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CMS's Final E-Prescribing Rule

Transmission standards for e-prescribing under Medicare Part D

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The Centers for Medicare & Medicaid Services (CMS) e-prescribing standard[1] went into effect Jan. 1, 2006, to coincide with the launch of the Part D prescription drug program. By standardizing e-prescribing transactions and establishing certain protections from fraud and abuse laws, CMS is helping to foster the proper climate to transition traditional paper-based offices toward an integrated EMR network.

According to CMS, the rate of physician e-prescribing varies from 5 to 18 percent, but usage is slowly on the rise. The current low rates of physician e-prescribing are attributed to the high cost of buying and installing systems, training employees, time and workflow impact, the lack of reimbursement for costs and resources, and the lack of knowledge about e-prescribing benefits.

Proponents of e-prescribing cite the prevention of adverse drug events (ADEs) as one of the most significant benefits of interoperable electronic systems. The Center for Information Technology Leadership, a prominent healthcare IT organization, estimates more than 8.8 million ADEs occur annually in ambulatory care, of which over 3 million are preventable. At a minimum, e-prescribing can help reduce improper dose or quantity errors that are attributed to misinterpretation of handwritten orders. E-prescribing will also improve information sharing between prescribers and dispensers by warning of potential drug-drug or drug-disease interactions or duplicate therapies. This issue is particularly critical for oncology drugs, which have a narrow therapeutic index and are toxic even at therapeutic dosages.

Oncology practitioners who currently use, or are considering instituting an e-prescription program, should review the federal e-prescribing rule carefully because it governs the transmission standards that must be employed in communicating prescription information between the physician and the pharmacy, as well as eligibility information exchanged between the physician and the Part D plan sponsor. If a physician e-prescribes for any Medicare beneficiary, he or she must implement these standards. In the original Part D rule, CMS defined a Part D eligible individual broadly to encompass any person enrolled in Part A or entitled to Part B. This broad definition carries over to the e-prescribing rule, as CMS notes, to promote consistent interpretation. The effect is to impose these standards upon any physician who e-prescribes for any Medicare beneficiary regardless of whether the beneficiary is enrolled in a Part D plan.

Practically speaking, if physicians are currently e-prescribing, they must use these transmission standards if they also treat and prescribe to Medicare beneficiaries. Eventually, these transmission standards will be established as the *de facto* industry standard for all electronic prescription systems used by physicians. Transmission of a prescription or prescription-related information between prescribers and a dispenser must employ the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard.[2] The NCPDP SCRIPT Standard is the current industry standard for electronically transmitting transactions and administrative messages between prescribers and dispensers. Eligibility and benefits inquiries between a prescriber and Part D plan sponsors must use the Accredited Standards Committee (ASC) X12N 270/271 Health Care Eligibility Benefit Inquiry and Response Standard.[3] The 270/271 Standards, as they are commonly known, are HIPAA standards and are already in widespread industry use in many medical applications, including e-prescribing programs.

Equally important, the rule preempts any state law or regulation that is contrary to the standards or restricts the ability to carry out Medicare Part D, and pertains to the electronic transmission of medication history and information on eligibility, benefits, and prescriptions with respect to covered Part D drugs.

While limited to the Part D program, the issuance of the e-prescription standard is part of CMS's broader effort to foster adoption of electronic health records within the U.S. civilian healthcare system. Given the investment in dollars and effort required to get e-prescribing off the ground, hospitals and others have inquired how to support and facilitate this effort for their community-based physicians. The federal government has attempted to balance its interest in EMRs within the framework of fraud and abuse laws that protect federally funded healthcare programs by proposing two additional rules promoting non-monetary remuneration (i.e., donated hardware, software, and related services) to set up and operate e-prescribing systems that otherwise might violate the physician self-referral law (the "Stark Law"), and the federal anti-kickback statute.

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References

[1] *See* E-Prescribing and the Prescription Drug Program, 70 Fed. Reg. 67,568 (Nov. 7, 2005) (to be codified at various portions of Subpart D of 42 C.F.R. pt 423).
[2] NCPDP SCRIPT Standard, Implementation Guide, Version 5, Release 0, May 12, 2004.
[3] ASC X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, A1, October 2002.