Background

The Centers for Medicare and Medicaid Services (CMS) rule proposes to adopt standards for an electronic prescription drug program (hereafter referred to as ‘E-Prescribing’) under Title I of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). These proposed standards would be the Foundation Standards or the first set of final uniform standards for an electronic prescription drug program under the MMA, and represent the first step in an incremental approach to adopting final uniform standards that are consistent with the MMA objectives of patient safety, quality of care, and efficiencies and cost savings in the delivery of care.

Section 1860D—4(e) of the Act specifies that initial standards, which are used in a pilot project that is to be conducted in calendar year 2006, must be adopted not later than September 1, 2005. Pilot testing is not required for those standards for which the Secretary of the Department of Health & Human Services (HHS), after consultation with affected standard setting organizations and industry users, determines there is “adequate industry experience.” The Secretary is required to provide a report to the Congress by April 1, 2007.

Final standards may be adopted by the Secretary as a result of the pilot project. However, if the Secretary, after consultations, determines that pilot testing is not required because there is adequate industry experience with the standards, those standards may be adopted as final without pilot testing.

Overview of HIMSS’ Response

HIMSS enthusiastically shares in the vision for E-Prescribing as described in the NPRM (Notice for Proposed Rule-Making). Relying on the subject matter expertise of our members, we were pleased to work through the process of responding to the proposed rule.

Overall, HIMSS applauds CMS for promulgating the proposed rule. E-Prescribing is one of the integral steps to achieving broad deployment of electronic health records (EHRs). However, we have several concerns that require comment. Most significantly, HIMSS is concerned that the Foundation Standards identified in the proposed rule may not be adequately tested, and therefore recommends a pilot program to determine understanding and use of the Foundation Standards in real settings.

Additionally, we have concerns that the National Provider Identifier has two essential limitations that need to be addressed by government and industry, including the decision to go with a legal entity versus a physical location or healthcare location enumeration. We would also like to emphasize that interoperability will be an important component of the E-Prescribing and EHR implementation processes. HIMSS is confident that Integrating the Healthcare Enterprise (IHE) will continue to help drive the healthcare industry toward interoperability.

Finally, HIMSS is encouraged by the public discussion that CMS is considering exemptions for the Anti Kickback Act and Stark Regulations for healthcare information technology (HIT) efforts between various entities. To reiterate our comments from the January 2005 Collaborative Response to the Office of the National Coordinator of Healthcare Information Technology (ONCHIT) Request for Information (RFI), complete interoperability of healthcare must be provided by any entity seeking a safe harbor. Establishing
a Standards and Policy Entity would provide the means of assessing the need for safe harbors as information-sharing networks are created, especially in meeting the needs of rural and underserved communities. We encourage CMS to work closely with ONCHIT to continue to move the process for the Standards and Policy Entity into an implementation phase of development.

**Standards-Section 1860D-4(e)**

**Summary of Proposed Rule**
Under the MMA, the HHS Secretary is given the authority to adopt proposed standards as final standards prior to the dates specified in the statute. Pilot testing is required only for standards that do not have prior adequate industry experience. Final standards are required by April 1, 2008.

**HIMSS’ Response**

I. A.1: Initial Standards Versus Final Standards
As the largest information systems organization representing healthcare providers and systems vendors, HIMSS respectively submits that there is not adequate industry experience with the standards proposed as “Foundations Standards.” Additionally, the proposed Foundation Standards may not fully meet the criteria set out in Sections 1.F and 1.G. We strongly encourage CMS to utilize the pilot process for all E-Prescribing standards.

This recommendation is based on sound information systems principles, the lack of experience with the proposed Foundation Standards in the healthcare provider community, and concern that the proposed Foundation Standards have too many implementation options to achieve the desired E-Prescribing capabilities.

**System Testing of Standards**
Successful deployment of information systems requires testing of individual components or units, and testing of collections of units through full system testing. If one unit changes, regression testing is required to ensure that the total system still performs as designed. A thorough design, analysis and testing process should be conducted for the full set of standards through pilot testing.

