Nicolas P. Terry, B.A. (Hons) Law, LL.M.
Chester A. Myers Professor of Law,
Saint Louis University School of Law

Nicolas P. Terry is the Chester A. Myers Professor of Law at Saint Louis University School of Law where he teaches Torts, Products Liability, Health Information Technology, Law & Science, and Health Care Quality. Educated at Kingston University and the University of Cambridge, Professor Terry began his academic career as a member of the law faculty of the University of Exeter in England. He has served as a Senior Fellow at Melbourne Law School and holds the secondary appointment of Professor of Health Management & Policy at the Saint Louis University School of Public Health. He has held visiting faculty positions at the law schools of Santa Clara University, the University of Missouri-Columbia, Washington University, and the University of Iowa. From 2000-08 Professor Terry served as co-director of Saint Louis University's Center for Health Law Studies — consistently ranked by U.S. News & World Report as the finest health law program in the nation. From 2008-10 Terry served as the School of Law's Senior Associate Dean. Professor Terry's research interests lie primarily at the intersection of medicine, law, and information technology. His recent law review publications dealing with health information privacy include "Physicians And Patients Who 'Friend' Or 'Tweet': Constructing A Legal Framework For Social Networking In A Highly Regulated Domain," http://works.bepress.com/nicolas_terry/1 43 Ind. L. Rev. 285-341 (2010); "Personal Health Records: Directing More Costs and Risks to Consumers?" 1 Drexel L. Rev. 216 (2009); "What's Wrong with Health Privacy?" 5 J. Health & Bio. L. 1-32 (2009), and "Ensuring The Privacy and Confidentiality of Electronic Health Records" (with Leslie P. Francis) 2007 U. Ill. L. Rev. 681-735.

CERTIFICATION AND MEANINGFUL USE: REFRAMING ADOPTION OF ELECTRONIC HEALTH RECORDS AS A QUALITY IMPERATIVE

Nicolas P. Terry*

ABSTRACT

This article examines the promise of the Health Information Technology for Economic and Clinical Health Act ("HITECH") to reduce or eliminate the market failures that have impeded the adoption of Electronic Health Records ("EHR"). Specifically, the article considers a key provision of the statute, a condition for receiving EHR subsidy funds, namely meaningful use. This deceptively simple requirement, that a health care provider must make "meaningful use of certified EHR technology," has become both the regulatory core and the talisman for the next decade's implementation of health information technology. This article describes the background of the subsidy program and examines the specifics of the "certification" and "meaningful use" regulations that have followed. The article concludes by taking a broader view of "meaningful use" and relating it to the concept of more fundamental health care reform.

> The provisions of the HITECH Act are best understood not as investments in technology *per se*, but as efforts to improve the health of Americans and the performance of their health care system . . . . Combined, [the HITECH] programs build the foundation for every American to benefit from an EHR, as part of a modernized, interconnected, and vastly improved

---

* Chester A. Myers Professor of Law, Saint Louis University. Email: terry@slu.edu. I thank Gina Marie Geheb, Karla Hutton, and Professor Margaret McDermott for their excellent research assistance.

system of care delivery.[1]

I. INTRODUCTION

Notwithstanding the 2004 commitment of President Bush to the adoption of a national Electronic Health Records ("EHR") system, by 2009 only seventeen percent of U.S. doctors and ten percent of hospitals had even basic EHR systems[2] and fewer than two percent of U.S. hospitals had comprehensive systems.[3] Furthermore, health care providers continue to lag in technologies related to EHRs. For example, only thirteen percent of hospitals have implemented Computerized Provider-Order Entry ("CPOE") technology.[4] According to Dr. David Blumenthal, the current National Coordinator for Health Information Technology ("ONC"),[5] "We have years of professional agreement and bipartisan consensus regarding the potential value of EHRs. Yet we have not moved significantly to extend the availability of EHRs from a few large institutions to the smaller clinics and practices where most Americans receive their health care."[6]

This article examines the promise of the market-failure-busting potential of the Health Information Technology for Economic and Clinical Health Act ("HITECH").[7] Specifically, it looks at a key provision of HITECH: the "meaningful use" condition required to receive EHR subsidy funds. This deceptively simple requirement, that a health care provider must make "meaningful use of certified EHR technology,"[8] has become both the regulatory core and the talisman for the next decade's implementa-

---

1. *Efforts to Promote the Adoptions and Meaningful Use of Health Information Technology: Hearing Before the Subcomm. on Health of the H. Comm. on Ways and Means*, 111th Cong. 3 (2010) [hereinafter *Hearings*] (statement of David Blumenthal, M.D., M.P.P., National Coordinator, Off. of the Nat'l Coordinator for Health IT, U.S. Dep't of Health and Human Services), *available at* http://waysandmeans.house.gov/media/pdf/111/2010Jul20_Blumenthal_Testimony.pdf.

2. David Blumenthal, *Stimulating the Adoption of Health Information Technology*, 360 NEW ENG. J. MED. 1477, 1477 (2009); *see also* Sean O. Hogan & Stephanie M. Kissam, *Measuring Meaningful Use*, 29 HEALTH AFF. 601, 603 (2010).

3. Ashish K. Jha, et al., *Use of Electronic Health Records in U.S. Hospitals*, 360 NEW ENG. J. MED. 1628, 1634 (2009), *see also* Hogan & Kissam, *supra* note 2, at 601.

4. Jha et al., *supra* note 3, at 1635.

5. *See generally About the Office of the National Coordinator for Health Information Technology (ONC)*, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_onc/1200 (last updated Aug. 13, 2010) (explaining that the Office of the National Coordinator for Health Information Technology ("ONC") is a federal agency located in the U.S. Department of Health and Human Services ("HHS")).

6. David Blumenthal & Marilyn Tavenner, *The "Meaningful Use" Regulation for Electronic Health Records*, 363 NEW ENG. J. MED. 501, 501 (2010).

7. Title XIII (Health Information Technology for Economic and Clinical Health Act, "HITECH") of the American Recovery and Reinvestment Act of 2009 ("AARA"), Pub. L. No. 111-5, 123 Stat. 115, 226-79 (2009) (codified in scattered sections of 42 U.S.C.).

8. 123 Stat. at 494.

tion of health information technology ("HIT").[9] This article considers the background of the EHR subsidy program and examines the specifics of the "certification" and "meaningful use" regulations that have followed. The article concludes by taking a broader view of "meaningful use" condition and relating it to the concept of more fundamental health care reform.

II. ELECTRONIC RECORDS AND MARKET FAILURE

While the most frequently cited reason for HIT's low adoption rate has been high cost, the far more nuanced barrier has been market failure, even multiple market failures. In discussing costs, the electronic record cost-benefit picture has always been opaque. For example, estimates for implementing a national system have been as high as $400 billion.[10] Yet, many of the projected savings after successful implementation of fully interoperable records, such as decreases in medical error, reductions in duplicate tests, and research into health outcomes,[11] are more diffuse and almost impossible to track to a provider's bottom line. Further, some benefits are based only indirectly on EHR technologies and are dependent on the implementation of other (and not inexpensive) HIT modules that interact with records systems, such as CPOE and Clinical Decision Support Systems ("CDSS") technologies.[12]

For EHR, the most obvious market failure (and a familiar one in U.S. health care analysis) has been "misaligned incentives."[13] Much of the savings from EHR will accrue to payers, such as health insurers, rather than the health care providers actually investing in the technology. As a result, it

---

9. *See generally* Nicolas P. Terry, *To HIPAA, A Son: Assessing the Technical, Conceptual, and Legal Frameworks for Patient Safety Information*, 12 WIDENER L. REV. 133 (2005); COMM. ON QUALITY OF HEALTH CARE IN AM., INSTITUTE OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 164-80 (2001) [hereinafter INSTITUTE OF MED.]; AARON MCKETHAN ET AL.,THE BIPARTISAN POL'Y CTR., IMPROVING QUALITY AND VALUE IN THE U.S. HEALTH CARE SYSTEM (2009), *available at* http://www.bipartisanpolicy.org/sites/default/files/BPC8-09-PCHC%20Qual%20rpt-8-20-09.pdf.

10. Peter Basch, *Electronic Health Records and the National Health Information Network: Affordable, Adoptable, and Ready for Prime Time?*, 143 ANNALS OF INTERNAL MED. 227, 227 (2005); *see also* Rainu Kaushal et al., *The Costs of a National Health Information Network*, 143 ANNALS OF INTERNAL MED. 165 (2005).

