

DISCUSSION AND DETERMINATION

E-PRESCRIBING OF C-II PRESCRIPTIONS

DRAFT FOR DISCUSSION AND DETERMINATION

JANUARY 18 OR 19, 2012

NAC 639.7105 Electronic transmission of prescription. (NRS 639.070, 639.0745)

Except as otherwise provided in NAC 639.711:

1. A prescription for[?]

~~[(a) A controlled substance listed in schedule II must not be transmitted electronically.]~~

~~[(b)]~~ A dangerous drug or a controlled substance listed in schedule *II*, III, IV or V may be transmitted electronically by a practitioner to a pharmacy.

2. A practitioner shall not transmit a prescription electronically to a pharmacy unless:

(a) The practitioner is the only person who will have access to the prescription until it is received by the pharmacy;

(b) The patient:

(1) Consents to the transmission of the prescription electronically; and

(2) Approves the pharmacy where the prescription will be transmitted; and

(c) All requirements 21 C.F.R. Part 1311 are satisfied.

3. In addition to the requirements set forth in NRS 639.2353 and 639.2589, a prescription that is transmitted electronically to a pharmacy must include:

(a) The registration number from the Drug Enforcement Administration of the prescribing practitioner if the prescription is for a controlled substance;

(b) The telephone number of the practitioner;

(c) The time and date of the transmission; ~~and~~

(d) The name of the pharmacy to which the prescription is sent[-];

(e) The controlled substance registration number;

(f) The date of the last physical examination; and

(g) The indication for use.

4. A pharmacist who receives a prescription that is transmitted electronically shall:

(a) Print a copy of the prescription on paper that is of sufficient quality to last for at least 2 years; and

(b) Keep a copy of the prescription for at least 2 years after the pharmacy receives the prescription.

5. A pharmacist shall not dispense a prescription that is transmitted electronically until the pharmacist determines that the prescription complies with the requirements of state and federal law.

6. A prescription that is transmitted electronically and complies with the provisions of this section shall be deemed an original prescription.



We just expanded our field of vision.

The Pitfalls of E-Prescribing

Published Online: Tuesday, November 29th, 2011

Laura Enderle, Associate Editor

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Pharmacists and physicians say electronic prescribing has potential to save time and reduce errors, but that systems currently in use are flawed.

It's become an all-too-familiar scenario for community pharmacists: during an appointment with a sick patient, a physician prescribes a drug, explaining that she'll send the prescription electronically. Moments after the check-up ends, the patient stops in at a nearby pharmacy, expecting to pick it up.

Then come the words every pharmacist dreads: "My doctor said it'd be ready when I got here."

In one-third of community pharmacies, the exchange happens at least once a day, a new study reports. Resolving it takes more than simply waiting a few extra minutes for the script to arrive. In many cases, the pharmacist is forced to call the physician for verbal orders—an extra step that wastes time and negates the purpose of electronic prescriptions.

Scripts lost in cyberspace are just one of the pitfalls exposed in a recent report detailing [flaws in e-prescribing](#), which is now in use by more than half of all physician practices. The research, funded by the US Department of Health and Human Services (HHS) Agency for Healthcare Research and Quality (AHRQ), focuses on the transmission of prescriptions from physicians to pharmacies.

WEIGH IN: *Is your practice plagued with e-prescribing problems? Share your thoughts in the comments below or cast your vote in our [news poll](#).*

This handoff of prescription data is at the heart of e-prescribing's potential to save time and advance patient safety, according to AHRQ director Carolyn M. Clancy, MD. It's also a source of daily frustration for pharmacists and physicians, researchers reported November 18 online in the *Journal of the American Medical Informatics Association*.

In more than 100 interviews with physician practices and pharmacies nationwide, researchers at the Center for Studying Health System Change found that e-prescribing's major flaws and inconsistencies are concentrated in 3 critical areas. These include prescription renewals, connectivity between physician offices and mail-order pharmacies, and manual entry of prescription information by pharmacists.

