



## E-Prescribing Alert

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The Centers for Medicare and Medicaid Services Proposes Rule to Spur Adoption of E-Prescribing - Comments due August 31, 2007

### Introduction

On July 2, 2007, the Centers for Medicare and Medicaid Services (CMS) released a proposed new rule designed to increase adoption of electronic-prescribing by physicians.<sup>1</sup> Under current rules, entities that transmit prescriptions using computer-generated faxes are exempt from the requirement that they comply with federal e-prescribing standards. The proposed rule would eliminate this exemption thus requiring entities using fax technology to transmit prescriptions between prescribers and dispensing pharmacies to modify or change their software and hardware products to be compliant with the relevant foundation standards. This E-Prescribing Alert summarizes the proposed rule, provides background and explains how interested parties can file comments.

### Background

To promote e-prescribing and increase utilization by physicians and pharmacies, Congress enacted the Electronic Prescription Program (EPP) as part of the historic Medicare Modernization Act (MMA) of 2003. The EPP directs the federal government to promulgate uniform, national standards governing the transmission of prescriptions and certain other information for use in the Medicare Prescription Drug Program.

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<sup>1</sup> The proposed e-prescribing rule is part of a much larger rulemaking addressing Proposed Revisions to the Medicare Physician Fee Schedule, and Other Part B Payment Policies for CY 2008. This rule is posted at <http://www.cms.hhs.gov/PhysicianFeeSched/PFSFRN/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=4&sortOrder=ascending&itemID=CMS1200867&intNumPerPage=10> and will be published in the Federal Register on July 12, 2007.

In accordance with the statutory deadlines, CMS finalized and published an initial set of “Foundation Standards” on November 7, 2005.<sup>2</sup> Two of the Foundation Standards address the exchange of eligibility information between prescribers, dispensers and Part D sponsors. The third Foundation Standard identifies NCPDP SCRIPT Standard, Version 5 or Version 8,<sup>3</sup> for the exchange of new prescriptions, changes, renewals, cancellations and certain other transactions between prescribers and dispensers. These Foundation Standards went into effect on January 1, 2006.

In addition to the Foundation Standards, CMS embarked upon a year- long pilot project to evaluate six additional “initial standards” for functionality and interoperability with the Foundation Standards, impact on workflow, clinical and other outcomes. These additional standards address: formulary and benefits, medication history, fill status notification, prior authorization, structured and codified *signature*<sup>4</sup>, RxNorm and Long-Term Care.<sup>5</sup> Based upon the evaluation of the pilot project, HHS must promulgate final, uniform e-prescribing standards not later than April 1, 2008. These final standards must be effective not later than one year after the date of their issuance.

#### Treatment of Computer-Generated Faxes under the November 7, 2005 Final Rule.

It is important to emphasize that no federal law or rule requires any entity to write prescriptions electronically. Rather, the law requires that *if* prescriptions and certain other information are being *transmitted electronically* for drugs covered under Medicare Part D, then the transmission of data must comply with CMS’ uniform e-prescribing standards.

As a general rule, computer-generated faxes fall within the definition of “electronic media.”<sup>6</sup> However, the November 7, 2005 final rule adopting the Foundation Standards

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<sup>2</sup> E-Prescribing and the Prescription Drug Program Final Rule, 70 Fed. Reg. 67568 (November 7, 2005).

<sup>3</sup> NCPDP SCRIPT Standard, Implementation Guide, Version 5, Release 0 (Version 5.0), May 12, 2004. The adopted SCRIPT standard, Version 5.0., subsequently was updated to Version 8, Release 1, and under an Interim Final Rule published on June 23, 2006, either version may be used. 71 Fed.Reg. 36020 (June 23, 2006).

<sup>4</sup> *Signatura*, commonly abbreviated as SIC, refers to patient instructions for taking medications.

<sup>5</sup> For a summary of the pilot testing program and its outcomes, go to:

[http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS\\_0\\_1248\\_227312\\_0\\_0\\_18/eRxReport\\_041607.pdf](http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_1248_227312_0_0_18/eRxReport_041607.pdf). For a copy of the complete evaluation of the pilot program, *Findings From The Evaluation of E-Prescribing Pilot Sites*, AHRQ Publication No. 07-0047-EF, April 2007, go to [http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS\\_0\\_1248\\_227460\\_0\\_0\\_18/Findings%20From%20The%20Evaluation%20of%20E-Prescribing%20Pilot%20Sites.pdf](http://healthit.ahrq.gov/portal/server.pt/gateway/PTARGS_0_1248_227460_0_0_18/Findings%20From%20The%20Evaluation%20of%20E-Prescribing%20Pilot%20Sites.pdf).

<sup>6</sup> Computer generated faxes are faxes that are generated by a computer. The computer then sends the fax to another fax machine where a hard copy of the computer-generated copy is printed. Under HIPAA, only computer-generated faxes are considered “electronic media.” 45 C.F.R.§160.103.

exempted computer-generated faxes from the definition of electronic media. As a result, entities utilizing computer-generated faxes to transmit prescriptions did not need to comply with NCPDP SCRIPT standard.