11. *See* Fact Sheet, Centers for Medicare & Medicaid Services Office of Public Affairs, Electronic Health Records at a Glance (July 13, 2010), *available at*, http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3788&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date [hereinafter Fact Sheet: EHR] (noting some of the projected benefits of EHRs).

12. *See generally* David W. Bates et al., *Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors*, 280 JAMA 1311-1316 (1998) (discussing the patient safety benefits of CPOE); INSTITUTE OF MED., *supra* note 9.

13. *See* Steven M. Teutsch & Marc L. Berger, *Misaligned Incentives in America's Health: Who's Minding the Store?*, 3 ANNALS OF FAM. MED. 485, 485-87 (2005).

has been difficult to make the business case for the adoption of EHR products and their Total Cost of Ownership ("TCO"), such as hardware and software updates, personnel, training, and technical support.[14] The compounding market failure, the "network effects" phenomenon, likely has contributed to the lack of provider enthusiasm for investing in EHR technology.[15] The marginal value for an individual provider to seek out a network-ready EHR is very low when so few (marginal at best) systems have been deployed.[16] The exception proves the rule—vertically integrated providers and some multispecialty groups have undertaken such investment because they possess the economies of scale required for advanced IT deployment and are often also insurers, thus aligning incentives.[17]

Implementing a national interoperable EHR system became the cornerstone of the Bush Administration's HIT policy when the President personally committed to the ten-year goal that all Americans would have electronic health records by 2014.[18] Although that administration was successful in guiding many of the conceptual and standards issues to a successful conclusion, it was not prepared to invest seriously in the endeavor, but rather relied on what it described as a "market-leading" approach.[19]

In 2005, the medical economist J.D. Kleinke concluded an essay in *Health Affairs* on the market failure associated with interoperable EHRs by suggesting, "[t]he federal government can and should write the huge check and be done with it."[20] By that stage, most stakeholders appear to have accepted the cost estimates published in a *Health Affairs* article in the fall of 2005: $44,000 purchase or capital cost per physician, plus $8,500 per phy-

---

14. *See generally* Steven R. Simon et al., *Correlates of Electronic Health Record Adoption in Office Practices: A Statewide Survey*, 14 J. AM. MED. INFORMATICS ASS'N, 110 (2007), *available at* http://jamia.bmj.com/content/14/1/110.full.pdf.; David W. Bates, *Physicians and Ambulatory Electronic Health Records*, 24 HEALTH AFF. 1180 (2005), *available at* http://content.healthaffairs.org/cgi/reprint/24/5/1180.

15. This issue also undermines the outcomes reporting potential of EHRs. *See* NANCY FERRIS, HEALTH AFFAIRS & THE ROBERT WOOD JOHNSON FOUNDATION, HEALTH POLICY BRIEF: 'MEANINGFUL USE' OF ELECTRONIC HEALTH RECORDS 2 (2010), *available at* http://www.healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_24.pdf.

16. A third but related type of market failure is the first mover/high information cost problem likely caused by having between 300 and 400 EHR vendors in the market. *See* Helaine Olen, *The Next Tech Goldmine: Medical Records*, CNNMONEY.COM (March 5, 2010), http://money.cnn.com/2010/03/05/smallbusiness/electronic_medical_records/.

17. *See generally* Steve Lohr, *Digital Health Records: The Hard Road Ahead*, BITS (Sept 10, 2009, 7:19 PM), http://bits.blogs.nytimes.com/2009/09/10/digital-health-records-the-hard-road-ahead/?hp.

18. . Press Release, The White House Office of the Press Secretary, Transforming Health Care: The President's Health Information Technology Plan (May 27, 2004), http://georgewbush-whitehouse.archives.gov/news/releases/2004/05/20040527-2.html.

19. *See e.g.*, Robert Cunningham, *Action Through Collaboration: A Conversation With David Brailer*, 24 HEALTH AFF. 1150, 1151-52 (2005).

20. J.D. Kleinke, *Dot-Gov: Market Failure and the Creation of a National Health Information Technology System*, 24 HEALTH AFF. 1246, 1258 (2005).

sician in annual costs, such as support and software updates.[21] Kleinke correctly tempered his enthusiasm for this bold stroke with a reality-based assessment, "[W]riting a check for a quarter of a trillion dollars is pure po-political fantasy . . . . The very idea of a public works project . . . sounds like an artifact from an era eclipsed by nearly three decades of hostility toward government-based solutions to domestic problems, combined with a seemingly religious belief in marketplace solutions for all of them."[22]

III. ARRA AND HITECH SUBSIDIES

Four years later, a recession and growing financial crisis transformed fantasy into reality. When President Obama signed the American Recovery and Reinvestment Act of 2009 ("ARRA"), HITECH was passed into law.[23] HITECH instructed the National Coordinator for Health Information Technology to update the Federal Health IT Strategic Plan to include specific objectives, milestones, and metrics with respect to, inter alia, "[t]he electronic exchange and use of health information and the enterprise integration of such information" and "[t]he utilization of an electronic health record for each person in the United States by 2014."[24] The core of the HIT package is the stimulation of EHR adoption and encouraging state and regional infrastructure for the interoperability of such records.[25]

The ARRA HIT funding provides roughly $30 billion for Department of Health and Human Services ("HHS") Agencies: approximately $27 billion for the Centers for Medicare & Medicaid Services ("CMS") and $2 billion for ONC.[26] With these budgets, CMS will fund the EHR incentive program while ONC will provide coordination and planning while also funding state and regional initiatives through grants and loans.[27] Medicaid

---

21. Robert H. Miller, et al., *The Value of Electronic Health Records in Solo or Small Group Practices*, 24 HEALTH AFF. 1127, 1127 (2005).

22. Kleinke, *supra* note 20, at 1257.

23. 123 Stat. at 226-79.

24. *Id.* at 231.

25. Kevin Freking, *Obama Team Sees Stimulus Advancing Health Reform*, ASSOCIATED PRESS FINANCIAL WIRE, Feb. 14, 2009.

26. U.S. DEP'T OF HEALTH AND HUMAN SERVICES, OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., ACCELERATING THE ADOPTION OF HEALTH INFORMATION TECHNOLOGY IMPLEMENTATION PLAN (2010), *available at* http://www.hhs.gov/recovery/reports/plans/onc_hit.pdf; SAMHSA FINANCING CENTER OF EXCELLENCE, SUBSTANCES ABUSE AND MENTAL HEALTH ADMINISTRATION, SAMHSA'S WEEKLY FINANCING NEWS PULSE: NATIONAL EDITION – JULY 23, 2010 (2010), *available at* http://www.samhsa.gov/financing/file.axd?file=2010%2f10%2f2010_10_WeeklyFinancingNewsPulseNational Editionfinal20100723.pdf.

27. HITECH-funded programs include: the State Health Information Exchange ("HIE") Cooperative Agreement program (HIE grants), the Beacon Community program (HIT grants), The Health IT Workforce Program (education and curriculum development), the Strategic Health IT Advanced Research Projects ("SHARP") program (grants to address barriers to HIT adoption), and The Health Information Technology Extension program

and Medicare incentive payments will be made to non-hospital-based doctors ("eligible providers" hereinafter "EP")[28] and eligible hospitals.[29] For example, a physician who participates in the full five-year program could receive the maximum subsidy of $44,000 through Medicare.[30] Hospital-employed physicians are expressly excluded from the reimbursement opportunity as it is assumed they will have access to their hospital's EHR systems.[31] Hospitals themselves are eligible for reimbursement with a $2 million baseline and thereafter a formula based on the number of inpatient discharges.[32] Currently there are approximately 500,000 eligible providers and 5000 eligible institutions.[33]

The subsidy program only applies to 2011 through 2016, with incentive payments declining after the first two years. Starting in 2016, HITECH's "carrots" will be replaced by "sticks."[34] At that point, EPs and hospitals that fail to use qualifying EHRs for meaningful purposes will see reductions in their Medicare and Medicaid payments.

IV. REGULATING EHR ADOPTION

Likely there were many forces that shaped the conditional nature of the EHR subsidy program including the broad politics surrounding the federal recovery program and latent skepticism about the worth of HIT. As written, HITECH provides that to qualify for such payments the provider

---

(grants to establish regional "help desks"). For a breakdown of budgets for these programs, see David Blumenthal, *Launching HITECH*, 5 NEW ENG. J. MED. 382, 383 (2010).