Among the study's other key findings:

- **In practice, e-prescribing use is inconsistent at best.** Despite broader adoption of e-prescribing thanks to federal incentives, the extent to which it is used by individual practices varies. In general, pharmacies and physicians are less likely to use e-prescribing for prescription renewals than for new prescriptions. The report also found that many physicians are unsure about whether mail-order pharmacies accept electronic prescriptions.
- **Electronic requests breed miscommunication and information overload.** Both pharmacies and physicians reported receiving or mistakenly sending duplicate or conflicting messages via fax, phone, and e-prescribing systems. One physician said, "Sometimes the patient will call, the pharmacy will fax, and send something via Surescripts, all for the same patient, the same prescription, on the same day. That is cumbersome."
- **"Shortcut" features need tweaking.** Timesaving features are often more trouble than they're worth. For example, fields that complete automatically often require additional follow-up calls or manual entry by pharmacists to clarify a physician's orders, verify quantities and sig codes, or provide patient-friendly instructions.

Despite these and countless other glitches outlined in the report, most physicians and pharmacists expressed satisfaction with e-prescribing—when it's working properly. Smoothing out the kinks in e-prescribing systems should be the focus of health IT initiatives going forward, according to the study's authors.

"Physicians and pharmacies have come a long way in their use of e-prescribing, and that's a very positive trend for safer patient care and improved efficiency," said Dr. Clancy. "This study identifies issues that need attention to improve e-prescribing for physicians, pharmacies, and patients."

For other articles in this issue, see:

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Jim Giddens November 29th, 2011 04:11:4104:41:38 PM

I have seen when e-scribed was just and I received the prescription sent with the generic name but no attention had been paid to the selection of the correct dosage form such a liquid or tablet and maybe not to the strength. Seems like, "find the work, punch it in". Also to the salt form of the drug such as hydroxyzine.

Jim Giddens November 29th, 2011 04:11:4504:45:19 PM

p.s. I should be proof reading my messages.

Rick McCoy November 30th, 2011 12:11:2412:24:34 AM

We are over 90% ERxs now that our clinic went to electronic. Many ERx were wrong and needed to be created, Ouch when I got a \$500 bill for processing all their mistakes.

Jason Opritza November 30th, 2011 10:11:5110:51:05 AM

destruction to a pharmacy because there is no provision in the law specifically allowing this. Regulations do permit a person to return controlled substances to a pharmacy, but only if the person submits a letter to the DEA including, among other information, how the person obtained the controlled substance and who possessed it previously.⁵⁸ Needless to say, few people are likely to take advantage of this means of disposal.

Recognizing that its position conflicts with its primary mission of reducing diversion and abuse, and that there should be a better procedure for persons to dispose of controlled substances, the DEA issued an advance notice of rulemaking in January 2009 seeking comments from stakeholders.⁵⁹ The DEA followed this notice with national take-back programs through local law enforcement agencies on September 25, 2010 and April 30, 2011.⁶⁰ It was Congress, however, that expedited a remedy to the situation by passing the Secure and Responsible Drug Disposal Act of 2010.⁶¹ This law permits an "ultimate user" such as a patient, who has lawfully obtained a controlled substance, to deliver it for disposal if the person or facility receiving it is authorized to dispose of controlled substances and does so according to DEA regulations. The law allows the DEA to authorize LTCFs to dispose of controlled substances on behalf of their patients. However, the DEA has not issued regulations clarifying who can dispose of controlled substances or how to dispose of them. Currently, pharmacists are authorized to dispose of controlled substances, but are not authorized to receive previously dispensed controlled substances.

Delivering Dispensed Controlled Substances to Patient's Prescriber

Another situation that has provoked complaints from the health care community involves this scenario: A pain management specialist issues a written prescription for a sterile morphine solution to be used in a patient's surgically-inserted intrathecal pump. The prescriber requests that the drug be delivered to the prescriber's office so that she can load it into the pump. Is this delivery legal under the CSA? The DEA contends that "the transfer of a controlled substance to anyone (including the prescribing practitioner) other than an 'ultimate user' constitutes a distribution" (not a dispensing) of a controlled substance.⁶² This position in itself might not be that adverse to pharmacies, because the CSA allows pharmacies to distribute up to 5% of the total controlled substance dosage units it distributes and dispenses in one year.⁶³ However, the DEA further contends that the compounding of controlled substances for distribution constitutes manufacturing,⁶² thus making it illegal for a pharmacy to deliver a compounded, controlled substance to a prescriber

er without registering as a manufacturer.

