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USING THE LAW TO CORRECT THE MARKET: THE ELECTRONIC HEALTH RECORD (EHR) INCENTIVES PROGRAM

Bryan Cleveland[*]

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I. INTRODUCTION

Technology is ubiquitous for managing information throughout the modern economy. It has improved efficiency and the sharing of information for many industries, and much of technology scholarship now focuses on how best to manage this newfound ability. Despite this general trend, one industry has remained entrenched against the use of technology for years: health care.

Information is at the center of the health care industry, which must coordinate patient care between physicians, hospitals, pharmacies, and a host of other providers and related services. Despite the need for better coordination of information, the industry continues to use paper records with few exceptions.[1] Vendors have entered the health care market offering systems of electronic health records ("EHRs") to facilitate storing and sharing information, but several factors deterred providers from adopting these systems.[2]

Finding that the lack of EHRs to be a failure of the market, the federal government enacted law to force the conversion to technology.[3] This law, called the Health Information Technology for Economic and Clinical Health (HITECH) Act, was passed in 2009 and has since been implemented.[4] The industry has received the resulting regulations with skepticism, and the literature on health information technology ("IT") disputes whether government interference in the health industry is truly worth the burdens it has imposed.[5]

This note proposes that while EHRs offer some of the benefits that proponents hoped for, the law unintentionally increased administrative burdens of transitioning and imposed unnecessary costs. Part II

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1. David Blumenthal & Marilyn Tavenner, *The "Meaningful Use" Regulation for Electronic Health Records*, 363 NEW ENG. J. MED 501, 501 (2010) ("We have years of professional agreement and bipartisan consensus regarding the value of EHRs. Yet we have not moved significantly to the availability of EHRs from a few large institutions to the smaller clinics and practices where most Americans receive their health care.").

2. *See* CONG. BUDGET OFFICE, EVIDENCE ON THE COSTS AND BENEFITS OF HEALTH INFORMATION TECHNOLOGY 19 (2008), https://www.cbo.gov/sites/default/files/05-20-healthit.pdf [http://perma.cc/L9P7-6XDM] (All of the incentive program regulations have cited this study to justify the benefits. *See, e.g.*, Electronic Health Record Incentive Program, 75 Fed. Reg. 44,314, 44,561 (July 28, 2010)).

3. David Blumenthal, *Wiring the Health System — Origins and Provisions of a New Federal Program,* 365 NEW ENG. J. MED 2323, 2323 (2011) ("Two basic arguments justified intervention by the federal government . . . . The first was a conviction that information technology could improve health and health care for the American people. The second was that major problems inhibit the spread of health information technology in ways that create the need for government remedies.").

4. *See* Health Information Technology for Economic and Clinical Health Act of 2009, Pub. L. No. 111-5, 123 Stat. 112, http://www.healthit.gov/sites/default/files/hitech_act_excerpt_from_arra_with_index.pdf [http://perma.cc/5UYX-ZJBW] [hereinafter HITECH Act].

5. *See infra* Part IV.

examines the components of the regulations, including the meaningful use requirement, the certification program, and the changes to both as the regulations have developed. Part III surveys the current data available on the results of the incentives program. Part IV examines the policy rationale that regulators have used in designing regulation. Part V reviews the proposed changes for the next phase of the regulation, analyzes and evaluates the policy rationale behind the regulation, and makes recommendations for future improvement. Part VI concludes, proposing that regulators could achieve greater benefits by placing more emphasis on quality outcomes from the use of EHRs and less emphasis on prescribing specific acts.

II. THE LAW AND THE REGULATION OF EHRS

A. The HITECH Act

The law shifting the health care industry to adopt EHRs, the HITECH Act, was part of the American Recovery and Reinvestment Act of 2009.[6] This act has three main functions. First, it officially recognizes the Office of the National Coordinator for Health Information Technology ("ONC"), which President George W. Bush created by executive order in 2004.[7] Second, it creates several programs for developing health IT infrastructure, including incentivizing the purchase of certain EHRs by Medicare and Medicaid providers.[8] Finally, it strengthens the privacy and security requirements in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").[9] This paper examines the second function through the lens of ONC and the Centers for Medicare & Medicaid Services ("CMS") regulations.

Two specific terms of the law create the regulations that this note examines: "meaningful use" and "certified."[10] These are the key terms because Section 4101 of the HITECH Act adds financial rewards for eligible professionals and hospitals that adopt and achieve meaningful use of certified EHRs.[11] The term "meaningful use" is the source of CMS's authority to determine what physicians and hospitals must do with EHRs to be eligible for financial assistance.[12] The reference to

6. *See* HITECH Act, *supra* note 4.

7. *See* 42 U.S.C. § 300jj-11 (2012); *see also* Exec. Order No. 13335, 3 C.F.R. § 13335 (creating ONC by executive order).

8. *See* 42 U.S.C. § 300jj, § 1395w-4 (2012).

9. *See id.* § § 17921–17953.

10. For further detail on the law, see C. STEPHEN REDHEAD, CONG. RESEARCH SERV., R40161, THE HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH (HITECH) ACT (2009).

11. *See* 42 U.S.C. § 1395w-4(o)(2)(A)(i) (2012).

12. 42 U.S.C. § 1395w-4(o)(2)(A)(i) ("The eligible professional demonstrates . . . that during such period the professional is using certified EHR technology in a meaningful man-

"certified" EHRs is the source of ONC's regulation of vendors and the EHRs they develop.[13] Both CMS and ONC have coordinated their regulations, typically issuing them together, and authorizing all of them on the basis of these two terms.[14]

The HITECH Act mandates a financial rewards program after enactment until 2015, and then it switches to penalties in Medicare and Medicaid reimbursement rates for entities eligible for the rewards program that have not joined.[15]

B. Meaningful Use Regulations

CMS issued the regulations implementing the meaningful use requirement on July 28, 2010.[16] In general, the agency defined meaningful use as using EHRs to "[i]mprove quality, safety, efficiency, and health disparities, [e]ngage patients and family, [i]mprove care coordination, and population and public health, [and] [m]aintain privacy and security of patient health information."[17] The agency created the regulation for physician and hospitals to achieve the meaningful use requirement over time in three stages.[18] In 2010, Stage 1 focused on capturing data and implementing tools for later use in health information exchange.[19] In 2011, Stage 2 was supposed to demand higher data quality at the point of care and establish health information exchanges.[20] Finally, in 2013, Stage 3 was supposed to improve health outcomes.[21]

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ner, which shall include the use of electronic prescribing as determined to be appropriate by the Secretary."). *See* 42 U.S.C. § § 1395f(l)(3)(A), w-4(n)(1) (for hospitals); *see also* Electronic Health Record Incentive Program, 75 Fed. Reg. 44,314, 44,3166 (July 28, 2010).

13. *See* Electronic Health Record Incentive Program, 75 Fed. Reg. at 44,317. Technically, the authority is given to the Secretary of Health and Human Services, who delegated the authority to ONC.

14. *See id.* at 44,316; *see also infra* Part V.A. CMS and ONC are decoupling these regulations going forward.

15. *See* 42 U.S.C. § 1395w-4(a)(7). Congress modified these penalties, but their modifications do not take effect until after 2015. *See* Medicare Access and CHIP Reauthorization Act ("MACRA"), Pub. L. No. 114-10, 129 Stat. 87 (2015) (creating a "Merit-based Incentive Payment System" beginning in 2019). CMS and ONC are attempting to make compliance easier in the meanwhile to avoid penalties. *See* Electronic Health Record Incentive Program — Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 Fed. Reg. 62,762, 62,906 (Oct. 16, 2015).

16. Electronic Health Record Incentive Program, 75 Fed. Reg. at 44,316.

17. *See Meaningful Use Definition & Objectives*, HEALTHIT.GOV, http://www.healthit.gov/providers-professionals/meaningful-use-definition-objectives [http://perma.cc/AMW3-FXJQ].

18. *See* Electronic Health Record Incentive Program, 75 Fed. Reg. at 44,321; 42 U.S.C. § 1395w-4(o)(2)(A)(i).

