



*Healthcare Information and Management Systems Society*

**Requests for Congress**  
***HIMSS Member Advocacy on the Hill***  
***September 23, 2009***

*Advancing the best use of information and management systems for the betterment of health care.*

**Specifically, what you can do now is:**

1. Ensure that the Executive Branch meets the timelines, requirements, and the needs of your Congressional constituents for the health information technology (IT) components included in the American Recovery and Reinvestment Act of 2009 (ARRA)
2. Require the Secretary of the Department of Health and Human Services (HHS) to conduct a study concerning the necessary funding needed to achieve the nationwide exchange of health information among health information exchanges (HIEs)
3. Apply Congressional oversight authority to ensure that the Drug Enforcement Administration (DEA) establishes a final regulation for the e-prescribing of controlled substances that would not impede the overall benefits of e-prescribing

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**Requests for Congress, Detailed Summaries**  
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**# 1 Ensure that the Executive Branch meets the timelines, requirements, and the needs of your Congressional constituents for the health IT components included in ARRA**

**Problem:** The effective transformation of healthcare depends upon the successful implementation of the health information technology (IT) components included in the American Recovery and Reinvestment Act of 2009 (ARRA).

**Background:** On February 17, 2009, President Barack Obama signed ARRA into law to stimulate the economy through investments in infrastructure, unemployment benefits, transportation, education, and healthcare. The Act included funding for health IT to aid in the development of a robust IT infrastructure for healthcare and to assist providers and other entities in adopting and using health IT. The Office of the National Coordinator for Health Information Technology (ONC) has over \$2 billion, and there are over \$30 billion in incentives through the Medicare and Medicaid reimbursement systems to reward providers for demonstrating a meaningful use of certified EHR technology. President Obama referred to the investment in health IT as a first major step for healthcare reform.

ARRA directs incentives for eligible hospitals to begin in fiscal year 2011 and incentives for eligible professionals to begin in 2011. For patients and providers to fully benefit from investments in health IT made possible by ARRA, it is essential that new regulations and guidance concerning funding opportunities be determined in advance of these deadlines.

As the Centers for Medicare and Medicaid Services (CMS) must award incentives to eligible hospitals and professionals, the Department of Health and Human Services (HHS), ONC, and CMS are working to establish EHR certification criteria and a definition for meaningful use. To aid in the process, the Health IT Policy Committee, a Federal Advisory Committee established through ARRA, is advising on such issues. The definition for meaningful use, and an EHR certification program, must be established in a timeframe that will incent the investment and adoption of health IT by the private sector. As many have acknowledged, this is an exceptionally-complex assignment with very high stakes.

**Solution:** *Congress should ensure that the Executive Branch meets the timelines, requirements, and the needs of their constituents for the health IT components included in ARRA.* With over \$30 billion appropriated for health IT, Congress should effectively leverage its oversight of the Executive Branch through the following activities:

- Call upon the Government Accountability Office (GAO) to conduct periodic studies to ensure that the healthcare industry is appropriately engaged with carrying out the health IT components of ARRA, and federal funds are appropriately being applied to those components.
- As needed, Congressional Committees can convene oversight hearings to ensure that ARRA's health IT components are being carried out in a transparent, accountable, and effective manner.
- Members of Congress should stay engaged with their constituencies concerning the ramifications of the health IT components and share feedback with relevant Congressional leaders on a timely basis.



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**#2 Require the Secretary of HHS to conduct a study concerning the necessary funding needed to achieve the nationwide exchange of health information among HIEs**

**Problem:** As we work to establish the nationwide exchange of health information through the support of health information exchanges (HIEs), no reliable cost estimates are available concerning the development, maintenance, and ongoing maintenance of various models for HIEs.

**Background:** Health Information Exchanges (HIEs) are critical components to achieving the nationwide electronic exchange of health information. Using nationally-recognized standards and policies, an HIE is the electronic movement of health-related information among healthcare stakeholders. HIEs are designed to result in improved patient care quality and safety, providing the means to reduce duplication of services with a reduction in healthcare costs, facilitating a reduction of operational costs by enabling automation of many manual administrative tasks, enabling the integration of sick care with well care, and stimulating consumer education and involvement in their healthcare decisions.

Multiple types of organizations are engaged with HIEs to help ensure the overall efficiency of healthcare: states, state-sponsored public/private partnerships, community-sponsored private entities, health plans, and hospital-system-wide initiatives. Through development of a Nationwide Health Information Network (NHIN), the federal government hopes to facilitate the appropriate and secure exchange of electronic health information throughout the country, regardless of an HIE's platform or business model. Achieving the nationwide electronic exchange of health information will help ensure that a provider can, in a secure and appropriate manner, access a patient's health record no matter the time or location.

The federal government's support for HIEs is further demonstrated through the recent enactment of ARRA. And on August 20, 2009, ONC announced the some of the first available funds for HIEs as included in ARRA. Specifically, ONC announced that it would provide \$564 million to help expand state-level health information exchanges, through the State Health Information Exchange Cooperative Agreement Program (a program to advance appropriate and secure health information exchange, providing funds to states or to State-Designated-Entities). Specifically, these funds were originally viewed as a stimulus for HIE initiatives throughout the country.

This level of funding is not sufficient to achieve a nationwide exchange of health information. To ensure that our nation realizes the optimal benefits of electronic health information and achieve the

nationwide electronic exchange of health information, it is essential that Congress ensures that adequate federal funding is available for implementing, maintaining, and sustaining HIEs.

**Solution:** To ensure that adequate federal funding is available for HIEs, *Congress should require the Secretary of HHS to conduct a study concerning the necessary funding needed to achieve the nationwide exchange of health information among HIEs.* To date, no reliable cost estimates are available concerning the development, maintenance, and ongoing maintenance of various HIE models. Such information would be valuable in appropriately allocating federal and state funds and increasing the chances of an NHIN becoming a significant tool in improving the quality, access, safety, and cost-effectiveness of patient care. The study should examine the:

- Current HIE landscape,
- Revenue opportunities,
- Opportunities for HIEs' engagement with population and public health activities, and
- Business cases among HIEs.

In addition, Congress should require that a report as a product of the study is submitted to relevant House and Senate Committees no later than 1 year after enactment of such legislation.



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**#3 Apply Congressional oversight authority to ensure that the DEA establishes a final regulation for the e-prescribing of controlled substances that would not impede the overall benefits of e-prescribing**

**Problem:** The full benefits of electronic prescribing (e-prescribing) will not be achieved until the Drug Enforcement Agency (DEA) develops a final regulation for the e-prescribing of controlled substances in the in-patient and out-patient settings.

**Background:** E-prescribing creates a prescription electronically. This process applies clinical decision support which improves the chances of a patient receiving the right medication, and sends the prescription digitally to the pharmacy. The pharmacy processes the prescription, and provides prescribers the opportunity to receive digital renewal requests from the pharmacy, and to track medication compliance rate (fill status). E-prescribing tools can include both software programs, as well as hardware like personal computers, handheld and wireless devices, and touch screens. E-prescribing is one of the integral steps to achieving improved patient safety and quality, and to accelerate the broad deployment of EHRs. Other issues related to this topic area include, but are not limited to, pharmacy automation, medication compliance, pharmacy databases, computerized practitioner order entry (CPOE) and preventing adverse drug events (ADE).

Today, many prescribers make their prescription decisions using whatever information is available to them – without the benefit of clinical decision support tools. Many continue to give a handwritten prescription to the patient, or fax the handwritten paper to the dispenser or pharmacy. Fortunately, once the prescription reaches the pharmacy, automation (through electronic claims, eligibility, and benefits submission) enabling the dispensing pharmacist to learn about contraindications, the need for prior authorization, or lower cost alternatives. The dispenser then contacts the prescriber by phone for approval of changes, refills, or renewals.

Currently, DEA regulations specifically require pharmacists to have an original practitioner prescription slip prior to dispensing Schedule II controlled substances (excluding long-term care facilities and emergency dispensing). In addition, some states require that such prescriptions can only be written on special, serially-numbered forms. The complication of prescribing controlled substances is a barrier to provider adoption of e-prescribing, which in turn, prevents the improvement of healthcare quality and safety.

For almost a decade, the DEA has recognized the need to address the e-prescribing of controlled substances. The latest effort by the DEA was on June 27, 2008, when the DEA released a draft rule outlining its approach for allowing the e-prescribing of controlled substances. Throughout its

proposal, DEA notes that electronic prescribing of controlled substances is in addition to, not a replacement of, existing requirements for written and oral prescriptions for controlled substances. This draft rule provides a new option to prescribing practitioners and pharmacies – it does not change existing regulatory requirements for written and oral prescriptions for controlled substances. Prescribing practitioners will still be able to write, and manually sign, prescriptions for Schedule II, III, IV, and V controlled substances, and pharmacies will still be able to dispense controlled substances based on those written prescriptions and archive those records of dispensing.

There are many challenges associated with the draft rule, such as:

- In-person identity proofing<sup>i</sup> imposes costs on practitioners, the institutions that conduct the identity proofing, and service providers (filing the information submitted and confirming the application).
- Two-factor authentication<sup>ii</sup> requires that each practitioner with authority to sign controlled substance prescriptions has a unique hard token to gain access to the system. This imposes costs on some practitioners who do not already have a token (e.g., a personal digital assistant).
- Monthly review of controlled substance prescription logs by practitioners imposes a cost<sup>iii</sup> on practitioners.
- System requirements<sup>iv</sup> impose reprogramming costs on service providers.
- Requirements<sup>v</sup> for annual third-party audits impose costs on service providers.

While comments on the draft rule were due on September 25, 2008, the DEA has not taken action on the issue. HIMSS provided a [formal response](#) to the draft rule on September 25, 2008. As e-prescribing will be included in the definition for “meaningful use”, to achieve the full benefits of this functionality, e-prescribing should be applied in a uniform and timely manner across healthcare.

**Solution:** As providers aim to achieve a meaningful use of certified EHR technology, and as healthcare works to reap the full benefits e-prescribing for patients, it is essential that *Congress applies its oversight authority to ensure that the DEA establishes a final regulation for the e-prescribing of controlled substances that would not impede the overall benefits of e-prescribing.* Such activities can be carried out through:

- Frequent written and oral communication with the Department of Justice and the DEA;
- The facilitation of oversight hearings as needed; and, the
- Continued call for collaboration between the DEA and the healthcare community in establishing the regulations.

It is important to note that, in harmony with the HIMSS response to the DEA draft rule, a rule should avoid significant new expenses, practitioner labor, and workflow impediments that could inadvertently, but powerfully, defeat or delay the overall intended benefits of e-prescribing in the full range of in-and out-patient settings. Defeat or deferral of e-prescribing systems would not be in the DEA’s or the public’s best interest, leaving the DEA and providers to rely on two disparate systems (computerized and antiquated manual paper prescription systems).

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<sup>i</sup> A system that fails to provide verification of the signer's identity and authority to issue controlled substance prescriptions, and/or fails to ensure that alteration of the record is detectable, would create new routes of diversion that could be even harder to prevent and detect. Under this alternative, practitioners would be required

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to undergo in-person identity proofing and submit documentation of that to a service provider. The identity proofing would be conducted by a DEA-registered hospital, a State licensing board, or State or local law enforcement agency. The service provider would be required to check the validity of the DEA registration and State license before issuing an authentication protocol to be used to sign controlled substance prescriptions. The pharmacy would also have to digitally sign and archive the prescription. The pharmacy system would need an internal audit trail to record any attempts to alter a record and conduct internal checks for such attempts. In addition, both the electronic prescription service provider and the pharmacy system provider would need to obtain annual third-party audits for security and processing integrity. The service provider would have to generate a monthly log, which practitioners would be required to check for obvious anomalies.

<sup>i i</sup> Two factor authentication consists of the practitioner declaring that information contained in the record constitutes the practitioner's legal authorization and signature, along with one factor stored on a hard token (e.g., a PDA, multifactor one-time-use password token, thumb drive, or smart card).

<sup>iii</sup> The monthly review of controlled substance prescription logs by practitioners consists of the systems generating and sending each practitioner a monthly log of all electronic prescriptions for review. Each practitioner must affirmatively indicate that he or she reviewed the log and must maintain the log for five years. This rule is an unrealistic expectation on a provider's time. This rule could place a tremendous and infeasible new workload on each provider. Practitioners who solely work in a single hospital and solely support in-patient care might be fortunate to receive a single monthly report. The vast majority of other clinicians will instead receive reports from dozens and dozens of disparate in- and out-of-state pharmacies each month. Not only is such an erratic avalanche of monthly reports unmanageable, it might also make it impossible for any clinician to effectively or reliably pick out the one or two patients who have intentionally abused the intended e-prescribing system safeguards. Another perspective for consideration is that a single provider may submit prescriptions to potentially 50 pharmacies, which are actively used by his patient base. Each system would be required to produce a log (50 logs), and each log would require physician review.

<sup>i v</sup> Some firms may not want to incur the reprogramming costs necessary to include electronic prescriptions for controlled substances, and it is highly unlikely that a firm would try to stay in the market without the controlled substances capability, as that would place a firm at a severe competitive disadvantage. An important point is that most firms offer electronic health records (EHRs), with the electronic prescription functionality as part of the EHR. The reprogramming costs may be much higher for firms that only support the electronic prescriptions (just under \$150,000, compared to under \$40,000 for firms with the EHR capability).

<sup>v</sup> For example, the DEA would impose certain system requirements and the pharmacy system would need an internal audit trail to record any attempts to alter a record and to conduct internal checks for such attempts. Both the electronic prescription service provider and the pharmacy system provider would need to obtain annual third-party audits for security and processing integrity. The service provider would have to generate a monthly log, which practitioners would be required to check for obvious anomalies.