The DEA's position on this issue has drawn the ire of several pharmacy and other health care practitioner organizations, and seems incongruous with the plain language of the CSA. The law defines dispensing as the delivery of a controlled substance to an ultimate user, and includes compounding necessary to prepare the product for delivery.⁵¹ Delivery includes the actual, constructive, or attempted transfer of a controlled substance.⁵¹ The law further provides that compounding as an incident to the administration or dispensing of the drug does not constitute manufacturing.⁵¹ Even though the law does not define "constructive," one has to wonder how delivery of the compounded and dispensed medication to the prescriber is not a constructive delivery, and how the compounding is not "incident to" dispensing. These are just some of the points that 8 pharmacy-related organizations made in a joint letter to the DEA in October 2010.⁶⁴

E-Prescription Regulation

After years of anticipation by practitioners, the DEA has authorized the electronic transmission of controlled substance prescriptions.⁶⁵ The regulation permits, but does not require, the e-prescribing of controlled substances in schedules II-V. Pharmacists, however, must follow their state laws and regulations as to whether electronic controlled substance prescriptions are permitted in their state, and if so, whether to the same extent as the federal regulations.⁶⁵

The DEA makes it clear that the e-prescription regulations were structured with 2 primary concerns in mind. First is security, so that only authorized persons have access to and are actually using the electronic system. Second is accountability for law enforcement purposes, so that authorship of or any involvement with a prescription cannot be denied and violators of the law can be readily identified.⁶⁵ The DEA's concerns are very valid, because an e-prescription transmitted from a practitioner to a pharmacy is generally routed through 3 to 5 intermediaries - creating several external and internal opportunities for fraud and diversion to occur. Moreover, e-prescriptions do not provide evidence of forgery and alteration like paper prescriptions do, thus making detection by pharmacies almost impossible. Without adequate controls, pinpointing accountability for fraud and diversion would be very difficult, because every party in the process could blame someone else.⁶⁵

Prescriber Requirements

In order to ensure that only authorized persons have access to an e-prescribing system, prescribers must undergo identity proofing, meaning that they must establish

identity, either in person or remotely, with a federally authorized credential service provider (CSP) or certification authority (CA). Once identity is proven, the prescriber is provided an authentication credential or a digital certificate. Institutional practitioners (for example, hospitals) are allowed to conduct in-house identity proofing of individual practitioners authorized to use the institution's DEA registration.⁶⁵

In order to sign and transmit controlled substance prescriptions electronically, the prescriber must use a 2-factor authentication method. The DEA allows prescribers to select 2 of 3 authentication factors for this purpose: (1) something you know (such as a password or pin number); (2) something you have (a hard token [device] separate from the computer such as a PDA, cell phone, or flash drive); (3) something you are (biometrics).⁶⁵

When a prescriber is ready to sign the prescriptions, a review screen with a list of the prescriptions for approval will appear. The prescriber will then use the 2-factor authentication method to sign and ultimately transmit the prescriptions. Alternatively, if the prescriber has a digital certificate and is transmitting the prescriptions directly to the pharmacy without using an intermediary, 2-factor authentication is not required.⁶⁵

An agent of the prescriber may enter the appropriate prescription information into the system for later approval and authentication by the prescriber. However, an agent cannot have access to the 2-factor authentication to sign the prescriptions. The prescription ultimately transmitted to the pharmacy must contain all the information required on paper prescriptions. Once the 2-factor authentication is completed, the digitally signed record is electronically archived prior to transmission, thus allowing the prescriber's staff to add information not required by DEA regulations, such as pharmacy URLs. The content of the required information on the prescription must not be altered during transmission between the prescriber and the pharmacy.⁶⁵

The application service provider (ASP) must generate a monthly log of all controlled substances prescribed electronically by the prescriber and present it to the prescriber, but the prescriber is not required to review and confirm the log. The prescriber may print copies of electronic prescriptions to place in the chart, but these must clearly be marked as copies and cannot be used as hard copy prescriptions in the event transmission fails, and cannot be used to satisfy the record keeping requirements.⁶⁵

