Good News for Physicians: E-Prescribing Will Not Be Another Unfunded Mandate, At Least Not Yet

By Justo Mendez, J.D., M.H.A., LL.M. Candidate

As an initial step in its initiative of developing and adopting a national electronic medical record system (EMR), the Bush administration has focused its efforts on the implementation of electronic prescriptions, a practice commonly known as “e-prescribing.” These efforts have led to the establishment of standards to be followed by physicians who decide to use electronic prescription systems when prescribing medications to Medicare beneficiaries enrolled in a Medicare Part D prescription drug plan.

On November 7, 2005, the U.S. Department of Health and Human Services (HHS) released a final rule adopting the foundation standards for electronic prescriptions of drugs covered by Medicare Part D. HHS refers to the final rule as the “foundation standards” because they provide a foundation for e-prescribing implementation. The establishment of industry-wide or national standards for e-prescribing technology should assist in educating and helping the healthcare industry adapt to the future of electronic health record keeping.

The e-prescribing standards became effective January 1, 2006, simultaneously with Medicare’s new prescription drug benefit. According to a White House statement, e-prescribing, which enables a physician to transmit a prescription electronically to the patient’s pharmacy, can improve patient safety and reduce health care costs. It can also decrease prescription errors caused by illegible handwriting and communication errors, and automate the process of checking for drug interactions and allergies. E-prescribing also will enable pharmacies to obtain information from drug plans about a patient’s eligibility. “These standards will allow Medicare, physicians, hospitals, group practices, other health providers, prescription drug plan sponsors and Medicare Advantage organizations to take advantage of e-prescribing technology to improve medication prescribing for Medicare beneficiaries that participate in the new prescription drug program,” said HHS Secretary Mike Leavitt in an agency news release.

The introductory regulation for the electronic prescription drug program can be found in 42 CFR § 423.159, while the standards for electronic prescribing are codified in § 423.160. In essence, the foundation standards cover:

Transactions between prescribing physician and dispensers for new prescriptions; refill requests and responses; prescription cancellation, request and response; and related messaging and administrative transactions;

Eligibility and benefits queries and responses between prescribing physician and Medicare Part D plan sponsors; and

Eligibility queries between dispensers and Medicare Part D plan sponsors.

Ever since the Bush administration announced its initiative to push the American healthcare industry towards electronic health records, healthcare providers have feared the imposition of obligatory electronic record keeping, viewing it as an unfunded mandate. Healthcare provider associations and some institutions have been very active in expressing this concern. A particular point of tension has been the risk of investment without the adoption of technical standards across the healthcare industry. Many practitioners and healthcare institutions have resisted investing in EMR technology and infrastructure that could be suddenly outdated or incompatible with other providers’ systems.

The Bush administration and HHS seem to have taken these concerns into consideration in drafting and adopting the recent EMR-related rules. First of all, healthcare providers and pharmacies are currently not required to use e-prescribing or other electronic systems. The rules just require that those providers and pharmacies who choose to do so must abide to the foundation standards. Under the e-prescribing rule, only drug plans participating in the new Medicare Part D prescription benefit are compelled to use and support electronic prescribing.

Another sign of the Bush administration’s sympathy for the providers’ concerns is the inclusion in the proposed rule of exceptions to and additional safe harbors under the Stark Law (physician self-referral prohibition) and the federal anti-kickback statute, respectively, in relation to the transfer of record keeping knowledge and technology. The proposed exceptions would allow hospitals, group practices, prescription drug plan sponsors and Medicare Advantage organizations to provide providers with e-prescribing and electronic health records technology and training services. The exceptions and safe harbors apply to “the provision of non-monetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information.” Because technology must be “necessary and used solely” for electronic prescription information, there is little room to include other services or transfer (donate) other assets as part of the technology. The exceptions and safe harbors apply to only three categories of technology donors and/or recipients:

- Hospital to its medical staff members,

- Group practices to its prescribing physician members, and

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• Prescription drug plan sponsors and Medicare Advantage organizations to pharmacists or pharmacies participating in their networks and to prescribing providers.

Healthcare providers must be advised that the safe harbors and exceptions described above have only been proposed and are still being considered for approval. In the meantime, compliance with current state and federal laws is required.

In light of the proposed rule, the worst fears of healthcare providers have not materialized with regard to e-prescribing. As HHS and the White House appear to be aware of the significant cost, financial risks, and need for assured interoperability in the adoption of EMRs, the transition from paper-based to electronic records seems likely to be gradual. Such a phased or gradual transition into electronic record keeping will not only allow healthcare providers to handle the cost, but will also assure the interoperability of a national electronic health record system.

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