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January 9, 2008

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0016-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: CMS-0016-P, Medicare Program; Proposed Standards for E-Prescribing Under Medicare Part D

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the proposed standards for e-prescribing under Medicare Part D. ASHP represents pharmacists who practice in hospitals and health systems. The Society's more than 30,000 members include pharmacists and pharmacy technicians who practice in a variety of health-system settings, including inpatient, outpatient, home care, and long-term-care settings.

Outpatient care is a major part of what hospitals do today. There were nearly 700,000 outpatient visits in hospitals in 2006. Nationwide, 28% of general and children's medical-surgical hospitals have an outpatient pharmacy. Among hospitals with more than 400 beds, 55% have an outpatient pharmacy. Many of these pharmacies serve a large number of patients. For example, the outpatient pharmacies at one large health system in the southeast have 500,000 patient visits and dispense 1.6 million prescriptions per year.

ASHP is pleased that CMS has published proposed standards for e-prescribing under Medicare Part D. However, the Society is concerned that, throughout the proposed rule, CMS refers to pharmacists as "dispensers." While dispensing medications is a component of the services pharmacists provide, referring to a pharmacist as a "dispenser" ignores the clinical component of pharmacist-patient interactions.

Pharmacists meet the primary care needs of patients by providing medication management and, in states where it is authorized, collaborative drug therapy

management. The activities of a pharmacist in collaborative drug therapy management may include, but are not limited to, initiating, modifying, and monitoring a patient's drug therapy, ordering and performing laboratory and related tests, assessing patient response to therapy, counseling and educating a patient on medications, and administering medications.

Recent research shows that 5% of ambulatory prescriptions contain significant clinical errors that are identified and corrected by pharmacists. Research has also shown that the decision support function in e-prescribing software only reduces these errors by 50%.¹ Therefore, the pharmacist provides a very important quality and safety check in the prescribing process.

Additionally, the Medicare Modernization Act of 2003 and its implementing regulations recognize pharmacists' participation in medication therapy management. Part D prescription drug plan sponsors are required to establish a medication therapy management program, provided by a pharmacist or other qualified provider, designed to optimize therapeutic outcomes for targeted beneficiaries by improving medication use and reducing adverse events.

Recommendation: ASHP strongly recommends that CMS refer to pharmacists, rather than "dispensers" in its final rule.

Pilot Test Findings

Standard for Formulary and Benefits

While the pilot sites demonstrated that The National Council for Prescription Drug Programs (NCPDP) Formulary and Benefits Standard 1.0 can be successfully implemented between the prescriber and the plan, the pilots failed to validate how this information can be incorporated into the prescriber's workflow, and also failed to show whether the information can be exchanged or secured into existing prescription writing tools or modules within fully functional electronic health record systems. The simple provision of this information does not ensure real time delivery when needed to optimize prescriber efficiency and expedite patient care. Non-interoperable formulary and benefit information will likely be unusable for the prescriber if this information is not introduced within the workflow, and may lead to confusion of formulary and benefit management roles and responsibilities between the pharmacist and prescriber. Delays in prescription processing and patient dissatisfaction could result.

¹ Research findings resulting from e-prescribing pilot at Brigham and Women's Hospital, presented by Thomas Moniz, PharmD, Informatics Research Fellow, Brigham and Women's Hospital, Clinical Pharmacist, Beth Israel Deaconess Medical Center, at ASHP Midyear Clinical Meeting and Exhibition, December 2007.

Recommendation: ASHP recommends further pilot testing of this standard within the framework of systems that can deliver the information real time and within the workflow of the prescriber and pharmacist.

Standard for Medication History

The Agency for Healthcare Research and Quality (AHRQ) report, Findings from the Evaluation of E-Prescribing Pilot Sites, notes on pages 34-35 that clinicians' willingness to access medication history was shown to be limited at the pilot sites. These clinicians believed the information was not complete enough to provide real value, suggesting a number of implementation and process issues that may lead to unintended results and false assumptions, resulting in error. The NCPDP Script 8.1 standard for medication history must support the source of medication history for over-the-counter (OTC) as well as herbal medications, and provide the degree of flexibility to transmit various levels of incomplete medication history information from healthcare providers and ancillary personnel (e.g. medication name with or without dosage form, strength and directions).

Recommendation: ASHP recommends further testing of this standard prior to adoption to clarify needed requirements for completeness and usability of information, and to determine where the information can be most effectively introduced and exchanged within the healthcare provider's workflow.