28. 123 Stat. at 467-77.

29. 123 Stat. at 477-86. The subsidy program applies to both eligible hospitals and Critical Access Hospitals ("CAH"). For the purpose of this article, "hospital" is used to refer to both. *See generally Critical Access Hospital Frequently Asked Questions,* RURAL ASSISTANCE CENTER, http://www.raconline.org/info_guides/hospitals/cah.php#faq (last updated Oct. 26, 2010).

30. Detailed provisions regarding incentive amounts are to be found at 42 C.F.R. § 495.102 (2010) (EPs), 42 C.F.R § 495.104 (hospitals), and 42 C.F.R § 495.106 (CAHs). The Medicaid option applies to physicians with at least thirty percent of Medicaid patients. Medicaid EPs attract potentially different subsidies (up to $63,750 per physician) and a longer timeline (up to six years). 42 C.F.R. § 495.308 (indicating net average allowable costs under Medicaid); § 4201, 123 Stat. at 489-94; Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844, 1,935 (proposed Jan. 13, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422, and 495) (indicating the maximum incentive payment amount for Medicaid professionals). *See* also 42 C.F.R. § 495.2 (noting specific HITECH Act authority for subsidies).

31. Electronic Health Record Incentive Program, 75 Fed. Reg. at 1,907.

32. 42 C.F.R. § 495.104 (summarizing that, basically, the payments are made as an add-on to their Medicare fees); Jason Fortin & Walt Zywiak, *Beyond Meaningful Use Getting Meaningful Value from IT*, 64 HEALTHCARE FIN. MGMT. 54, issue 2 (2010) (estimating that final hospital incentives vary from between $2 million to $6 million); Joseph Goedert & Howard Anderson, *Digging Into the Economic Stimulus Law*, HEALTH DATA MGMT., Apr. 2009, at 16 (estimating the final value of hospital incentives to be between $2 million and $11 million).

33. FERRIS, *supra* note 15, at 2.

34. *Id.*

must make a "meaningful use of certified EHR technology."[35] This requirement is being executed by regulations from ONC and CMS, which address certification[36] and meaningful use, respectively.[37]

Although the core program under the stimulus provisions was (and remains) the provision of incentives for EHR adoption, HHS clearly has taken its cue from the broader objectives detailed in the HITECH Act[38] and the national health care reform that was to follow a year later. As CMS noted in its 2010 regulatory commentary, "reforming the health care system and improving health care quality, efficiency and patient safety should drive the definition of meaningful use."[39]

A. Meaningful Use

CMS, ONC, and the HIT advisory committees (specifically the Meaningful Use workgroup, a subset of the Health IT Policy committee[40]) developed the regulations by first drawing up a "meaningful use matrix."[41] The elements of this matrix are "Objectives," "Measures," and "Stages."[42] Essentially, the matrix is a functional reflection of meaningful use informed by HITECH's broad health outcome goals. It ties together those broad outcome goals, defined sub-goals (Objectives), reporting tools that represent sub-goal compliance (Measures) and the timeline for the project (Stages).[43]

HITECH's broad health outcome goals are: (1) improving the quality, safety, and efficiency of care while reducing disparities; (2) engaging patients and families in their care; (3) promoting public and population health; (4) improving care coordination; and (5) promoting EHR privacy and security.[44] The secondary elements of the matrix are the Objectives under each

---

35. 123 Stat. at 494.

36. *See infra* Part IV.B.

37. *See infra* Part IV.A.

38. HITECH, Pub. L. No. 111-5 § 3001(b), 123 Stat. 115, 353-73 (2009).

39. Electronic Health Record Incentive Program, 75 Fed. Reg. 44, 314 (July 28, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422, 495).

40. *Health IT Policy Committee (a Federal Advisory Committee),* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__health_it_policy_committee/1269 (last updated Oct. 7, 2010).

41. Fact Sheet, Centers for Medicare & Medicaid Services Office of Public Affairs, CMS Proposes Definition of Meaningful Use of Certified Electronic Health Records (HER) (Dec. 20, 2009), *available at* http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3564&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date [hereinafter Fact Sheet: CMS Proposes].

42. *Id.*

43. *See generally* Bob Brown, *The Definition of "Meaningful Use"*, J. HEALTH CARE COMPLIANCE, Sept.-Oct. 2009, at 45.

44. *See generally* Letter from Paul Tang, Vice Chair, Health IT Pol'y Comm., to David Blumenthal, MD, MPP, Nat'l Coordinator for Health Info. Tech., Off. of the Nat'l Coordinator, Dep't Health and Human Services, (Aug. 10, 2009) *available at* http://www.google.com/search?client=safari&rls=en&q=paul+tang+to+david+blumenthal+a

of these goals. For example, "improving quality" includes "access to comprehensive patient health data for patient's health care team" and use of "evidence-based order sets and CPOE."[45]

The third elements of the matrix, "Measures" provide criteria or metrics (typically a usage "floor") to report progress towards the Objectives.[46] The final element, set against these Objectives and Measures, is a three-stage program timeline, with Stage 1 beginning in 2011, Stage 2 beginning in 2013, and Stage 3 beginning in 2015.[47]

CMS published its proposed rule in January 2010.[48] The proposed rule mandated twenty-three objectives for hospitals and twenty-five for clinicians. Criticisms and comments were legion. In March 2010, 249 members of Congress signed a letter to CMS urging the agency to revise meaningful use with a "narrow[er] base" of 2011 Objectives and an extension of the transition to 2017.[49] The letter stated:

> [The proposed rule is] an ambitious all-or-nothing approach in which hospitals would be required to adopt all 23 separate EHR objectives . . . that very few hospitals have yet been able to accomplish. The rule should be altered to recognize a practical, staged approach to EHR adoption that rewards the efforts already underway in America's hospitals.[50]

The primary objection among stakeholders was that CMS had taken an "all or nothing" approach; "Doctors could not have received any federal bonus payments unless they met 25 criteria, or objectives, and hospitals would have been required to meet 23."[51] A second objection was that CMS

---

ugust+10,+2009&ie=UTF-8&oe=UTF-8; Blumenthal, *supra* note 27; News Release, U.S. Department of Health & Human Services Press Office, CMS and ONC Issue Regulations Proposing a Definition of 'Meaningful Use' and Setting Standards for Electronic Health Record Incentive Program (Dec. 30, 2009), *available at* http://www.hhs.gov/news/press/2009pres/12/20091230a.html; Brown, *supra* note 43, at 72; Catherine M. DesRoches & Sara J. Rosenbaum, *Meaningful Use of Health Information Technology in U.S. Hospitals*, 362 NEW ENG. J. MED. 1153 (2010).

45. Electronic Health Record Incentive Program, 75 Fed. Reg. 44, 314, 44,331 (July 28, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422, 495).

46. 42 C.F.R. § 495.6 (2010).

47. Fact Sheet: CMS Proposes, *supra* note 41; Blumenthal, *supra* note 27, at 382.

48. Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844, (proposed Jan. 13, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422, and 495).

49. Letter from U.S. Congress Members to Charlene Frizzera, Acting Administer, CMS (Feb. 24, 2010), *available at* http://www.aha.org/aha/content/2010/pdf/100224 dear-colleagueHIT.pdf.

50. *Id.*

51. Robert Pear, *Standards Issued for Electronic Health Records*, N.Y. TIMES, July 13, 2010, at A16, *available at* http://www.nytimes.com/2010/07/14/health/policy/14health.html?_r=2&ref=technology; *see also* Pamela Lewis Dolan, *"Meaningful Use" Takes Time (HIMSS 2010 Conference)*, AMEDNEWS.COM (April 19, 2010), http://www.ama-assn.org/amednews/2010/04/19/bisa0419.htm.

had created a very difficult target; what the regulators had listed as Stage 1 objectives were viewed as more appropriate for Stage 3 (2015) and thereafter.[52] It was argued, for example, that fewer than six percent of physician practices would meet the proposed meaningful use criteria.[53] Notwithstanding, there were some more muted criticisms that the Proposed Rule did not go far enough. For example, during a hearing in July 2010 before a subcommittee of the House Ways and Means Committee, two Republican Congressmen challenged Dr. Blumenthal on the appropriateness of the measure for interoperability;[54] specifically, that the interoperability objective (the "[c]apability to exchange key clinical information")[55] could be successfully measured by a single exchange of proxy data.[56] Dr. Blumenthal stood his ground on the basis that such interoperability was a function of infrastructure building outside the control of an EP.[57]

The Final Rule was published in July 2010.[58] At this time CMS noted that the rule now used a "phased approach . . . [that] initially establishes criteria for meaningful use based on currently available technological capabilities and providers' practice experience."[59] Thus, the final rule backpedaled from the "all or nothing" approach of the initially proposed rule. Instead, for the first two years of the funding program CMS has established a two tier model: first, a set of fifteen "core objectives" that eligible providers and hospitals must satisfy to qualify for EHR funding, and second, a "menu set" of ten objectives (twelve for professionals) from which five must be chosen and fulfilled.[60]

As noted in the media, "Standards in the new rules are less demanding

---

52. Joseph Goedert, *Meaningful Use: This Is Gonna Hurt*, 18 HEALTH DATA MGMT. 40 (2010); Brown, *supra* note 43, at 45-46, 72; Barbara J. Hoehn, *Meaningful Use: What Does It Mean for Healthcare Organizations?*, 24 J. HEALTHCARE INFO. MGMT. 11 (2010).