E-Prescribing, as envisioned in the mandates of MMA, is a very complex system unlike any current implementation. The full collection of pertinent standards should be tested both as individual components and collectively as a complete system. Pilot testing is needed on the as-yet-undeveloped or unfinished standards (e.g., Formulary, Medication History, RxNorm or similar prescriber-level drug dictionary and the Sig standard).

**Lack of Healthcare Provider Experience with Proposed Standards**
While widely used in retail pharmacy and pharmacy benefits management, NCPDP standards have had very limited use in provider environments. Providers are, of course, a significant constituency that will be essential for the success of E-Prescribing. In the HIMSS/Phoenix Systems Winter 2005 survey of HIPAA compliance, we found that even two years after the mandated implementation date, only 73% of providers and 70% of payors are capable of handling HIPAA transactions including the 270/271. Compliance with the 270/271 was a mere 31% for providers and 33% for payors. We know that the percentage actually using the transactions routinely is substantially less than the percentage claiming capability. (See [http://www.himss.org/Content/files/WinterSurvey2005.pdf](http://www.himss.org/Content/files/WinterSurvey2005.pdf) for the full survey report.)

HIMSS considers this low level of utilization as evidence of a failure to meet the requirement for “adequate industry experience” for acceptance of any standard as a foundation standard.
Proposed Standards Necessary But Not Sufficient
The standards proposed by CMS as Foundation Standards can be used to meet E-Prescribing objectives. However, the standards allow so many options that a system may be perfectly compliant in the standard but not capable of supporting Part D E-Prescribing, let alone a “uniform means” of conducting E-Prescribing. The 270/271 illustrates this problem. This transaction pair has a number of levels. While a Level 1 implementation is HIPAA compliant, it is useless for E-Prescribing because the 271 response is a basic Yes/No. Part D E-Prescribing standards need a minimum of Level 3 of the 271 response, which will include benefit information (the “EB” record segment 2110) such as co-payment. Substantial study through pilot testing is needed to determine if the 270/271 can accommodate the total possible benefit/formulary structure a PDP or MA-PD may want to implement. While the 270/271 transaction may be capable of meeting the objectives of an E-Prescription, there are too many optional segments and fields in this standard for simply specifying ASC X12N 270/271. An MMA E-Prescribing Companion Guide, if not a separate standard, is necessary. Because E-Prescribing must support-tiered and other benefit structures related to formulary, the 270/271 Companion Guide must be prepared in the context of formulary communication standards and all other E-Prescribing standards. Please see our response in the Interoperability section (starting on line 370) regarding other best practices that could be used to ensure the proper profiling, testing and implementation of E-Prescribing standards.

The details that make the 270/271 inadequate reflect one of the major reasons HIPAA has failed to meet the promise of efficiency and savings. Realization of the benefits of Part D E-Prescribing as envisioned by the Legislature requires well planned and executed testing and piloting of the full set of standards. HIMSS stands ready to assist CMS in accomplishing this important task.

State Preemption-Section 1860D-4(e) (5)

Summary of Proposed Rule
The standards promulgated under this subsection shall supersede any state law or regulation that is (A) contrary to the standards or restricts the ability to carry out this part; and (B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

HIMSS’ Response
Clarification is needed regarding whether the state law preemption also applies to the prescription of controlled drugs. HIMSS believes that state law preemption should be very inclusive and incorporate controlled drugs, as well as any other state rules or laws that discourage or prevent electronic prescribing.

Testimony was previously given to the National Committee on Vital and Health Statistics (NCVHS) indicating that state variations would impede the development and implementation of E-Prescription systems by adding complexity to the HIT industry.

It has been HIMSS’ position that E-Prescribing regulations, to every extent possible, should also be preemptive of state regulations regarding transaction standards and pertinent vocabularies. If preemption is not possible, CMS should prepare, distribute and support model state legislation and regulations to promote interstate consistency.

