



March 12, 2010

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-0033-P; Medicare & Medicaid Programs; Electronic Health Record Incentive Program Proposed Rule

Dossia is pleased to comment on the HHS proposed rule implementing ARRA provisions that provide incentive payments to eligible professionals (EPs) and eligible hospitals participating in Medicare and Medicaid programs that adopt and meaningfully use certified electronic health record (EHR) technology.

Dossia commends HHS for including the transmission of electronic information to a Personal Health Record (PHR) as one of the activities demonstrating meaningful use. Dossia also urges HHS to revise the proposed rule to: (1) clarify that patients have the right to specify that they want electronically transmitted information sent to their PHR; (2) ensure that a single patient authorization will suffice for future transmittals; (3) establish that the cost of providing electronically transmitted information should be presumptively zero and never more than the cost of sending the same information to other EPs, hospitals and insurers; and (4) require that at least 80% of EP patients have electronic access to new health information within 96 hours.

Background: Dossia

Dossia¹ was initiated by a consortium of large U.S. employers for the purpose of creating a national system to deliver personal health records for their employees and other individuals. Dossia represents ten large U.S. companies representing over five million employees and their dependents.²

Dossia believes that personal health records can change U.S. healthcare by directly connecting individuals with their personal health information – making every citizen a true

¹ DOSSIA Consortium is a 501(c)(6) not-for-profit organization focused on supporting policy that promotes the creation of personal health records and employee health and wellness. DOSSIA Foundation is a 501(c)(3) charitable organization focused on educating healthcare consumers about the utility and value of Personally Controlled Health Records and the development of meaningful architecture and standards to realize the goal of a national health record infrastructure. DOSSIA Service Corporation is a for-profit entity focused on creating, maintaining and providing Personally Controlled Health Records to individuals.

² Abraxis Bioscience, Applied Materials, AT&T, BP America, Inc., Cardinal Health, Intel, Pitney Bowes, sanofi-aventis, Vanguard Health Systems, and Wal-Mart.

stakeholder in our shared responsibility and mutual interest to manage the health and wellness of the nation.³ Healthcare literacy is key to driving healthcare costs down and improving the quality of care for everyone.

Too often, the U.S. healthcare system leaves patients confused and in the dark. They struggle to navigate a complex and bureaucratic system in which each clinician has only an incomplete and limited view of their relevant history, conditions, medications, and lab results, and lacks any practical means of getting complete medical records in time for clinical decision-making. Making matters worse, patients themselves rarely have access to their own important records unless they have exerted huge efforts to obtain and manage them. Medical decisions are thus often made on the basis of incorrect and incomplete information, with correspondingly poor outcomes.

It is our view that real change can only come about if the American healthcare consumer is empowered through access to their own information. We believe that empowering every citizen with access to their own personal health information will enable them to take personal responsibility – to ask smarter questions and make smarter decisions about health and healthcare. We think that patient control and ownership of health data will ultimately facilitate competition, reduce costs, and lead to better health outcomes.

Dossia's Personally Controlled Health Record is a way for individuals to store copies of their personal health information. A Personally Controlled Health Record can assemble information from a multiplicity of sources into one place. Dossia's plan is to gather health data, at the individual's request, from both institutional sources – insurance claims, laboratory, pharmacy, hospital, physician – and personal sources – health devices, self-entered information, personal biometrics – and facilitate the transfer of electronic copies into the individual's personally controlled health record.

Dossia's system has been developed in collaboration with researchers at Children's Hospital Boston and Harvard Medical School. The Dossia system attempts to maximize use of existing data systems and networks and open interfaces in order to facilitate the population of such PHRs.

Dossia is a non-tethered solution. Once gathered and securely stored in the Dossia database, the electronic summary of health information is portable. Dossia's intent is to make the PHRs continually available to individuals for life, even if they change employers, insurers, or healthcare providers.

³ The benefits of this high-tech, patient-driven model can be seen in the speed with which healthcare providers and the Center for Disease Control and Prevention (CDC) have been able to analyze instances of H1N1 flu. For many years, states have been required to report potential epidemics to the CDC and have done so through paper-based systems, which were slow and inefficient. Now, electronic tools have begun to transform the reporting system, decreasing the reporting burden on healthcare providers and providing more instantaneous analysis of the instances and trends of the H1N1 flu.

We strongly believe that this model is critical to persuading individuals to invest their effort in using a lifelong health tool. Solutions that are tethered to one health plan or one health institution can only reveal a subset of the information for one person given the fragmented nature of the US healthcare sector and the mobile nature of employees who regularly change jobs, health plans, doctors, and pharmacies.

Under ARRA Everyone is Entitled to a Copy of their Personal Health Information Sent to a Destination of their Choice

HIPAA years ago made clear that everyone is entitled to a copy of their own medical information.⁴ The American Recovery and Reinvestment Act took this one step further by explicitly providing that “individuals shall have a right to obtain from such covered entity a copy of such information in an electronic format and, if the individual chooses, to direct the covered entity to transmit such copy directly to an entity or person designated by the individual.”⁵

The Proposed Rule Recognizes and Promotes this Requirement by Including Transmitting Electronic Information to a PHR as One of the Activities Demonstrating Meaningful Use

The proposed rule sets forth Stage 1 Criteria for Meaningful Use. The proposed rule requires that an EP or eligible hospital must demonstrate that they meet specific objectives and their associated measures as set forth in the proposed regulation (Proposed 42 CFR 495.6). “In discussing the objectives that constitute the Stage 1 Criteria of Meaningful Use, we adopted a structure derived from recommendations of the HIT Policy Committee of grouping the objectives under care goals, which are in turn grouped under health outcomes policy priorities.”⁶

The proposed rule notes that the second health outcomes policy priority identified by the HIT Policy Committee is to “engage patients and families in their health care.” HHS states that the goal for meaningful use to address this priority is to “provide patients and families with timely access to data, knowledge, and tools to make informed decisions and manage their health.”⁷

Specifically, HHS has proposed two objectives to further this care goal. First, “provide patients with an electronic copy of their health information (including diagnostics, test results, problem lists, medication lists, allergies) upon request.” Second, “provide patients with timely access to their electronic access to their health information (including lab results, problem lists, medication lists, allergies) within 96 hours of the information being available to the EP.”⁸ In both cases, HHS further clarified that consistent with the HIT Policy Committee’s Recommendations, electronic copies or electronic access could be provided through a number of secure electronic methods such as personal health records, patient portals, CD, USB drive.