19. *See* Electronic Health Record Incentive Program, 75 Fed. Reg. at 44,321.

20. *See id.*

21. *See id.*

In response to comments, CMS created two sets of objectives in the stages: "core objectives" that grantees must accomplish, and "menu objectives," of which grantees need only to meet a certain number of the objectives.[22] The initial list for Stage 1 had fifteen core objectives for physicians and fourteen core objectives for hospitals, along with lists of ten menu objectives, of which both physicians and hospitals are required to meet at least five.[23] These objectives varied in difficulty, from maintaining an active medications list with at least one entry for more than 80% of patients, to compiling and reporting ambulatory clinical quality measures.[24]

CMS finalized the Stage 2 rule on September 4, 2012, one year behind the original schedule.[25] The rule added an additional seventeen core objectives for physicians and sixteen for hospitals, with six menu objectives, of which three must be met.[26] Many of the Stage 2 objectives were simply updates on previous objectives, such as the requirement to record patient demographics, increasing from 50% of patients recorded at Stage 1 to 80% at Stage 2.[27] The Stage 2 regulation also modified Stage 1, eliminating the requirement to exchange key clinical information in favor of electronically exchanging summary of care documents in Stage 2.[28]

CMS proposed regulations for Stage 3 on March 30, 2015 and adopted final regulations on October 16, 2015.[29] Prior rule changes promulgated this delay by extending Stage 2 through 2016, putting the timeline for meaningful use three years behind the original sched-

22. *See id.* at 44,327.

23. *See id.* at 44,566–70; 42 C.F.R. § 495.6.

24. *See* Electronic Health Record Incentive Program, 75 Fed. Reg. at 44,567 (stating core objectives 5 and 10 for eligible professionals in Stage 1).

25. *See* Electronic Health Record Incentive Program — Stage 2, 77 Fed. Reg. 53,968, 53,971 (Sept. 4, 2012); *see also supra* note 20.

26. *See* Electronic Health Record Incentive Program — Stage 2, 77 Fed. Reg. at 54,152–57; *see also* CTRS. FOR MEDICARE & MEDICAID SERVS., STAGE 1 VS. STAGE 2 COMPARISON TABLE FOR ELIGIBLE PROFESSIONALS (2012), http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Stage1vsStage2CompTablesforEP.pdf [http://perma.cc/3M42-34JM] (a helpful comparison of the changes in stage 2); CTRS. FOR MEDICARE & MEDICAID SERVS., COMPARISON TABLE FOR ELIGIBLE HOSPITALS AND CAHS (2012), https://www.cms.gov/regulations-and-guiance/legislation/ ehrincentive-programs/downloads/stage1vsstage2comptablesforhospitals.pdf [http://perma.cc/ZSL2-LMRS].

27. 42 C.F.R. 495.6(c)(7)(ii); 42 C.F.R. 495.6(j)(3)(ii).

28. *See* Electronic Health Record Incentive Program — Stage 2, 77 Fed. Reg. at 53,970 (explaining that the requirement was replaced with "transitions of care" in Stage 2).

29. *See* Electronic Health Record Incentive Program — Stage 3, 80 Fed. Reg. 16,732 (proposed March 30, 2015); Electronic Health Record Incentive Program — Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 Fed. Reg. 62,762 (Oct. 16, 2015).

ule.[30] Since Stage 3 is still open for public comment on the final rules, this note will focus on Stage 3 in examining potential reforms to the regulation.[31]

C. Certification Regulations

ONC released requirements for certified electronic health record technology ("CEHRT") on the same day that CMS released the meaningful use rules.[32] ONC and CMS worked closely on both of these regulations, and they explicitly linked certification criteria to the meaningful use requirement in Stages 1 and 2.[33] The 2011 Edition CEHRT rules provided forty-two certification criteria matching Stage 1 of meaningful use, while the 2014 Edition provided forty-nine criteria designed to implement Stage 2.[34] These criteria specified types of features that developers needed to create in their software before ONC would certify the software for use by physicians and hospitals seeking financial incentives.

Going forward, ONC intends to develop the CEHRT regulations separately from the meaningful use program, supporting technology for stakeholders such as long-term care facilities that are not eligible for incentive payments.[35] This note will further address the effects of decoupling the regulations in the discussion of future options.[36]

III. THE REGULATORS' PERSPECTIVE

The philosophy of spurring demand and then letting the marketplace solve implementation issues drove much of the regulatory approach to the incentives program. The regulators were not entirely free to craft the program, as the statute constrained their tools and

30. *See* Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program for 2014 and Revisions to the Certified EHR Technology Definition, 79 Fed. Reg. 52,910, 52,927 (Sept. 4, 2014); *see also supra* note 20 and accompanying text.

31. *See infra* Part V.A.

32. *See* Certification Criteria for Electronic Health Record Technology, 75 Fed. Reg. 44,590, 44,591 (July 28, 2010).

33. *See* Electronic Health Record Incentive Program, 75 Fed. Reg. 44,314, 44,331 (July 28, 2010).

34. *See* CMS & ONC, MEDICARE AND MEDICAID EHR INCENTIVE PROGRAMS: CERTIFIED EHR TECHNOLOGY 24 (2013), http://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2013-06-27NPC-EHR.pdf [http://perma.cc/9YTF-VMVJ]. For the 2014 rules, see generally Certification Criteria for Electronic Health Record Technology, 2014 Edition, 77 Fed. Reg. 54,163 (Sept. 4, 2012) (to be codified at 45 C.F.R. pt. 170). These criteria match the meaningful use objectives for stages 1 and 2, although the precise numbers of criteria are different for both stages.

35. *See* ONC, ONC FACT SHEET: VOLUNTARY 2015 EDITION EHR CERTIFICATION CRITERIA ("2015 EDITION") PROPOSED RULE 2 (2014), http://healthit.gov/sites/default/files/final2015certedfactsheet.022114.pdf [http://perma.cc/VN3H-23AS].

36. *See infra* Part V.

goals. The regulations themselves and further comments by ONC directors elaborated the rationale behind the regulations, as explained below.

A. Why They Chose Their Approach

"The regulation must be both ambitious and achievable."[37] Dr. Blumenthal and Ms. Marilyn Tavenner of CMS drafted the regulation under this mindset, attempting to improve the health system while acknowledging the actual capacity of institutions to change.[38] They believed that the meaningful use objectives required by the HITECH Act required them to achieve not just adoption of EHRs, but also "their use by providers to achieve significant improvements in care."[39] In addition, they enacted certification requirements for EHRs to assist providers in meeting meaningful use objectives and to implement new safety and privacy protections in the HITECH Act.[40] While the HITECH Act mandated what the incentive payments or penalties would be and defined a base level of EHR, it gave CMS and ONC discretion in what burdens to impose through meaningful use objectives or certification beyond that base level.[41]

Assessing the relative burden on physicians and hospitals is difficult because of the flexibility in the regulation. In response to comments opposing the original inflexible system, CMS and ONC agreed to create sets of "core" and "menu" objectives with options to choose from objectives listed in the latter, as well as easing the requirements on several of the core objectives.[42] CMS and ONC calculated low and high costs to give a range based on the easiest and hardest regulations. However, some of the presumptions that enter those costs may be incorrect; for example, the assumption that a certified EHR system will cost approximately $54,000.[43] The regulation estimates the work requirement for physicians complying with Stage 1 objectives as 8 hours and 52 minutes to attest to using a certified EHR and complete the core objectives, and an additional 42 minutes to 2 hours and 40 minutes to complete enough menu objectives to meet the meaningful use requirement.[44] The combined estimate of labor costs indicates that

37. Blumenthal & Tavenner, *supra* note 1, at 504.

38. *See id.*

39. *See id.* at 501.

40. *See id.* at 504.

41. *See* Electronic Health Record Incentive Program, 75 Fed. Reg. 44,314, 44,548 (July 28, 2010).

42. *See id.* at 44,520.

43. *Compare id.* at 44,518 *with infra* notes 71–73 and accompanying text.