In addition, HIMSS recommends that these preemptions cover all electronic prescriptions including those covered by all other health plans, and not only Medicare Part D drug coverage as it is unreasonable to expect providers to use different rules for different patients.
Anti-kickback Statute Safe Harbor and Stark Exception –

Section 1860D-4(e) (6)

Summary of Proposed Rule
HHS’ Office of the Inspector General will provide regulations for a “safe harbor” from sanctions and prohibition with respect to the provision of non-monetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information. This applies in the case of hospitals to their members of medical staff; group practices, by the practice to prescribing healthcare professionals who are members of such practice; or a prescription drug plan (PDP) sponsor or MA organizations, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization and to prescribing healthcare professionals.

HIMSS’ Response
Legal and policy changes (e.g., Stark Safe Harbor and Anti-kickback Safe Harbor) and financial incentives that increase the healthcare IT market should be structured to align the economic incentives of all stakeholders with the achievement of effective, practical interoperability. A significant barrier to achieving interoperability is the current challenge of building consensus among stakeholders, including healthcare providers, who have competing economic interests with respect to interoperability standards and policies, whether it pertains to E-Prescribing or other types of healthcare information exchange.

Significant legal and policy changes and financial incentives that encourage market expansion should be used to foster the deployment of true, practical interoperability standards once they have been established.

The present Stark law exemptions must be clarified. HIMSS recommends that safe harbor status for health information exchange be provided under a Standards and Policy Entity (SPE), as proposed in the Collaborative Response to the ONCHIT RFI, January 18, 2005. The SPE is a public-private collaborative entity that identifies and specifies the detailed implementation rules, including business rules, for the standards and policies that make up the common framework – which consists of the essential technical and policy standards necessary to ensure interoperability, serve the patients whose data it shares, and connect systems of varying technical sophistication. The SPE identifies and recommends the technical standards and information policies essential for establishing privacy, security and interoperability. The SPE is responsible for the identification, specification, interpretation, and dissemination of these standards and policies. E-Prescribing and related health information exchange standards should be governed by the SPE, who can determine if full interoperability is provided and recommend what safe harbors, if any, should be allowed. (See the Collaborative Response to RFI for the National Health Information Network (NHIN), lines 189-192 and 1048-1054, http://www.himss.org/ASP/ContentRedirector.asp?ContentID=64748.)

It is critical that such anti-kickback exemptions and safe harbors also be pre-emptive of any state regulations or rules that are more restrictive in order to promote E-Prescribing use.

Electronic Prescription Drug Program

Summary of Proposed Rule
The Act specifies that an electronic prescription drug program for covered Part D drugs for part D enrolled individuals shall provide for the electronic transmittal to the prescribing healthcare professional and the dispensing pharmacy and pharmacist of the following:
• Prescription;
• Information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization);
• Information on the drug being prescribed or dispensed and other drugs listed on the medication history;
• Information on drug-drug interactions, warnings or cautions, and when indicated, dosage adjustments; and
• Information that related to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed upon request of the professional or pharmacist involved.

HIMSS’ Response

Formulary

HIMSS believes that a controlled vocabulary for drugs correlated to National Drug Code (NDC) code will be essential to the success of the program. In the “Bar Code Label Requirements for Human Drug Products and Biological Products; Final Rule,” as well as in the Proposed Rule, the Food & Drug Administration (FDA) committed to a separate rulemaking initiative to address the inadequacies and deficiencies of the NDC system (II.C.1) and to maintaining a database of all unique NDC numbers identifying dosage, strength, nature, and form of administration (VII.D and VII.E.6.). We are unaware of any movement on these critical issues. While the NDC system has apparently been acceptable for the pharmacy supply chain, E-Prescribing and point-of-care systems would require a much improved system for identifying medications at the time of prescribing. As our industry moves forward with not only bar code-enabled medication administration, but also initiatives such as computerized provider order entry (CPOE) or E-Prescribing, the deficiencies and limitations of the current NDC system become all too evident. From the provider perspective, there is a need for development of a standard “doctor-level” dictionary of medications. The NDC code standard addresses pharmacy packages. Even if there were no problems with the NDC code, it does not meet provider needs where different systems will use different vocabularies.

