
EPRESCRIBING PERSPECTIVES

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1. CMS Releases Proposed Rule for ePrescribing?

by Tony Schueth, Editor-in-Chief

On Friday, February 4, the Centers for Medicare & Medicaid Services (CMS) published proposed ePrescribing rules in the *Federal Register*. It submits standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). Go to <http://www.gpoaccess.gov/fr/> and either search for "E-Prescribing" or browse the table of contents for 2005, and then February 4.

Here is some information you might want to have about the proposed rule:

- It lays out "foundational standards;" that is, a first set of standards that do not need to be pilot tested because there is adequate industry experience with these transactions.
- The "foundational standards" include the National Council for Prescription Drug Programs (NCPDP) SCRIPT, ASC X12N 270/271 eligibility inquiries between prescribers and Medicare Part D plans and the NCPDP Telecommunications standard for eligibility and benefit inquiries between pharmacies and Medicare Part D plans.
- CMS lays out requirements for a formulary and benefits and drug history standards, respectively. It does not name one; however, it is presumed that both will be NCPDP's. In each case, NCPDP is starting with Rx Hub formats. Drug history has had minimal changes, while formulary and benefits has had input from MediMedia, ProxyMed and others.
- "Foundational standards" were selected through recommendations received by the National Committee on Vital and Health Statistics (NCVHS). That's why we have been following NCVHS so closely.
- While the MMA contains no requirement that providers write prescriptions electronically, Part D sponsors (plans) are required to support and comply with ePrescribing standards, and providers who submit prescriptions electronically must use them.
- The word "standard" is often used loosely. In the proposed rules, CMS recognizes standards that have been developed by American National Standards Institute (ANSI)-accredited institutions, such as NCPDP, ASC X12N, HL7 and others. Why? Because ANSI has a consensus-based process that allows all stakeholders a say. To illustrate, NCVHS is requiring that "standards" such as Rx Hub's drug history and formulary formats to go through an ANSI-accredited process.
- The proposed rules also ask for comments on federal preemption of state board of pharmacy (BOP) rules and regulations. As any ePrescribing stakeholder knows, state BOPs are one of the biggest barriers to ePrescribing, as software companies must comply with different rules and transaction companies must petition BOPs. (We'll write more about this in the next issue.)
- They're also proposing providing a safe harbor from Stark for ePrescribing. This is so hospitals, pharmaceutical manufacturers and others who are currently restricted from providing physicians with hardware and software will feel comfortable doing so for ePrescribing.
- Stakeholders have 60 days to comment. CMS welcomes feedback and must review, log and make all of them available for public review.

Finally, note that ancillary transactions and other components of ePrescribing not having adequate industry experience will need to be tested in demonstration projects beginning January 1, 2006. Requests for proposals will be released by CMS very soon.

As a stakeholder, what does all this mean to you? To state the obvious, this is the most monumental driver of ePrescribing ever. At a minimum, you should download the proposed rules and invest the time to read them. It'll take you some time, but it's well worth it.

Furthermore, if you've been sitting back thinking "this won't happen," you'd better get moving because it *is* happening. If you see anything in these proposed rules and regulations that you think might hurt or help you, you'd better "speak now or forever hold your peace." If you have an interest in ancillary transactions, you'd better be looking into how you can become involved in the pilots.

And don't forget about Point-of-Care Partners, which can help you with any of these steps.

2. NCVHS Update: Drafting April Letter

Since our last issue, the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards and Security has hosted two rounds of testimony on ePrescribing and is now working on an April letter to the US Department of Health and Human Services (HHS). As we've stated before, NCVHS makes recommendations to HHS about ePrescribing, among other things.

The letter follows a similar one provided on September 2, 2004. CMS strongly considered that document when formulating the proposed rules and regulations highlighted in the previous article ("CMS Issues Proposed Rules for ePrescribing"). It follows, then, that this letter may have an impact on future proposed rules and the demonstration projects highlighted in the previous article.

On February 2, the subcommittee began drafting the letter, and there has been one conference call. A significant component will be dedicated to electronic signature, as was several rounds of testimony. From discussions, it appears that the subcommittee holds the security provisions provided by the current ePrescribing networks (SureScripts, ProxyMed and Rx Hub) in high regard.

Nevertheless, best practices need to be established so that those existing or emerging networks that aren't as secure as SureScripts, ProxyMed and Rx Hub have standards. Other components of the continuum, such as software companies and pharmacies, must also be considered. The subcommittee had asked the National Council for Prescription Drug Programs (NCPDP) to help, but its task group testified that it was having difficulty gathering such information, and that it is beyond its scope. This may have to be handled through CMS rules and regulations.

On January 14, the Drug Enforcement Agency (DEA) testified that it intends to designate the eSignature methodology, public-key/private-key infrastructure (PKI) for controlled substances. Several industry experts testified that PKI's cost and complexity have not been proven effective enough for eHealthcare.

Furthermore, several industry representatives testified that should PKI be required for controlled substances, they will likely exclude them from their system, facilitating prescribers who write paper prescriptions. It has also been pointed out that having two separate systems – electronic and paper – is and will continue to be a barrier to utilization.

However, it is unlikely the DEA will budge on Schedule II controlled substances because of the potential for abuse. Nevertheless, the DEA has left the door open for considering alternatives on schedule III to V medications, which are considered to have less risk for abuse.

