



January 15, 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: File Code CMS-0016-P

Dear Sir/Madam:

The Academy of Managed Care Pharmacy (AMCP) is pleased to have the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the proposed standards for e-prescribing under Medicare Part D.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's 5,700 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

The Academy commends the leadership role of the Secretary in the promotion of electronic prescribing technology. Electronic prescribing offers benefits to all parties involved. Patient benefits include: enhanced safety of the medication management process and the improved efficiency of having prescriptions electronically transmitted to the pharmacy. Prescribers benefit through the greater accuracy of the prescribing process due to improved access to patient medical data and increased efficiency because of the reduction in phone calls to/from pharmacists. Pharmacists benefit from the increased efficiency of fewer phone calls to/from prescribers, allowing additional time to care for patients. In order to reap these benefits, all parties must strictly adhere to the e-prescribing standards to ensure interoperability. CMS must ensure that all users implement the standards in the same manner.

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A major obstacle to prescriber adoption of e-prescribing is the fact that the Drug Enforcement Administration (DEA) prohibits prescriptions for controlled substances from being transmitted electronically. Controlled substances constitute approximately 12.5% of all prescriptions. Many prescribers, however, are not willing to embrace e-prescribing if they can e-prescribe for non-controlled substances only. They object to engaging in one process for non-controlled substances, and then engaging in another process for the percentage of prescriptions that cannot be transmitted electronically. Accordingly, the DEA prohibition of the e-prescribing of controlled substances has proven to be a barrier to the widespread adoption of e-prescribing. The Academy asks that CMS give top priority to encouraging DEA to allow e-prescribing for controlled substances.

Electronic prescribing is a rapidly evolving field, with advancements occurring almost daily. Standards in use today quickly become outdated and newer versions with enhanced capabilities are released and adopted by the industry. Electronic prescribing in the Medicare Part D Prescription Drug Program should not be hampered by requirements that place restrictions on the software version that may be used. CMS should develop standardized procedures to review newer versions of e-prescribing standards as they are released and standardized approaches to adopt these newer standards once their benefits and the business needs for the updated standards have been demonstrated.

The Academy's comments on the proposed rule follow.

Pilot Test Findings

Pilot testing was performed on several standards that enhanced the previously identified foundation standards. Pilot testing was performed on several standards that enhanced the functionality of the foundation standards. The pilot testing produced the following results:

- National Council for Prescription Drug Programs (NCPDP) Formulary and Benefits Standard 1.0.
Pilot testing showed that it may be successfully implemented.
- The medication history standard included as a transaction in NCPDP SCRIPT 8.1.
Pilot testing found that this standard is well structured, supports the exchange of information and would not impose an undue administrative burden. CMS proposes that this standard also be implemented.
- The NCPDP Structured and Codified SIG standard 1.0.
Patient instructions for taking medications are called the *signatura*, commonly abbreviated SIG; however, there is no standardized format or vocabulary for SIGs, leaving room for misinterpretation and error. Pilot testing found it to be not

sufficiently developed for use at this time. CMS proposes that it not be implemented in its current state.

- The standard for clinical drug terminology (RxNorm).
RxNorm is a vocabulary that provides standard names for drugs and dosage forms. Pilot testing found that it has significant potential, but is also not sufficiently developed for effective and accurate use. CMS proposes that it not be implemented at this time.
- The standard for fill status notification.
The standard enables a pharmacy to notify a prescriber when a prescription has been fully dispensed, partially dispensed or not dispensed. Pilot testing found it to have challenges in its implementation, have no marketplace demand for the information and may cause unnecessary administrative burdens on prescribers and dispensers. CMS does not propose its implementation.
- The standard for prior authorization.
Pilot testing found that modifications would be required before it could be adopted as a final standard. CMS proposes that it not be implemented in its current form.
- The use of the standards in the long-term care (LTC) setting.
Pilot testing showed that modifications were required in order to ensure accurate transmission of the data. Long-term care is currently exempt from the e-prescribing provisions; however, CMS will consider removing the exemption when a version of the NCPDP SCRIPT Standard becomes available that can accommodate the unique workflow of the LTC setting.

The Academy is in agreement with the CMS proposals to implement the standard for formulary and benefits and the standard for medication history, and the decision that the standards for structured and codified SIG, RxNorm, prescription fill status and prior authorization are not sufficiently evolved and should not be implemented without further modifications and enhancements. Development will progress for each of the non-implemented standards, and continued testing for possible future adoption must occur.

Adoption of NCPDP SCRIPT 8.1

CMS proposes to revise § 423.160(b)(1) to replace the NCPDP SCRIPT 5.0 standard with NCPDP SCRIPT 8.1. While this change will benefit e-prescribing because of the addition of the formulary and benefits standard and the medication history standard, modifications are still required for use in the LTC environment. NCPDP has adopted changes in later versions of the SCRIPT standard to accommodate the needs of LTC pharmacies and facilities. NCPDP SCRIPT 10.5 incorporates these changes and is more suitable for use in all settings, including LTC. Therefore, the Academy recommends that CMS adopt NCPDP SCRIPT 10.5 as a final standard.

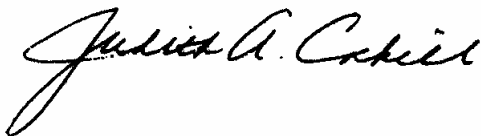
Adoption of the National Provider Identifier

Although the National Provider Identifier (NPI) was not tested in the pilot project, CMS believes there is adequate industry experience to support its use in e-prescribing. In addition, use of the NPI is required in HIPAA-compliant transactions, and has proposed that it be adopted as the standard identifier for electronic prescribing.

The Academy does not agree that the NPI should become an e-prescribing standard because it has its limitations. When used in e-prescribing, it identifies the prescriber, but does not have the capability of identifying where the prescriber is located, nor the device used in the electronic transaction. Prescribers are assigned one NPI, but may have more than one office location, and may use different devices for the electronic transaction, such as: desk top computer, hand held device, smart phone, etc. When routing transmissions to and from prescribers, it is necessary to identify the specific location and device used in the transmission of information. The NPI cannot provide this information; therefore additional identifiers are required for electronic prescribing transactions, such as the SureScripts SPI, which does convey location/routing information. The SureScripts SPI renders the NPI superfluous, and it becomes little more than unnecessary transaction overhead.

AMCP appreciates the opportunity to comment on the proposed standards for e-prescribing under Medicare Part D. If you have any questions regarding our comments or wish additional information, please contact me at (703) 683-8416 or jcahill@amcp.org.

Sincerely,

A handwritten signature in black ink that reads "Judith A. Cahill". The signature is written in a cursive style with a large, sweeping initial 'J'.

Judith A. Cahill
Executive Director