Testimony of

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Good morning Chairman Leahy, Senator Specter and distinguished members of the Committee. It is my pleasure to be here today to discuss the Centers for Medicare & Medicaid Services' (CMS) role in promoting widespread adoption of electronic prescribing (e-prescribing). The current medication prescribing process, which predominantly relies on handwritten prescriptions, is prone to errors.1 Physicians and other prescribing health care professionals typically make drug-prescribing decisions using whatever information is known or readily available at the time they write a prescription. They often do not have a complete and accurate medication list or medical history for their patient and, as a result, they can miss potential contraindications or duplicate therapies.

It is estimated that each year some 530,000 adverse drug events take place among Medicare beneficiaries alone because of drugs negatively interacting with other drugs the patient is already taking, or insufficient information about the patient's medical history.2 The Institute of Medicine (IOM) reported last year that more than 1.5 million Americans are injured annually by drug errors in hospitals, nursing homes and doctor's offices.3 These negative drug events may require costly interventions in order to stabilize the patient, including hospitalization.

The Benefits of Electronic-Prescribing

E-prescribing has the potential for improving beneficiary health outcomes. For providers who choose to invest in e-prescribing technology, the adoption also could improve quality and efficiency and could show promise in reducing costs by actively promoting appropriate drug usage; providing information to providers and dispensers about formulary-based drug coverage, including formulary alternatives and co-pay information; and speeding up the process of renewing medications. E-prescribing also may play a significant role in efforts to reduce the incidence of drug diversion by alerting providers and pharmacists of duplicative prescriptions for controlled substances.

E-prescribing has the potential to empower both prescribers and pharmacists to deliver higher quality care and improve workflow efficiencies. Typically, providers give a handwritten prescription to the patient or fax it to a pharmacy or other dispenser. Pharmacists can have a difficult time reading handwritten prescriptions and may have little or no information about the patient's condition for which the prescription is written. Contacting the provider by phone to clarify the prescription often results in delays for the patient and is time-consuming for both the provider and dispenser. According to some estimates, almost 30 percent of prescriptions require pharmacy callbacks.4 This translates into less time available to the pharmacist for other important functions, such as educating consumers about their medications. A potential benefit of e-prescribing in preventing errors is that each prescription can be checked electronically - and quickly - at the time of prescribing.

In addition to the potential for saving time, the IOM has noted that widespread adoption of e-prescribing could eliminate thousands of adverse drug events each year.5 For those individuals who require multiple medications, e-prescribing could help to promote medication therapy management and support care coordination across various providers. This could, in turn, decrease the financial impact of treating the results of adverse drug interactions. Additionally, having information about formulary alternatives could reduce patients' out-of-pocket costs, such as co-pays.

Currently just 5 to 18 percent of providers are estimated to use available e-prescribing. 6 The technology required to electronically receive prescriptions is already in use by many pharmacies, however.

CMS Efforts to Promote Widespread Adoption of E-Prescribing

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directed CMS to establish standards to support a voluntary e-prescribing program for the Medicare prescription drug program (Part D). Although there is no requirement that providers write prescriptions electronically, providers that prescribe or dispense Part D drugs must comply with adopted standards when conducting electronic prescription transactions or seeking or transmitting prescription information for Part D drugs prescribed to Part D eligible individuals. CMS, based on National Committee on Vital and Health Statistics (NCVHS) recommendations reflecting industry and other stakeholder input, has taken an incremental approach to adopting final uniform standards for e-prescribing in Part D. This approach identified foundation standards that could be implemented by January 2006 and built upon through subsequent rulemaking. All standards will be consistent with the MMA objectives of patient safety, quality of care, and efficiencies and cost savings in the delivery of care.

CMS published a final rule establishing electronic prescribing foundation standards for the Part D program at the beginning of November 2005. Based on industry consensus and recommendations from the NCVHS,7 the final rule identified three well-accepted standards that were ready for immediate implementation - "foundation" standards. The foundation standards took effect on January 1, 2006, and related to transactions involving: the communication of prescriptions and prescription-related information between prescribers and dispensers; eligibility and benefits inquiries and responses between prescribers and Part D sponsors; and eligibility and benefits inquiries and responses between dispensers and Part D sponsors.8 The foundation standards were not pilot tested because there was already adequate industry experience with these standards. The publication of foundation standards in 2005 helped establish a basis for future e-prescribing implementation and interoperability.