The government project, the National Library of Medicine RxNorm project, is making headway in resolving this, but it has not been established as a recognized standard. We encourage the FDA to coordinate with the CMS as they revise their drug establishment registration and listing regulations to make the NDC number unique and more useful to informational databases. We believe that RxNorm and NDC should be mutually supportive and consistent. Together, the NDC packaging information and RxNorm vocabulary should be accepted as the drug identification standards for all federal initiatives. We are eager to see publication of a Preliminary Rule for the NDC system and establishment of the NDC database.

HIMSS recommends the development of a standard clinician dictionary of medications. While there is a standard for pharmacy packages (the NDC code), clinicians use different systems with different vocabularies. It is also recommended that the RxNorm project be accelerated and adopted as the standard medication vocabulary for E-Prescribing. We believe NDC and RxNorm should be mutually supportive and consistent. Together, the NDC packaging information and RxNorm vocabulary should be the drug identification standards accepted for E-Prescribing.

While RxNorm shows promise in providing semantic interoperability between systems using different proprietary drug databases, the use of RxNorm in real world E-Prescribing situations has not yet been established and needs to be tested for comprehensiveness. In particular, E-Prescribing transactions using RxNorm as a common orderable drug identifier need to be tested to ensure that the prescriber’s intent can...
be fully captured – especially when characteristics of a medication other than dose form, strength and chemical composition can impact the prescribing decision. Such characteristics include the presence of animal products in a medication or allergens such as egg products or preservatives situations where the patient is unable to consume such products for medical, personal or religious reasons.

HIMSS recommends that CMS conduct pilots to adequately test the ability of RxNorm to provide a bridge between prescribing systems using different databases, while fully communicating the prescriber’s intent.

HIPAA

Summary of Proposed Rule
Transactions subject to regulation under HIPAA standards, including those for privacy and security, must continue to comply with HIPAA standards. Providers are HIPAA-covered entities if they engage in electronic transactions for which there are HIPAA standards. If a provider was not otherwise a covered entity under HIPAA, the provider would become a covered entity if it conducts an E-Prescribing transaction that is also a HIPAA transaction, such as the 270/271 eligibility and response.

While HIPAA privacy standards are in place, the public concerns regarding access to, or dissemination of personally identifiable health information persist. The AOA should consider public announcements to ease the concerns of our patients in this regard.

HIMSS’ Response
HIMSS supports present federal HIPAA standards, including those for privacy and security. HIMSS interprets the present HIPAA rules as stating that any provider that is not otherwise a covered entity under HIPAA would become a covered entity if they conduct E-Prescribing transactions.

While HIPAA privacy standards are in place, the public concerns regarding access to, or dissemination of personally identifiable health information persist. HIMSS, therefore, recommends more aggressive educational programs for the public.

HIMSS also urges HHS to write federal HIPAA regulations to preempt more restrictive state privacy regulations whenever these state regulations would impede the implementation of E-Prescribing.

NPRM

Use of Standards In "Closed Enterprises"

Summary of Proposed Rule
CMS recognizes that many closed networks currently conduct E-Prescribing within the confines of their enterprise. Recommendations have been offered by NCVHS that closed enterprises should not be subject to the proposed E-Prescription Standards unless the prescription is sent outside the organization.
The NCVHS recommendation is different from HIPAA transaction requirements; therefore, CMS is soliciting comment on whether they should adhere to the NCVHS recommendations or require closed enterprises to be compliant with the HIPAA transaction requirements.
HIMSS’ Response

HIMSS supports the principles espoused in section II. C of the NPRM with regard to continuing to allow "closed" enterprises to use whatever means they have in place for electronic transactions covered under the NPRM. We support the interpretation that Part D plans should not be required to use the standards defined in the regulation within the confines of an enterprise. Specifically, we recommend that the proposed language for Section 423.160 (a) (2) be amended not to apply to transactions within closed enterprises.

