_0_18/Meaningful%20Use_7.16.09.ppt.

69. See 42 U.S.C.A. § 1395w-4(o)(2) (West Supp. 2010).

70. See Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,871.

71. See *id.*

72. See *supra* Part III.A.2.

requires the EHR to be used in a “meaningful manner.” The lack of explicit guidance provided by the statute effectively leaves interpretation of what qualifies as “meaningful” up to the Secretary’s discretion.

1. *The Plain Meaning*

Oftentimes, courts can look for the “plain meaning” of a statute’s words to provide assistance with interpretation.⁷³ In the case of HITECH, however, looking only at the words provides little helpful insight to what Congress intended “meaningful use” to require. Turning to the dictionary, “use” is defined as “[t]he act of employing a thing for any . . . purpose.”⁷⁴ This indicates Congress intended providers to, at a minimum, actually use the certified technology; but the statute requires more than simply use—its requirement is “*meaningful* use.”⁷⁵ “Meaningful” is defined as that which is “[f]ull of meaning or expression.”⁷⁶ Given that it has traditionally been the legislature’s responsibility to make the laws, one would presume that the meaning or purpose would be Congress’s purpose. Thus, a review of the legislative history should provide additional guidance.

2. *Legislative Intent*

Congress has big plans for HITECH.⁷⁷ The goal is not just to provide financial incentives for physicians to purchase technology; the goal is to have doctors use better practice protocols to lower costs and provide better patient outcomes.⁷⁸ Congress also expects the legislation’s improvements to include correcting errors caused by poor physician handwriting, increasing the use of generic drugs, decreasing duplicative orders, reminding physicians to use preventive care, providing clinical decision support with evidence-based order sets, identifying drug interactions, and helping physicians handle chronically ill patients.⁷⁹

One member of Congress described the legislation as an attempt to address three of the principal issues with HIT adoption—the cost of the technology, the complexity of the technology, and the lack of uniform standards for the technology—so that the physicians can be confident that the technology they invest in will be useful in their practice of medicine;

73. *Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 508 (1981).

74. OXFORD ENGLISH DICTIONARY 3573 (1971).

75. 42 U.S.C.A. 1395w-4(o) (West Supp. 2010) (emphasis added).

76. OXFORD ENGLISH DICTIONARY 275 (1971).

77. Here is one Senator’s description of the task: “The Romans could not build an electronic health information infrastructure, but we can and we must, and this legislation will.” 155 CONG. REC. S1,511 (daily ed. Feb. 4, 2009) (statement of Sen. Whitehouse).

78. See 155 CONG. REC. S1,511 (daily ed. Feb. 4, 2009) (statement of Sen. Whitehouse).

79. See 155 CONG. REC. S264 (daily ed. Jan. 11, 2009) (statement of Sen. Stabenow).

“[h]ealth information technology is about much more than digitizing data, more than going from illegible handwriting to clear electronic type.”⁸⁰ The Congressman also made clear that HITECH “does not just hand out grants to buy big fancy new boxes of equipment to sit in office closets.”⁸¹ Another member of Congress imagined HITECH “affect[ing] every part of health care, from medical and nursing education, to how patients are treated and how much hospitals get paid.”⁸² HITECH’s legislative history, therefore, indicates that Congress intended “meaningful use” to have an immense scope.

3. *Net Effect: An Enabling Principle*

The broad purpose envisioned by Congress, coupled with the loose language provided by Congress, effectively functions to enable the Executive Branch to require health care providers to do whatever it deems necessary in order to qualify as a meaningful user. The reality that HITECH and the financial effects of the Secretary’s meaningful use definition do not simply end after the initial incentives period demonstrates the immense scope of the freedom Congress has delegated to the Executive in this context.

Traditionally, the power to make the laws has been the exclusive power of Congress, just as it has always been the exclusive power of the Executive Branch to carry out those laws.⁸³ To avoid an improper delegation of its lawmaking authority, Congress must provide the Executive Branch with an “intelligible principle” to guide its rulemaking.⁸⁴ The purpose behind this doctrine is to ensure that the branch of government making the laws is the branch that is subject to a popular vote.⁸⁵ Nevertheless, Congress does not violate the doctrine by using broad or open-ended language; the Court has “‘almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law.’”⁸⁶

Here, the plain words and legislative history of HITECH demonstrate the broad scope of authority that the term “meaningful use” is meant to convey to implementing agencies. David Blumenthal, the current Coordinator, stated that the structure of the legislation was “an innovative and powerful concept” intended to have sweeping affects.⁸⁷ In addition, it will

80. 155 CONG. REC. S1,511 (daily ed. Feb. 4, 2009) (statement of Sen. Whitehouse).

81. *Id.*

82. 155 CONG. REC. H1136–03 (daily ed. Feb. 10, 2009) (statement of Rep. Burton).

83. *See* U.S. CONST. art. I, § 1, cl. 1; U.S. CONST. art. II, § 2, cl. 1.

84. *See* *Whitman v. Am. Trucking Ass’ns, Inc.*, 531 U.S. 457, 472 (2001).

85. *See* *Touby v. United States*, 500 U.S. 160, 165 (1991).

86. *Whitman*, 531 U.S. at 474–75 (quoting *Mistretta v. United States*, 488 U.S. 361, 416 (1989) (Scalia, J., dissenting)).