53. Goedert, *supra* note 52, at 42. *See also* FERRIS, *supra* note 15, at 5. *See generally* WILLIAM S. BERNSTEIN ET AL, MANATT HEALTH SOLUTIONS, HITECH REVISITED, (June 2010), *available at* http://www.manatt.com/uploadedFiles/News_and_Events/Newsletters/HealthLaw@Manatt/HITECH%20Revisited_Final%20May%2031,%202010.pdf.

54. *Hearings*, *supra* note 1 (statements of Reps. Herger and Johnson, Members, H. Comm. on Ways & Means).

55. 42 C.F.R. § 495.6(d)(14)(i) (2010).

56. *Id.*

57. *Hearings*, *supra* note 1 (statement of David Blumenthal, M.D., M.P.P., Nat'l Coordinator, Off, of the Nat'l Coordinator for Health IT, U.S. Dep't of Health and Human Services).

58. Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844, 1,935 (proposed Jan. 13, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422, and 495).

59. Fact Sheet, Centers for Medicare & Medicaid Services Office of Public Affairs, CMS and ONC Final Regulations Define Meaningful Use and Set Standards for Electronic Health Record Incentive Program (July 13, 2010), *available at* http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3787&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date [hereinafter Fact Sheet: CMS Defines MU].

60. *Id.*

and more flexible."[61] In its own introduction to the final rule, CMS tried hard to disguise disappointment that its more radical proposals had been delayed,"

> By having [continuous quality improvement and ease of information exchange] in certified EHR technology at the onset of the program and requiring that the EP eligible hospital or CAH become familiar with them through the varying levels of engagement required by Stage 1, we believe we will create a strong foundation to build on in later years.[62]

The final rule promulgates parallel groups of objectives (criteria), one for EPs,[63] and the other for eligible hospitals.[64] Each group of objectives includes a series of core (or mandatory) criteria and a series of menu criteria.[65] Each criterion is accompanied by an outcome measure and, in a few cases, exclusionary criteria detailing when a provider does not have to comply with a particular objective.[66]

For example, the fifteen objectives in the EP core set[67] include the use

---

61. Pear, *supra* note 51, at A16.

62. Electronic Health Record Incentive Program, 75 Fed. Reg. 44, 314, 44,321 (July 28, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422, 495).

63. 42 C.F.R. § 495.6(d) (2010) (Stage 1 core criteria for EPs); 42 C.F.R. § 495.6(e) (Stage 1 menu set criteria for EPs).

64. 42 C.F.R. § 495.6(f) (Stage 1 core criteria for eligible hospitals); 42 C.F.R. § 495.6(g) (Stage 1 menu set criteria for eligible hospitals or CAHs).

65. *Id.*

66. 42 C.F.R. § 495.6(a)(2)-(3) (EPs); 42 C.F.R. § 495.6(b)(2)-(3) (hospitals or CAHs).

67. 42 C.F.R. § 495.6(d)(1)(i)-(15)(i) (

> (1) Use computerized provider order entry (CPOE) for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines.
> (2) Implement drug-drug and drug-allergy interaction checks.
> (3) Maintain an up-to-date problem list of current and active diagnoses.
> (4) Generate and transmit permissible prescriptions electronically (eRx).
> (5) Maintain active medication list.
> (6) Maintain active medication allergy list.
> (7) Record all of the following demographics: (A) Preferred language. (B) Gender. (C) Race. (D) Ethnicity. (E) Date of birth.
> (8) Record and chart changes in the following vital signs: (A) Height. (B) Weight. (C) Blood pressure. (D) Calculate and display body mass index (BMI). (E) Plot and display growth charts for children 2 - 20 years, including BMI.
> (9) Record smoking status for patients 13 years old or older.
> (10) Report ambulatory clinical quality measures to CMS or, in the case of Medicaid EPs, the States.
> (11) Implement one clinical decision support rules relevant to specialty or high clinical priority along with the ability to track compliance with

of CPOE for medication orders and the documentation of the smoking status of patients thirteen years old or older.[68] The menu set[69] includes objectives such as incorporating clinical lab-test results into the record as structured data[70] and providing patients with timely electronic access to their health information.[71]

Since the final rule decreased the provider eligibility objectives by introducing the core set/menu set distinction, providers now face considerably less burdensome (outcome) measures. Take for example the core objective of using CPOEs for medication orders.[72] The proposed rule called for an eighty percent measure,[73] yet the final rule reduces the measure to "more than 30 percent of all unique patients with at least one medication in their medication list seen by the EP have at least one medication order entered

---

that rule.

(12) Provide patients with an electronic copy of their health information (including diagnostics test results, problem list, medication lists, medication allergies) upon request.

(13) Provide clinical summaries for patients for each office visit.

(14) Capability to exchange key clinical information (for example, problem list, medication list, allergies, and diagnostic test results), among providers of care and patient authorized entities electronically.

(15) Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.)

68. 42 C.F.R. § 495.6(d)(9)(i).

69. 42 C.F.R. § 495.6(e)(1)(i)-(10)(i):

(1) Implement drug-formulary checks.

(2) Incorporate clinical lab-test results into EHR as structured data.

(3) Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

(4) Send reminders to patients per patient preference for preventive/follow- up care.

(5) Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, and allergies) within 4 business days of the information being available to the EP.

(6) Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient if appropriate.

(7) The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

(8) The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.

(9) Capability to submit electronic data to immunization registries or immunization information systems and actual submission according to applicable law and practice.

(10) Capability to submit electronic syndromic surveillance data to public health agencies and actual submission according to applicable law and practice.

70. 42 C.F.R. § 495.6(e)(2)(i).

71. 42 C.F.R. § 495.6(e)(5)(i).

72. 42 C.F.R. § 495.6(d)(1)(i).

73. Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844 (proposed Jan. 13, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422, and 495).

using CPOE."[74] Similarly, the e-prescribing measure declined from seventy-five percent[75] to forty percent.[76] Exclusions apply when the objective is irrelevant or not cost-effective; for example, the same CPOE objective does not have to be complied with by an EP "who writes fewer than 100 prescriptions during the EHR reporting period."[77]

Hospital eligibility is determined by almost identical sets of objectives. Some EP Objectives are not carried over to reflect context or omission to reflect relevance. There are also some unique objectives such as the menu set objective to "[g]enerate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach."[78]

In general, EPs and hospitals demonstrate that they have complied with the meaningful use criteria through a CMS approved attestation process.[79] Later iterations of meaningful use likely will move that reporting to the EHR system itself.

As already noted these objectives and measures apply only to the first two years (Stage 1) of the program. Two additional stages are anticipated, with Stage 2 criteria to be published in late 2011 and Stage 3 criteria to appear in late 2013.[80] Together Stages 2 and 3 will demand more robust health information exchange (including orders and test results) and the ability of the data to better "follow" the patient.[81] Specifically, Stage 2, beginning in 2013, will expand Stage 1 criteria to encompass care delivery standards in the areas of disease management, clinical decision support, medication management, patient access to their own health information, transitions in care, quality measurement and research, and bi-directional communication with public health agencies.[82] Finally, Stage 3, beginning in 2015, likely will focus on decision support, self-management tools for patients, and improving population health outcomes.[83]

CMS is playing its cards closely as far as the ratcheting up of the ob-

---

74. 42 C.F.R. § 495.6(d)(1)(ii).

75. Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844.

76. 42 C.F.R. § 495.6(d)(4)(ii).

77. 42 C.F.R. § 495.6(d)(1)(iii).

