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CMS Issue Alert

Medicare Modernization Act E-Prescribing

Final Rule for Adoption of Final Uniform Standards – Summary & Implications

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On April 2, 2008, CMS released a final rule regarding the adoption of electronic prescription drug program uniform standards and the adoption of a standard identifier for provider and dispenser use in e-prescribing transactions. Under the *Medicare Prescription Drug Improvement and Modernization Act of 2003* (MMA), Congress mandated that all Medicare prescription drug benefit (Part D) plans (PDPs) and pharmacies participating in Part D support an electronic prescription program. Although prescribers are not required to use e-prescribing (eRx), PDPs must have a system in place for those who do want to use e-prescribing technology. By adopting uniform standards for three additional e-prescribing standards and utilizing a national provider identifier to identify healthcare providers, CMS provides an interoperable framework that enables communications between prescribers, dispensers, and Medicare PDPs aimed at increasing efficiencies and quality of care. These standards enable an e-prescribing process that allows physicians to better track medication adherence by patients and to increase coordination through improved provider identification thereby minimizing callbacks to verify identity.

The full final rule, which is expected to be published in the Federal Register on April 7, can be found at **http://www.cms.hhs.gov/EPrescribing/**. Below is a brief summary of the final rule and implications for the healthcare industry.

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Background

The MMA directed HHS to promulgate uniform standards for the electronic transmission of data associated with the new electronic prescription drug program established under this legislation. Such data includes information about eligibility, benefits, prescribed or dispensed drugs, other drugs in the medication history and availability of less expensive, therapeutically appropriate alternatives for the prescribed drugs. The first set of e-prescribing standards, known as "foundation standards," were adopted and finalized in a final rule on November 7, 2005 (70 FR 67568), which made them effective January 1, 2006, when the Part D benefit took effect. These included (ASC) X12N 270/271, NCPDP Telecommunication Standard Specification Version 5.1 and NCPDP SCRIPT Standard Version 5.0.

On November 16, 2007, CMS released a proposed rule to formally adopt two of the three standards found ready for implementation from its six pilot projects. The two standards were Medication History and Formulary Benefits. The third standard, Fill Status Notification (RxFill), was found ready for implementation but was not proposed as it was not widely adopted in the marketplace and CMS was concerned that it would place an undue administrative burden on the industry. Additionally, CMS planned to replace NCPDP SCRIPT 5.0 with a backwards compatible NCPDP SCRIPT 8.1 and adopt the national provider identifier as a standard for transactions between the PDP, the prescriber and the dispenser.

Final Rule Summary

CMS adopted the following uniform standards in the final rule:

- **Utilizing NCPDP SCRIPT 8.1 for Medication History** - Adopting NCPDP SCRIPT 8.1 for MMA-related electronic medication history transactions and retiring NCPDP SCRIPT 5.0;

- **Adopting NCPDP Formulary and Benefit Standard 1.0 -** Adopting the NCPDP Formulary and Benefit Standard 1.0 for communicating formulary and benefit information between the prescriber and PDP for Medicare Part D e-prescribing;

- **Adopting NCPDP SCRIPT 8.1 for Fill Status Notification -** Adopting the Fill Status Notification portion of NCPDP SCRIPT 8.1, or RxFill, to enable a pharmacy to notify a prescriber when the prescription has been dispensed, partially dispensed, or not

dispensed;

- **Retirement of NCPDP SCRIPT 5.0 -** Replacing NCPDP SCRIPT 5.0 with NCPDP SCRIPT 8.1 in the final electronic prescription drug program standards set;

- **National Provider Identifier (NPI) Adoption for MMA eRX Transactions** - Adopting the national provider identifier as a standard for e-prescribing transactions among the PDP, prescriber and dispenser.

While not part of the November proposed rule, CMS decided to adopt the RxFill standard by adding the prescription Fill Status Notification and its three business cases to provide for the communication of Fill Status Notification to the list of transactions for which NCPDP SCRIPT 8.1 is used. As there exists functionality by which prescribers would be able to use their e-prescribing systems to switch on Fill Status Notification transactions for those patients whose medication adherence they wish to monitor, industry comments suggested prescribers would realize real value from the additional information exchanged.

Regarding the NPIs adoption as a standard for e-prescribing transactions among the PDPs, prescribers and dispensers, CMS notes that the NPI is already in widespread use by HIPAA covered entities in HIPAA transactions. In this final rule, CMS responds to comments confirming its intention in adopting the NPI was to extend the ability to identify healthcare providers, such as prescribers and dispensers. CMS will provide guidance in the future regarding how the NPI should and should not be used during e-prescribing.

Implications for Health Plans

CMS states in the impact analysis portion of the final rule that the cost of implementing its provisions is minimal with quantifiable benefits reaped by pharmacies, providers and beneficiaries. Average predicted benefits are expected to range from $218 million to $863.9 million from use of formulary, benefit and medication history transactions and promulgation of standards.

CMS reiterates during its impact review that e-prescribing Medicare Part D covered drugs for Medicare Part D eligible individuals is voluntary for both prescribers and dispensers. However, the standards adopted under this rule apply to all Part D sponsors, including freestanding prescription drug plan sponsors, Medicare Advantage Prescription Drug Plans and other Part D sponsors. In addition to a one-year compliance

date, many of the expected cost savings derived from e-prescribing accrue to health plans and pharmacy benefit managers resulting in opportunities for investment to promote the use of generic drugs, increase formulary compliance and improve medication adherence. With these uniform standards in place, PDPs may move forward with evaluating approaches to preparing and enabling their systems to support the exchange of eligibility, benefit and medication history.

Implications for the Pharmaceutical and Biotechnology Industries

While the final uniform standards play an important role in ensuring the interoperability and, thus, success of e-prescribing systems under Medicare, they do not have broad implications for the pharmaceutical and biotechnology industries above and beyond the traditional impact of data transmission standards.

That said, provider organizations indicated in feedback that they envision increased use of RxFill to track medication adherence for Medicare Part D beneficiaries who have chronic medical conditions, such as diabetes and hypertension. With the adoption of the Fill Status Notification, prescribers will be able to better monitor patient adherence to medications. Additionally, improved provider identification provides an opportunity for better outcomes analysis and benchmarking at the physician level and may help organizations develop more robust medication adherence approaches. Health plans, pharmacy benefit managers and pharmaceutical manufacturers are encouraged to continue to monitor and participate in the activities of standard-setting bodies.

CMS is implementing a one-year compliance date after the publication of these final uniform standards (that is, April 1, 2009). We will continue to keep you apprised of significant developments on this issue. For questions or additional information, please contact **Wendy Krasner** at 202-585-6548 or **Julie Murchinson** at 415-291-7440.

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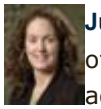
Wendy Krasner Ms. Krasner has extensive expertise in federal healthcare programs in areas including Medicare coverage, pharmaceutical reimbursement, and Medicare and Medicaid managed care arrangements. In particular she has a unique expertise with regard to the legal, regulatory and policy implications of the new prescription drug benefit now offered under Medicare and how the new benefit interacts with

the many other facets of our healthcare system.



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