Standard for Structured and Codified SIG

ASHP agrees with CMS that the NCPDP's proposed Structured and Codified Signatura (SIG) Standard 1.0 is not sufficiently developed for use for Medicare Part D e-prescribing in its current state. ASHP also notes that existing standards only require that the e-prescription be "viewable." There is no requirement for the information to integrate or "pre-populate" the dispensing software used in the receiving pharmacy, so in most instances the pharmacist must re-enter SIG information into existing pharmacy dispensing systems.

Recommendation: ASHP strongly recommends that CMS ensure that e-prescribing systems are interoperable with pharmacy dispensing systems to reduce opportunities for transcription and eliminate chance of error.

Standard for Fill Status Notification

Although sufficient to support the pharmacy sending prescription status messages to the prescriber, the Fill Status Notification standard does not allow support for reconciliation of the prescription order and pick-up cycle, including pharmacy receipt, patient pick up, reason for refusal of fill, and the placement of the order in the prescription filling process. This standard must ensure that e-prescribing systems and supporting pharmacy systems are interoperable in order to secure closure of the prescription process from ordering to

pickup, thus guaranteeing patient safety and reducing possibilities for fraud and redundant processes. A number of implementation, process and operational feasibility issues remain regarding this standard.

Recommendation: ASHP strongly recommends that a further analysis be performed that fully utilizes the already-developed systems in order to ensure prescription order cycle closure and to fully test this standard prior to adoption.

Proposed Compliance Date

ASHP believes a number of implementation, process and operational feasibility issues, particularly surrounding interoperability with e-prescribing/pharmacy dispensing and electronic health record systems, remain. The proposed compliance dates are extremely aggressive and do not take into consideration vendor system development life cycles, generally available release dates of supporting systems, and time and resources required for health systems to adopt and deploy the needed infrastructure to attain the expected financial and safety benefits of e-prescribing.

Pharmacy software must be modified to support the manual transcription and matching of e-prescribing identifiers with the pharmacy system identifiers. Such identifiers include the codified SIG, patient selection and drug product selection. Standards are currently not in place to support automating this need. As a result, pharmacists must transcribe the e-prescription into their computer systems. This transcription is most often accomplished by printing the e-prescription prior to this re-entry of the data. Such lack of integration of the e-prescription into the pharmacy system results in an e-prescription that is essentially no different than a fax.

As identified in the American Health Information Community (AHIC) e-prescribing recommendation 2.2: “With appropriate Congressional authority, all pharmacies and pharmacy benefit managers must participate in such mandatory e-prescribing.” It is important for all pharmacies to be enabled with e-prescribing in order for physicians to be compliant. Other than testimony provided by SureScripts, there is no existing study that identifies whether pharmacies are prepared.

Recommendation: ASHP recommends that a study be implemented to identify pharmacy preparedness, the pharmacy enabled goal, and what is needed to reach that goal.

Recommendation: CMS should develop a structure to support the quality management and safe use of these standards.

AHIC recommendation 2.7 states: “Pursuant to Patient Safety legislation of 2005, the Agency for Healthcare Research and Quality (AHRQ) should designate Patient Safety Organizations to monitor and address possible patient issues that may arise as a result of

e-prescribing, and patient safety criteria should be included in an e-prescribing certification process.” There is currently no organization monitoring the safe use of e-prescribing. If a problem is found by a patient, prescriber or other individual, there is no organization to which the problem can be reported for a quick resolution of the problem.

Regulatory Impact Analysis

Small Rural Hospitals

CMS notes that the Agency is required to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. The Agency further states that this proposed rule will not affect small rural hospitals because the program will be directed at outpatient prescription drugs covered under Medicare Part D, and not drugs provided during a hospital stay.

Recommendation: ASHP recommends the CMS prepare a regulatory impact analysis for small rural hospitals, since this rule may have a significant impact on the operations of a substantial number of small rural hospitals that dispense discharge medication and “after hours” emergency medications to patients.

Costs; Retail Pharmacy

In its regulatory impact analysis, CMS states that the NCPDP Script 8.1 Medication History transaction supports communication between the pharmacist and the prescriber. Furthermore, CMS assumes that the Medication History transaction will be carried out between the plan and prescriber, and therefore preliminarily concludes that pharmacies will not incur costs related to this transaction.