78. 42 C.F.R. § 495.6(g)(4)(i).

79. 42 C.F.R. § 495.8; *see also* § 495.210.

80. Electronic Health Record Incentive Program, 75 Fed. Reg. 44, 314 (July 28, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422, 495).

81. *See* Emily Long, *Officials Defend Meaningful Use Standards as a Work In Progress*, NEXTGOV (Jul. 20, 2010), http://www.nextgov.com/nextgov/ng_20100720_9874.php?oref=topnews (reporting on Congressional testimony from Dr. Blumenthal and CMS's Tony Trenkle that Stages 2 and 3 will have stricter requirements).

82. *Id.*

83. Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844 (proposed Jan. 13, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422, and 495); Melinda Beewkes Buntin et al., *Health Information Technology: Laying the Infrastructure for National Health Reform*, 29 HEALTH AFF. 1214, 1219 (2010). *See generally* Electronic Health Record Incentive Program, 75 Fed. Reg. at 44,321-22 (additional detail regarding Stage 2 and 3).

jectives and measures in future iterations of the meaningful use regulations, stating that the criteria will be "consistent with anticipated developments in technology and providers' capabilities."[84] A notice of proposed rulemaking for Stages 2 and 3 is expected in the fourth quarter of 2011 and will focus on infrastructure and interoperability.[85] In the meantime and with regard to Stage 1, the scaled back objectives and measures may result in the current meaningful use criteria being more attuned to the actual use of EHR technologies by those physicians already using them.[86] In an interview published after the publication of the Proposed Rule, Dr. Blumenthal explained what he calls the "escalator problem,"

> We have to get providers on the escalator, get them moving up the escalator, keep them on the escalator toward more and more sophisticated and demanding uses of electronic technologies. We don't want them jumping off, we don't want them running back down in terror at what we've asked of them. But we also don't want the escalator to turn into one of those airport moving walkways where you end up after [a] long trip at precisely the same altitude as where you started.[87]

At the time of publication of the Final Rule Dr. Blumenthal noted how it "strikes a balance between acknowledging the urgency of adopting EHRs to improve our health care system and recognizing the challenges that adoption will pose to health care providers. The regulation must be both ambitious and achievable."[88] The unanswered question is whether HHS found that correct balance or whether the less ambitious first stage will end up jeopardizing the EHR initiative's sustainability.

B. Certification

As already explained, physician and hospital eligibility for the HITECH subsidy program is dependent upon meaningful use of certified health records. As a result and accompanying CMS's meaningful use rule, ONC has issued final rules setting out the standards for certification and

---

84. Fact Sheet: CMS Defines MU, *supra* note 59.

85. Diana Manos, *Government Planning for Less 'Rushed' Next Stages of Meaningful Use*, HEALTHCARE IT NEWS, Oct. 21, 2010, http://www.healthcareitnews.com/news/ government-planning-less-rushed-next-stages-meaningful-use.

86. *See generally* Hogan & Kissam, *supra* note 2, at 603.

87. David J. Brailer, *Guiding the Health Information Technology Agenda*, 29 HEALTH AFF. 588, 589 (2010).

88. Blumenthal & Tavenner, *supra* note 6, at 504.

certification processes for EHR products.[89] In CMS's words, "Providers and patients must be confident that the electronic health information technology (health IT) products and systems they use are secure, can maintain data confidentially, can work with other systems to share information, and can perform a set of well-defined functions."[90]

While the meaningful use rule applies to providers who wish to benefit from stimulus funding, the Certification rule applies to the technology they will use.[91] Thus, this latter rule[92] provides EHR vendors with the minimum specifications necessary to build and have certified an EHR system.[93] Specifications include; the ability to record and chart vital signs,[94] the maintenance of active medication lists,[95] the maintenance of medication allergy lists,[96] the ability to include laboratory test results,[97] and the capability to generate lists of patients with specific conditions.[98] The rule applies to both EHRs and modular systems that satisfy one or more but not all criteria.[99]

As an example of the required functionality of a certified EHR, consider drug interactions. The relevant EP Core Set Meaningful Use Objective is the implementation of drug-drug and drug-allergy interaction

---

89. *See generally* Fact Sheet: CMS Defines MU, *supra* note 59.

90. *Standards and Certification*, U.S. DEP'T. HEALTH AND HUMAN SERVICES, http://healthit.hhs.gov/portal/server.pt?open=512&objID=1153&mode=2 (last updated Oct. 6, 2010).

91. Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 44,590 (July 28, 2010) (to be codified 45 C.F.R. pt. 170).

> The purpose of this final rule, therefore, is to adopt standards, implementation specifications, and certification criteria to test and certify that a Complete EHR or EHR Module provides certain capabilities, and where applicable, to require that those capabilities be implemented in accordance with adopted standards and implementation specifications. The adopted standards, implementation specifications, and certification criteria were not intended to impose independent requirements on the entities using Certified EHR Technology. Unlike certain other regulatory requirements to which eligible professionals or eligible hospitals may be subject, it is not within the intended scope of this final rule to specify the requirements for entities using Certified EHR Technology.

92. 45 C.F.R. § 170 (2010).

93. *See Certification Programs*, U.S. DEP'T. HEALTH AND HUMAN SERVICES, http://healthit.hhs.gov/portal/server.pt?open=512&objID=2884&parentname=CommunityPage&parentid=357&mode=2&in_hi_userid=12059&cached=true (last updated Dec. 16, 2010); Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 33,590.

94. 45 C.F.R. § 170.302(f).

95. 45 C.F.R. § 170.302(d).

96. 45 C.F.R. § 170.302(e).

97. 45 C.F.R. § 170.302(h).

98. 45 C.F.R. § 170.302(i).

99. 45 C.F.R. §170.300 (in which case to qualify the meaningful user would have to be using modules that together satisfy all the certification criteria).

checks,[100] while the measure is that "The EP has enabled this functionality for the entire EHR reporting period."[101] The parallel certification criterion for drug-drug and drug-allergy interaction is: "[a]utomatically and electronically generate and indicate in real-time, notifications at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, and computerized provider order entry (CPOE)."[102]

Ironically, given the error-reducing goal of EHR adoption, the certification standard does not expressly address the issue of errors in EHRs themselves and their potential adverse effect on patient safety.[103] In February 2009, a device regulator for the Food and Drug Administration ("FDA") updated the HIT Policy Committee on a series of HIT adverse events including EHR data errors and misidentification of patients.[104] Although there was no formal reporting system the FDA had recorded 260 "HIT-related malfunctions" in the preceding two years.[105] Potential regulatory responses range from post-market surveillance to full FDA device premarket approval.[106] The committee, although accepting of a Meaningful Use Stage 2 reporting or feedback function that would tag EHR errors, believed that FDA regulation would inhibit innovation and increase costs.[107] There have been press reports that the FDA and ONC continue to be at odds as to the correct path to follow.[108]

A single certification body, the Certification Commission for Health Information Technology ("CCHIT"),[109] had existed since the Bush era (though, of course, with little work to do). However, ONC was determined to have multiple bodies qualified to provide certification. In mid-2010 ONC introduced a temporary certification process that enabled providers

---

100. 42 C.F.R. § 495.6(d)(2)(i) (2010).

101. 42 C.F.R. § 495.6(d)(2)(ii).

102. 45 C.F.R. §170.302(a)(1).

103. *See generally* Nicolas P. Terry, *When the "Machine That Goes 'Ping'" Causes Harm: Default Torts Rules and Technologically-Mediated Health Care Injuries*, 46 ST. LOUIS U. L. J. 37, 37-59 (2002).

104. *HIT Safety, Hearing before the Certification/Adoption Workgroup of the Office of the National Coordinator for Health Information Technology HIT Policy Committee* (Feb. 25, 2010) (testimony of Dr. Jeffrey Shuren, M.D., Director of FDA's Ctr. for Devices and Radiological Health), *available at* http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_910717_0_0_18/3Shuren_Testimony022510.pdf.

105. *Id.*

106. *See generally Overview of Device Regulations*, FOOD AND DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm (last updated Aug. 31, 2009).

107. Mary Mosquera, *HHS Panel Endorses Patient Safety Database*, GOV'T HEALTH IT (April 22, 2010), http://govhealthit.com/newsitem.aspx?nid=73573.