87. Blumenthal, *supra* note 1, at 382.

be extremely important to health care providers for the Secretary to get the rule right, as HITECH provides that “[t]here shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, *or otherwise*” of the methodology and standards for determining what constitutes meaningful use of EHR.⁸⁸

C. The Currently Proposed Rule

As previously indicated, HITECH gave the Secretary the responsibility of defining “meaningful use.”⁸⁹ The Secretary placed the responsibility of defining meaningful use with CMS.⁹⁰ In its proposed rule, CMS said that it “adopted a structure derived from recommendations of the HIT Policy Committee of grouping the objectives under care goals, which are in turn grouped under health outcomes policy priorities.”⁹¹ The HIT Policy Committee (Committee) is a federal advisory activity established by the ARRA.⁹² The Committee is divided into subcommittees with its Meaningful Use Workgroup (Workgroup) responsible for making recommendations to CMS on what should constitute “meaningful use.”⁹³ CMS also worked closely with the ONC to ensure that any EHR certification standards and implementation specifications approved would complement its meaningful use definition.⁹⁴

88. 42 U.S.C.A. § 1395w-4(k)(7) (West Supp. 2010) (emphasis added). *But see* McNary v. Haitian Refugee Ctr., Inc., 498 U.S. 479 (1991) (finding judicial review preclusion was limited to issues the statute was intended to preclude).

89. *See* 42 U.S.C.A. § 1395w-4 (West Supp. 2010).

90. *See* Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844, 1,846 (Jan. 13, 2010) (to be codified at 42 C.F.R. pt. 412, 413, 422, & 495).

91. *Id.* at 1,854.

92. *See id.* at 1,850; *compare id.* at 1,854–70, with HEALTH IT POLICY COUNCIL, RECOMMENDATIONS TO NATIONAL COORDINATOR FOR DEFINING MEANINGFUL USE FINAL (Aug. 2009), http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10741_888532_0_0_18/FINAL%20MU%20RECOMMENDATIONS%20TABLE.pdf.

93. The Workgroup is comprised of representatives from a number of organizations, including the following: the Palo Alto Medical Center; Columbia University; Brigham & Women’s Hospital; National Partnership for Women & Families; The Institute for Family Health; Denver Public Health Department; Pacific Business Group on Health; Center for Democracy & Technology; Carnegie Mellon University; and the Department of Veterans Affairs. *See* The Office of the National Coordinator for Health Information Technology, *Meaningful Use Workgroup*, <http://healthit.hhs.gov/portal/server.pt?open=512&objID=1472&mode=2> (last visited Oct. 12, 2010).

94. *See* Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,850. The ONC has released an interim final rule on what the criteria of the certification are. *See* Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 2,014, 2,014 (Jan. 13, 2010) (to be codified at 45 C.F.R. pt. 170). CMS proposes to use the ONC’s interim final rule. *See* Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844, 1,848. In addition, input on the rule was sought from the public and other governmental agencies, such as the National Committee on Vital and Health Statistics, the HIT Policy Committee, and the HIT Standards Committee. *See* Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,850.

The Workgroup chose its priorities for meaningful use from a report developed by the NQF.⁹⁵ Each of the chosen priorities was then broken down into objectives and care goals with each containing measures that health care providers must report to qualify as a meaningful user.⁹⁶ These measures are not the clinical quality measures discussed above; they are “health IT functionality” measures.⁹⁷ The policy priorities from the NQF report, and those ultimately used by the Secretary to define meaningful use, are: (1) to increase health care quality, safety, and efficiency, (2) to increase provider engagement with patients and their families, (3) to improve care coordination, (4) to improve the health of the general public, and (5) to meet each of those priorities while still ensuring the adequate security and privacy of patients’ health information.⁹⁸

1. Priority One: Increasing Health Care Quality, Safety, and Efficiency

To meet the first priority of improving the quality and efficiency of the U.S. health care system, CMS established goals designed to provide the patient’s health care team access to comprehensive patient information and to increase provider use of evidence-based order sets, computerized physician order entry (CPOE), and clinical decision support at the point of care. CMS’s goals for this first priority also include reaching out to patients and reporting information to public entities for quality improvement and public reporting.⁹⁹ The overarching objective of the goals is to ensure that physicians not only possess certified EHR technology but also are using it in an effective manner.¹⁰⁰

The reportable health IT functionality measures for the first priority that are required to demonstrate meaningful use include physician use of CPOE on 80% of all orders; use of drug–drug, drug–allergy, and drug–formulary checks; transmission of prescriptions electronically; maintenance of active medication lists; the electronic charting of vital signs; and

95. See Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,851. The National Quality Forum is a non-profit organization that CMS contracted with, pursuant to the Medicare Improvements for Patients and Providers Act, to provide quality measures for health care quality reporting. See National Quality Forum, *HHS Performance Measurement*, http://www.qualityforum.org/About_NQF/HHS_Performance_Measurement.aspx (last visited Oct. 12, 2010). The actual priorities were developed in a group convened by the National Quality Forum called the National Priorities Partnership. See The National Priorities Partnership, *Priorities*, <http://www.nationalprioritiespartnership.org/Priorities.aspx>.

96. See Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,854.

97. See *infra* Part III.C; see also Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,858.

98. See *infra* Part III.C.

99. See Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,854.

100. See *id.* at 1,860.

provider implementation of at least five clinical decision support rules.¹⁰¹ Physician offices must also record patient demographics, generate and report information, incorporate lab results into their EHR as structured data, check insurance eligibility, and bill electronically.¹⁰²

2. Priority Two: Provider Engagement with Families

The second policy priority is to involve patients and families more extensively in their own health care decision making.¹⁰³ The goal is to increase involvement by providing “families with timely access to data, knowledge, and tools to make informed decisions and to manage their health.”¹⁰⁴ Providers will also need to furnish patients and their families with electronic records of their health information, both at their request and as required by state disclosure laws.¹⁰⁵ An example of one of the required measures is for 80% of patients to be provided with a copy of their health information within 48 hours.¹⁰⁶

3. Priority Three: Care Coordination

The third policy priority is to improve care coordination.¹⁰⁷ For purposes of this priority, care coordination will include the exchange of clinical information between health care providers, medical reconciliation, and provision of a summary-of-care record for both transitions of care and referrals.¹⁰⁸ An example of a required measure for care coordination is that medication reconciliation must take place for 80% of relevant patient encounters and transitions of care.¹⁰⁹

4. Priority Four: Improve Population Health

The fourth policy priority is to improve the health of the general population.¹¹⁰ The objective is to use the information collected on patients to

101. See *id.* at 1,855.

102. See *id.* at 1,855–56.

103. See *id.* at 1,856–57.

104. *Id.* at 1857.

105. See *id.*

106. See *id.* at 1,864.

107. See Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,857.

108. See *id.* at 1,857–58. Because of the confusion that sometimes exists as to what “medication reconciliation” really is, CMS proposes the definition to mean “the process of identifying the most accurate list of all medications that the patient is taking, including name, dosage, frequency and route, by comparing the medical record to an external list of medications obtained from a patient, hospital or other provider.” *Id.* This can be crucial when there are long gaps between patient visits or the administration of new medication. See *id.* “Transition[s] of care” refers to changes in the patient’s clinical setting; for example, if an emergency room patient is admitted to the hospital. *Id.* at 1858.

109. See Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,865.

110. See *id.* at 1,858.

communicate with public health agencies.¹¹¹ The provider's system will need to possess the capability to submit electronic syndromic surveillance data and provide electronic immunization data to the agencies.¹¹² This requirement also calls for the electronic exchange of information, which is not currently possible; therefore, at this point, the provider will only have to demonstrate the capability to do so.¹¹³

5. *Priority Five: Privacy Assurance*

The fifth policy priority is to ensure adequate privacy for patients' personal health information.¹¹⁴ Here, the goal is to "[e]nsure privacy and security protections for confidential information through operating policies, procedures, and technologies and compliance with applicable law."¹¹⁵ To meet this goal, CMS will not create additional guidelines.¹¹⁶ The guidelines are already established via HIPAA's privacy and security rules.¹¹⁷ The Secretary believes the meaningful use regulations are not the appropriate means to enforce HIPAA compliance.¹¹⁸

D. *The Future Direction of Meaningful Use*

To balance the costs and benefits within the short time frame for the incentives, it is proposed that the objectives and measures grow more stringent over time, with the process being divided into three stages: 2011, 2013, and 2015.¹¹⁹ However, due to the limited information provided in the current regulations and the potentially broad application of the statute, it is still not clear what the future holds for meaningful use.

To illustrate this lack of clarity: when asked what type of information will be included in a patient's electronic record, Representative Patrick Kennedy said that individuals will be able to "opt out" if they do not want their records to include information about sexually transmitted diseases or abortions in their medical history.¹²⁰ But Representative Michael Burgess, a physician, suggested that completeness might be required for clinical and medical liability purposes: "If I refer a patient to a specialist, yeah, that information needs to go along. It is not only unfair, it is probably a liabili-

111. *See id.*

112. *See id.*

113. *See id.* at 1,866.

114. *See id.* at 1,858.

115. Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,858.

116. *See id.*

117. *See id.*

118. *See id.*

119. *See id.* at 1,852.

120. *See* Nicholas Ballasy, *People Can Opt Out of Listing STDs, Abortions in Gov't-Mandated Electronic Health Records*, Patrick Kennedy Says, CNSNEWS.COM (Sept. 28, 2009), <http://www.cnsnews.com/news/article/54608>.

ty on my part if I did not disclose that information to the physician to whom I am referring a patient.”¹²¹

Of course, both Congressmen’s thoughts on the proper amount of control that patients should have over the information in their EHR were made known to the press after HITECH’s enactment and are not embodied in HITECH’s statutory provisions; therefore, at the time of the statements to the press, Congress had already delegated the decision to the Secretary and the decision was no longer in their control.¹²² HIPAA currently allows doctors to share information for any reason that falls under treatment, payment, and health care operations despite a patient’s request to “opt out.”¹²³ The ONC initially intended to modify HIPAA’s requirements;¹²⁴ in the end, however, the rule followed the current HIPAA requirement, so it appears Representative Burgess’s approach currently has the Secretary’s favor.¹²⁵

The currently proposed rule adds to the uncertainty by devoting only half a page to the requirements of meaningful use beyond Stage 1.¹²⁶ The Workgroup took issue with this lack of clarity in a letter it sent to the Secretary.¹²⁷ The Workgroup itself has already proposed what the next stages of “meaningful use” should entail, and envisions the “meaningful use” requirements increasing in scope from data capture, in 2011, to advanced clinical process, in 2013, to improved patient outcomes, by 2015.¹²⁸

Lofty goals exist for meaningful use in 2015, such as reducing the number of heart attacks and strokes by a million, cutting medication errors in half, cutting the racial gap for diabetes in half, cutting readmissions in half, and providing patients with electronic access to all of their health information.¹²⁹ The Workgroup is also aiming to meet the CMS EHR Demonstration’s goal to transition from “pay for reporting” under the Physician Quality Reporting Initiative to paying physicians based on patient outcomes.¹³⁰ The Coordinator shares the Workgroup’s view, and also

121. *Id.*

122. *See* 42 U.S.C.A. § 1395w-4 (West Supp. 2010).

123. *See* Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

124. *See* Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,858.

125. *See* Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 2,014, 2,017 (Jan. 13, 2010) (to be codified at 45 C.F.R. pt. 170).

126. *See* Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,870.

127. *See id.*

128. *See* DEPARTMENT OF HEALTH & HUMAN SERVICES, OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY, MEANINGFUL USE WORKGROUP PRESENTATION, at 5 (July 16, 2009), http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10741_876941_0_0_18/Meaningful%20Use_7.16.09.ppt.

129. *See id.* at 15.

