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HHS PROPOSES NEW MEDICARE E-PRESCRIBING RULES PROCESS WILL IMPROVE QUALITY, ACCURACY

HHS Secretary Mike Leavitt today announced new proposed regulations that will support electronic prescriptions for Medicare when the prescription drug benefit takes effect in January 2006.

“These proposed e-prescription rules would set standards to help Medicare, physicians and pharmacies take advantage of new technology that can improve the health care of seniors and persons with disabilities.” Secretary Leavitt said.

“We are committed to widespread use of e-prescribing as quickly as possible,” said Mark B. McClellan, M.D., Ph.D., administrator of the Centers for Medicare & Medicaid Services (CMS). “In issuing these proposed rules today, seven months ahead of the deadline set by the Medicare Modernization Act (MMA), we are laying the foundation for having major e-prescribing standards in place when the Medicare drug benefit begins.

The proposed e-prescribing regulations will adopt standards for:

- Transactions between prescribers and dispensers for new prescriptions, prescription refill request and response, prescription change request and response, prescription cancellation request and response, and related messaging and administrative transactions.
- Eligibility and benefits inquiries and responses between drug prescribers and prescription drug plans.
- Eligibility and benefits inquiries and responses between dispensers and Part D sponsors.
- Formulary and benefit coverage information, including information on the availability of lower cost, therapeutically appropriate alternative drugs, if certain characteristics are met.

CMS proposes to make the compliance date for these foundation standards Jan. 1, 2006, so they will be ready for immediate use when the Medicare drug benefit begins. Additional electronic information can be used in conjunction with these foundation standards, to provide more support for using drugs safely and effectively.

“These standards reflect consensus by stakeholders through the National Committee on Vital and Health Statistics to get there quickly,” said Dr. McClellan. “This kind of public-private collaboration is the most effective way for Medicare to help lead the way to an effective electronic health care system. We’re going to take further collaborative steps to enhance our support for e-prescribing as quickly as possible.”

The MMA called upon the National Committee on Vital and Health Statistics (NCVHS) to develop recommendations for uniform standards for e-prescribing to promote patient safety and quality health care. From March to September 2004, NCVHS heard testimony from 65 witnesses and other industry experts including all stakeholder groups identified in the MMA, as well as e-prescribing networks, demonstration projects, software developers, and consumer advocacy organizations. Today's proposed e-prescribing foundation standards are based on NCVHS' recommendations to the Secretary. More information on NCVHS, its deliberations and recommendations on e-prescribing can be found at the NCVHS Web site at <http://ncvhs.hhs.gov/>.

The proposed regulations, which are now available for public comment, are an important part of the MMA, signed into law by President Bush on Dec. 8, 2003. As part of the MMA, Medicare will require drug plans participating in the new prescription drug benefit to support electronic prescribing but it will be voluntary for physicians and pharmacies.

Additional standards will be tested through a pilot project and recommended for adoption in a final rule to be issued no later than April 1, 2008, and which will take effect no later than one year from the date the standards are issued. Participation by physicians in e-prescribing will be optional, but the establishment of standards and steps to encourage the adoption of effective e-prescribing programs will make e-prescribing more attractive.

The MMA calls for a pilot project to test e-prescribing standards for which there is not adequate industry experience before their adoption by CMS. CMS soon will be soliciting applications from physicians, physician groups, hospitals, prescription drug plan sponsors, Medicare Advantage organizations, pharmacies, and other appropriate entities to participate in pilots to test new or emerging standards and other aspects of e-prescribing implementations. These standards could provide for transmission of medical history, alerts to adverse drug interactions, and suggestions for lower-cost, therapeutically equivalent alternative medications.

Electronic prescribing, or "e-prescribing," enables a physician to transmit a prescription electronically to the patient's choice of pharmacy. It also enables physicians and pharmacies to obtain from drug plans information about the patient's eligibility and medication history.

Having access to this information at the point of care makes writing, filling and receiving prescriptions quicker and easier, and it also makes it possible for physicians and pharmacies to make informed decisions about appropriate and lower-cost therapeutically-equivalent alternative medications.

E-prescribing can improve patient safety and reduce avoidable health care costs by decreasing prescription errors due to hard-to-read physician handwriting and by automating the process of checking for drug interactions and allergies. E-prescribing can also help make sure that patients and health professionals have the best and latest medical information at hand when they make important decisions about choosing medicines, and enabling beneficiaries to get the most benefits at the lowest cost.

Standards for communicating and interpreting health data are essential for obtaining greater benefits of e-prescribing. The current lack of common standards is a barrier to the use of health information technology, including e-prescribing. Adoption of e-prescribing standards by Medicare is expected to spur the use of e-prescribing throughout the nation's health care system.

The proposed rule will be published in the Feb. 4 Federal Register. Public comments will be accepted through April 5, 2005.

Note: For more information, visit the CMS Web site at: www.cms.hhs.gov.

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