108. *See, e.g.*, Fred Schultz & Emma Schwartz, *FDA, Obama Digital Medical Records Team at Odds over Safety Oversight*, HUFFINGTON POST INVESTIGATIVE FUND (Aug. 3, 2010, 5:07 PM), http://huffpostfund.org/stories/2010/08/fda-obama-digital-medical-records-team-odds-over-safety-oversight.

109. CERTIFICATION COMM'N FOR HEALTH INFO. TECH., http://www.cchit.org/ (last visited Dec. 30, 2010).

and hospitals to implement the technology necessary to qualify for Stage 1 Meaningful Use incentive payments during the first year of the program.[110] The regulation provided for ONC-Authorized Testing and Certification Bodies ("ONC-ATCB") [111] and detailed the process that testing agencies should take to become one of these certifying bodies.[112] That temporary process sun-sets in December 2011 and will be replaced by a permanent certification program. This latter also provides for post-certification surveillance.[113] On August 30, 2010, ONC announced its first two ONC-ATCBs, CCHIT and the Drummond Group.[114] On September 17, 2010, ONC announced a third, InfoGard Laboratories, Inc.[115] Subsequent announcements have increased the number of ATCBs to six.[116] The ONC web site now features a searchable listing of all EHRs and EHR Modules that have been tested and certified under the Temporary Certification Program; the so-called Certified HIT Product List ("CHPL").[117] As one HHS consultant noted, the new rule "really filled the gap for providers," and provides security for their EHR adoption since "they'll have a product so they'll be able to get their incentive payments."[118]

The temporary program is due to expire at the end of 2011.[119] Subsequently, a permanent program will divide the responsibilities of testing and certifying EHR products between two organizations: the National Institute of Standards and Technology would be responsible for testing the "compe-

---

110. Establishment of the Temporary Certification Program for Health Information Technology, 75 Fed. Reg. 36,158 (Jun. 24, 2010) (to be codified at 45 C.F.R. pt. 170); *see also Certification Programs*, *supra* note 93

111. Press Release, U.S. Dep't of Health and Human Services, ONC Issues Final Rule to Establish the Temporary Certification Program Health Record Technology (June 18, 2010), *available at* http://www.hhs.gov/news/press/2010pres/06/20100618d.html.

112. 45 C.F.R. § 170.401 (2010).

113. Establishment of the Permanent Certification Program for Health Information Technology, 76 Fed. Reg. 5,1262 (Jan. 7, 2011), http://origin.www.gpo.gov/fdsys/pkg/FR-2011-01-07/pdf/2010-33174.pdf.

114. Frank Irving, *ONC Names CCHIT and Drummond Group as Initial EHR Certification Bodies*, THE POLITICS OF HEALTH CARE (Sep. 1, 2010, 10:35 AM), http://community.advanceweb.com/blogs/ot_11/archive/2010/09/01/onc-names-cchit-and-drummond-group-as-initial-ehr-certification-bodies.aspx.

115. Mary Mosquera, *ONC Names InfoGard as Third EHR Certifier*, GOV'T HEALTH IT (Sep. 17, 2010), http://www.govhealthit.com/newsitem.aspx?nid=74676; *see also InfoGuard Laboratories Approved to Certify EHR*, INFOGUARD (Sept. 20, 2010) http://www.infogard.com/ig.nsf/html/Approved+ONC-ATCB+Laboratory.

116. *ONC-Authorized Testing and Certification Bodies*, ONC, http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3120 (last visited Jan. 8, 2011).

117. *Certified Health IT Product List*, ONC, http://onc-chpl.force.com/ehrcert/CHPLHome (last visited Jan. 8, 2011).

118. Joseph Conn, *Certification Proclamation; HHS Unveils Process to Help Providers with IT Subsidies for EHRs*, MOD. HEALTHCARE, March 8, 2010, at 8.

119. Establishment of the Temporary Certification Program for Health Information Technology, 75 Fed. Reg. 36,158, 36161, 36184 (Jun. 24, 2010) (to be codified at 45 C.F.R. pt. 170).

tency" of the product for usability, while one of the ONC-ATCBs will provide the actual certification.[120]

In spite of a lingering concern that ONC gave up too much of the Proposed Rule's ground in the Final Meaningful Use Rule, examined together, the meaningful use and certification regulations are a noteworthy accomplishment, particularly given the collapsed timetable that HHS was forced to use.

V. IMPROVING QUALITY: A BROADER FRAME FOR MEANINGFUL USE

No doubt it was fortuitous that EHR, rather than some other public works project, was "shovel-ready" as the 2009 economic stimulus package was being constructed. The privatized governance models and market-led approaches to EHR adoption of the Bush Administration had failed to counter widespread market failure. However, the Administration's structured cheerleading had moved some important conceptual and technical balls down the field. It was also key that from 2004 to 2009, the major political issue of public funding aside, EHR adoption work had found broad nonpartisan support within Congress and among health care and HIT industries. The tipping point was likely the existence of the 2005 and 2007 *Wired for Health Care Quality Act* texts that could be reworked into the new HITECH legislation within the ARRA timetable.[121]

There is no doubt that the initial and still primary goal of HITECH is the stimulation of EHR adoption. In defraying some of the costs associated with implementing EHRs, we should see a reduction in the historical barriers to EHR adoption especially among small physician office practices.[122]

However, even as an economic stimulus during a time of financial crisis, $27 billion is an enormous sum to pay out to economically successful private individuals and entities. Further, this is third-party investment that potentially will bring considerable and measurable financial benefits to healthcare providers. For example, it has been estimated that if health care providers introduced "best-practice" IT platforms they could see savings of $40 billion annually.[123] As EHR penetration increases and meaningful use and related criteria expand to include analytical tools designed to test the quality outcomes associated with electronic records and other HIT the true

---

120. *Id.;* Joseph Goedert, *Proposed Certification Rule Changes Game: EHR Testing, Certification to be Split*, HEALTH DATA MGMT., April 2010, at 22.

121. Wired for Health Care Quality Act 2005, S. 1418, 109th Cong. (2005), *available at* http://frwebgate.access.gpo.gov/cgibin/getdoc.cgi?dbname=109_cong_bills&docid=f:s1418rfh.txt.pdf; Wired for Health Care Quality Act 2007, S. 1693, 110th Cong. (2007), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:s1693rs.txt.pdf.

122. Hogan & Kissam, *supra* note 2, at 601.

123. Francois M. Laflamme et al., *Reforming Hospitals with IT Investment*, MCKINSEY ON BUS. TECH., Summer 2010, at 27,

quality picture should emerge. Today, however, the picture lacks clarity with mixed messages as to the quality impact of EHRs and the suitability of existing metrics.[124]

In 1991, and again in a 1997 revision, the Institute of Medicine had called for a nationwide implementation of EMRs.[125] In 2001, in its canonical *Crossing the Quality Chasm*, the Institute declared, "IT must pay a central role in the redesign of the health care system if a substantial improvement in health care quality is to be achieved during the coming decade."[126] With such calls to action broadly ignored, it was no surprise that almost a decade later the HITECH-funded HHS took a broad view of HIT and how to incentivize its use. Future headlines might refer to EHRs but the department's initiative is about HIT more generally, including CPOEs, CDSS systems, and the networks needed to bind them together.

In 2009, Dr. Blumenthal had remarked that it would be "tempting to measure HITECH's payoff . . . in narrow terms — for example, the numbers of computers newly deployed in doctors' offices and hospital nursing stations."[127] "That," he argued, "does not seem to be Congress's intent."[128] Rather, "[i]t wants improvements in health and health care through the use of HIT."[129] Indeed, it is difficult to see the Meaningful Use Proposed Rule's ambitiously high bar for funding as anything other than a determination by HHS to play hardball with the stimulus funds, no doubt recognizing that it had been presented with a once in a generation opportunity to bring about major change.

Not surprisingly therefore, the inclusion in HITECH of the elegant phrase "meaningful use" together with the emerging political reality of broader health care reform under the Obama administration discloses a considerably broadened agenda. As described by CMS, "Ultimately, consistent with other provisions of law, Meaningful Use of certified EHR technology should result in health care that is patient-centered, evidence-based, prevention-oriented, efficient, and equitable."[130] Once again, however, Dr. Blumenthal extracted the true value of meaningful use, "It is an incredibly powerful concept. It's a brilliant use of language. It's simple but extremely meaningful . . . ."[131] Indeed, the meaningful use structure transcends any

---

124. Spencer S. Jones et. al., *Electronic Health Record Adoption and Quality Improvement in US Hospitals*, 16(12 Special Issue) Am. J. Managed Care SP64-SP71 (2010).

125. Paul C. Tang & W. Ed Hammond, *A Progress Report on Computer-Based Patient Records in the United States*, THE COMPUTER-BASED PATIENT RECORD, 189 (Richard S. Dick et al. eds., revised ed. 1997).

126. INSTITUTE OF MED., *supra* note 9, at 165.

127. Blumenthal, *supra* note 2, at 1477-78.

128. *Id.*

129. *Id.*

130. Electronic Health Record Incentive Program, 75 Fed. Reg. 1,844, 1,852 (proposed Jan. 13, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422, and 495).

131. Brailer, *supra* note 87, at 588.

expected accountability-for-stimulus-funds model. Access to funding, however imperfect and incomplete, was accomplished with 2010's health care reform. At stake with the HITECH billions is the new health care trinity of "quality, efficiency, and patient safety."[132]

Indeed, the key to understanding where HHS wishes to take HITECH is to be found in yet another of Dr. Blumenthal's comments, "The passage of the Patient Protection and Affordable Care Act of 2010[PPACA][133] marks a new era in American health care. Yet in many ways, this era began more than a year earlier, with the passage of . . . [HITECH]."[134]

This reading places EHR subsidies, HITECH, and meaningful use in a subtly different frame. Recall that PPACA eschewed a public option let alone a single-payer model.[135] For these, among many other reasons, it is arguable that the legislation fell short of fundamental health care reform.[136] On the other hand, it did introduce quite fundamental health care financing and insurance reforms. HHS likely believes that HITECH provisions can be leveraged both to operationalize some PPACA goals and to tease out some structural reforms not directly provided for by the broader health care reform legislation. Dr. Blumenthal and his HHS colleagues have promoted the synergy between their HIT work and PPACA's goals of improving quality,[137] reducing costs,[138] and accelerating outcomes research.[139] This is ambition on a different scale from a national roll out of EHRs.

If there is an HIT Trojan horse at work here, it is likely to disgorge its forces in the cause of health quality. The "Meaningful Use" matrix will lead to changes in established health care workflows and imagines the future of health care as one based on outcomes and effectiveness research and on evidence-based medicine.[140] As noted in a recent *Bipartisan Policy Center* report,

> HIT has the potential to facilitate many types of improvements in health care delivery, including reduc-

---

132. *See* Fact Sheet: CMS Proposes, *supra* note 41.

133. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (March 23, 2010) *amended by* Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (March 30, 2010) (to be codified at various sections of 42 U.S.C.).

134. Buntin et al., *supra* note 83, at 1214.

135. Not coincidentally HITECH also eschews a "public option" such as the federal government building a national EHR. *See generally* Margarit Gur-Arie, *The Government EHR*, ON HEALTH CARE TECH. BLOG (Aug. 22, 2010, 10:34 PM), http://onhealthtech.blogspot.com/2010/08/government-ehr.html.

136. *See, e.g.*, Paul Krugman, *Why the Public Option Matters*, THE CONSCIENCE OF A LIBERAL, (Sept. 8, 2009, 4:56 PM), http://krugman.blogs.nytimes.com/2009/09/08/why-the-public-option-matters/.

137. Buntin et al., *supra* note 83, at 1215-16.

138. *Id.* at 1216-17.

139. *Id.* at 1217-18.

140. *See* Goedert, *supra* note 52, at 40.

> ing medical errors; improving access to timely information, thereby enabling patients to become more actively engaged in – and responsible for – their own care; reducing paperwork and other administrative costs; and collecting and disseminating quality metrics that can improve the evidence base for medical decisions.[141]

PPACA itself includes several outcomes initiatives.[142] Potentially the most important is the establishment and funding of the nonprofit Patient-Centered Outcomes Research Institute ("PCORI").[143] HHS-led HIT will be a crucial factor in collecting and disseminating such research.[144] Regarding publicly-funded care PPACA also mandated an HHS plan for modernizing CMS computer and data systems with particular focus on outcomes.[145]

The extent to which HITECH-funded HIT will reduce costs is more of an open question. PPACA itself makes only modest attempts to bend the cost curve.[146] Indeed, some analysts argue that the cost curve has bent in the wrong direction.[147] Notwithstanding, PPACA calls for a voluntary gain-sharing program called Medicare Shared Savings,[148] a pilot program on Medicare payment bundling,[149] and the "Hospital Readmissions Reduction program" that will decrease hospital Medicare payments for preventable readmissions.[150] The most that can be said is that a patient record focused

---

141. MCKETHAN ET AL., *supra* note 9, at 19.

142. *See generally* STACEY MCMORROW, ROBERT WOOD JOHNSON FOUNDATION/URBAN INSTITUTE, WILL THE PATIENT PROTECTION AND AFFORDABLE CARE ACT OF 2010 IMPROVE HEALTH OUTCOMES FOR INDIVIDUALS AND FAMILIES? (2010), *available at* http://www.urban.org/UploadedPDF/412127-2010-health-outcome.pdf.

143. 42 U.S.C.A. § 1320e(b) (West 2010). *See generally* Editorial, *Is Newer Better? Not Always*, N.Y. TIMES, Sept. 11, 2010, at WK10, *available at* http://www.nytimes.com/2010/09/12/opinion/12sun1.html. *See also* Peter J. Neumann & Milton C. Weinstein, *Legislating against Use of Cost-Effectiveness Information*, 363(16) NEW ENG. J. MED. 1495 at 1495 (2010), *available at* http://www.nejm.org/doi/pdf/10.1056/NEJMp1007168.

144. *See, e.g.*, 42 U.S.C.A. § 1320e(c)-(d).

145. 42 U.S.C.A. §10330 (2010). CMS has responded with a detailed plan that promises quality improvements. *See, Modernizing CMS Computer and Data Systems to Support Improvements in Care Delivery*, CMS (Dec. 23 2010), http://www.cms.gov/InfoTechGenInfo/downloads/CMSSection10330Plan.pdf.

146. Implicit attempts at improving the cost picture primarily are a bet on preventative care. *See, e.g.*, Howard K. Koh & Kathleen G. Sebelius, *Promoting Prevention through the Affordable Care Act*, 363 NEW ENG. J. MED. 1296 (2010).

147. JEANNE S. RINGEL ET AL., RAND CORP., RB-9514, POLICY BRIEF: ANALYSIS OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT (H.R. 3590) (2010), *available at* ,http://www.rand.org/pubs/research_briefs/2010/RAND_RB9514.pdf (estimating a 2% increase in national health care spending between 2014 and 2019). *Cf.* Peter R. Orszag & Ezekiel J. Emanuel, *Health Care Reform and Cost Control*, 363 NEW ENG. J. MED. 601, 603 (2010).

148. 42 U.S.C.A. § 1395jjj (West 2010).

149. 42 U.S.C.A. § 1395cc-4.

150. 42 U.S.C.A. § 1395ww(q). *See generally* Orszag & Emanuel, *supra* note 147

HIT system will support such programs. There are some estimates of savings that will flow directly from system-wide implementation of primary care EHRs: $85,000 per provider or some $70 billion.[151] More important are the quality and cost reduction programs that are not yet legislated but likely will be necessary going forward. As Fortin and Zywiak note, "Payment for health care in the United States is on the cusp of a rapid shift from payment based on volume and intensity of service to a model that ties payment to high-quality and tightly coordinated care."[152]

An additional area where HITECH and PPACA intersect is in the latter's requirements of transparency and patient empowerment. For example, the Hospital Value-Based purchasing program requires web-based information for stakeholders including patients,[153] while the health reform legislation requires HHS to open a web portal "through which a resident of any . . . state may identify affordable health insurance coverage options in that state."[154] HHS has issued interim regulations regarding its new web portal[155] and already has opened its one-stop-shop for healthcare website.[156] Related initiatives such as the patient bill of rights that is being constructed out of the insurance reforms (for example, the prohibition of preexisting condition exclusions),[157] the new Office of Consumer Information and Insurance Oversight,[158] can all leverage improved HIT.

Although there may be some exaggeration of the role of HITECH in facilitating more general health care reform, there is truth in Dr Blumenthal's message that "[a]lthough HITECH may be viewed narrowly as legislation to stimulate the adoption of health information technology . . . it is better understood as an essential foundation for our broader efforts to restructure health care delivery."[159]

(detailing the cost-control elements of ACA and calling for a reduction in health care cost inflation).