The subcommittee's letter will likely concede on Schedule IIs, recommending additional risk analysis. It will also likely recommend that Schedule III to V drugs be included with medications that are not controlled substances. That seems a possibility.

The April letter will also likely address other ancillary standards being worked on by NCPDP. These include: the fill status notification of NCPDP SCRIPT, a cross-walk between SCRIPT and HL7, clinical drug terminology, the National Library of Medicine's Rx Norm, structured and codified SIG and prior authorization.

NCPDP spent some time on prior authorization. In the September 2, 2004 letter, NCVHS recommended that ASC X12N's 278 transaction be used for prior authorization. A multi-standards development organization (SDO) task group, however, pointed out that ASC X12N's 278 is just one piece of the flow and has significant gaps, the biggest of which is not having either structured or standardized prior authorization rules criteria presented to the prescriber. The task group has identified these gaps and is working with ASC X12N and HL7 to address them.

The letter is still being written. Three conference calls have been scheduled to work on its drafting the letter. These calls are open to the public. If you are interested in listening in, please drop an eMail to us at information@pocp.com, and we will forward you the dates, times and call-in information.

3. News and Announcements

Since our last issue, a great deal has happened relative to ePrescribing and health information technology. The two most significant developments are highlighted in the two previous articles. Here is a sampling of some others:

- On Friday, February 4, the **Council for Affordable Quality Healthcare**, a Washington-based coalition of health insurers, released results of a pilot project using **DrFirst, Inc's Rcopia** in the Washington, DC region. More than 400 of the 125,000 electronic prescriptions written generated a serious drug interaction on which prescribers acted. Furthermore, there was an estimated \$100,000 in savings from reduced hospitalizations and ER visits, and an average savings of \$29 per fill for prescriptions to comply with formulary. As with all other studies on ePrescribing, there was a documented reduction in telephone calls between prescribers and pharmacists.
- In the Winter 2005 issue of the *SureScripts Newsletter*, the company announced it has a new feature that allows prescribers to use their ePrescribing software to translate the prescription into a fax delivered to nonconnected pharmacies.
- On February 2, President George W. Bush called for "improved information technology to prevent medical errors and needless costs" in his **State of the Union Address**, the second year in a row that healthcare IT has been addressed in that speech.
- On January 31, Douglas Holtz-Eakin, PhD, made the point that **Medicare spending is a bigger issue than Social Security**, pointing out that the Medicare trust fund will be depleted by 2019 while the Social Security trust fund will last until 2043. Dr. Holtz-Eakin spoke at the World Health Congress in Washington, DC.
- In a January 28 letter to *The New York Times*, the Bush administration said it plans to **restore \$50 million** to fund the Office of the National Coordinator for Health Information Technology, the office of David Brailer, MD, PhD. On January 31 at the **World Health Congress**, Dr. Brailer revealed that President Bush has asked him how much he needs, and he hasn't asked for more. The reason: "we're not ready yet, as we are still laying the foundation."
- According to *Information Week*, **President Bush has requested an additional \$100 million for the 2005** budget for health care IT projects, and will include \$125 million in 2006.
- On January 27, the **Electronic Healthcare Network Accreditation Commission** posted draft accreditation criteria for electronic prescription vendors. The commission, created by the health care data interchange industry, accredits claims clearinghouses, value-added networks and other transaction processors. For 60 days, it is accepting comments on the draft e-Script criteria. For more information, visit its Web site: www.ehnac.org.
- On January 27, **DrFirst** announced it is joining the eRx Collaborative, a joint effort of **Blue Cross Blue Shield of Massachusetts, Tufts Health Plan, Neighborhood Health Plan and Zix Corporation**.
- During mid-January hearings, **Mike Leavitt**, President Bush's **nominee for secretary of the US Department of Health and Human Services**, exclaimed support for health care IT, calling it "essential economic competitiveness issue, as well as an important health care issue."

4. Offenhartz Affiliates with POCP

Lynn Offenhartz has elected to affiliate with Point-of-Care Partners, LLC (POCP). The former director of strategic group operations for ePhysician, she brings 22 years of health care experience to POCP.

"Since starting POCP, I've had Lynn in mind as someone who fits the profile of the kind of professional we want affiliating with," said Tony Schueth, managing partner, POCP. "She has experience developing and executing point-of-care strategies, including working for an ePrescribing company. Furthermore, when she was responsible for the relationship with Medco (my former employer), I found her to be thorough, ethical, professional, hard working and highly competent – all qualities we strive for at POCP."

Ms. Offenhartz has a unique blend of experience that combines health care technology and medical malpractice insurance.

At ePhysician, she worked closely with managed care companies, pharmacy benefit managers (PBMs) and physicians to implement ePrescribing projects. She was also actively involved with the state boards of pharmacy to influence their acceptance of electronic prescribing.

Ms. Offenhartz began her career handling malpractice claims for a physician-owned professional liability company. After several years, she transitioned to a malpractice program for hospitals. She ultimately advanced to become the chief operating officer of one of the largest hospital and health care entity risk-sharing pools in California. Her firsthand experience with the issues facing health care providers today, particularly in the area of medical errors, led her career to transition to health care technology.

ABOUT US

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