130. *See generally id.*

believes that Stages 2 and 3 will include the increased use of incentives that reward providers for improved processes of care and outcomes.¹³¹

IV. AN EARLY LOOK

A. Time and Cost-Based Challenges to Provider HIT Adoption

HITECH's short, inflexible time frame for its cash payments, coupled with several cost-based challenges, will make it difficult for the legislation to transform the U.S. health care system by the end of 2014. Transforming the U.S. health care system as envisioned by HITECH requires, at the very least, substantial provider adoption of HIT. The Secretary recognizes the provider adoption rate of EHR technology will be a function of both industry costs and the limited time period of the incentives.¹³² The Secretary, however, cannot change the time frame or raise the amount of the incentives to meet a provider's actual costs.¹³³ The earliest providers can receive any reimbursement is 2011.¹³⁴ For a provider to receive full reimbursement, the provider must demonstrate meaningful use by 2012.¹³⁵

The first challenge HITECH must surpass for the legislation to increase provider EHR adoption is for HIT vendors to have certified EHR products. Without the existence of certified EHR technology, none of the meaningful use requirements can be met.¹³⁶ As mentioned earlier, government-certified EHR technology has only recently come into existence; prior CCHIT certification will not prevent a vendor from having to make changes to their current EHR technology.¹³⁷ Moreover, the rule defining EHR for purposes of HITECH was published January 13, 2010; the rule that guides the government's certification program was published March 10, 2010.¹³⁸ The financial incentive payments begin in 2011.¹³⁹ This means for a timely start to HITECH's incentive program, HIT vendors must have their EHR technology programmed, tested, and certified by 2011. At this point, it is not clear how many, if any, HIT vendors can have a product that meets the rule's specifications ready by the beginning of the payment period. It is also unclear whether the government's certification program

131. See David Blumenthal, *Launching HITECH*, 362 NEW ENG. J. MED. 382, 384 (2010).

132. See Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,976.

133. See 42 U.S.C.A. § 1395w-4(o)(1)(B)(i) (West Supp. 2010).

134. See *id.* § 1395w-4(o)(1)(E)(i).

135. See *id.* § 1395w-4(o)(1)(B)(ii).

136. See *supra* Part III.A.

137. See *supra* Part III.A.1

138. Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 2,014, 2,016 (Jan. 13, 2010); Proposed Establishment of Certification Programs for Health Information Technology, 75 Fed. Reg. 11,328 (Mar. 10, 2010).

139. See 42 U.S.C.A. § 1395w-4(o)(1)(E)(i) (West Supp. 2010).

will develop to the point that it can certify a vendor's EHR product in a timely manner.

Once certified EHR technology exists, health care providers will still have to purchase or upgrade to a HIT vendor's system that is certified to meet the requirements of "meaningful use." Many providers will have to bear the costs up front, as physicians will not be eligible to receive payments until they have actually purchased and implemented the technology, although Medicaid providers will be able to receive some incentive payments before demonstrating "meaningful use."¹⁴⁰ Moreover, the financial incentive payments for physicians who adopt EHR technology are not even a sure bet to offset the cost to obtain the EHR technology. The Secretary estimates the average cost to adopt an EHR is \$54,000 per physician FTE, with annual maintenance costs of \$10,000.¹⁴¹ With total reimbursement for Medicare physicians capped at \$44,000, those figures do not indicate that obtaining an EHR will lead to a positive return on investment; the annual maintenance costs alone will eat up HITECH's incentive payments.

Health care providers will also face time constraints from EHR adoption. Training, workflow redesign, and implementation all have to take place before a provider can qualify as a "meaningful user." In addition, Congress said HITECH is not just a government credit for the purchase of EHR technology.¹⁴² Therefore, once the EHR is implemented, providers must still make "meaningful use" of the technology.

Adoption of EHR could also be a bad financial move for physicians for reasons that are less apparent.¹⁴³ It is commonly thought that most of the savings of HIT systems go to payers and not to physicians because the systems translate into loss of revenue through service reductions.¹⁴⁴ One of the stated goals of HITECH is to reduce physician services through prevention of duplicate and unnecessary procedures.¹⁴⁵ If HITECH succeeds in its goal, physicians will lose payments for those duplicate and unnecessary services. It is in this way that the perverse incentives created by reimbursing physicians on a fee-for-service basis works to create perverse incentives for physician adoption of EHR.

Despite these challenges, the Secretary still believes that the savings benefit providers more than CMS and will lead to quicker EHR adoption than if just left to market forces.¹⁴⁶ The Secretary believes that the incen-

140. See *id.* § 1395w-4(o)(1)(D)(iii).

141. See Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844, 1,976 (Jan. 13, 2010). For hospitals the average estimate is for a \$5 million cost with \$1 million a year for maintenance, upgrades, and support. See *id.*

142. See *infra* Part II.B.2.

143. See Hillestad, *supra* note 1, at 1108.

144. See *id.*

145. See *supra* Part III.C.

146. See Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,987-88.

tive payments and the “prospect of significant payment penalties for non-participation” will be sufficient to lead most providers to choose to adopt certified EHR technology during the beginning of the program.¹⁴⁷ The Secretary also argues that even without HITECH, providers would still increase their use of technology.¹⁴⁸ While this may be true, the low reward and high costs of provider EHR adoption, coupled with decreased reimbursement on the horizon, may lead some providers to simply choose to drop Medicare coverage. However, many physicians will likely look to other avenues to adopt EHR as painlessly as possible.

One available avenue is for physicians to combine HITECH’s financial incentives with funds available from better-positioned health care entities through a Stark Law exception or Anti-Kickback Statute safe harbor for EHR. For example, North Shore Hospital System in New York is willing to pay physicians up to \$40,000 each for adopting North Shore’s EHR.¹⁴⁹ This would push the total incentive payments available to eligible physicians upwards of \$80,000. Incentives such as this will likely lead to greater health care organization integration, particularly as the physician incentives are phased out and the physician penalties phased in.