44. Electronic Health Record Incentive Program, 75 Fed. Reg. at 44,518. They created similar estimates for hospitals, expecting 9 hours and 12 minutes of work for core objectives and between 42 minutes and 3 hours and 30 minutes for menu objectives. *Id.* at 44,519.

each physician on average would spend $836.93 on meeting the requirements in the program in addition to the funds spent on purchasing an EHR.[45]

These assessments of the burden only address costs and do not include a commensurate measure of benefits, because CMS and ONC believed that the analysis was not possible with the limited data available when they drafted the regulation.[46] Furthermore, the agencies expected that the first five years would focus on implementation rather than on capturing benefits.[47] They expected eventual benefits such as a reduction in record-keeping costs and reduced errors, but they punted thorough assessment of the benefits until after the regulation was implemented, only citing recent pilot projects and the 2008 Congressional Budget Office ("CBO") study for the proposition that their expectations were reasonable.[48] Lacking quantifiable benefits does not necessarily disqualify a regulation from being beneficial.[49] However, the studies discussing the benefits of widespread EHR adoption do indicate large societal improvements from the success of these programs,[50] which allows for some basis for discussion. Two years later, the Stage 2 rule largely used the same sources to predict eventual benefits, with the addition of a 2011 literature review indicating that studies of health IT were overwhelmingly positive on its benefits.[51] The Stage 3 rule again declined to quantify benefits, using the same sources and adding an updated literature review.[52]

B. Current Perspective

The current ONC/CMS coordinator, Dr. Karen DeSalvo, while acting consistently with her predecessors, emphasized achievements beyond the EHR incentives program. While ONC and CMS are still developing Stage 3, she wants to "move beyond thinking that health IT is only EHRs," focusing on other policies that may inhibit health information exchange.[53] She believes that federal programs can better

45. *See id.* (indicating a cost of $703.42 for attestation and core objectives and an average of $133.51 for menu criteria).

46. *See id.* at 44,560.

47. *See id.*

48. *See id.* at 44,561.

49. *See* Cass R. Sunstein, *The Real World of Cost-Benefit Analysis: Thirty-Six Questions (and Almost as Many Answers)* 20 (Harvard Law Sch. Pub. Law & Legal Theory Working Paper Series, Paper No. 13-11, 2013), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2199112 [http://perma.cc/ZNF2-A4VW].

50. *See supra* Part III.A.

51. *See* Electronic Health Record Incentive Program — Stage 2, 77 Fed. Reg. at 54,144.

52. *See* Electronic Health Record Incentive Program — Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 Fed. Reg. 62,762, 62,937–38 (Oct. 14, 2015).

53. Interview with Karen DeSalvo. *DeSalvo: Health IT Is 'More Than Just EHRs*,*'* 49 BIOMEDICAL INSTRUMENTATION & TECH. 55, 58 (Jan./Feb. 2015).

address barriers to success by renewing their strategic plan for health IT, coordinating across agencies and stakeholders to achieve interoperability.[54] She also led the development of the proposed interoperability framework.[55] This framework and proposal for revising the federal strategic plan are both part of her office's goal to improve the quality of health care, explained in a paper outlining ONC's vision for the next ten years.[56] Within all of this activity, there are signs that Dr. DeSalvo still holds to the original thesis of her predecessors, focusing on finding that balance between ambition and feasibility in health IT regulations.[57] Her approach also seems to echo their view, moving the regulatory focus to quality of care now that adoption rates have dramatically improved for EHRs. However, if the vision is entirely consistent, then the proposal for meaningful use in Stage 3 should also move toward these quality improvements.

IV. THE RESULTS OF LEGAL INTERVENTION

Under the HITECH Act, eligible hospitals are primarily acute care hospitals, and eligible professionals are primarily physicians.[58] Thus, the data reviewed below on how EHRs affect adopters generally examines those two categories of health care professionals.

A. Adoption Rates for EHR

One of the clearest achievements of the EHR Incentives Program is the substantial increase in the number of practitioners using EHRs. The ONC regulations defined basic EHRs by a minimum number of features needed for certification, and studies generally agree that 34% of physicians were using basic EHRs when the incentives program

54. *See* Karen DeSalvo, *Health Information Technology: Where We Stand and Where We Need To Go*, HEALTH AFF. BLOG (Apr. 24, 2015), http://healthaffairs.org/blog/2015/04/24/health-information-technology-where-we-stand-and-where-we-need-to-go/ [http://perma.cc/Y7ZJ-4ME9].

55. *See* THE OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., CONNECTING HEALTH AND CARE FOR THE NATION: A SHARED NATIONWIDE INTEROPERABILITY ROADMAP 4–5 (2014), http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf [http://perma.cc/9NLJ-V8LY] [hereinafter ONC INTEROPERABILITY ROADMAP DRAFT].

56. THE OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., HEALTH IT ENABLED QUALITY IMPROVEMENT: A VISION TO ACHIEVE BETTER HEALTH AND HEALTH CARE 1–2 (2014), http://www.healthit.gov/sites/default/files/HITEnabledQualityImprovement-111214.pdf [http://perma.cc/3LBY-LMA2].

57. *Id.* at 18 ("ONC is committed to working with our partners to coordinate and align measures, reduce reporting burden, retire unnecessary or redundant measures and adopt new CDEs to facilitate quality improvement.").

58. Larry Wolf et al., *Hospitals Ineligible for Federal Meaningful-Use Incentives Have Dismally Low Rates of Adoption Of Electronic Health Records*, 31 HEALTH AFF. 505, 511 (2012).

began in early 2011.[59] By 2014, 83% of physicians used some form of EHR, and 51% of physicians used a system that qualified as basic, including 56% of primary care physicians.[60] Similarly, only 15.6% of non-federal acute care hospitals had a basic EHR in place the year before the incentives program began.[61] Their adoption rate reached 58.9% in 2013, with 25.5% of hospitals using the "comprehensive" EHR with all of the features recommended by ONC.[62]

Despite increased adoption of EHRs, not all adopters actually satisfy the meaningful use requirement. The most challenging elements of Stage 1 were exchanging information with other entities, generating the required quality metrics, and giving patients summaries of their visit.[63] Heading into Stage 2, the combination of information exchange and patient access continues to be the most difficult criteria; in fact, the least-used feature implemented by health care providers is a method that allows patients to electronically transmit information about a hospital visit to a doctor.[64]

Part of the reason for the gap between the adoption of EHRs and achieving meaningful use is the different areas of a practice group that must change their habits to meet those two goals. Purchasing and im-

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59. *See, e.g.*, Catherine M. DesRoches et al., *Meeting Meaningful Use Criteria and Managing Patient Populations: A National Survey of Practicing Physicians*, 158 ANNALS INTERNAL MED. 791, 797 (2013) (finding 34% of physicians were using basic EHRs in 2011, when EHRs began). The survey defined Basic EHR Adoption as having the following functions: "Maintain patient problem lists," "View laboratory results," "View radiology or imaging results," "Record clinical notes," "Maintain a patient's active medication list," and "Order prescriptions electronically." *Id.* at 793. Another study using a similar definition found a 33.9% adoption rate. *See* CHUN-JU HSIAO ET AL., NAT'L CTR. FOR HEALTH STATS., CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., DATA BRIEF NO. 79, ELECTRONIC HEALTH RECORD SYSTEMS AND INTENT TO APPLY FOR MEANINGFUL USE INCENTIVES AMONG OFFICE-BASED PHYSICIAN PRACTICES: UNITED STATES, 2001–2011 1 (2011), http://www.cdc.gov/nchs/data/databriefs/DB79.pdf [http://perma.cc/XC2W-UEXQ].

60. DAWN HEISEY-GROVE & VAISHALI PATEL, OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., U.S. DEP'T OF HEALTH & HUMAN SERVS., ONC DATA BRIEF NO. 28, ANY, CERTIFIED, AND BASIC: QUANTIFYING PHYSICIAN EHR ADOPTION THROUGH 2014 1, 4 (2015), https://www.healthit.gov/sites/default/files/briefs/oncdatabrief28_certified_vs_basic.pdf [http://perma.cc/E3LW-ZH2F].