However, in the Medication History section of the proposed rule, CMS correctly acknowledges that adoption of the NCPDP SCRIPT 8.1 standard for the medication history transaction will provide a uniform communications mechanism for prescribers, pharmacists, and payers, support reconciliation of useful data from a large number of sources, and raise awareness of its availability among providers.

Additionally, in the Pilot Test Findings section of the proposed rule, CMS states that a medication history standard provides a way for prescribers, pharmacists, and payers to communicate about a listing of drugs that have been prescribed or claimed for a patient within a certain timeframe. It may provide information that would be of use in helping to identify drug interactions, including the dispensing pharmacy and the prescribing physician. CMS further notes that this standard has been useful in preventing medication errors, as well as understanding medication management and compliance.

Recommendation: ASHP strongly recommends that CMS acknowledge in its regulatory impact analysis, as it did in previous sections of the proposed rule, that the medication history transaction will be carried out between the plan, the prescriber, and the pharmacist, and further recognize the costs incurred by pharmacies related to this transaction.

Recommendation: ASHP also recommends that CMS recognize the importance of pharmacist access to the medication history as this is needed for their professional verification of the prescriptions and medication therapy. This verification is a Joint Commission requirement in the hospital environment to ensure patient medication safety.

Benefits; Formulary and Benefit Standard – Administrative Savings; Pharmacists

ASHP is concerned that, in Table 4 of the proposed rule reflecting administrative savings for pharmacists, CMS overestimated the administrative cost savings for pharmacists. The number of hours a pharmacist spends handling formulary-related and benefit transaction issues is often less than, not equivalent to, the number of hours spent by a physician, or a physician's staff member handling these same issues. For example, the pharmacist will often call the physician and, while waiting for a response from the physician, continue to perform other tasks, thus devoting less time to handling the formulary-related issue.

The e-prescribing pilots identified a shift in work from the physician's office to the pharmacy. Part of this shift is caused by the new workflow in pharmacies that have to track down e-prescriptions that were sent but not received by the pharmacy. The additional workflow and tools to support it are not addressed in the standards. Additionally, pharmacists must continually follow up on eligibility, formulary and pre-authorization issues. This work has shifted to the pharmacies because, as identified in the pilots, the physician offices are finding it difficult to enter prescription benefit plan information into their systems. This plan information is required to do checks for eligibility, formulary compliance and pre-authorization.

ASHP believes that full integration of e-prescribing standards is necessary to facilitate the functionality needed for real administrative savings in the pharmacy.

Recommendation: As noted previously, ASHP strongly recommends that CMS ensure that standards to facilitate additional functionality are goals that are expressly stated by CMS as part of the intent of e-prescribing.

The additional per prescription charge to receive what is essentially a digital fax offers minimal benefit or value for a pharmacy to participate. This lack of operational benefit further underscores the need to make clinically relevant information, such as the patient's medication history, available to the pharmacist.

Benefits; Medication History Standard – Reduction of Adverse Drug Events

ASHP supports the adoption of the NCPDP SCRIPT 8.1 standard for the medication history transaction, and agrees that it will provide a uniform communications mechanism for prescribers, pharmacists, and payers, support reconciliation of useful data from a large number of sources, and raise awareness of its availability and use among providers. However, ASHP cautions CMS that oversight of the medication history transactions is needed, in order to ensure that automating the transmission of medication history information will provide a safer and more effective health care system.

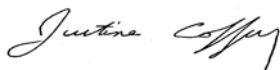
CMS should also recognize the importance of making the medication history information available to the pharmacist. The pharmacist verifies the prescription against other medications the patient is taking and consults with patients on their medication therapies and OTC medication use. Access to this medication history information is extremely important in order for the pharmacist to assure safe and cost effective medication therapies and to meet their clinical obligations to the patient.

Additionally, AHRQ, Findings from the Evaluation of E-Prescribing Pilot Sites, notes on pages 105-106 that, “Although the standard worked technically, only a small fraction of prescribers used the [medication history standard] function or knew it was available. More research must be done to determine the optimal way to display and maintain the list.... The experience from the pilots suggests that more work is necessary before the standards driven medication history information can be reconciled effectively from multiple sources and be displayed in a user-friendly manner within the e-prescribing system.”

Recommendation: ASHP strongly recommends that further research be performed to determine methods to effectively reconcile standards driven medication history information prior to implementation of this standard.

ASHP appreciates this opportunity to present its written comments on the proposed standards for e-prescribing under Medicare Part D. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,



Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs