

Comments of Arlene Holen<sup>1</sup>  
Senior Fellow, Technology Policy Institute  
On  
Notice of Proposed Rulemaking  
Centers for Medicare & Medicaid Services  
42 CFR Parts 412, 413, 422, and 495  
CMS-0033-P  
RIN 0938-AP78  
Electronic Health Record Incentive Program  
Meaningful Use

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Ms. Charlene Frizzera  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
P.O. Box 8013  
Baltimore, Maryland 21244-8013

## I. Introduction and Summary

These comments are submitted in response to the Centers for Medicare & Medicaid Services (CMS) Notice of Proposed Rulemaking (NPRM) issued January 13, 2010. The NPRM implements provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) that provide incentive payments for adoption and meaningful use of certified electronic health record (EHR) technology among eligible professionals (EPs) and eligible hospitals participating in Medicare and Medicaid. On the same day, the Office of the National Coordinator for Health Information Technology (ONC) issued a closely related interim final rule that specifies the Secretary of Health and Human Service's adoption of an initial set of standards and certification criteria for electronic health records (EHRs). A condition of meaningful use is the use of a certified EHR system. As also required by the ARRA, ONC issued an NPRM March 9, 2010 on the certification process for electronic health care technology.

The Technology Policy Institute is a think tank that focuses on the economics of innovation, technological change, and related regulation in the United States and around the world. TPI

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<sup>1</sup> The views expressed here are those of the author and not necessarily those of the TPI board, fellows, or staff. Arlene Holen is a former Associate Director of the Congressional Budget Office, where among other duties she managed the agency's reports to Congress on Budget Options. She also served as Associate Director of the White House Office of Management and Budget, where she was responsible for health and human resources policies. She has published papers in peer-reviewed journals on health economics.

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Health outcome policy priorities specified in the NPRM include improving quality, safety, efficiency, and reducing health disparities; engaging patients and families in their health care; improving care coordination; improving population and public health; and ensuring adequate privacy and security protections for personal health information.

All NPRMs for major rules require a regulatory impact analysis assessing their benefits and costs.<sup>2</sup> The requisite analysis is absent in this NPRM. To explain this, CMS points out the difficulty of determining the impact of the proposed rule. First, incentive payments under the ARRA are optional—no provider of health care is forced to take an incentive payment. CMS does acknowledge, however, that potential reductions in Medicare reimbursement after 2015 are effectively mandates. CMS also notes that aspects of the NPRM could change based on comments; the ultimate impact is therefore difficult to assess. It will be also be affected by providers' readiness to implement or upgrade EHRs.

These comments argue that the proposed rule is likely to slow down rather than speed up (as the ARRA incentives and penalties are intended to do) the adoption of EHRs among EPs. They also argue that the rule as formulated fails to incorporate health care cost information:

- First, the complexity and detail of the evolving definition of meaningful use, particularly in combination with uncertainty regarding ultimate standards, certification criteria, and the technology certification process, are confusing to EPs and weaken their incentives to invest in EHRs. Providers need to be confident that their investments will qualify for incentive payments under the ARRA and meet the requirements of CMS and ONC. The definition of meaningful use should be simplified in the final rule and made easier for EPs to readily implement. Regulatory simplification and greater certainty will spur innovation in health information technology.
- Second, although the proposed definition of meaningful use supports consumer engagement generally, it fails to incorporate information on the costs of health services and thus fails to provide a sound basis for moving the U.S. health system toward greater efficiency and higher value per dollar spent. Price transparency and cost awareness among health care providers and consumers are essential to controlling the nation's ballooning health expenditures. The final rule should give greater emphasis to consumer engagement and should encourage price transparency.

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<sup>2</sup> See Executive Order 12866, September 30, 1993, which states: "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets... In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives... Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits... unless a statute requires another regulatory approach." E.O. 12866 is one of a series of executive orders issued during the past 30 years that require this type of analysis, which represents widely accepted principles of sound regulatory decision making.

