Response to

Medicare Program: Proposed Standards for E-prescribing Under Part D

A. “Adoption of NCPDP SCRIPT 8.1 as a Final Standard” Proposed Retirement of NCPDP SCRIPT 5.0 and Adoption of NCPDP SCRIPT 8.1 as a Final Standard

HIMSS appreciates the opportunity to comment on the question. The 2007 report by the Secretary of Health and Human Services based on the Agency for Healthcare Research and Quality (AHRQ) analysis of five E-prescribing pilots found that the NCPDP SCRIPT 8.1 was technically able to convey the information needed to support the E-prescribing function. The report states on page 32, “This standard is relatively mature, widely adopted by the prescribing industry, and is useful in preventing medication errors, and for understanding medication management compliance. The pilot sites found that the proposed standard is technically well structured, supports the exchange of information, and is ready to be used in Part D prescribing.”

HIMSS supports adopting NCPDP SCRIPT 8.1 as a final standard and retiring NCPDP SCRIPT 5.0.

B. “Medication History” Proposed Adoption of an E-prescribing Standard for Medication History Transaction

HIMSS appreciates the opportunity to comment on the question. The Secretary’s report developed based on the AHRQ evaluation of the E-prescribing pilots mentioned in Section A found that the NCPDP SCRIPT 8.1 was technically able to convey the information needed to support the E-prescribing function. The report states on page 32, “This standard is relatively mature, widely adopted by the prescribing industry, and is useful in preventing medication errors, and for understanding medication management compliance. The pilot sites found that the proposed standard is technically well structured, supports the exchange of information, and is ready to be used in Part D prescribing.”

HIMSS realizes that the competing HL7 RDS standard is available and is in use by at least several of our member organizations. However, in the interest of uniform standards adoption, HIMSS supports the recommendation of CMS for the use of the NCPDP SCRIPT 8.1 for medication history in conjunction with E-prescribing.

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2 Ibid, page 32
C. “Formulary and Benefit Transactions” Proposed Adoption of an E-prescribing Standard for Formulary and Benefit Transactions

HIMSS appreciates the opportunity to comment on the question. The Secretary’s report developed based on the AHRQ evaluation of the E-prescribing pilots mentioned in the prior response determined that the NCPDP Formulary and Benefit Standard Version 1.0 was technically able to convey the information needed to support the formulary and benefit information function. The report states on page 29, “While complex, it has been clearly demonstrated that the standard can technically support the transaction and that it is ready for implementation under Part D. However, as with all standards, the pilot project identified implementation issues that must be addressed in order to achieve the potential benefits, the most important of which is that systems must be able to match patients to health plans, or the formulary and benefits data will not be available.”

Based on this evaluation, HIMSS supports the recommendation by CMS for the use of the NCPDP Formulary and Benefit Standard Version 1.0 for E-prescribing. See our recommendation regarding timing in response to that question.

D. “Adoption of the National Provider Identifier” (NPI) as a Standard for Use in E-prescribing Transactions

HIMSS appreciates the opportunity to comment on the question of the National Provider Identifier and use in the E-prescribing transactions. The “Provisions of the Proposed Rule, Adoption of the National Provider Identifier (NPI) as a Standard for Use in E-prescribing Transactions,” states:

The NPI is in widespread use by HIPAA covered entities in HIPAA transactions.

This likely represents an expectation that by now this would be the case. In the April 5, 2005, commentary on the CMS Proposed Rule: “Medicare Program: E-prescribing and the Prescription Drug Program,” HIMSS commented that the National Provider Identifier (NPI) was selected to represent a legal entity and not a physical location or a healthcare location. Providers and payers are struggling to cope with these features of the NPI at this time. Some of the difficulties that organizations implementing the NPI are developing work-arounds to avoid include the following:

1. Provider identification. Some large corporate entities (e.g., a large California integrated delivery system has one NPI for its large multi-county system of hospitals, physicians, PT, ancillary services, and many other service providers) initially billed using the corporate NPI which does not identify the type of service

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3 Ibid, page 29

Healthcare Information and Management Systems Society
(physician, ancillary service, home health, etc.) or which provider rendered the service. **Solution.** Payers are gradually requiring that the service subunit NPI (e.g., PT in Fairfield) and the rendering provider’s NPI appears on each claim.