61. DUSTIN CHARLES ET AL., OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., U.S. DEP'T OF HEALTH & HUMAN SERVS., ONC DATA BRIEF NO. 23, ADOPTION OF ELECTRONIC HEALTH RECORD SYSTEMS AMONG U.S. NON-FEDERAL ACUTE CARE HOSPITALS: 2008–2014 1 (2015), https://www.healthit.gov/sites/default/files/data-brief/2014HospitalAdoptionDataBrief.pdf [http://perma.cc/7RR2-975C].

62. Julia Adler-Milstein et al., *More Than Half of US Hospitals Have At Least A Basic EHR, But Stage 2 Criteria Remain Challenging For Most*, 33 HEALTH AFF. 1664, 1667 (2014).

63. DesRoches, *supra* note 59, at 794; *see also* Anne-Marie Audet et al., *Where Are We on the Diffusion Curve? Trends and Drivers of Primary Care Physicians' Use of Health Information Technology,* 49 HEALTH SERVICES RES. 347, 355 (2014).

64. Adler-Milstein et al., *supra* note 62, at 4 (explaining that only 11.6% of hospitals have the transmit feature); Audet, *supra* note 63, at 355 (explaining that only 12% of physicians have received a hospital visit report electronically).

plementing an EHR mostly affects staff assisting physicians, as it requires monetary, administrative, and technical resources, part of which the EHR incentives program supplies.[65] In contrast, meaningful use requires changing providers' workflow and behavior.[66] Providers cannot easily overcome staff shortages and limited capacity for training, even with additional funds from the incentive program or technical support from Regional Extension Centers ("REC").[67]

B. Return on Investment

1. Cost of Implementing EHRs

Despite the difficulties in implementing EHRs, policymakers might presume that at least the incentive payments solved one source of concern: cost. Unfortunately, some recent data indicates that cost remains substantial despite financial assistance. A literature review found that costs vary widely, with the EHRs causing anywhere from a 75% decrease to a 69% increase in operating costs.[68]

While ONC and CMS have data indicating that their incentive payments match costs, recent surveys offer larger cost estimates than the agencies calculated. The maximum incentives for physicians are $44,000 from Medicare and $63,750 from Medicaid.[69] ONC offers data showing that costs vary between $15,000 and $70,000 per physician, depending on whether the EHR is on-site or a web-based service with recurring subscription fees.[70] Focusing on physicians specifically, a national survey found that about 45% of physicians spent more than $100,000 on their EHR system.[71] Another recent study supports these survey figures, finding that an average five-physician practice would spend $117,900 each during the incentives program.[72] The difference

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65. Cleo A Samuel, *Area-Level Factors Associated With Electronic Health Record Adoption and Meaningful Use in the Regional Extension Center Program*, 21 J. AM. MED. INFORMATICS ASS'N 976, 979 (2014).

66. *Id.* at 979–80.

67. *Id.*

68. Spencer S. Jones et al., *Health Information Technology: An Updated Systematic Review With a Focus on Meaningful Use*, 160 ANNALS INTERNAL MED. 48, 51 (2014).

69. Electronic Health Record Incentive Program, 75 Fed. Reg. at 44,317.

70. *How Much Is This Going to Cost Me?*, HEALTHIT.GOV, http://www.healthit.gov/providers-professionals/faqs/how-much-going-cost-me [http://perma.cc/LC5Y-Y8BY] (follow uploaded page).

71. Daniel R. Verdon, *EHRs: The Real Story*, MED. ECON. 18, 18 (2014) (citing data from marketing and research firm MPI Group). About two-thirds of the 45% figure resulted from physicians in the largest practice groups who spent over $200,000 on their systems. *Id.*

72. *See* Neil S. Fleming et al., *The Financial and Nonfinancial Costs of Implementing Electronic Health Records in Primary Care Practices*, 30 HEALTH AFF. 481, 481 (Mar. 2011) (finding that the practice would spend $162,000 on implementation and $85,500 annually on recurring maintenance, presuming maintenance remains the same). This figure

between those figures and doctors' actual experiences results from such factors as money and time devoted to training, new staff hires, new maintenance expenses, or updates for new required features.[73]

The costs for hospitals are more difficult to assess due to hospitals' varied sizes, but these costs are also higher than the incentive payments. The hospital incentive payments are not as static as physicians' amounts, varying according to the hospital's size and the number of Medicare or Medicaid patients they serve.[74] In the first year of the program, the amounts varied from as little as $22,300 to as large as $4.4 million for the year, with the median at around $1.7 million.[75] By comparison, a recent survey of community hospitals found that 38% had spent less than $5 million on their EHR, while 18% had spent more than $20 million.[76] By their own estimates, about 60% of community hospitals expect to pay more than half of the EHR costs after accounting for the incentive payments.[77]

2. Improvement of Health Care Quality

Given the high costs of implementing EHRs, an important consideration is whether the industry is experiencing the expected quality improvements. Studies can measure benefits in different ways de-

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also does not account for the hundreds of hours devoted to training instead of gaining revenue from seeing patients. *See id.* at 485–87.

73. Gienna Shaw, *The Cost-Benefit Calculation of Electronic Health Records Systems*, FIERCEHEALTHIT (Aug. 19, 2013), http://www.fiercehealthit.com/story/cost-benefit-calculation-electronic-health-records-systems/2013-08-19 [http://perma.cc/XK9Z-KNCU]. This set of expenses was also smaller before the incentives program. *See* Neil S. Fleming et al., *The Impact of Electronic Health Records on Workflow and Financial Measures in Primary Care Practices*, 49 HEALTH SERVS. RES. 405, 415 (Feb. 2014) (using data from 2004–2009 to estimate an average annual cost of $19,800 per physician). One recent study found that the primary difference between physicians who achieved cost savings with an EHR and those who did not was that the former lacked billing software prior to the transition and benefitted from any billing support in the EHR, while the latter incurred additional transition costs. *See* Julia Adler-Milstein et al., *A Survey Analysis Suggests That Electronic Health Records Will Yield Revenue Gains For Some Practices And Losses For Many*, 32 HEALTH AFF. 562, 565–66 (2013).

74. *See Eligible Hospital Information*, CTRS. FOR MEDICARE & MEDICAID SERVS., http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Eligible_Hospital_Information.html [http://perma.cc/Q9TU-5T6L]; *see also, e.g.*, *Tip Sheet for Medicare Hospitals*, CTRS. FOR MEDICARE & MEDICAID SERVS., http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/MLN_TipSheet_MedicareHospitals.pdf [http://perma.cc/4V72-4AHG] (explaining the formula for the Medicare version of incentive payments).

75. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-778R, ELECTRONIC HEALTH RECORDS: NUMBER AND CHARACTERISTICS OF PROVIDERS AWARDED MEDICARE INCENTIVE PAYMENTS FOR 2011 5 (2012).

76. ANTHELIO, 3RD ANNUAL COMMUNITY HOSPITAL SURVEY: FINANCIAL HEALTH AND NEW INITIATIVES (2013), http://go.antheliohealth.com/rs/antheliohealth/images/Anthelio_Community_Hospital_100_Survey_Results_2013.pdf [http://perma.cc/S8VY-UTSM].

77. *See id.*

pending on what types of quality improvements EHRs should produce.[78] These studies' conclusions about whether the quality of health care has improved or declined are often determined by the methods that these studies initially select to measure health care quality.