The overall regulatory structure and information requirements of the electronic health record incentive program are unusually complex, encompassing (in addition to the meaningful use rule) technical standards, certification criteria, and the technology certification process. In designing the rules, CMS and ONC should maximize their practical utility so that their overall effects will advance the public policy objectives of the program—to speed the adoption of electronic health records.<sup>3</sup>

## **II. Complexity, Detail, and Uncertainty of Meaningful Use Definition and Certification Criteria Will Slow Adoption of EHRs and Will Slow Innovation**

The extraordinary complexity and detail of the regulatory requirements in the NPRM—especially in conjunction with numerous planned and perhaps unplanned revisions that create uncertainty—will slow adoption of EHRs and will slow innovation in health information technology. Innovation and technological change are hampered by detailed and uncertain regulatory constraints. The final rule should simplify the requirements EPs must meet to qualify for ARRA incentive payments and make them consistent with their day-to-day practice requirements.

The NPRM, which is over 550 pages long, defines proposed criteria for Stage 1, which will initially cover only payment years 2011 and 2012. CMS intends to propose through future rulemaking two subsequent stages of meaningful use criteria, with Stage 3 covering payment year 2015 and thereafter. Aspects of the meaningful use definition, and presumably its application, are likely to change based on the comments received to this NPRM. An effective date has not been announced, but CMS is expected to issue a final rule by June 2010. The ARRA aims to provide incentive payments by 2011. ONC’s interim final rule, also several hundred pages long, specifying initial standards and certification criteria for EHRs, has yet to be issued in final form.

Several industry organizations have concluded that the complex criteria of the NPRM may be overly ambitious and may need to be dialed down.<sup>4</sup>

As the NPRM states, “Most physicians and hospitals have not yet invested in the hardware, software, testing and training to implement EHRs for a number of reasons—lack of standards, lack of interoperability, limited physician acceptance, fear of maintenance costs, and lack of capital. Perhaps most importantly, adoption of EHR technology necessitates major changes in business processes and practices throughout a provider’s office or facility. Business process reengineering on such a scale is not undertaken lightly.” Many EPs report that EHRs require far more time from physicians, perhaps several hours each day. The final rule should not complicate adoption, it should ease it. If qualifying EHRs are consistent with health care providers’ normal workflow, it will be in their interest to adopt them more readily.

The cost-benefit considerations that determine EPs’ adoption of technology are changing.<sup>5</sup> Changing financial incentives are a major factor. Prices of EHRs have fallen along with costs of

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<sup>3</sup> See Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

<sup>4</sup> Joseph Conn, “Proposed EHR rule might be too ambitious: experts,” *ModernHealthcare.com*, January 13, 2010.

data entry. In addition, system usability has improved as a result of competition and consumer avoidance of more cumbersome products. On the other hand, the time investment, training, and downtime costs associated with implementing a new system—which often requires a period of overlap with its predecessor—have likely increased. Software solutions are still under development. So far, there is no interoperable EHR system available that is suitable for a wide range of medical offices, hospitals, and clinics, particularly those without a base level of experience with electronic systems and a staff to support them.

Although the level of EHR use is low among EPs, many physicians were installing electronic systems even before the ARRA. Adoption rates have been highest for large and group practices. In December 2008 the Congressional Budget Office (CBO) projected that under then-current law, “about 40 percent of physicians will have adopted health information technology systems by 2019, with near-universal adoption anticipated over the next quarter century.”<sup>6</sup> More recently CBO projected that, under law prior to the ARRA, 65 percent of physicians would have adopted EHRs by 2019.<sup>7</sup>

The degree to which ARRA incentives will hasten ongoing EHR adoption depends in part on the level of incentive payments relative to the total costs of implementing a system. The \$44,000 maximum stimulus incentives over five years for eligible physicians under Medicare, or \$65,000 under Medicaid, are not large amounts given the potential costs of implementing the initiatives.<sup>8</sup> The NPRM cites an estimate of initial EHR costs per full-time-equivalent billing provider of almost \$54,000, with much variation, and ongoing annual costs of about \$20,000. Those payments by themselves are insufficient to motivate EHR investments for many health care providers. EPs must perceive that it is in their overall interest, consistent with their professional responsibilities and practice obligations, to install new electronic systems that place a number of simultaneous demands on their finances and their level of effort.

Because EPs are uncertain as to evolving CMS and ONC requirements, have difficulty discerning the practical meaning of interim guidelines on meaningful use, and cannot be sure that a system they are considering will meet CMS’s ultimate criteria, many will postpone investing in EHRs.<sup>9</sup> Uncertainties about qualifying for the ARRA incentive payments create more general uncertainty about what health information systems will become standard and increase the risk of investing in the wrong system. Thus, unless the final rule incorporates simpler goals and targets and is seen as reasonably certain, the \$14 billion to \$27 billion over 10 years of prospective ARRA incentive payments can backfire and actually slow EHR adoption,.