2. **Location of service.** Some national and regional organizations bill for a function such as dialysis. The service is authorized for a specific location and the location may not be discernable from the claim. **Solution.** The address of the service location is used to determine the service location. This is now a largely manual process. When most providers submit 9-digit zip codes, this can be automated.

3. **Line of business.** In many markets, health plans have different contracts and fee schedules based on line-of-business, e.g., Medicare, Medicaid, commercial, etc.). **Solution.** Payers determine line-of-business by member number and decision rules, since some members are covered by several lines-of-business. In the past, some providers used different provider numbers or codes added to provider numbers for different lines of business.

4. **Type of service.** Some specialty physicians also serve as primary care physicians and receive a higher rate for specialty services. **Solution.** The Provider Taxonomy Code on a claim allows the provider to indicate for what specialty the provider is billing (e.g., primary care or a higher-compensated specialty such as nephrology).

The NPI structure allows an institutional provider or medical group to require or recommend that each of its providers obtain a separate provider NPIs but that is not always implemented. As a result, some institutional provider systems are submitting claims using the NPI that either

1. **Must rely upon the inclusion of legacy provider numbers** to determine the facility or provider actually billing and applicable payment arrangements (and the legacy provider numbers make them noncompliant with the NPI regulation) or

2. **Are incomplete and cannot be paid** without manual research by the payer, by soliciting further information from the provider, or rejecting the claim and requiring resubmission with additional data. Some such claims appear to meet regulations but cannot be processed because the information provided is insufficient.

This above experience with the NPI reflects the need of providers, health plans, and other payers to work through processes to determine the correct use of the NPI. There are powerful market incentives driving this accommodation. HIMSS does not believe that there are inherent problems in the structure of the NPI. Problems being experienced arise from the wholesale change of existing processes and from lack of advance understanding of the problems that implementation of the NPI would cause. Two of these are loss of location specificity and the failure to require 9-digit zip codes in conjunction with the NPI implementation so that provider-finding could be automated instead of largely manual.
HIMSS recommends that CMS use this or another regulatory vehicle to clarify general NPI use as follows:

- **NPI of provider rendering the service.** HIMSS recommends that CMS require that every claim for CMS services billed to CMS or to any Part D or Medicare Advantage health plan or payer provide (1) the NPI of the rendering provider and (2) the NPI of the pay-to organization.

- **Guidance for use of NPI.** HIMSS recommends that CMS provide more detailed guidance in proper use of the NPI for billing using its various claim forms and for other functions. For example, the recommended way to bill as a) a provider who is a member of a medical group b) a specialist who provides primary care, c) a specialist (who also provides primary care) to bill as a specialist using the provider taxonomy code, d) organizations (like dialysis centers) constituted as one national or regional entity to use NPIs or 9-digit zip codes to identify individual provider locations, etc.

It makes sense to solve the problems with the existing NPI use as CMS moves to the new E-prescribing environment. These may seem remarkably simple steps but organizations moving to the NPI are stumbling over them.

With respect to the use of the NPI in E-prescribing, HIMSS notes that there are particular requirements if the NPI is to be used in E-prescribing:

1. **Provider specificity.** The NPI used for E-prescribing must uniquely identify the prescriber. Using the NPI of the rendering provider (the prescriber) will accomplish this for practicing physicians, nurse practitioners, physician assistants and midwives.

2. **Residents, interns and fellows.** The sponsoring organizations for these professionals-in-training need to be instructed to apply for NPIs for each of them or they need to be required to apply themselves.

HIMSS notes that some industry experts argue that an alternative to clearing up ambiguous NPI numbers (not for a specific provider) is to use the DEA number to clarify the identity of the prescribing provider when the NPI number is not adequately specific, e.g., is that of an integrated delivery system or medical group. This has the following limitations:

1. **Multiple DEA numbers for some providers.** There are 10 million DEA numbers and fewer providers. This needs to be reconciled but would be complex since prescription histories tied to any DEA numbers that are retired need to remain valid. Retired DEA numbers would need to be retained and cross-referenced to the active DEA numbers for the same provider.
2. **DEA numbers for residents, interns and fellows.** Residents, interns and fellows have DEA numbers assigned from a block of teaching hospital DEA numbers. Once these residents, interns and fellows leave the teaching hospital, the numbers are reassigned. When residents, interns and fellows go to a new position or get a new fellowship at the original institution or at a new institution or move into private practice, they get a new DEA number or numbers (several fellowships or affiliations). The reassignment of DEA numbers for residents, interns and fellows make tracking E-prescribing history problematic.

Thus, the DEA number is not a good candidate for clarifying non-specific NPI numbers. It is up to CMS to assure that regulations specify the correct use of NPIs for E-prescribing.

HIMSS recommends that the regulation require that each prescriber, including residents, interns, and fellows, have and use his/her personal NPI for E-prescribing, not an organizational NPI.

**E. Proposed Compliance Date**

HIMSS appreciates the opportunity to comment on the proposed compliance date. As an organization, HIMSS is an active supporter of the universal use of E-prescribing solutions to improve the safety, quality, cost effectiveness, and efficiency of healthcare delivery in the U.S. CMS is well aware of the IOM and RAND studies that address the benefits E-prescribing brings to healthcare delivery.

In looking at the April 1, 2009 compliance date, HIMSS is concerned the date will impose a challenge for parts of industry. There are several reasons to institute broader healthcare industry education over the next 12 months:

- The additional standards introduce new procedures in the prescriber’s work flow.
- It will take vendors more time to incorporate the new standard transactions into their products.
- Prescribers will then need time to acquire or upgrade their information systems to support these standards as well as time to train office staff.

The industry needs time to overcome the financial burden, or provider adoption of E-prescribing will continue to lag. One of the proposed standards, NCPDP Formulary and Benefits, was approved in July 2005 and is not widely used in the industry. It introduces a new procedure in the prescriber’s work flow and is predicated on the checking of Medicare Part D eligibility when the patient presents and making that information available at the time of E-prescribing. Issues identified with this transaction include:

- difficulty matching the patient to their Prescription Drug Plan,
- variation from PDP to PDP in the information provided,
- lack of timely updates to PDP systems when patients change enrollment.
Proceeding with E-prescribing without standards for *signatura* (SIG) and drug naming may further hinder adoption. The pilot projects found that neither these standards were ready to support use in Medicare Part D E-prescribing. The lack of these standards do not make E-prescribing infeasible but do require use of remarks rather than standards for communication of some information. HIMSS believes that E-prescribing will still deliver on the promised benefits of simplification, accuracy improvement and efficiency in the ordering and dispensing processes. The biggest hurdle faced by E-prescribing is adoption by prescribers. This issue is primarily at the provider level, not at the pharmacy level. Until providers can see the productivity and cost reduction benefits of E-prescribing, they will not make the changes required to implement E-prescribing – investment and workflow changes.

HIMSS recommends that CMS work with the Healthcare Information Technology Standards Panel (HITSP) and other concerned parties to refine the three E-prescribing standards that were not accepted by the pilots on a priority basis. CMS should then retest the three initial standards that did not pass in the pilots, as these have been so refined. This process will bring the complete set of six standards to operational readiness as soon as is feasible.

Finally, the benefits of E-prescribing are expected to be substantial in lives saved through avoided medication errors, cost saved in formulary compliance, and time saved in prescribing and reordering. Therefore, HIMSS supports the April 1, 2009 compliance date, but encourages CMS to consider the challenges the deadline may impose on some provider organizations, and the necessary education that may need to occur over the next 12 months to minimize adverse impacts on providers, patients, and industry initiatives.