EHR technology is already much more prevalent in larger practices; further consolidation is likely as physicians look to escape the costs and hassle of implementing the technology in their practices.¹⁵⁰ It is certainly not a stretch to foresee a frustrated solo practitioner simply joining a group with certified EHR technology already in place to avoid taking a 5% reduction in reimbursement. Adding to HITECH’s push towards greater integration is that it is more likely that those health care organizations that already have HIT systems in place will be in a better position to reap the benefits. The providers without prior investment in HIT will be on the outside looking in as they compete for limited positions on HIT vendors’ implementation schedules. The Secretary admits that vendors will be limited in the number of systems they can install due to the increased demand for EHR from HITECH.¹⁵¹ Therefore, providers who are already in a strong technological position and have contracts with top HIT vendors will stand the greatest chance of receiving the payments. This factor and the prospect of future penalties will likely operate to increase the size of those entities best situated to reap the benefits of meaningful use.

Despite all of those challenges, the Secretary has no discretion to change the time frame of the incentive payments or reduce the penalty for

147. Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,988.

148. *See id.*

149. *See* Steven Shea & George Hripcsak, *Accelerating the Use of Electronic Health Records in Physician Practices*, 362 NEW ENG. J. MED. 192, 192 (2010).

150. *See* KATERYNA FONKYCH & ROGER TAYLOR, *THE STATE AND PATTERN OF HEALTH INFORMATION TECHNOLOGY ADOPTION* 41 (2005).

151. *See* Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,982.

providers that fail to demonstrate “meaningful use”; the Secretary’s discretion only lies in his ability to change the stringency of the “meaningful use” requirements.¹⁵² It, therefore, should be more important for the measures to be attainable, or the opportunities to use the incentive payments to accelerate the adoption of EHR technology will be lost. Moving beyond the Stage 1 requirements should not take place until there is substantial provider adoption of EHR technology. With the economic burdens being squarely on the shoulders of the physicians, the first years must operate to get the infrastructure in place for the future transformational goals to become possible.

B. The Government Practice of Medicine

HITECH’s use of financial incentives provides the means necessary for the federal government to increase its role in the delivery of health care. Most health care providers will be penalized after 2014 if they do not follow the government’s recommended processes for the delivery of health care. HITECH seems to represent a shift from the Court’s proclamation in *Linder v. United States* that “direct control of medical practice in the States is beyond the power of the Federal Government.”¹⁵³

Traditionally, lay control was not allowed to even *influence* the practice of a profession founded on such “sturdy, sterling human character,”¹⁵⁴ the goal being to not let interference by unlicensed persons function to allow for them to directly or indirectly administer medical care to the public.¹⁵⁵ This prohibition manifested itself through both professional licensing statutes and through statutes and common law prohibitions of the “corporate practice of medicine.”¹⁵⁶ The laws were designed to protect the public “by excluding from practice persons with inadequate ability, morality, and training.”¹⁵⁷

Administrative details, however, were always an appropriate area for institutional control. Only when lay persons “exercise substantial supervision over the professional activities of the physicians employed is there ground for arguing that the corporation is enabling unlicensed persons to practice medicine.”¹⁵⁸ The question was simply whether “in each individual case physicians are *actually* controlled in their purely professional functions by unlicensed persons.”¹⁵⁹

152. See *id.* at 1,975.

153. *Linder v. United States*, 268 U.S. 5, 18 (1925).

154. *Bartron v. Codrington County*, 2 N.W.2d 337, 345 (S.D. 1942); see also Note, *Right of Corporation to Practice Medicine*, 48 Yale L. J. 346, 348 (1938).

155. See Note, *Right of Corporation to Practice Medicine*, *supra* note 153, at 348.

156. *Id.* at 347.

157. *Id.* at 348.

158. *Id.*

159. *Id.*

HITECH exceeds mere influence and will require physicians to use EHR in the manner required by the regulations. Many of the measures required for a physician to demonstrate meaningful use involve the use of verbs like “use,” “utilize,” and “implement”; these terms are often used at the point of care.¹⁶⁰ In this way, the government is taking an additional step forward into the delivery of the health care. For example, in order to demonstrate “meaningful use” of certified EHR technology, physicians will have to report to CMS that they used CPOE in 80% of their orders.¹⁶¹ The Secretary specifically states that the goal of this measure cannot be attained by meeting the requirement once, but only by utilizing the “capability as part of the daily work process.”¹⁶²

Physicians will also be required to utilize clinical decision support at the point of care to guide their determination of the appropriate course of action.¹⁶³ The Secretary defines clinical decision support “as health information technology functionality that builds upon the foundation of an EHR to provide persons involved in care processes with general and person-specific information, intelligently filtered and organized . . . to enhance health and health care.”¹⁶⁴ Clinical decision support goes beyond mere involvement in the physicians’ daily work process; requiring the use of clinical decision support necessarily involves influencing physicians’ decision-making processes.

HITECH’s meaningful use requirement uses the payment system to increase the government’s influence on the delivery of health care; this further collapses the traditional split between the delivery of and the payment for health care services. HITECH requires physicians to use technology in the practice of medicine; moreover, it requires them to use the technology in a manner that is meaningful to the Secretary. This demonstrates the continuing shift towards the demise of physician autonomy.

Some will argue that HITECH is a voluntary program; physicians don’t have to participate, and thereby still have complete autonomy. The reality, however, is that failure to comply with HITECH will cause providers to incur penalties from the nation’s largest health care payer.¹⁶⁵ Many physicians facing a possible 5% reduction in their payments will not feel the program is voluntary due its effects on their bottom line. From a public policy perspective, this expansion would appear to put to rest the

160. See Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844, 1,858–1868 (Jan. 13, 2010) (to be codified at 42 C.F.R. pt. 495).

161. See *id.* at 1,858.

162. *Id.* at 1,863.

163. See *id.* at 1,860.

164. *Id.* at 1,855.