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<sup>5</sup> See Steven Shea and George Hripcsak, “Accelerating the Use of Electronic Health Records in Physician Practices,” *New England Journal of Medicine*, Vol. 362, No.3, pp. 192-195.

<sup>6</sup> Congressional Budget Office, *Budget Options Volume 1, Health Care*, December 2008, p. 89.

<sup>7</sup> Congressional Budget Office, “Estimated Effect on Direct Spending and Revenues of Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Public Law 111-5): Health Information Technology”; available at <http://www.cbo.gov/ftpdocs/101xx/doc10106/health1.pdf>

<sup>8</sup> See Jeff Byers, “Meaningful use has positives, uncertainties and a few fantasies,” Health Information Exchange Portal, Jan 25, 2010.

<sup>9</sup> See Janice Simmons, “Provider Organizations Unhappy with Proposed Health IT Rules,” *HealthLeaders Media*, January 4, 2010 (quoting the head of a prominent physicians’ association, who says the proposed rules are “overly complex and that medical groups will confront significant challenges trying to meet the program requirements.”)

Some proponents of health information technology predict that the ambitious meaningful use rule and time frame for EHR certification and adoption will lead to wasted resources.<sup>10</sup> Stephen Lieber, president and CEO of the Healthcare Information and Management Systems Society (HIMSS), the largest organization representing the health information technology industry, said that the NPRM will result in provider uncertainty about which systems to adopt, higher costs, and delayed improvements in patient outcomes.<sup>11</sup> Another common criticism of the compressed time frame is that technologies could be installed without taking sufficient time to tailor systems, which could undermine patient privacy and safety, increasing adverse events.<sup>12</sup> A simpler meaningful use rule that is easier for EPs to implement is more consistent with an ambitious time frame.

Prospective penalties for Medicare providers under the ARRA constitute additional reasons for EPs to postpone making decisions on and investments in information technologies that they find confusing and fear may not meet eventual CMS requirements. These penalties come on top of sharply constrained Medicare reimbursement levels to health care providers under current law. As the NPRM states, penalty adjustments in reimbursement to providers who do not achieve meaningful use in 2015 and beyond amount to an estimated \$2.3 billion to \$5.1 billion.

### **III. Consumer Engagement and Cost Transparency Are Essential to Slowing Health Care Cost Increases**

Rapidly increasing health care costs threaten the nation's fiscal future and place a heavy burden on individuals and families, with a growing share of workers' total compensation going to health care costs.<sup>13</sup> The growth of spending on health care is the single greatest threat to the federal budget balance over the long run; such spending will have to be controlled in order for the fiscal situation to be sustainable in future decades.<sup>14</sup> Health care costs—both public and private—are on a path to crowd out other national priorities and investments.

Policy makers have looked at numerous options for “bending the cost curve” in the context of health reform, but there is little agreement on how that may be achieved without shifting cost burdens to health care consumers. There is broad agreement among analysts, however, that markets for health care services can function more efficiently when consumers and providers have better information and stronger incentives to focus on health behaviors and choose care that is clinically effective and of high value.<sup>15</sup> The final rule should give greater emphasis to consumer engagement and should encourage price transparency.

By all accounts, health information technology offers tremendous potential for providing quality and cost information to both providers and patients. The NPRM improves on previous versions

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<sup>10</sup> Statement of Nancy Anthracite, President of WorldVista, iHealthBeat, January 26, 2010.

<sup>11</sup> Kathy Mahdoubi, “Meaningful Use Rule May Prove Problematic,” Dotmed News, January 5, 2010.

<sup>12</sup> Neil Versell, “Short EHR implementation timeline could lead to errors,” FierceHealthIT, February 8, 2010, citing Dean Sittig and Dr. David Classen in the *Journal of the American Medical Association*.

<sup>13</sup> *Economic Report of the President*, January 2010, p. 182.