⁴ HIPAA Pub. L. 104-191 Sec. 264; 45 CFR 164.522(a)(1)(i)(A)

⁵ ARRA Sec. 13405(c)(3)

⁶ Proposed rule at 47-48

⁷ Id. at 58

⁸ Id. at 58-59

Importantly, the proposed regulation provides specific measures to assess performance against these objectives. At least 80% of all patient requests for an electronic copy of their information must be provided within 48 hours; at least 10% of all unique patients seen by an EP must be provided electronic access to their health information within 96 hours.⁹

We understand that at the HIT Policy Committee's meeting on February 17th, the Committee reaffirmed that there should be no delay in meeting these requirements.

The Proposed Rule Needs to be Clarified in Several Respects

1. Patients Must Have the Right to Choose the "Secure Electronic Method" of Transmitting Information.

Under ARRA it is the patient who has the right to obtain information in an electronic format and the right to direct the covered entity to transmit such copy directly to an entity or person designated by the individual. The proposed rule should similarly verify that patients have the right to specify that they want their information transmitted electronically to their PHR (or delivered in some other format).

The patient should be in control – after all, it is the patient's health and care that is of concern. If a patient has established a PHR to which he or she wants health information transmitted electronically, it can hardly be considered "meaningful use" of that health information if an EP is instead permitted to give or mail that individual a CD. Even worse would be to permit an EP to electronically transmit that information to a "patient portal" that the patient had not established and did not want, rather than a PHR that the patient created and desired.

Requiring an EP to electronically transmit such information to a PHR vendor or service also is the easiest and cheapest alternative. At a minimum, no objection can be raised if the PHR accepts electronic transmissions in the same manner as other EPs and eligible hospitals receive electronic transmissions from that EP.

2. *Only a Single Patient Authorization Should be Required*

An issue not addressed in the proposed rule is the way in which a patient can authorize an EP to electronically transmit a copy of their health information or updated information to a PHR following each visit. The final regulation should make clear that the EP may only ask for authorization in the first instance, and shall deem that authorization to cover all future electronic transmittals. This is, in fact, the current standard and practice for HIPAA authorizations and should similarly apply in the context of ARRA.

⁹ Id. at 474; Proposed 42 CFR 495.6(d)(5)(ii)(6)(ii).

3. The Cost of Electronically Transmitting Information Should Presumptively be Zero

The ARRA limits fees that providers may charge patients for electronic copies of health information to the entities' labor costs in responding to such a request.¹⁰ Congress clearly was concerned about the possibility of excessive fees effectively eviscerating the patient's right to an electronic copy of his or her health information.

The final rule should specify that the cost of electronically transmitting such information is presumptively zero. Consider: the EP is essentially being asked to send an e-mail. The marginal cost of any transmission is zero and there is no cost for a physical medium (i.e. CD; USB drive).

Even if there is some discrete apportionable labor cost associated with electronically finding and transmitting a particular patient's electronic health record or new information, the administrative costs of determining, recording and compiling such information would be far greater than the actual cost of the electronic search and transmission. To recover a penny might require spending a dollar.

The final regulation should clearly state that such labor costs of electronic transactions are presumptively zero. At a minimum, the regulation should provide that the cost cannot be more than the cost of electronically transmitting the same information to other EPs and eligible hospitals.

4. The Regulation Must Establish a Stricter Standard for Making Health Information Available to Patients

In the proposed rule, HHS clearly recognizes that it is important not only for a patient to be able to receive an electronic copy of his or her health record at any single moment in time, but also to quickly receive electronic copies of new health information. The proposed rule requires electronic access to such health information within 96 hours of the information being available to the EP.

We have several comments. First, we assume, but believe HHS should clarify, that electronic "access" means that in fact the patient was the right to direct the EP to electronically transmit information to a patient's destination of choice. Second, Dossia agrees that 96 hours is appropriate to be considered "timely." Third, however, Dossia believes that the measure of this objective needs to be significantly improved. The proposed measure requires only that "at least 10% of all unique patients seen by the EP are provided timely electronic access to their health information." This is a radical departure from the 80% requirement used to measure most other objectives. Dossia strongly urges HHS to increase this final requirement in the final rule to 80% of all unique patients seen by the EP. This requirement would be consistent with that imposed by eligible hospitals' obligation to provide discharge instructions and procedures.¹¹

¹⁰ ARRA Sec. 13405(e)(2)

¹¹ Compare proposed regulation 42 CFR 495.6(d)(6) with (e)(4)

Conclusion

Dossia believes that empowering the American health care consumer through access to their own information is critical to improving care and reducing costs in the long run. Electronic Personal Health Records can play an essential role in this regard. To be an effective tool, patients must be able to specify that EPs and eligible hospitals electronically transmit their information to their PHRs. The proposed rule is a valiant attempt to ensure this will happen in practice – Dossia has suggested four changes which would help make this a reality.

A handwritten signature in black ink, appearing to read "Colin Evans", with a long horizontal stroke extending to the right.

Colin Evans
President