165. See 42 U.S.C.A. § 1395w-4 (West Supp. 2010).

corporate practice of medicine doctrine; HITECH represents institutional, government influence over the practice of medicine.¹⁶⁶

Strong arguments can be built for the case that greater institutional involvement is necessary. Medical care for conditions such as pneumonia and diabetes have been shown to meet national guidelines slightly more than half the time.¹⁶⁷ Automated physician order entry with clinical decision support is expected to improve patient health care quality and improve patient safety.¹⁶⁸ CPOE provides information to physicians when they place an order, such as warnings on potential drug interactions.¹⁶⁹ It has been estimated that CPOE could eliminate 200,000 adverse drug events per year if all hospitals utilized it.¹⁷⁰ In outpatient settings, three or four million adverse drug events could be prevented.¹⁷¹

Regardless of the propriety, the continuing shift of the government into the delivery of health care will stand as an additional barrier to physician adoption of HIT. Some physicians will realize “[t]his is inevitable, and now is the time,” but others will resist and disapprove of the federal government using HITECH to increase its control over their practice of medicine.¹⁷²

C. Tort Reform and the Meaningful Defenses?

As explained above, most of HITECH’s costs will likely be borne by the physician providers.¹⁷³ But perhaps a positive trade-off exists in tort law for physicians who embrace HITECH and choose to use certified EHR in a meaningful manner. In addition to effective EHR technology possibly reducing the total number of actionable tort claims, requiring providers to use government-certified technology in conjunction with government-approved processes has several possible tort ramifications. To be clear, it was not the intention of Congress or of the administration for HITECH to disrupt state tort law.¹⁷⁴ Nevertheless, HITECH potentially affects physicians’ behavior and decision-making at an intimate level. It,

166. See *Berlin v. Sarah Bush Lincoln Health Ctr.*, 688 N.E.2d 106 (Ill. 1997).

167. See Sandeep Jauhar, *One Thing After Another*, N.Y. TIMES, SUNDAY BOOK REVIEW 1, 7 (Jan. 22, 2010), available at <http://www.nytimes.com/2010/01/24/books/review/Jauhar-t.html>.

168. See Linda R. Peitzman, *Advancing the Practice of Evidence-Based Medicine with Standardized Order Sets*, PATIENT SAFETY & QUALITY HEALTHCARE 1, 1 (Nov./Dec. 2009), <http://www.psqh.com/novemberdecember-2009/312-advancing-the-practice-of-evidence-based-medicine-with-standardized-order-sets.html>.

169. See Hillestad, *supra* note 1, at 1108.

170. See *id.* at 1109.

171. See *id.*

172. Steve Lohr, *E-Records Get Backing of Hospital*, N.Y. TIMES, at B1, Sept. 28, 2009 (quoting Dr. Randolph DiLorenzo).

173. See *supra* Part IV.A.–B.

174. See 42 U.S.C.A. § 1395w-4 (West Supp. 2010); Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844, 1,975–89 (Jan. 13, 2010) (to be codified at 42 C.F.R. pt. 412).

therefore, seems likely that, over the long haul, the legislation will impact state tort law in a manner that is favorable for physicians by either (1) providing a federal preemption defense, (2) unifying physicians' standard of care, (3) or shifting liability to new parties.

1. Federal Preemption

Federal preemption would provide an attractive defense for physicians, as it would operate to dismiss the claim at the outset of the litigation. The Constitution's Supremacy Clause establishes that laws passed by Congress are the supreme laws of the land and in doing so establishes the principles that form the basis of any preemption defense.¹⁷⁵ The Court looks for two general types of preemption: express and implied.¹⁷⁶ Express preemption is not an avenue provided by HITECH, because Congress did not request preemption.¹⁷⁷ The absence of an express preemption provision does not rule out implied preemption through either the Court's "impossibility" doctrine or through its "obstacles and purposes" doctrine.¹⁷⁸

a. Impossibility Doctrine

The "impossibility" doctrine applies in cases where compliance with both federal law and state law is impossible; this type of implied preemption requires no judicial inquiry into Congressional intent¹⁷⁹ because the Court assumes Congress would not want compliance with a federal law to result in a violation of a state law.¹⁸⁰ This doctrine, however, is treated very narrowly, and typically requires a finding of physical impossibility.¹⁸¹

To illustrate the application of the impossibility doctrine as a defense, in *Mobile OB-GYN, P.C. v. Baggett*, a plaintiff sued a physician on the grounds that the physician's group did not have the appropriate procedures and safeguards in place to prevent a medication error.¹⁸² If the physician, or his practice, had instead been using technology certified by a federal program and following HITECH's requirements for medication error checking, it would arguably have been impossible for the physician to use any other procedures or safeguards. Admittedly, that argument would face

175. See U.S. CONST. art. VI, § 2. "[I]t is equally clear that the Supremacy Clause does not give unelected federal judges *carte blanche* to use federal law as a means of imposing their own ideas of tort reform on the States." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 894 (2000) (Thomas, J., dissenting).

176. See *Geier*, 529 U.S. at 884.

177. See *id.*

178. See *Fidelity Fed. Sav. & Loan Assn. v. de la Cuesta*, 458 U.S. 141, 153 (1982); see also *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

179. See *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963).

180. See *Geier*, 529 U.S. at 885.

181. See *Wyeth v. Levine*, 129 S.Ct. 1187, 1208 (2009).

182. See *Mobile OB-GYN, P.C. v. Baggett*, 25 So. 3d 1129, 1131-33 (Ala. 2009).

difficulty in a court that chose to apply a strict *physical* impossibility standard. The arguments would, of course, be that the physicians could always implement additional procedures and safeguards, or the physician could simply choose not to participate in HITECH's "meaningful use" program. Those arguments, however, would fail to acknowledge the real possibilities of a reality where many physicians cannot implement multiple systems and safeguards, or simply choose to forego 5% of their reimbursement.