One common method of assessing quality is focusing on the physicians' benefits from specific EHR requirements in meaningful use. Many studies of clinical decision support[79] demonstrate that it generally creates process improvements for providers, with a few negative studies demonstrating failure in particular contexts.[80] Similarly, many studies of computerized physician order entry ("CPOE") indicate that it reduces medication errors.[81] However, studies focusing on one feature of EHRs are somewhat limited because they do not address the cumulative effects of new information from a large set of interactive features. Scholars refer to this effect as "alert fatigue," referencing the alerts that EHR features use to convey new information.[82]

Other studies examine quality of health care by assessing the organizational culture fostered by sharing information over technology. This focus renders some of the strongest criticisms of the EHR transition. One large concern right now is that certain efficiency features in EHRs may cause quality problems later, such as the copy-and-paste function, which allows providers to repeat commonly-used text across several records.[83] Both physicians and administrative workers are concerned that medical records are becoming incomplete as doctors write more generic descriptions to avoid spending too much time with EHRs.[84] Compliance officers are focusing on ways to limit their own liability from errors due to copy-and-paste mistakes in EHRs, as the

78. Albert Boonstra et al., *Implementing Electronic Health Records in Hospitals: A Systematic Literature Review*, 14:370 BIOMED CENT. HEALTH SERVICES RES. 1, 9 (2014), http://www.biomedcentral.com/1472-6963/14/370 [http://perma.cc/5Q8S-UN8M]. The article earlier elaborates that using a sociotechnical framework means "emphasizing the importance of focusing both on the social aspects of an EHR implementation and on the technical aspects of the system." *Id.*

79. Clinical decision support is intelligent filtering of information to enhance decision-making in health care. Clinical Decision Support (CDS), OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., https://www.healthit.gov/policy-researchers-implementers/clinical-decision-support-cds [http://perma.cc/WS6U-TEZR].

80. *See id.* at 20–24 (listing findings from selected studies on the quality of EHR implementation).

81. *Id.*; *see also, e.g.*, Sara H. Forrester et al., *Cost-Effectiveness of a Computerized Provider Order Entry System in Improving Medication Safety Ambulatory Care*, 17 VALUE HEALTH 340, 345 (2014).

82. Jones et al., *supra* note 68, at 51.

83. Julia Brown, *Be Wary of Copy-and-Paste EHR Mistakes*, 34 BEHAVIORAL HEALTHCARE 29, 29 (2014).

84. Ann Scheck McAlearney et al., *Fundamental Issues in Implementing an Ambulatory Care Electronic Health Record*, 28 J. AM. BOARD FAM. MED. 55, 61 (2015).

meaningful use requirement does not restrict using that feature.[85] Meanwhile, some physicians are reluctant to trust clinical information in EHRs because of the proliferation of copied-and-pasted data.[86]

While many studies assess EHRs broadly, others assess the benefits of the meaningful use regulation by comparing EHR users who can satisfy the meaningful use requirement with those who cannot.[87] These studies are limited, however, because under the regulations, physicians can claim exclusions from certain criteria and still be noted as achieving the meaningful use requirement. Thus, satisfying the meaningful use requirement does not necessarily mean achieving the core and menu objectives. Over ninety percent of physicians that meet the meaningful use requirement claim exclusions to satisfy objectives, with more than three-fourths claiming exclusions on core objectives.[88]

C. Physician Reaction

As the EHR incentive program has advanced, one of the major barriers to successful implementation of EHRs has been providers' resistance.[89] Physicians who resist implementation of EHRs can often subtly oppose changes to their own workflows by creating worka-

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85. Jennifer Wilson, *Copy and Paste Function in the EHR: Steps Compliance Officers Can Take to Encourage Proper Use*, 16 J. HEALTH CARE COMPLIANCE 67, 67 (2014).

86. *See* Mark Friedberg et al., *Physicians' Concerns About Electronic Health Records: Implications and Steps Toward Solutions*, HEALTH AFF. BLOG (Mar. 11, 2014), http://healthaffairs.org/blog/2014/03/11/physicians-concerns-about-electronic-health-records-implications-and-steps-towards-solutions/ [http://perma.cc/ZMF6-LJ8Y].

87. *See*, *e.g.*, Lisa M. Kern et al., *The Meaningful Use of Electronic Health Records and Health Care Utilization*, AM. J. MED. QUALITY 1, 3 (2015), http://www.ncbi.nlm.nih.gov/pubmed/25712134 [http://perma.cc/8HJL-D6FJ] (finding a 6% reduction in visits, a 4% reduction in lab tests, and a trend toward fewer ER visits among patients whose primary care physicians achieved the meaningful use requirement). At least one study that found the opposite — an increase in visits — also found that normalizing the data to per physician per month removed the distinction. *See* Karishma G. Reddy & Jack C. Yu, *The Impact of Electronic Medical Record Implementation on the Outpatient Volumes of a Midsize Academic Center*, 73 ANNALS PLASTIC SURGERY 330, 331 (2014). Perhaps such normalization would be helpful in future studies if they reach opposite conclusions of Kern et al.

88. Adam Wright et al., *The Medicare Electronic Health Record Incentive Program: Provider Performance on Core and Menu Measures*, 49 HEALTH SERVS. RES. 325, 338, 340 (2014). CMS later modified the exclusions rules to prevent providers from counting exclusions — at least on menu objectives — as meeting those objectives starting in 2014. *See generally* CTRS. FOR MEDICARE & MEDICAID SERVS., STAGE 1 CHANGES TIPSHEET (2012), https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/stage1changestipsheet.pdf [http://perma.cc/B8WY-84GN] (follow uploaded page).

89. Boonstra et al., *supra* note 78, at 15. Interestingly, while it is largely the major barrier in choosing to adopt an EHR, physician resistance is only the third most important barrier to implementation once started, with the first and second spots going to problems with meaningful use implementation and administrative implementation, respectively. *See* Dawn Heisey-Grove et al., *A National Study of Challenges to Electronic Health Record Adoption and Meaningful Use*, 52 MED. CARE 144, 146 (2014) (includes former ONC head Farzad Mostashari as one of the authors).

rounds that impede successful implementation.[90] Several factors cause physician resistance to EHRs. Many concerns involve changes to a clinic's methods more broadly or a doctor's method in particular.[91] Other concerns are about threats to the professionalism of the medical field.[92] Of course, some resistance results from older physicians who are not as technologically savvy as their younger counterparts.[93] Perhaps the biggest threat is burnout from "work after clinic," the endless array of tasks dissociated from patient care that physicians must perform after seeing patients.[94] Even the medical teams that use EHRs well still suffer from extremely high rates of unnecessary work for physicians.[95]

This physician resistance matters to the incentives program because physicians experience the most difficulty in implementing the features directly related to patient quality.[96] In fact, physicians largely support EHRs in theory, but their resistance stems from the poor quality of currently available products.[97] Large practice groups might be reinforcing this poor quality, because health care administrators often select vendors without input from physicians, leading to products that are better at administrative tasks than patient care.[98] Physician adoption rates for EHRs also correlate to the number of physicians in the

90. Boonstra et al., *supra* note 78, at 14. For example, a study of Florida hospital uses of CPOE found that at hospitals where physicians resist, adverse drug events *increased* by 14% after the hospital met meaningful use. *See* William E. Encinosa & Jaeyong Bae, *Meaningful Use IT reduces hospital-caused adverse drug events even at challenged hospitals*, 3 HEALTHCARE 12, 15 (2015) (using data from Florida in 2010).

91. McAlearney et al., *supra* note 84, at 57.

92. *Id.*

93. Michael D. Botta & David M. Cutler, *Meaningful use: Floor or Ceiling?*, 2 HEALTHCARE 48, 51 (2014) ("'I have an older physician staff that's not computer savvy," one CIO pointed out. "What do you do with people who can't type?"').

94. Shawn Martin, *Whack the 'WAC,'* IN THE TRENCHES, AMERICAN ACADEMY OF FAMILY PHYSICIANS (Oct. 27, 2015), http://blogs.aafp.org/cfr/inthetrenches/entry/whack_the_wac [http://perma.cc/33XV-HBZ9].

95. Larry Beresford, *AMA's Christine Sinsky, MD, Explains EHR's Contribution to Physician Burnout*, THE HOSPITALIST, THE SOC'Y OF HOSPITAL MED. (Oct. 23, 2015), http://www.the-hospitalist.org/article/amas-christine-sinsky-md-explains-ehrs-contribution-to-physician-burnout/ [http://perma.cc/276W-3QH7].

96. McAlearney et al., *supra* note 84, at 62.

97. *See* MARK FRIEDBERG ET AL., RAND HEALTH, FACTORS AFFECTING PHYSICIAN PROFESSIONAL SATISFACTION AND THEIR IMPLICATIONS FOR PATIENT CARE, HEALTH SYSTEMS, AND HEALTH POLICY 33 (2013). RAND actually added the portion about EHRs after starting the study because of the high volume of feedback they received from physicians on EHRs when RAND asked about professional satisfaction. *See* Friedberg et al., *Physicians' Concerns*, *supra* note 86, at 2.