151. MCKETHAN ET AL., *supra* note 9, at 20.

152. Fortin & Zywiak, *supra* note 32, at 54. *See also* Steve Lohr, *The Agenda Behind Electronic Health Records*, BITS, (May 9, 2010, 6:29 PM), http://bits.blogs.nytimes.com/2010/05/09/the-agenda-behind-electronic-health-records/ ("The electronic health record, in Dr. Blumenthal's view, is a tool – and yes, a stalking horse – for bringing measurement, data-based decision-making and accountability to the practice of medicine. The computerized patient record, then, is a step toward changing compensation of medicine and the economics of health care.").

153. 42 U.S.C.A. § 1395ww(b)(3)(B)(x)(I).

154. 42 U.S.C.A. § 18003(a) (West 2010).

155. 45 C.F.R. § 159 (2010).

156. HEALTHCARE.GOV, http://www.healthcare.gov/ (last visited Dec. 30, 2010).

157. *See, e.g.*, 45 C.F.R. §§ 144, 146-47 (2010). *See generally Fact Sheet: The Affordable Care Act's New Patient's Bill of Rights*, HEALTHREFORM.GOV (June 22, 2010), http://www.healthreform.gov/newsroom/new_patients_bill_of_rights.html.

158. *The Office of Consumer Information and Insurance Oversight*, U.S. DEP'T HEALTH AND HUMAN SERVICES, http://www.hhs.gov/ociio/index.html (last visited Dec. 30, 2010).

159. Buntin et al., *supra* note 83, at 1214.

VI. CONCLUSION

The Obama Administration has recently "re-branded" the Patient Protection and Affordable Care Act ("PPACA") as the pithier Affordable Care Act ("ACA").[160] Bill Sage has argued that even this truncated version is uninspiring and lacks "expressive value," preferring a title such as "Americare."[161] As a title, the *Health Information Technology for Economic and Clinical Health Act* is already a better descriptor than what could have been; say "An Act to Subsidize Health Records."

Whatever its name the stimulus-funded EHR program is indeed a "transformational opportunity."[162] Of course, what is unknown is whether the stimulus program will produce dramatic or, for that matter, even relatively modest gains in EHR penetration. Some of the barriers are notable. Thirty to forty percent of hospitals were unlikely to meet qualifying requirements for Stage 1 incentives under the proposed rule.[163] The final rule will increase that number, but it is unknown by how much.[164] The barrier to funding is not simply financial; cultures must be challenged, personnel hired, EHR and HIT strategic plans must be developed.[165] Longer term, the extent of the shortfall between the stimulus funds and the TCO of the records and related technologies must be managed by EPs and hospitals.[166] Budgets will have to be developed to support the purchase of the next generations of HIT that are bound to follow.

Even with the incentive payments defraying initial costs, the investment by providers and hospitals remain considerable. To meet the Meaningful Use standards, hospitals and providers with existing EHRs will have a specific need for technological support that can effectively integrate the new "certified" EHR systems with existing systems to meet Meaningful Use[167] – a particular challenge for those with home-grown IT systems. While the incentive is generous, the upfront cost of implementation and continuing maintenance likely will remain problematic for hospital and

---

160. *The Affordable Care Act*, WHITEHOUSE.GOV, http://www.whitehouse.gov/health reform/healthcare-overview (last visited Dec. 30, 2010).

161. William M. Sage, *Why The Affordable Care Act Needs A Better Name: 'Americare'*, 29 HEALTH AFF. 1496, 1496 (2010).

162. Blumenthal & Tavenner, *supra* note 6, at 501.

163. Joseph Conn, *Hospital EMR Reimbursements at Risk: HIMSS*, MODERNHEALTHCARE.COM (May 21, 2010, 12:45 PM), http://www.modernhealthcare.com/apps/pbcs.dll/article?AID=/20100521/NEWS/100529983.

164. *See e.g.*, Pear, *supra* note 51 (stating that the president of the American Hospital Association said the final rules were an improvement over the original proposal, but that he was concerned that many hospitals would be unable to obtain federal aid).

165. *See generally* Kimberley Klein, *So Much to Do, So Little Time*, J. HEALTHCARE INFO. MGMT., Winter 2010, at 31.

166. *See generally* Catherine Arnst, *Doctors Not in Stampede to Go Digital*, BOS. GLOBE, May 4, 2010, at 1.

167. DesRoches & Rosenbaum, *supra* note 44, at 1153.

physician providers. For example, it has been estimated that "US hospitals will need to spend approximately $120 billion" while the ARRA subsidies will "offset only approximately 15 to 20 per cent of total expenditures . . . . A spending gap of about $60,000 to $80,000 a bed."[168]

Between one-third to two-thirds of health information system implementations fail.[169] This begs another difficult question: what happens in 2016 and beyond—will the EHR project be sustainable after funding ceases?[170] Can cultures and investment strategies be changed in such a short timeframe? After all, more limited summary records systems in Australia and the UK[171] have either failed or suffered massive cost overruns.[172] And, in the US the only two successful implementations of comprehensive EHRs have been through the Veterans Administration ("VA") [173] and within Kaiser Permanente;[174] institutions that are fully vertically integrated, *de facto* single-payer systems, and so quite unlike most of the U.S. health care system.

At its most literal level "meaningful use" is an appropriate (and fascinating) outcome measure for the investment in HIT provided by the federal stimulus package. The far more significant level is the tying together of HIT, health quality outcomes, and health care financing. If that process seeps into the culture then HITECH's mixture of plenty of carrots and a few

---

168. Laflamme et al., *supra* note 123, at 28.

169. Klein, *supra* note 165, at 32.

170. The success of the project will also depend on changes in the supply side. Currently there are 300 to 400 EHR providers in the United States. *See* Olen, *supra* note 16. Efficiencies and cost reductions likely will depend on new technology models such as low(er) cost web services technologies or through consolidation around dominant, large scale suppliers. *See e.g.*, Steve Lohr, *I.B.M.'s Strategy in Electronic Health Records*, BITS (Aug. 5, 2010, 11:00 AM), http://bits.blogs.nytimes.com/2010/08/05/i-b-m-s-strategy-in-electronic-health-records/?ref=technology (describing IBM's linkage with ActiveHealth Management, a subsidiary of health insurer Aetna); *HP Health: EHReadySM Program*, HEWLETT PACKARD, http://h71036.www7.hp.com/enterprise/us/ehready-program.html (last visited Dec. 30, 2010); *Healthcare IT Solutions*, GENERAL ELECTRIC (GE) HEALTHCARE, https://www2.gehealthcare.com/portal/site/usen/menuitem.f76842a5b0610162d6354a1074c84130/?vgnextoid=cc8da52fcea2d110VgnVCM100000258c1403RCRD (last visited Dec. 30, 2010); NEXTGEN HEALTHCARE, http://www.nextgen.com/ (last visited Dec. 30, 2010); ALLSCRIPTS, http://www.allscripts.com/ (last visited Dec. 30, 2010). There is already a measurable increase in the priority of EHR implementation among HIT professionals. *See* EMBARCADERO TECHNOLOGIES, TECH NOTE: HEALTHCARE DATA MANAGEMENT SURVEY REPORT 3 (2010), *available at* http://www.embarcadero.com/images/dm/healthcare-it-survey-report-2010.pdf.

171. *Summary Care Record (SCR)*, NHS CONNECTING FOR HEALTH, http://www.connectingforhealth.nhs.uk/systemsandservices/scr (last visited Dec. 30, 2010).

172. Nicolas P. Terry & Leslie P. Francis, *Ensuring the Privacy and Confidentiality of Electronic Health Records*, 2007 U. ILL. L. REV., 681, 688-90 (2007).

173. *See generally* David Brown, *VA Takes the Lead in Paperless Care*, WASH. POST, Apr. 10, 2007, at HE01.

174. *See e.g.*, Press Release, Kaiser Permanente, Kaiser Permanente Honored for Electronic Health Record Implementation (Mar. 2, 2010), *available at* http://xnet.kp.org/newscenter/pressreleases/nat/2010/030210stage7.html.

sticks will have paid astounding dividends. Alas, we are unlikely to learn for several years whether HITECH and its Meaningful Use touchstone will have transcended the status of a "public works project,"[175] (albeit a massive one) and transformed our health care system. Meaningful use creates a powerful linkage to general health care reform. However, there is one connection that no one wants to see: the failure of both HITECH and PPACA to spur outcomes that neither health care nor HIT markets have achieved in the past.

175. Kleinke, *supra* note 20, at 1257.