That lack of a strict physical impossibility may change, however, as implementing regulations with respect to "meaningful use" become increasingly stringent over time. As indicated above, the plan moving forward is for HITECH to reach deeper into the underlying processes of health care delivery and further into provider's clinical decision making.¹⁸³ Deviation from the use of any required processes will lead to no incentives and the incurrance of penalties after 2015.¹⁸⁴ At the least, HITECH will create situations where it is logically impossible and physically impractical for a physician to comply with both state law and the implementing regulations.

b. Obstacle and Purposes Preemption

The "obstacles and purposes" preemption doctrine offers physicians another opportunity for a preemption defense because it provides for federal preemption when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."¹⁸⁵ To illustrate the doctrine, in *Geier* the Court held that a Department of Transportation (DOT) standard that required auto manufacturers to equip some, but not all, cars with airbags allowed for federal preemption of a state tort law products liability claim.¹⁸⁶ The claim was preempted because a "state tort law imposing such a duty—by its terms would have required manufacturers of all similar cars to install airbags rather than other passive restraint systems."¹⁸⁷

Congress's objective with HITECH is to create a uniform national health information network by using incentives to require all physicians to use a government-certified EHR technology in a meaningful manner. Congress's objectives would be thwarted by any substantial state law interference that resulted in physicians choosing not to take part in HITECH. To illustrate the significance of this point, meaningful use includes utilizing an EHR system's drug–drug, drug–allergy, and drug–formulary alerts.¹⁸⁸ If physicians are using certified EHR technology and follow the

183. See 42 U.S.C.A. § 1395w-4 (West Supp. 2010).

184. See *supra* Part IV.B.

185. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

186. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 881 (2000).

187. *Geier*, 529 U.S. at 881.

188. See Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844, 1,860 (Jan. 13, 2010)

advice of the system's drug-drug check, resulting in an actionable tort claim under state law, those physicians could have breached their standard of care by simply following the EHR's advice. Those physicians may have even suspected the EHR's drug-drug check was incorrect, but felt compelled to continue with the EHR's advice due to the likelihood that if an adverse event took place, the drug-drug check results would be evidence used against them. If physicians know they could be held liable with evidence of skipping that alert, or ignoring the evidence provided by an evidence-based order set, they might be hesitant to adopt the EHR. This type of state law interference would operate as a substantial obstacle to adoption of EHR.

Moreover, similar to HITECH's implementing regulation, the DOT's regulation in *Geier* was "intended to result in uniformity of standards so that the public as well as industry will be guided by one set of criteria rather than by a multiplicity of diverse standards."¹⁸⁹ The Court found "[t]his policy by itself favors pre-emption of state tort suits."¹⁹⁰ The Court also stressed the negative impact that tort liability would impose on the DOT's desire to encourage "public acceptance of the airbag technology . . . through gradual implementation of a passive restraint requirement."¹⁹¹ These purposes are similar to those found in HITECH of a uniform system with substantial physician acceptance through adoption of the federal regulations.

The Court also stressed the negative impact that tort liability would impose on the DOT's desire to encourage "public acceptance of the airbag technology . . . through gradual implementation of a passive restraint requirement."¹⁹² But the state's proper domain will be challenged when a physician is sued for negligently adhering to a government process. Participating physicians will be upset if a state jury can overturn a federally mandated process and hold a physician liable. Nevertheless, at this point, the scope of "meaningful use" is likely not large enough for preemption to operate in more than a few isolated areas, but if "meaningful use" transforms health care as desired, it could become much more protective of physicians.

2. *Uniform Standards of Care and Meaningful Use Safe Harbors*

Even if courts find that state's police powers are too broad for application of federal preemption to medical malpractice cases, widespread adop-

(to be codified at 42 C.F.R. pt. 412).

189. *Geier*, 529 U.S. at 871 (quoting S. Rep. No. 1301, at 12 (1966)).

190. *Id.*

191. *Id.* at 900-01 (Thomas, J., dissenting).

192. *Id.*

tion of certified EHR technology and HITECH's complementary government-approved processes could lead to other changes in tort law that are favorable for physicians who take part in the "meaningful use" program.

Physicians currently have to navigate through an uncertain maze of standards and norms.¹⁹³ The standard applied by courts for medical practice is based on a professional standard that looks to the "customary practice" of the profession.¹⁹⁴ This standard is ordinarily determined through the use of an expert witness that provides testimony that "focuses on the ways things are customarily done in the [relevant] medical community."¹⁹⁵ Thus, if a large number of physicians adopt a uniform system of practice, the customary practice will be based on that system.

If the majority of physicians purchase government certified technology and the goal of improved provider processes is effectively implemented, a uniform national standard will exist. Adopting physicians would thereby also lose the uncertainty of not knowing which standard will apply in the courtroom. Deviation from the customary practice ordinarily subjects a physician to tort liability, but a substantial provider adoption of EHR and following the HITECH regulations could bring the provider within the protection of a customary practice.

Arguments have already been made that "safe harbors" for adherence to evidence-based practices would promote the use of comparative research and evidence-based care.¹⁹⁶ This is because "safe harbors . . . would give physicians legal incentive to practice evidence-based medicine [and] liability reform could be an effective way to foster the uptake" of comparative effectiveness research.¹⁹⁷ The ARRA's goals include promoting comparative effectiveness research and using evidence-based care.¹⁹⁸

A bill was introduced in Congress that would create a rebuttable presumption that the provider's care was not negligent if the physician followed clinically accepted guidelines.¹⁹⁹ The bill also provided a presumption against negligence if the provider practiced within the findings of credible comparative-effectiveness research.²⁰⁰ The bill says that states who agreed to the rebuttable presumption would receive bonus payments.²⁰¹ The ARRA also has over \$1 billion allocated for comparative-effectiveness research, so it is likely that HITECH will provide additional

193. See James F. Blumstein, *Medical Malpractice Standard-Setting: Developing Malpractice "Safe Harbors" as a New Role for QIOs?*, 59 VAND. L. REV. 1017, 1021 (2006).

