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E-Prescribing's Dirty Little Secret

Status Update on the DEA Controlled Substances Ban

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Electronic prescribing (e-prescribing) initiatives have been underway nationwide for over five years, yet according to the December 2007 *SureScripts National Progress Report on E-Prescribing*, physician adoption of e-prescribing has hit a plateau at under 10 percent. One of the greatest physician barriers to adoption is the Drug Enforcement Administration's (DEA's) ban on e-prescribing of controlled substances. Once considered insurmountable, staff at the Office of Management and Budget (OMB) is currently reviewing a draft rule, submitted by the DEA in February, that would ease the restriction and could potentially allow stakeholders to cross the ban off the e-prescribing barriers list.

By way of background, federal law (21 U.S.C. Sec. 829) states that "…no controlled substance in schedule II…may be dispensed without the written prescription of a practitioner…." Similarly, it states that "no controlled substance in schedule III or IV…may be dispensed without a written or oral prescription…." Section 1306.05 of the Code of Federal Regulations states that a written prescription must be manually signed. Section 1306.21 further states that a prescription for a schedule III, IV, or V drug may be:

- written and signed,
- written, signed, and faxed, or
- orally communicated and promptly reduced to writing by the pharmacist.

The requirement of a manual signature prevents consideration

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of computer generated and transmitted prescriptions as "written." As a result of the inability to e-prescribe controlled substances, providers who e-prescribe must maintain two separate and inconvenient prescribing workflows. Indeed, physicians who have invested in e-prescribing technology, whether as part of an electronic medical record (EMR) or a stand-alone application, are unable to write all prescriptions electronically because controlled substances account for 11 to 13 percent of total prescriptions written. The workflow disruptions and associated hassle caused by switching between paper and e-prescribing are enough to make physicians choose not to e-prescribe.

The DEA's rule will remove this barrier only if it proposes a workable, technology-neutral e-prescribing regulation that builds on today's safe and secure e-prescribing infrastructure and does not include burdensome, unscalable requirements that would inhibit provider adoption of e-prescribing.

The DEA is staying relatively mum on the proposed regulation's content, but it could be published in the Federal Register any day. The issue has garnered the attention of Senator Sheldon Whitehouse (D-RI), a health information technology/quality improvement advocate, who presided over a hearing in December 2007 that is largely credited with spurring the DEA to action. Should the DEA's proposed rule include burdensome requirements, the Senator is prepared to address the issue legislatively.

A coalition of stakeholders in support of broad e-prescribing has also been actively advocating with Congress and the Administration for the ban's removal. Called the e-Prescribing Controlled Substances Coalition, it consists of a diverse group of retail chains, Pharmacy Benefit Managers (PBMs), pharmacies, insurers, employers, trade associations, software/technology companies and providers. According to the coalition's leader, Anne Canfield, "The coalition is encouraged that the process is moving forward and is confident that a reasonable solution can be reached through the rulemaking process." The Coalition is, of course, prepared to continue lobbying on the Hill if such a solution is not realized.

Meanwhile, congressional legislators are moving ahead with proposals to drive use of e-prescribing for non controlled substances in the Medicare program. A Medicare bill is expected to be finalized by June 30, 2008. The package passed by the U.S. House of Representatives last year requires the Secretary of Health and Human Services to submit a plan for a health information technology system that

incorporates e-prescribing and computerized physician order entry by January 1, 2010. Although the final Medicare package has not been negotiated, this e-prescribing provision is expected to be expanded to include provisions that mandate e-prescribing, such as those included in the Medicare Electronic Medication and Safety Protection (E-MEDS) Act sponsored by Rep. Schwartz (H.R. 4296) and Sen. Kerry (S. 2408). These bills would:

- Give physicians one-time Medicare grants to help offset the startup costs of e-prescribing;
- Award bonuses to physicians for e-prescribing in Medicare;
- Reduce reimbursement rates for doctors who write Medicare prescriptions by hand instead of electronically after January 1, 2011; and
- Grant one- or two-year waivers to practices that face difficulties in acquiring and implementing e-prescribing technology, especially if they are rural, small, or solo practices.

There is a great deal of interest in these bills because they are expected to save approximately $3 billion over 10 years, which could help pay for some of the costly physician payment provisions in the Medicare package.

Manatt will continue to monitor the status of any e-prescribing language that may be included in the Medicare reform package moving through Congress this spring. We will also keep clients abreast of the status of the DEA's proposed rule and will analyze the rule for clients upon its release. For more information, or if you are interested in joining the e-Prescribing Controlled Substances Coalition, please contact Timi Leslie, Elizabeth Mundinger or Susan Ingargiola. Please see contact information below.

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