### CMS' Proposed Change to Treatment of Computer Generated Faxes

CMS' proposes revising 42 C.F.R. §423.160(a)(3)(i) to eliminate the computer-generated fax exemption to the NCPDP SCRIPT Standard. The exemption would apply to all communications of prescription or certain prescription-related information between prescribers and dispensers for the following listed transactions:

- Get message.
- Status response.
- Error response.
- New prescription.
- Prescription change request.
- Prescription change response.
- Refill prescription request.
- Refill prescription response.
- Verification.
- Password change.
- Cancel prescription request.
- Cancel prescription response.<sup>7</sup>

This change would be effective one year after the effective date of the rule establishing the final e-prescribing standards, which must be published not later than April 1, 2008.

### CMS' Rationale

CMS is disappointed that more physicians and pharmacies have not migrated to e-prescribing software. Overall, there has been little reduction in the use of computer-generated fax technology. CMS estimates that approximately 150,000 prescribers already are using software capable of generating SCRIPT transactions, yet only 15 percent are doing so. The remaining 85 percent are still generating paper faxes. While all chain pharmacies have implemented e-prescribing, only 20 percent of independent pharmacies are capable of sending and receiving SCRIPT transactions.<sup>8</sup>

CMS believes that by eliminating the exemption for computer-generated faxing, the 85% of prescribers and dispensers who already have the technology but do not use it

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<sup>7</sup> 42 C.F.R. §423.160(b)(1)(i)–(xii).

<sup>8</sup> These estimates are based upon data from SureScripts, the operator of the Pharmacy Health Information Exchange, the largest network to link electronic communications between pharmacies and physicians. Preamble to the Proposed Rule at 399, \_\_\_ Fed. Reg. \_\_\_\_\_ (July 12, 2007).

would be motivated to upgrade software products and begin generating SCRIPT transactions. CMS opines that the number of SCRIPT transactions would increase fairly significantly in a relatively short period of time. This in turn would “create a ‘tipping point’ that could create an economic incentive for independent pharmacies to adopt software to begin to exchange SCRIPT transactions with their prescriber partners.”<sup>9</sup>

### Comments Sought

CMS acknowledges that the proposed rule change would require providers and pharmacies that are now e-prescribing using legacy products that generate faxes to obtain software upgrades to send and receive the SCRIPT transactions. CMS believes that this software will generally be available to providers through automatic version upgrades built into annual software vendor maintenance fees. However, other providers and pharmacies would need to purchase and install new e-prescribing software or revert to sending paper fax transactions. Because pharmacies customarily bear the cost of SCRIPT transaction fees, these costs would increase as the rate of e-prescribing increases. However, with increased utilization of e-prescribing, patient safety is expected to improve.

Acknowledging these issues, CMS is soliciting comments on the impact of eliminating the computer-generated fax exemption. In particular, CMS would like to know how many practices and pharmacies are currently using legacy versions of software that are not capable of generating SCRIPT transactions and the amount of lead time needed to comply with the SCRIPT transaction standard. CMS would also like to know if eliminating the exemption for computer-generated faxes would cause entities using such fax technology to revert to paper rather than update current software.

CMS needs to be commended for trying to find a way to increase adoption of electronic prescribing. As recently noted in an article published in *Health Affairs*, research suggests that even the most basic e-prescribing functionality has the potential to increase patient safety and reduce costs through improved legibility and practice efficiency.<sup>10</sup>

While there is widespread support for e-prescribing, however, it remains to be seen whether the elimination of the computer-generated fax exemption alone will be enough to create the desired “tipping point” effect. Again, research suggests that there are substantial gaps between those who envision widespread adoption of e-prescribing and the extent to which physicians and pharmacies currently utilize available technology. For example, in the *Health Affairs* study, identified barriers to adoption of e-prescribing by

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<sup>9</sup> Preamble to proposed rule at 401, \_\_\_\_ Fed. Reg. \_\_\_\_\_ (July 12, 2007).

<sup>10</sup> Grossman, J., Gerland, A., et al. “Physicians’ Experiences Using Commercial E-Prescribing Systems,” *Health Affairs* 26, no. 3 (2007): w393–w404 (published online 3 April 2007; 10.1377/hlthaff.26.3.w393).

physicians and pharmacies include: challenges to maintaining complete patient medication lists; limited use and utility of available decision support tools; difficulty in obtaining accurate patient specific formulary information and limited connectivity with pharmacies and mail-order PBMS.<sup>11</sup>

In sum, overcoming challenges to e-prescribing is likely to require a multi-faceted, multi-disciplinary approach, and may well require additional resources. While prescribers and pharmacies are encouraged to respond to CMS' request for comments regarding the proposed rule change, you may also wish to share your recommendations regarding additional steps CMS should consider that would promote widespread adoption of e-prescribing technology.

### How to File Comments

Written comments must be filed no later than August 31, 2007 at 5:00 p.m. Comments may be filed in one of four ways: electronically ([go to: http://www.cms.hhs.gov/eRulemaking](http://www.cms.hhs.gov/eRulemaking)), by regular mail, by overnight mail or by courier. Comments should reference the file code **[CMS-1385-P]** and the caption "Proposed Elimination of Exemption for Computer-Generated Facsimilies." Please remember that all comments become part of the public record and will be made available for public inspection.

If you need further information about this proposed rule or how to file comments with CMS or if you would like assistance to help formulate and submit comments, please contact:

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<sup>11</sup> *Id.*