<sup>14</sup> Congressional Budget Office, *The Budget and Economic Outlook, Fiscal Years 2009 to 2019*, January 2009, <http://www.cbo.gov/ftpdocs/99xx/doc9957/MainText.3.1.shtml#1091114>

<sup>15</sup> See *Economic Report of the President*, January 2009, p. 197. See also, Len Burman, “Give Up a Benefit, Gain Jobs.” *The Washington Post*, July 9, 2009; available at <http://www.urban.org/publications/901269.html>

in moving in the direction of point-of-service modernization. However, it fails to address cost and price information and thus fails to provide a basis for improving cost transparency and awareness, which are critical to “bending the cost curve.” Despite alluding to health care costs in a general sense 662 times, the NPRM contains the word “price” only eight times, and only in the context of public agency procurement. This is a major missed opportunity. Facilitating greater cost transparency would help move the nation toward higher health care value per dollar spent.

A widely-cited example of price transparency reducing health care costs is that of Medicare Part D, which covers prescription drugs and relies on price incentives.<sup>16</sup> The program is performing better than expected; its budget costs are about a third lower than original estimates by the Congressional Budget Office. Further, the program slowed the growth in economy-wide drug spending and reduced Medicare hospital costs.

An innovative policy change that would significantly increase cost transparency and could result in billions of dollars of cost savings is the removal of barriers in state laws that require health plans to provide explanations of benefits (EOB’s) for every insurance claim. EOBs, usually delivered by mail, describe services provided, payment sent to the provider, and amount the patient is responsible for based on applicable deductible and coinsurance amounts.<sup>17</sup> Individual EOBs could be replaced with a much more informative periodic health statement that would combine health activity information and clearly set out services received, costs per service, and insurance coverage. Such statements should also be made available electronically to patients, saving mailing and processing costs.

The Federal Employees Health Benefits Program (FEHB) is already moving in this direction of encouraging consumer engagement with price and cost transparency. CMS should follow that model in its NPRM. The Office of Personnel Management (OPM), which administers FEHB, has encouraged federal health benefit plans to increase their use of health information technology to assist employees in organizing health information, access information targeted to individual health needs, and determine the price and cost of physicians’ and other health providers’ services.<sup>18</sup> Forty-five participating FEHB health plans have made a commitment to offer quality and price/cost information to help employees make more informed choices about their health care. That information will facilitate comparisons of price, cost, and value, thereby improving efficiency and enhancing value per dollar spent on health care by both employees and the federal government.

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<sup>16</sup> See David Wessel, “The Lessons of Medicare Part D,” *The Wall Street Journal*, January 7, 2010.

<sup>17</sup> “Health Care Cost Containment—How Technology Can Cut Red Tape and Simplify Health Care Administration,” UnitedHealth Center for Health Reform & Modernization, Working Paper 2, June 2009, p. 7.

<sup>18</sup> U.S. Office of Personnel Management (OPM), Health Information Technology (HIT) Transparency <http://www.opm.gov/insure/health/reference/hittransparency.asp>.

## V. Conclusion

The lengthy and complex NPRM on meaningful use of EHRs threatens to backfire and actually slow EHR adoption by health care providers, contrary to the intent of the \$14 billion to \$27 billion in federal incentive payments included in the economic stimulus legislation. The NPRM's lack of a full regulatory impact analysis is a serious omission.

The complexity and uncertainty of the evolving definition of meaningful use, particularly in combination with uncertainty regarding the ultimate technical standards that will be required, certification criteria, and the technology certification process, weaken incentives to invest in EHRs and will slow innovation in health information technology. Innovation and technological change are hampered by detailed and uncertain regulatory constraints. The definition of meaningful use in the final rule should be simplified and made easier for health care providers to implement.

Better information would improve the ability of health care providers and consumers to identify and use health care services of higher value, thus helping to "bend the health care cost curve" and improve the nation's fiscal outlook. The final rule should give greater emphasis to consumer engagement and should encourage price transparency. CMS should follow the example of the Office of Personnel Management (OPM), which is now encouraging health plans participating in the Federal Employees Health Benefits Program (FEHB) to increase the use of health information technology in offering price and quality information to participants.

The overall regulatory structure and information requirements of the electronic health record incentive program are unusually complex. In designing the rules, CMS and ONC should maximize their practical utility so that their overall effects will advance the public policy objectives of the program—to speed the adoption of electronic health records.

Respectfully submitted,



Arlene Holen  
Senior Fellow, Technology Policy Institute