98. *See* Jeffrey Bendix, *Best EHRs: Physician Reviewed*, MED. ECON. at 3 (Oct. 25, 2015), http://medicaleconomics.modernmedicine.com/medical-economics/news/best-ehrs-physician-reviewed?page=0,3 [http://perma.cc/CE28-TWKR].

practice,[99] indicating that the EHRs are most widely deployed to physicians who had little input in selecting the software.

For physicians who have input into vendor selection, or at least requesting improvements, part of the difficulty is that meaningful use requirements limit vendors' ability to respond to providers' needs.[100] Providers also have less time to seek improvements that would help the software, regardless of whether vendors have the capacity to implement those changes.[101] In all fairness, the vendors did note that a transition in hospital coding is also limiting their development resources.[102] Data breaches are far more consequential for providers than failing to satisfy the meaningful use requirement, making coding transitions predominate over other concerns in EHRs and demonstrating that meaningful use alone is not the only constraint on development.[103]

Physicians are still optimistic about EHRs despite the current problems.[104] Many value the increased access to patient information and the ability to better communicate with patients and other providers.[105] Many are also excited about opportunities for health information exchange.[106] In fact, over half of the physicians who do not intend to participate in the EHR incentives program still use EHRs in their practice.[107] Part of the benefits of EHRs also derives from the cohesion of multi-physician practices rather than from the software

99. Heisey-Grove & Patel, *supra* note 60, at 5.

100. Botta & Cutler, *supra* note 93, at 51. Providers also echoed these sentiments: "The vendors quit working on usability factors — the things we had been asking for to make things work more smoothly, particularly for the doctors. If it wasn't for HITECH, we would have been doing this much more gradually, and it would have been much more measured." *Id.* at 50 (quoting a CIO).

101. *Id.* at 51.

102. *Id.* ICD-10 is a new coding system required in 2015 for everyone covered by HIPAA. *See ICD-10*, CTRS. FOR MEDICARE & MEDICAID SERVS., http://www.cms.gov/Medicare/Coding/ICD10/index.html [http://perma.cc/9SMF-4XHP].

103. Botta & Cutler, *supra* note 93, at 50 ("We were so busy doing meaningful use that we didn't have time to look at nursing, and I think that's a shame . . . we're not doing things that would be great for nurse productivity, like interfacing IV pumps and monitors into our system."). For those providers who do have time for additional features, at least some have tried developing their own software. *See, e.g.*, Andrew Schutzbank & Rushika Fernandopulle, *Doubling down: Lessons learned from building a new electronic health Record as part of primary care practice redesign*, 2 HEALTHCARE 14, 14–15 (2014).

104. Ken Terry, *Satisfaction with EHR Systems Grows Among Physicians*, MED. ECON., Oct. 10, 2014, at 24, 36 ("More than half of physician respondents say their EHR has had a positive impact on the quality of care they provide.").

105. Friedberg et al., *Factors Affecting Physician Professional Satisfaction*, *supra* note 97, at 35.

106. Eric W. Jamoom et al., *EHR Adopters vs. Non-Adopters: Impacts of, Barriers to, and Federal Initiatives for EHR Adoption*, 2 HEALTHCARE 22, 35 (2014).

107. Heisey-Grove & Patel, *supra* note 60, at 3. In fact, 47% of physicians not applying to the EHR incentives program still have a certified EHR. *Id.*

itself.[108] Physicians who coordinate care and are willing to work with one another directly are more likely to experience improvements in quality from implementing an EHR.[109] This coordination is limited if their EHR cannot communicate with other systems.[110]

D. Missing Interoperability

Despite the incentives program, interoperability is still lagging among EHR products.[111] ONC is working with stakeholders to address the interoperability gap in existing software.[112] Their approach to interoperability encompasses a wide variety of devices and data sources in order to be practical for all stakeholders.[113] This loose approach contrasts with their approach to health information exchange itself, which ONC increasingly mandates through meaningful use measures.[114] The former ONC director, Dr. David Blumenthal, justified this difference on the belief that through the spread of EHRs, the demand for exchanging information will increase, spurring solutions in the market for interoperability.[115] Unfortunately, several stakeholders indicate that the resources and attention diverted to achieving meaningful use are actually hindering the market from addressing operability.[116]

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108. Ilana Graetz et al., *The Association between EHRs and Care Coordination Varies by Team Cohesion*, 49 HEALTH SERVS. RES. 438, 446 (2014) (using data from 2006–2008).

109. *Id.*

110. Friedberg et al., *Factors Affecting Physician Professional Satisfaction*, *supra* note 97, at 39 ("[F]axes were a common mode of communicating patient information between care settings.").

111. *See id.*

112. *See generally* ONC INTEROPERABILITY ROADMAP DRAFT, *supra* note 55.

113. Dan Bowman, *Federal Advisers Share Comments, Concerns About Draft Interoperability Road Map*, FIERCEHEALTHIT (Oct. 15, 2014), http://www.fiercehealthit.com/node/32546/print [http://perma.cc/4GWD-BNRT] (quoting Erica Galvez, ONC's interoperability and exchange portfolio manager).

114. *See* OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., U.S. DEP'T OF HEALTH & HUMAN SERVS., REPORT TO CONGRESS: UPDATE ON THE ADOPTION OF HEALTH INFORMATION TECHNOLOGY AND RELATED EFFORTS TO FACILITATE THE ELECTRONIC USE AND EXCHANGE OF HEALTH INFORMATION 34 (2014), https://www.healthit.gov/sites/default/files/rtc_adoption_and_exchange9302014.pdf [http://perma.cc/T94V-CPPQ] ("Eligible professionals and hospitals are required to provide a summary of care record for more than 50 percent of transitions and referrals and use either certified EHR technology or the eHealth exchange for more than ten percent of transitions and referrals.").

115. Katie Dvorak, *Former ONC Heads: Payment Reform Beneficial, But Business Model Still Broken*, FIERCEHEALTHIT (Feb. 4, 2015), http://www.fiercehealthit.com/story/former-onc-heads-payment-reform-beneficial-business-model-still-broken/2015-02-04 [http://perma.cc/5J7Q-DUGL].

116. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-15-817, ELECTRONIC HEALTH RECORDS: NONFEDERAL EFFORTS TO HELP ACHIEVE HEALTH INFORMATION INTEROPERABILITY 20–21 (2014).

V. THE FUTURE OF LEGAL INTERVENTION

While CMS and ONC finalized the latest rules, they may still revise Stage 3 and the certification criteria in future years. Several flaws hinder even these new rules, and although the regulatory approach has constraints, there are several options that the agencies could pursue to improve their regulations.

A. The Next Phase of Meaningful Use

One of the biggest changes to the incentives program in Stage 3 is that ONC and CMS have decoupled their respective rules, and ONC is developing certification criteria more frequently and without a complete connection to the meaningful use requirement.[117] This change is consistent with stakeholder feedback, demonstrating the regulators' responsiveness to concerns as they continue developing the regulations.[118] The American Medical Association ("AMA") believed that decoupling the regulations would allow more flexibility in the development of certified EHRs, helping resolve the innovation limits that the regulations have unintentionally imposed so far.[119] Nevertheless, the latest rules indicate that decoupling may not create the flexibility that the AMA desired.[120] ONC has adopted sixty requirements for

117. *See* 2015 Edition Health Information Technology (Health IT) Certification Criteria, 80 Fed. Reg. 62,601, 62,604–05 (Oct. 16, 2015); Jacob Reider, *AMA's Letter to ONC*, DOCNOTES (Jan. 22, 2015), http://www.docnotes.com/2015/01/amas-letter-to-onc.html [http://perma.cc/JX24-L6ZB] (former ONC deputy coordinator explaining that decoupling is arguably already happening and will continue to happen).

118. *See* Jacob Reider, *Usability of EHRs Remains a Priority for ONC*, HEALTH IT BUZZ BLOG (Jan. 6, 2014, 2:00 PM), http://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/usability-ehrs-remains-priority-onc/ [http://perma.cc/2TK2-3RXR]; *see also* AMA Letter, *supra* note 117, at 2–3.

119. AMA Letter, *supra* note 117, at 3.

120. Micky Tripathi & John Halamka, *The CMS and ONC NPRMs*, LIFE AS A HEALTHCARE CIO (Mar. 24, 2015), http://geekdoctor.blogspot.com/2015/03/the-cms-and-onc-nprms_24.html [http://perma.cc/WT8Q-46K8] (discussing the proposals). Micky Tripathi is the President and CEO of the Massachusetts eHealth Collaborative, and John Halamka is the CIO of Beth Israel Deaconess Medical Center, a professor at Harvard Medical School, and co-chair of the ONC's HIT Standards Committee. The final certification rule contained many of the extraneous features found in the proposal, but several are optional because certification is modular-based rather than comprehensive. ONC also released guidance for software vendors that only want to develop software for Meaningful Use support for now. *See* 2015 Edition Health Information Technology (Health IT) Certification Criteria, 80 Fed. Reg. 62,601 (Oct. 16, 2015) (the text of the rule); Elise Sweeney Anthony and Michael L. Lipinski, 2015 Edition Final Rule: Overview of the 2015 Edition Health IT Certification Criteria & ONC Health IT Certification Program Provisions, THE OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH. at 35, https://www.healthit.gov/sites/default /files/onc_2015_edition_final_rule_presentation_10-9-15_1.pptx [http://perma.cc/ET6R-L76Y] (illustrating which components are required for meaningful use); *see also* John Halamka, *The ONC 2015 Certification Rule*, LIFE AS A

certified EHRs in its voluntary 2015 criteria, twenty-two of which are not required for the meaningful use requirement.[121] None of the requirements are bad ideas on their own, but the cumulative effect may overwhelm developers.[122]

One major change that failed to make it into the regulations was an alternative pathway to meet meaningful use by achieving certain performance measures, then being "deemed" to have met the functionality criteria. The HIT Policy Committee's meaningful use work group considered that alternative as part of simplifying objectives in meaningful use.[123] Ultimately, the work group did not recommend the deeming option because it could not agree on how to measure performance and because versions under discussion all added too many burdens.[124] Former ONC principal deputy director David Muntz called the lack of the deeming option in the new regulations "the greatest disappointment" about Stage 3.[125] Unfortunately, the absence of this option means that Stage 3 still focuses on specific features instead of allowing the latitude to achieve favorable outcomes.[126]

B. Flaws in the Regulatory Approach

1. Data Quality

The regulations intend to create a health IT infrastructure that allows the changes necessary to improve quality of the health care industry, but doctors that adapt to the new technology are improving efficiency at the expense of accuracy. Physicians form habits during

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HEALTHCARE CIO (Oct. 28, 2015), http://geekdoctor.blogspot.com/2015/10/the-onc-2015-certification-rule.html [http://perma.cc/SKU4-PP5Z].

121. Anthony and Lipinski, *supra* note 120.

122. *See* Medicare and Medicaid Programs; Electronic Health Record Incentive Program — Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 Fed. Reg. at 62,735–36 (estimating an additional 31,200–47,560 hours to develop all of the new requirements). ONC also may be underestimating the development time required. *See* Tripathi & Halamka, *supra* note 120 (explaining that the safety-enhanced design has taken most vendors more than 1,000 hours in the past, but ONC estimates only 300–600 hours in their latest regulation).

123. Paul Tang & George Hripcsak, Meaningful Use Work Group, HIT Policy Comm., Draft Recommendations: Meaningful Use Stage 3, 6 (2013), http://www.healthit.gov/facas/sites/faca/files/muwg_stage3_draft_rec_07_aug_13_.v3.pdf [http://perma.cc/TF9A-PL2K].

124. David Raths, *MU Work Group Drops Deeming Option Idea*, HEALTHCARE INFORMATICS (Nov. 21, 2013), http://www.healthcare-informatics.com/article/mu-work-group-drops-deeming-option-idea [http://perma.cc/D4G5-5MEP]. One member of the work group also opposed the deeming option because he believed ONC should not be measuring quality when other programs already accomplish that objective. *Id.*

125. Heather Caspi, *Pros and Cons: What 3 IT Experts Have to Say About the MU Stage 3 Proposal*, HEALTHCARE DIVE (Mar. 26, 2015), http://www.healthcaredive.com/news/pros-and-cons-what-3-it-experts-have-to-say-about-the-mu-stage-3-proposal/379466/ [http://perma.cc/LFA5-TT9B].

126. *See id.*

rushed implementations that undermine the key item desired by promoters of EHRs: data.[127] The records are not necessarily full of errors; instead, some are too generic to be useful, and others mask subtle differences in generic language.[128]

The appeal of a health IT infrastructure is the ability to enable population management through data analytics.[129] This ability only benefits doctors and hospitals over time if the data enables the analytical tools. While the limited implementation thus far does not provide sufficient information to assess how the developing data would function in those tools, the ongoing concerns about gaps in the data should raise alarm that the physicians' undesirable habits need to be more seriously addressed.

2. Physician Reaction

Flaws in EHR use are inevitable to some degree. The combination of wide-scale change to the industry combined with those physicians lacking familiarity with the new technology will continue to spur resistance.[130] The existence of dissatisfaction and protests alone does not prove that the new technology is not working, and regulators have tried to work with stakeholders rather than resist these complaints. In fact, ONC may rightly indicate that stakeholders are better at identifying problems to regulators than contributing solutions to the task.[131]

Ironically, regulators may be unintentionally causing problems by being too responsive to stakeholder concerns.[132] The latest changes reflect a long list of what every stakeholder wants in the regulations and as a result manage to be incredibly burdensome.[133] The cumulative effect of the regulatory requirements is to keep vendors occupied with a huge list of requirements and physicians and hospitals occupied with a comparable list of tasks to perform, preventing them from working together to achieve the changes desired in usability and interoperability.[134] ONC and CMS should find some limiting principle to avoid wish list regulations, as the discretion granted in the statute

127. *See supra* notes 83–86 and accompanying text.

128. *See id.*

129. *See* Jeffrey Bendix, *Assessing the Payoff from Meaningful Use of EHRs*, MED. ECON., Jan. 25, 2014, at 74.

130. *See supra* notes 89–93 and accompanying text.

131. Susan D. Hall, *Jacob Reider to Med Societies: Be Part of the Solution to HIT Progress*, FIERCEHEALTHIT (Jan. 27, 2015), http://www.fiercehealthit.com/node/36841/print [http://perma.cc/DSQ5-N6TC] (quoting John Reider's response to health care providers' demands to protect them from venders and issue fewer regulations, encouraging them to help provide solutions to these problems).

132. *See supra* notes 117–14 and accompanying text.

133. *See id.*

134. *See supra* notes 96–106 and accompanying text.

allows them to set the terms for achieving the meaningful use requirement and certification.

3. Markets and Vendor Power

An unavoidable tension in regulating in this space is the lock-in effect on hospitals or physicians once they select a vendor. Because EHRs are incredibly expensive, providers are very reluctant to incur that cost a second time, which allows vendors to charge exorbitant fees for needed upgrades because providers would rather pay those fees than switch vendors.[135] Thus, as the regulation keeps increasing the requirements for meeting meaningful use, providers have to keep paying for updates from their vendors or risk losing further incentive payments.

The government's intervention in the market has not really corrected this market flaw. While the requirements for certification direct development of EHRs more strongly than providers could in the market, those requirements alone will not stop vendors from taking advantage of their position where they can. ONC has found soft ways to prevent practices it views as the most problematic, using a report to Congress to label vendors' extra charges for health information exchange as "information blocking."[136] Because providers must be using a certified EHR to meet the meaningful use requirement, ONC has little direct leverage over vendors once it certifies their software, as decertification would potentially harm users too.

C. Limits to a Regulatory Approach

Not all of the problems affecting the regulation are within the regulators' control. In addition to the limited power over vendors, ONC and CMS face two additional problems where the statute denies discretion: cost and timing. The HITECH Act specifies both payments and the timing and amount of penalties, denying that power to the regulatory agencies.[137] Congress has recently taken action to consoli-

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135. *See* Reider, *supra* note 118. Another related problem is that vendors sometimes charge thousands of dollars in fees to release patient data to another vendor when a practice does want to switch. *See, e.g.*, Tatiana Melnik, *Doctors, Unhappy with Their EHR System, Sue the Vendor in a Class Action*, 16 J. HEALTH CARE COMPLIANCE 51, 52 (2014).

136. *See generally* OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., U.S. DEP'T OF HEALTH & HUMAN SERVS. REPORT TO CONGRESS: REPORT ON HEALTH INFORMATION BLOCKING (2015), http://healthit.gov/sites/default/files/reports/info_blocking_040915.pdf [http://perma.cc/2QNN-9MQA]. Within a week of this report being issued, several vendors agreed to waive those fees for their customers. *See* Joseph Conn, *Epic, Other EHR Vendors Agree to Waive Record-Sharing Fees*, MODERN HEALTHCARE (Apr. 15, 2015), http://www.modernhealthcare.com/article/20150415/NEWS/150419944 [http://perma.cc/E8HC-CGBA].

137. 42 U.S.C. § 1395w-4(o) (2012).

date the penalties with other reward and penalty systems in Medicare reimbursements,[138] which may eventually improve the cumulative financial effects for practitioners. Beyond any discretion in overall reimbursement rates, regulators will still have little ability to further assist with costs, and they cannot adjust the timing of the penalties.

D. Recommendations for Improvement

1. Focus on Quality over Specific Performance

The agencies could improve the regulation by better adhering to the statute's multiple goals. In the HITECH Act, Congress specified several metrics that the General Accountability Office would use to measure the effectiveness of the regulations.[139] These measurements consisted of the program's impact on "health insurance premiums, overall health care costs, adoption of electronic health records by providers, and reduction in medical errors and other quality improvements."[140] They correspond to the statutory requirements for the incentives program: meaningful use (including electronic prescribing), information exchange, and reporting on clinical quality measures, which together are supposed to "improve the use of electronic health records and health care quality over time."[141]

In the way that the agencies have written the regulations now, the regulations provide no usable performance measures for quality.[142] While regulators intended to shift toward health care quality in Stage 3, it appears that they have abandoned that goal thus far.[143] Focusing on achieving health care quality with EHRs proved difficult at Stage 3 precisely because it is a different approach to regulating than the approach CMS and ONC have taken thus far.[144] They have a public comment period on the final rule to consider adapting it to fit the quality-based metrics of the forthcoming Merit-Based Incentive Payment System for Medicare more broadly,[145] and it is hoped they will revive

138. *See* Medicare Access and CHIP Reauthorization Act ("MACRA"), Pub. L. No. 114-10, 129 Stat. 87 (2015) (creating a "Merit-based Incentive Payment System" beginning in 2019).

139. 42 U.S.C. § 17953(e) (2012).

140. *Id.*

141. 42 U.S.C. § 1395w-4(o)(2)(A) (2012).

142. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-14-207, ELECTRONIC HEALTH RECORD PROGRAMS: PARTICIPATION HAS INCREASED, BUT ACTION NEEDED TO ACHIEVE GOALS, INCLUDING IMPROVED QUALITY OF CARE 39 (2014).

143. *See supra* notes 123–17 and accompanying text.

144. *See id.*

145. Electronic Health Record Incentive Program — Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 Fed. Reg. 62,762, 62,764–65 (Oct. 16, 2015); *HHS Issues Rules to Advance Electronic Health Records With Added Simplicity and Flexibility*, Press Release, U.S. DEP'T OF HEALTH & HUMAN SERVS. (October 6, 2015),

their past quality ideas in future revisions. One possible change they could make is using the deeming option they considered, which would allow achieving certain performance measures in lieu of functionality criteria. The agencies could apply it as an alternative to the entire Stage 3, rather than as a partial fulfillment of the requirements as they discussed. Allowing providers who have survived Stages 1 and 2 to prove benefits in Stage 3 would better meet the goals of the statute, because it would verify quality improvements as well as adoption rates during the incentives program.

2. Rewrite Certification Criteria to Favor Performance over Features

One other potential change is implementing methods of assessing usability and performance quality for EHR software. The current approach to certification leads to software that meets statutory requirements by providing functions of questionable utility, such as drop-down lists featuring all 68,000 potential diagnosis codes.[146] ONC is well aware that many of the usability problems that afflicted early adopters still occur in modern EHRs and is actively searching for solutions.[147] Extending a requirement in the 2014 rule, the 2015 certification process requires that developers apply user-centered design processes to safety-enhanced design criteria, which ensures that usability is best where patients have the greatest risk of harm from misuse of information.[148] Due to a multitude of potential standards and an element of subjectivity in assessing usability, ONC appears reluctant to create a stronger regulatory metric for usability.[149]

ONC could also create a framework for usability as it has done for interoperability, opening negotiations between providers and vendors for the best approach to find a good solution. This framework could be paired with some sort of limiting principle on what the feature requirements are, sparing vendors the work saturation that is currently occurring in exchange for working with practitioners to improve the value of their software.[150] The goal of regulating the vendors is to fix the market imbalance in power, not to achieve a long list of features.[151] Many methods for testing usability already exist,[152]

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http://www.hhs.gov/about/news/2015/10/06/hhs-issues-rules-advance-electronic-health-records-added-simplicity-and-flexibility.html [http://perma.cc/45L2-SCL2].

146. Nicolas P. Terry, *Pit Crews with Computers: Can Health Information Technology Fix Fragmented Care?*, 14 HOUS. J. HEALTH L. & POL'Y 129, 173 (2014).

147. *See* Reider, *supra* note 118.

148. *See generally* 2015 Edition Health Information Technology (Health IT) Certification Criteria, 80 Fed. Reg. 62,601, 62,670–72 (Oct. 16, 2015).

149. *See generally id.*

150. *See supra* notes 117–12 and accompanying text.

151. *See supra* note 118 and accompanying text.

and if physicians and hospitals can agree on one of those methods that is valuable to their needs, certification that accomplishes better usability might improve the acceptance of EHRs among physicians and hospitals.

Certified software will still need to have sufficient features to meet meaningful use, meaning that this approach could not completely resolve the burden on vendors. Nevertheless, shifting the current burden to give stakeholders power over usability rather than a long features list seems more likely to resolve flaws in software. Stakeholders will still interact with a responsive regulator, and regulators will channel concerns toward solutions that are more likely to supply health care providers with good software.

VI. CONCLUSION

By stepping into the health care market to transition the industry's record-keeping to EHRs, the law has achieved the narrow goal of increasing adoption of EHRs while unfortunately retaining early adopters' problems on a larger scale. The benefits of this expensive program largely derive from the population management capabilities enabled by large-scale data, and the regulations risk losing that key benefit in their current format. Usability and interoperability are still lagging, and physicians must perform a multitude of tasks, largely with unclear quality benefits, just to receive credit for adopting EHRs. The law sets a restrictive timeline which regulators cannot adjust, and that time pressure may be causing some of the perpetuation of shortcuts, such as copy-and-paste functions, that threaten the quality of data in EHRs. The initial regulatory thesis of using adoption to create a market that resolves the other problems may be making some progress on issues like interoperability, but it fails to resolve many of the flaws in software and in physicians' habits of use that are becoming ingrained in the system.

Regulators still have time to adjust the program for Stage 3 to repair the situation. Changing the meaningful use regulation to focus on improving health care quality will help physicians and hospitals internalize the benefits of the regulations and relieve the pressure of excessive burdens, while changing the certification regulation to focus on usability will improve the comfort practitioners need with software to input good data. With those two changes, the regulations may still achieve the long-term societal benefits that would justify their costs.

152. *See* 2015 Edition Health Information Technology (Health IT) Certification Criteria, 80 Fed. Reg. at 62,670–72.