III. Collection of Information

A. “Regulatory Impact Analysis” Overall Impact

HIMSS appreciates the opportunity to comment on the regulatory impact analysis section of this rule. Healthcare providers – hospitals, employed and private practice physicians – recognize the positive contribution to healthcare quality afforded by automation. While hospitals and health systems are largely adopting automation to support improved outcomes and reduce costs, solo and small group physician practices struggle to afford the financial means to implement and maintain such systems given the current healthcare environment.

Healthcare providers recognize E-prescribing as a valuable and natural extension of base electronic medical record and practice management systems that support patient safety and quality care. The prospect not only of improved prescription accuracy, but the ability to verify that the prescriptions were filled and appropriately refilled, assures providers that patients understand and follow the medical care plan.
In that E-prescribing works best as add-on function to computer systems that register patients, track their medical histories and document treatment plans, the larger healthcare provider organizations are well-positioned to adopt E-prescribing. Stand-alone E-prescribing software may be useful for physician practices that do not currently employ electronic medical record systems.

Healthcare providers appreciate the federal government’s role in establishing efficient technical standards to facilitate installation and insure sound investment of precious healthcare dollars.

B. Costs

HIMSS appreciates the opportunity to comment on the cost analysis section of this rule. All systems implementations have related costs regardless of the status of system standards. System implementations require the analysis, and implementation and support costs as well as lost opportunities for practices during the implementation and training periods. In addition hardware costs and annual system support for upgrades are additional costs for provider organizations. Hence providers will remain cautious in the adoption of health information technology including E-prescribing. Smaller “Physician Groups” are implementing the “E-prescribing solution” at a much lower level of integration with the EMR. The level of integration has and will continue to have a direct impact on the utilization of the E-prescribing solution. Costs for implementation of the E-prescribing standards will impact Retail Pharmacies, Medical Practices, Vendors, Payers and Clearinghouses.

The two main additions to the standard, Formulary and Benefit Information, and Medication History change the work-flow of the clinician significantly, since these two features directly impact point of care processes. As with any major functionality, there will be a disruption to productivity of the clinicians until the workflow associated with these two functions is incorporated.

- The AHRQ report, entitled, “Findings From the Evaluation of E-prescribing Pilot Sites,” highlighted the complexity of the Formulary feature given the lack (or limited) implementation by the payers). This leads to addition integration by the physician practice in order to yield the benefits of this feature. From the Executive Summary, page vii: As with medication history, however, there are important implementation issues. First, systems must adequately match patients to health plans, or the formulary and benefits data will not be available. Second, payers vary
in the level of information that they provide, and data elements can be difficult to interpret even when they are transmitted accurately.\(^5\)

- The Findings also highlight that practice staff play a significant role in the E-prescribing process, which suggests that the process is not dependent on a single person and a simplified process, but one requiring coordination and integration.

> Page ix: One finding that was consistent across all sites was that prescribers’ staff played a much more important role in the E-prescribing process than most pilot sites had anticipated. The evaluation team recommends that future E-prescribing efforts take the role of these staff, or "surrogate prescribers" into account in their planning.\(^6\)

- Most physician practices are small, and the Findings note that there may be productivity loss due to decrease in verbal communications for the office processes in these small practices. This suggests that CMS should analyze cost and benefits based on practice size. The Findings state, Page ix: Finally, preliminary findings suggest that E-prescribing tools may decrease reliance on verbal orders and generate certain efficiencies for small physician offices. The analysis needs to fully identify the costs associated with disruptions to updating existing E-prescribing capabilities to the new capabilities, as well as the cost of implementing new sites to incorporate the new capabilities, since we know from actual E-prescribing implementation practices suffer productivity loss, which results in temporary loss in patient volume and increased labor costs to cover minimize impact to practice volume.\(^7\)

a) Workflow Impact

The NPRM states on page 64911, B. Costs: We assume that implementation of the NCPDP SCRIPT standards would not significantly affect the implementation cost; to implement the foundation standards and these two standards is not significantly higher than the cost of implementing the foundation standards alone.