In addition to publishing foundation standards in 2005, the Secretary also recognized six "initial standards" for pilot testing, consistent with the MMA's requirement. Those six initial standards address: formulary and benefit information; exchange of medication history; fill status notification (RxFill); structured patient instructions (SIG); clinical drug terminology (RxNorm); and prior authorization messaging.9 The HHS e-prescribing pilot utilizes five pilot sites to test the initial standards. The pilot was set up to validate initial standards and their interoperability with existing foundation standards as well as to look at workflow issues associated with e-prescribing. CMS published a Report to Congress in April 2007, detailing the results of the pilot testing.10

On November 16, 2007, CMS published a notice of proposed rulemaking to adopt two of the six pilot tested initial standards (related formulary and benefit information, and exchange of medication history) as "Final Uniform Standards."11 These proposed standards would supplement the foundation standards that took effect on January 1, 2006. The proposed formulary and benefit standard is intended to provide prescribers with information about a patient's drug coverage at the point of care. This may include information on formulary status and a list of alternative drugs that allow the provider in many cases to substitute a generic drug, thus saving the patient money. The goal is to enable the prescriber to take this information into account at the time of prescribing, which could reduce the amount of back-and-forth communication needed with the pharmacy or the health plan.

The medication history standard is the second standard CMS proposes to implement in the near term. This standard is intended to provide a uniform means for prescribers, dispensers, and payers to communicate about the list of drugs that have been dispensed to the patient. This standard is widely accepted and employed by those currently using e-prescribing.

Pilot testing found that three remaining initial standards - Codified SIG, RxNorm, and prior authorization messaging - require additional work before they could be proposed as final uniform standards. The sixth standard - RxFill - is ready for Part D use but has not been proposed as a final standard due to an absence of marketplace demand at this time.12

At the end of the day, regardless of rulemaking, industry collaboration, or pilot testing, e-prescribing remains voluntary in Medicare and essentially throughout the health care marketplace. CMS is committed to continued testing

and work with industry experts to advance the development of secure, scaleable and administratively feasible e-prescribing standards for use throughout the health care system. The challenge in moving forward is that the law does not treat all prescriptions the same. We look forward to addressing the challenges posed by controlled substances in future pilot programs.

Collaboration with DEA and Others

Concurrent with work to standardize e-prescribing in the Part D arena, CMS has been collaborating with the Drug Enforcement Administration (DEA) of the U.S. Department of Justice in recent years to identify and adopt commercially scaleable solutions that will allow for the e-prescribing of controlled substances consistent with the e-prescribing of non-controlled substances. The NCVHS held hearings in 2005 with testimony from various stakeholders including DEA, and published a recommendation letter to the Secretary in March 2005 in which they recommended that HHS, DEA, and state boards of pharmacy recognize "current e-prescribing network practices...as a basis for securing electronic prescriptions."13 In July 2006, HHS and DEA co-sponsored a public meeting on e-prescribing of controlled substances and solicited input from stakeholders. At that time, CMS stated that we welcomed an opportunity to work jointly with DEA and industry to integrate DEA e-prescribing requirements related to controlled substances into mainstream industry e-prescribing products. CMS looks forward to partnering with DEA on this important step to combat fraud and harmful drug diversion, which also would help advance broader HHS and health care stakeholder goals in the public health arena.

Interagency cooperation, working closely together with all interested stakeholders, utilizing current platforms as much as possible, is vital to further growth in e-prescribing. Toward this end, the Administration supports pilot programs that could identify gaps in current e-prescribing security measures as a useful starting point. Pilots should be coordinated with other key health care stakeholders to ensure that mainstream solutions are developed.

Conclusion

Thank you for the opportunity to talk about CMS' role in promoting e-prescribing. We are committed to ensuring patient safety not only for the Medicare population, but for all Americans. CMS looks forward to continued work with DEA and others. I am happy to address any questions or concerns the Committee may have.

1 See Institute of Medicine (IOM). Preventing Medication Errors, July 2006. Retrieved from http://www.iom.edu/Object.File/Master/35/943/medication%20errors%20new.pdf.

2 Field TS, et al. 2005. The costs associated with adverse drug events among older adults in the ambulatory setting. Medical Care 43(12):1171, 1176.

3 IOM July 2006.

4 Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule. 70 FR 6256, February 4, 2005.

5 IOM July 2006.

6 70 FR 6256 at 6260 - 6261.

7 See the September 2004 and March 2005 NCVHS letters to the Secretary of HHS (Thompson and Leavitt, respectively) at http://www.ncvhs.hhs.gov/040902lt2.htm and http://www.ncvhs.hhs.gov/050304lt.pdf.

8 Medicare Program; E-Prescribing and the Prescription Drug Program; Final Rule. 70 FR 67568, November 7, 2005.

9 Findings from the Evaluation of E-Prescribing Pilot Sites. Agency for Healthcare Research and Quality (AHRQ) Publication 07-0047 EF, April 2007, at viii.

10 Id.

11 72 FR 64900.

12 72 FR 64905

13 NCVHS Letter, March 4, 2005, Recommended Action 1.1.