We specifically note that HL7 and NCPDP have worked together to ensure that the information content of HL7 and NCPDP SCRIPT transactions can be translated between the two standards for outpatient prescriptions. It is critical that entities be required to provide for interoperability for E-Prescribing with outside entities – even though they may choose to use proprietary methods within their enterprise. This interoperability is critical for the promotion of the NHIN, as well as the safe transfer of patient care from inpatient to outpatient settings. Many of the most serious and costly adverse drug reactions occur due to lack of accurate medication lists during patient transfers between hospitals and outpatient setting, resulting in duplicate or omitted medications.

The language in the NPRM regarding the exclusive use of NCPDP SCRIPT for the purposes of electronically transmitting a Medicare Part D prescription could be interpreted to mean that a provider entity (e.g., a hospital) using some other internal method for generating prescriptions electronically (e.g., a CPOE system using HL7) would be required to generate an NCPDP SCRIPT message for outpatient prescriptions without the use of an intermediary. While some larger provider organizations may be able to create their own means for translating these messages internally, many provider entities do not have these resources and would be dependent upon an intermediary to provide these services. As long as the receiving entity (e.g., the community pharmacy) receives a NCPDP SCRIPT message, there should be no restriction on the use of intermediaries for performing this translation. HIMSS requests that this appropriate use of intermediaries be clearly permitted in the final rule.

HIMSS also recommends that specific rules are included to prevent restrictions of choice of E-Prescribing software as well as patient choice for provider, pharmacy and medication so that optimum patient care is protected.

National Provider Identifier

Summary of Proposed Rule

NCVHS found that it was important to address the issue of provider identifiers for various E-Prescribing standards it reviewed and, more generally, for an E-Prescribing drug program. They further recommend the use of National Provider Identifier (NPI) as the primary identifier for dispensers and prescribers, once it becomes available. The NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdia® for identifying prescribers can be used in the event that the National Provider System is not available in time for Medicare Part D E-Prescribing.

HIMSS’ Response

HIMSS shares CMS and NCVHS anticipation of broad-ranging benefits the industry will receive once the NPI becomes ubiquitous. Efforts urging for faster implementation of the NPI are supported by HIMSS. However, we have two concerns with the proposal to use NPI for E-Prescribing:

- NPIs will enumerate legal entities but it may be more useful to identify physical locations in E-Prescribing systems and processing; and
NCPDP’s Provider Identifier Number enumerates the dispenser’s physical location, but a broader consideration of healthcare location enumeration may be warranted.

Both of these issues should be subject of careful study and pilot testing before CMS designates interim or final enumeration of dispensers and prescribers.

NPI will enumerate legal entities. This information is useful for many purposes, but identification of the dispenser’s legal entity may not be the most useful identification for E-Prescribing. In fact, enumeration of physical location may be essential for the envisioned E-Prescribing. For providers, NPI may be ideal, but there must also be a mechanism for patients and dispensers to identify an authorized person for questions or other follow-up related to a prescription. Until they are implemented, we cannot know whether NPI enumeration will meet all functional requirements of E-Prescribing. HIMSS recommends that as part of the comprehensive assessment and pilots, the primary identifier for dispensers and prescribers be more carefully evaluated.

HIMSS further recommends that similar careful study and pilot testing be done of any interim enumeration of dispensers and prescribers. The NCPDP Provider Identifier Number, which enumerates dispensers, is widely used and seems effective for the current retail e-commerce. Its effectiveness for broader use in the envisioned MMA E-Prescribing environment should be evaluated and tested.

HIMSS is also concerned by the number of healthcare enumerators. A confusing collection of competing enumeration systems actually inhibits technology adoption. Fees increase healthcare costs without benefits to patient care. The Coalition for eHealth Standards (CHeS) has addressed this situation and recommends the EAN.UCC Global Location Identification Number (GLIN) for enumeration of locations of healthcare entities. In the pilot testing, HIMSS recommends consideration of GLIN for enumeration of dispensers and prescribers.

Whether NCPDP, GLIN, or another enumerator is selected, HIMSS requests that fees and maintenance costs of the identifier be added to the Regulatory Impact Analysis.

Interoperability

Summary of Proposed Rule

CMS acknowledges that E-Prescribing must be interoperable with other parts of an electronic health record (EHR) and that there is much support for postponing the adoption of standards for E-Prescribing until interoperability standards are developed for EHRs. CMS has chosen to proceed with E-Prescribing standards to take advantage of the obvious patient safety and healthcare quality benefits associated with E-Prescribing. CMS proposes foundation ANSI-accredited standards to begin the E-Prescribing process. CMS is convinced that E-Prescribing standards will spur interoperability standards for EHRs and other HIT hardware and software solutions.

HIMSS’ Response

While there is extensive industry experience in transmitting prescriptions electronically in general, the proposed foundational standards and the additional E-Prescribing requirements under MMA not addressed by the Foundation Standards have not been adequately tested together in a wide range of settings that represent healthcare delivery today. HIMSS requests that CMS conduct one or more pilots that incorporate all the Foundation Standards and the proposed additional standards in order to assess the overall impact of E-Prescribing on Medicare and the impact to E-Prescribing performed outside of Medicare.
Additionally, with respect to achieving interoperability between E-Prescribing tools, EHRs, and the entire HIT continuum, HIMSS offers to work with CMS to leverage the successes and findings from IHE.  IHE is a multi-year, global initiative that creates the framework for passing vital health information seamlessly—from application to application, system to system, and setting to setting—across multiple healthcare enterprises.  IHE brings together HIT stakeholders to implement standards for communicating patient information efficiently throughout and among healthcare enterprises by developing a framework for interoperability that is made available in the public domain.  In its seven-year history, IHE has succeeded in engaging vendors and establishing implementation momentum.  Hundreds of HIT, radiology, laboratory, and cardiology products have already successfully demonstrated support for IHE.  Because of its proven process of collaboration, demonstration and real world implementation of interoperable solutions, IHE is in a unique position to significantly accelerate the process for defining, testing, and implementing the standards-based interoperability that is necessary for E-Prescribing and ultimately the President’s goal of achieving widespread adoption of HIT solutions and ultimately the NHIN.

IHE has developed a unique process for producing its framework for interoperability by: (1) combining the collaboration of the primary stakeholders in an efficient and focused manner; (2) operating on a yearly cycle to ensure rapid and immediately applicable advances in HIT innovation; (3) providing practical tools and information resources in the public domain that facilitate adoption of standards-based integration solutions, and (4) enabling both healthcare entities and vendors to improve access to information incrementally.

HIMSS and its partner organizations, including the Radiological Society of North America (RSNA) and the American College of Cardiology (ACC) recommend the IHE process to the federal government for consideration in developing a role for the IHE process in its efforts to advance E-Prescribing and other pertinent HIT initiatives.

Finally, the HIMSS’ Integration & Interoperability Steering Committee has been working on a proposed interoperability definition that may be useful to CMS.  HIMSS is coordinating an industry-wide interoperability definition for later this summer and looks forward to the opportunity to showcase the completed product to CMS and our industry partners.

**Impact Analysis**

**Summary of Proposed Rule**

Included as a requirement of the Regulatory Flexibility Act of 1980, the CMS impact analysis reviews the likely impact of the E-Prescribing regulation on the delivery of healthcare in the U.S., as well as on a number of healthcare constituencies, including health plans and pharmacy benefit managers (PBMs), clinician prescribers, pharmacies and dispensers, individual patients, and small businesses.  CMS concludes that the E-Prescribing regulation will positively impact healthcare delivery, particularly in measurable clinical outcomes, cost reductions, and improvements in business processes.  Impact analyses are based largely on testimony before NCVHS and documents in the public domain.