194. See *id.* at 1023.

195. *Id.* at 1024.

196. See Michelle M. Mello et al., *The Role of Medical Liability Reform in Federal Health Care Reform*, 361 NEW ENG. J. MED. 1, 2 (2009).

197. *Id.* at 3.

198. 42 U.S.C §§ 1301–1320 (2006 & Supp. 2008).

199. See Healthy Americans Act, S. 334, 111th Cong. (2007); Mello, *supra* note 194, at 3.

200. See Mello, *supra* note 196, at 3.

201. See *id.*

support for a bill of this nature.²⁰² The “meaningful use” regulations could provide the means to mandate adherence to the research findings because they do provide standards to an extent. It would make sense for the administration to adopt a “strategy of dealing with the problem of defensive medicine through a liability-based (and not only a remedy-centric) approach.”²⁰³

3. *Liability Shifting*

Individual physicians will likely not configure things such as an EHR system’s medication alerts or provide the clinical evidence necessary to establish an effective EHR clinical decision support system. These types of system configuration decisions that ultimately affect clinical decision making will often result from decisions not made at the individual physician level, but at the institutional level. For this reason, physicians will be able to make strong arguments in an increasing number of cases that the burden of liability has been shifted to the facilities, or to those individuals responsible for the maintenance of the systems and their software. The burden will shift towards health care organizations and their non-physician staff in cases where the doctors are essentially just following along with what the federally required technology is telling them to do.

It is commonly thought that “defensive medicine” practiced by physicians is a driver of health care costs.²⁰⁴ Estimating the magnitude of these costs, however, is extremely difficult.²⁰⁵ Nevertheless, it is certain that at least some physicians do order services, and are paid by the federal government for ordering services that were simply ordered to avoid purported tort liability. Therefore, a reduction in tort liability would not only garner additional support from physicians for HITECH, but also work towards HITECH’s goal of increased health care quality and efficiency through reduction in services. According to the *New England Journal of Medicine* “[m]ost physicians find the litigation system unfair, financially and psychologically burdensome, and unhelpful in promoting safety and quality.”²⁰⁶ Physicians “would welcome relief of some sort.”²⁰⁷

202. *See id.*

203. Blumstein, *supra* note 193, at 1044.

204. Mello, *supra* note 196, at 1.

205. *See id.*

206. *Id.* at 2.

207. *Id.*

V. CONCLUSION

Most studies still correctly use “potential” to describe the estimated savings from health care provider adoption of EHR technology.²⁰⁸ Information technology, in general, produced gains of only 1.5% in productivity per year in the retail/sales industry, but has produced gains of 8% per year in productivity in the securities and telecommunication industries.²⁰⁹ It is not yet clear whether either of those productivity gains would be possible in a HITECH-transformed U.S. health care system.

HITECH’s implementing regulations state that the main goal for the regulation’s first five years is only for providers to implement the EHR technology.²¹⁰ A review of those regulations, the plain text of the statute, and the Congressional history make clear, however, that “implement” does not just mean a provider must simply purchase EHR technology—HITECH does not “just hand out grants” but requires meaningful use of EHR technology.²¹¹ In addition, HITECH makes clear it is not designed to be a static piece of legislation; it is intended to function as a “rising tide” that will increase in stringency over time.²¹² The Secretary in turn developed rules and laid a foundation for the future of HITECH that ensures the program is not just a handout of money.

Congress, however, with the aid of multitudes of health care industry stakeholders, may have begun to realize the difficulties and problems with its sweeping, crisis-driven delegation of legislative power. Two hundred and ninety seven U.S. Representatives recently signed a letter urging the director of CMS to reconsider the regulations because they may be “too much too soon.”²¹³ The Representatives requested “a longer transition that recognizes a practical, incremental approach to EHR adoption that rewards the efforts already underway in America’s hospitals.”²¹⁴ Another letter with nearly identical text was written and sent to the CMS’s director by twenty-seven U.S. Senators.²¹⁵

208. See, e.g., Hillestad, *supra* note 1; KATERYNA FONKYCH & ROGER TAYLOR, *THE STATE AND PATTERN OF HEALTH INFORMATION TECHNOLOGY ADOPTION* (2005).

209. See Hillestad, *supra* note 1, at 1106–07.

210. See Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844, 1,987 (Jan. 13, 2010) (to be codified at 42 C.F.R. pt. 412).

211. 155 CONG. REC. S1,511 (daily ed. Feb. 4, 2009) (statement of Sen. Whitehouse).

212. See Carolyn Barley Britton, National Medical Association, Position Statement, *Widespread Adoption and Meaningful Use of Health Information Technology*, June 2009, http://www.nmanet.org/images/uploads/Documents/HIT_and_Meaningful_Use_Position_Statement.pdf.

213. Letter from U.S. Representatives to Charlene Frizzera, Acting Administrator of the Centers for Medicare & Medicaid Services (Mar. 15, 2010), *available at* <http://www.aha.org/aha/letter/2010/100224dearcolleagueHIT.pdf>.

214. Letter from U.S. Senators to Charlene Frizzera, Acting Administrator of the Centers for Medicare & Medicaid Services (Mar. 2, 2010), *available at* <http://www.aha.org/aha/letter/2010/100302dearcolleagueSenateHIT.pdf>.

215. See *id.*

This leaves the immediate path of the “meaningful use” regulations at least slightly uncertain. Long-term, though, achieving the transformational vision will first and foremost require health care provider adoption of EHR.²¹⁶ Early physician acceptance will be crucial to widespread provider adoption; therefore, in light of the costs being imposed on physicians’ wallets and psyche, it might be worth emphasizing not only HIT’s power to revolutionize the delivery of health care, but also HIT’s power to act as a powerful driver for tort reform.

Matthew T. Wimberley

216. See *supra* Part IV.A.