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b) Incomplete Physician Savings calculation

Table 3 suggests savings associated with Administrative and Physicians and Medical Office Staff that use E-prescribing. The NPRM recognizes that there are costs associated with the implementation of E-prescribing, but states that they are minimal. Based on the E-prescribing Pilot Findings and experience from real E-prescribing implementations, CMS should include an analysis of the real costs associated with the implementation of E-prescribing, and factor those costs into the calculation to determine a more accurate Net Savings value. Costs include additional staff and physician labor needed to compensate for lost productivity, vendor or consultant labor needed to resolve integration issues between PBM’s or E-prescribing suppliers providing accurate formulary and medication history information and lost revenue associated with loss of patient volume. Several studies

\textsuperscript{8} Ibid, page vii.
\textsuperscript{9} Ibid, page ix.
\textsuperscript{10} Ibid, page ix.
analyzing E-prescribing and EMR implementation have quantified a net loss to a practice ranging from nine to 14 months. The administrative savings also may provide benefits, but the savings also needs to reflect the start-up costs to deal with the implementation of the features that change the practice workflow, similar to the costs incurred by the physician. Administrative costs are more tangible for large practices than small practices. Several E-prescribing studies highlight the reduction in chart pulls, calls to confirm benefits, refill information, etc., by office staff, to the extent that in large practices they have eliminated FTE's that were no longer needed to perform these tasks once E-prescribing was implemented. However, for small practices, the elimination of some of these tasks may not allow small practices to realize similar savings. Therefore, in addition to quantifying the costs to determine Net Administrative Savings, CMS should considering scaling the savings to practice size. Furthermore, given the above discussion on workflow impact related to "surrogate prescribers" described in the pilot findings report, the saving should be minimal in the early years of deployment.

c) Clarifying Administrative Physician Office and Pharmacy Savings associated with E-prescribing in Total Benefits Roll-up

Table 6 compiles the savings / benefits for the various stakeholders in the E-prescribing process, represent total societal benefit. We suggest that CMS clarify this table to ensure that policymakers do not construe that these savings directly correlate to savings to Medicare or the private payers when E-prescribing is implemented. This is especially important in the wake of efforts to incentivize adoption of E-prescribing to reduce Medicare costs: in order to make appropriate policy decisions the costs and benefits, direct costs and direct benefits that can be realized by CMS must be identified, with other benefits characterized as positive externalities of implementing E-prescribing. Physician Office and Pharmacy benefits do not roll up to benefits for CMS. These benefits are cost savings that may be instructive in determining future reimbursement or E-prescribing adoption policies by CMS, but they are not direct benefits in the same manner that real savings associated with generic drug use (versus name brand) provide, or the cost avoidance associated with eliminating adverse drug events (ADE’s).

d) CMS E-prescribing Costs should reflect increase Rx cost due to increased patient compliance of script fulfillment

In the discussion of benefits, CMS does not include the likelihood that actual drug costs will increase due to increase volume related to improved patient compliance. A study by Walgreens, SureScripts and IMS identified that retail pharmacies that deploy electronic prescribing saw an 11% increase in prescriptions. The study also cites that 20% of all prescriptions go unfilled. Retail pharmacy drug costs totaled $201 billion; according to a February 2007 GAO study citing CMS data. That means the potential cost of full compliance could have been as high as $251 billion, a $50 billion increase. That means the

number of Medicare E-Prescriptions in Table 1 needs to reflect an increase number of prescriptions due to the use of prescriptions and the increased transaction costs. In addition, CMS should include the increased cost associated with increased drug prescription fulfillment that is attributable to E-prescribing. Note that the original E-prescribing Final Rule CMS-0011-F did not identify increased prescription volume and its associated costs related to E-prescribing.