**HIMSS’ Response**

HIMSS concurs with the CMS assessment that E-Prescribing will have a positive impact on healthcare delivery in the U.S.  Overall, we anticipate an increased interest in E-Prescribing as the inclusion of E-Prescribing provisions in MMA has already heightened awareness of the benefits the variety of devices and connectivity solutions available offers prescribers, along with the fact that many of the standards under consideration are already in use.  Given the experiences of many of our members, we anticipate a reduction in adverse health events associated with anticipated improvements in prescription drug compliance as identified in previous sections of our response.
HIMSS’ subject matter experts stress that E-Prescribing will be successful if all constituencies are empowered to participate in the process. To that end, HIMSS encourages CMS to continue interacting with the community-at-large as CMS develops the E-Prescribing program to ensure that the necessary tools and metrics are in place to provide appropriate and timely information to the provider. At every step along the chain of custody of an E-Prescription, measurements need to be in place to provide adequate incentives for implementation and long-term use by participants. Additionally, CMS must demonstrate that E-Prescribing will streamline clinician workflow and ensure the availability of necessary interoperability tools within and between systems to gain clinician buy-in.

HIMSS expects that, if the necessary business and clinical tools are in place, as many as 15-25% of physicians would elect to participate in the early stages of an MMA E-Prescribing Program with another 50% joining after a year or two. The last 25-35% may be very slow to participate and may eventually require other measures to encourage their participation.

Finally, HIMSS encourages CMS to address the issue of incentives to participate in the E-Prescribing program. A number of organizations within the healthcare continuum will participate based on community empowerment and federal regulation. However, HIMSS anticipates that a significant number of organizations will not participate until they receive adequate reimbursement through implementation funding, deferential reimbursement, or pay-for-performance.

**Conclusion**

HIMSS enthusiastically shares in the vision for E-Prescribing as described in the NPRM. Relying on the subject matter expertise of our members, we were pleased to work through the process of responding to the proposed rule. We are pleased to have worked closely with the HIMSS Board of Directors and various entities within the HIMSS community to develop a response that is consistent with the views of our membership.

In summary, HIMSS is concerned that the Foundation Standards may not be adequately tested, and therefore recommend a pilot program to determine understanding and use of the Foundation Standards in real settings. Our membership would be pleased to discuss this issue further with CMS to ensure adequate metrics are collected during scheduled pilot programs.

We are also concerned that the National Provider Identifier has two essential limitations that need to be addressed by government and industry, including the decision to use a legal entity versus a physical location or healthcare location enumeration.

HIMSS is encouraged by the public discussion that CMS is considering exemptions for the Anti Kickback Act and Stark Regulations for HIT efforts between various entities. As we stated in the Collaborative Response to the ONCHIT RFI, complete interoperability of healthcare must be provided by any entity seeking a safe harbor. Establishing a Standards and Policy Entity would provide the means of assessing the need for safe harbors as information sharing networks are created, especially in meeting the needs of rural and underserved communities.

In closing, HIMSS would like to emphasize that interoperability will be an important component of the E-Prescribing and EHR implementation processes. HIMSS is confident that IHE will continue to help drive the healthcare industry toward interoperability. We look forward to continuing our excellent working
relationship with CMS, and to offering the collective voice of our membership as the proposed rule is finalized and the collaboration is underway.

HIMSS and our members look forward to continuing the necessary dialogue with CMS as we strive to achieve a successful rollout of the E-Prescribing program, from the pilot program through full implementation. If you need any additional information, please feel free to contact Thomas M. Leary, HIMSS Director of Federal Affairs, at tleary@himss.org or 703.299.9712.