1. **Retail Pharmacy:**

Retail pharmacies in general like e-prescription due to its ability to improve the quality, safety and reduce overall costs of care. However, some pharmacies experience challenges with the timeliness and delivery of prescriptions due to system reliability, and network architecture issues. These issues must be addressed to enable the adoption of E-prescribing with retail pharmacies.

Pharmacists also work with physicians, prescribers, and other health professionals as medication use experts. The real-time patient medical information described in the preamble can truly enable the ability of pharmacist services to improve health, increase quality, and reduce both drug and overall health costs. Robust literature also supports pharmacists educating prescribers about new drugs, evidence-based medicine, and formulary and benefit design. These activities - provided during or in addition to the dispensing process - will rely on the proposed standards required of all "dispensers," and may have a role in overcoming shortcomings experienced in the pilots. The evolution of electronic prescribing to support all aspects of pharmacy practice will help align incentives for the continuity of care. Patients and providers alike benefit from innovations in drug therapy, patient education, and disease management.

In addition, HIMSS appreciates the opportunity to provide the impact on private and non-retail chain pharmacies. Although e-prescribing is voluntary, the impact to private pharmacy practices (non-retail chain) will require upgrades to the retail pharmacy systems in order to accommodate e-prescribing. Costs associated with such an upgrade will be passed on or absorbed in the private pharmacy practice.

In the community health center setting, in-house pharmacies often maintain the formulary for the community health center and the formulary would not be available through the proposed system standards. In these settings, e-prescribing transactions sent through outside clearinghouses will introduce additional costs to obtain prescriptions from ambulatory EMR systems into a pharmacy system. The pharmacy transaction standards will help community health centers avoid the transaction costs of outside clearinghouses by re-using the technology to go directly between the ambulatory EMR and the pharmacy system.
2. Medical Practices

Medical practices have the same types of hardware, software costs and costs for broadband Internet connections as other facilities. As discussed earlier in our response, workflow changes required to use e-prescribing usually can result in decreases in productivity, which are most difficult to absorb in small practices. The major cost savings associated with e-prescribing for a medical practice do not occur until refills can be handled electronically eliminating phone calls. This feature is often not turned on in e-prescribing systems imbedded in electronic health records and pharmacies do not change workflow to electronic refill requests until sufficient numbers of physicians and prescriptions are sent electronically. Although physician practices bear the burden of the costs associated with buying, implementing and supporting electronic prescribing, they may not see significant cost savings for months to years with small, rural practices taking the longest.

3. Vendors

The rule suggests that costs for development and testing to bring products into compliance are minimal and come under the cost of doing business. For vendors of stand-alone E-prescribing systems and ambulatory EMRs, the cost may be minimal since they support the foundation standards. However, even those systems that have obtained CCHIT and other certifications may not yet support the Formulary and Benefit transaction and will incur cost for development and testing.

Conclusion

HIMSS is grateful to CMS for allowing us the opportunity to provide comment to CMS’ Proposed Final Rule “Medicare Program: Proposed Standards for E-prescribing Under Medicare Part D; Proposed Rule” (CMS Reference Number: CMS-0016-P posted in November 2007). We commend CMS for issuing the final uniform standards for the electronic prescription drug program.

HIMSS members represent more than 20,000 individual, 330 corporate members, and 47 chapters nationwide. HIMSS seeks to shape healthcare public policy and industry practices through its educational, professional development, and advocacy initiatives designed to promote information and management systems’ contribution to quality patient care. Providing comment on this rule aligns with our mission to lead change in the healthcare information and management systems field through knowledge sharing, advocacy, collaboration, innovation, and community affiliations for healthcare IT professionals and providers represented by our membership. We are dedicated to work with Industry and Government leaders by providing comment on issues and rules that impact the delivery and quality of care provided to all patients.
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