Pharmacy Requirements

When the e-prescription is transmitted to the pharmacy, either the pharmacy or its ASP (if it uses one) must digi-

tally sign it, and the pharmacy must archive the e-prescription. If a prescription transmission fails, the prescriber may print a copy of the transmitted prescription and sign it. The copy must indicate that the prescription was originally transmitted to a specific pharmacy and that the transmission failed. The pharmacy must check to ensure that the e-prescription was not received or dispensed, before it dispenses the paper prescription. Similarly, if a pharmacist receives a paper or oral prescription indicating that it was originally transmitted electronically to another pharmacy, the pharmacist must check with that pharmacy to determine whether the e-prescription was received. If the original e-prescription was received but not dispensed, the pharmacy that received it must void it. If the original e-prescription was dispensed, the pharmacy with the paper prescription must void it.⁶⁵

A pharmacy may make changes to the e-prescription after receipt in the same manner that it may make changes to paper controlled substance prescriptions. The pharmacy application system must document any such changes, in addition to documenting prescription receipt, annotation or deletion. The pharmacy, as well as the ASP, must also maintain a daily internal audit trail that compiles a list of auditable events. Auditable events are those that indicate a potential security problem. For example, an unauthorized person attempting to sign or alter a prescription is an auditable event. However, a pharmacist annotating the prescription to indicate a change to a generic drug would not be an auditable event.⁶⁵

Pharmacies must back up all e-prescription records daily. Back-up records may be kept on site; however the DEA recommends that pharmacies keep these records off-site. All records related to an e-prescription must be maintained by the pharmacy for 2 years, the same as for paper prescriptions, unless state law requires a longer period of time.⁶⁵

Prescriptions may be electronically transferred between pharmacies subject to the same requirements as for written or oral transfers. The transferring pharmacist must provide with the electronic transfer all the information that the recipient pharmacist would transcribe if the prescription were transferred orally.⁶⁵

Pharmacies, as well as prescribers, must use e-prescription systems that meet all DEA requirements. The DEA will not audit or approve these systems itself; instead, the systems must be audited for compliance by a third party every 2 years, or whenever the system is altered in a way that could affect its functionality. The third-party audit is the responsibility of the ASP. Pharmacies and prescribers are not responsible for these audits unless they use their own applications.⁶⁵

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DISCUSSION AND DETERMINATION

NAC 639.753

Draft language for declination of a pharmacist to fill a prescription

At the Board's request, staff has drafted the following page as a starting point for discussion.

Draft Language for Discussion and Determination

NAC 639.753 Declination of pharmacist to fill prescription. (NRS 639.070)

It is the intent by adoption of this regulation that a pharmacist or pharmacy who has dispensed lawfully prescribed controlled substances or dangerous drugs to a patient pursuant to this regulation should not be legally accountable for damages suffered by any third party resulting from the ingestion of the controlled substances or dangerous drugs.

1. A pharmacist may decline to fill a prescription that satisfies the requirements of this chapter and chapter 639 of NRS only if the pharmacist reasonably believes, in his professional judgment, that:

- (a) The filling of the prescription would be unlawful;
- (b) The filling of the prescription would be potentially harmful to the medical health of the patient;
- (c) The prescription is fraudulent; or
- (d) The prescription is not for a legitimate medical purpose.

2. If a pharmacist declines to fill a prescription pursuant to this section, the pharmacist shall speak with the prescribing practitioner in a timely manner to discuss and resolve the concerns of the pharmacist regarding the prescription. Before the pharmacist speaks with the prescribing practitioner, the pharmacist may, based on his professional judgment:

- (a) Retain the prescription and not return the prescription to the patient;
- (b) Return the prescription to the patient;
- (c) Make a photocopy of the prescription and return the prescription to the patient; and
- (d) Unless the prescription is for a controlled substance that is listed in schedule II, dispense a quantity of the drug prescribed, not to exceed a 3 days' supply, to allow a reasonable period for the pharmacist to speak with the prescribing practitioner about the concerns of the pharmacist regarding the prescription.

3. If, after speaking with the prescribing practitioner, the pharmacist reasonably believes, in his professional judgment, that the prescription is:

- (a) Lawful;
 - (b) Not potentially harmful to the medical health of the patient;
 - (c) Not fraudulent; and
 - (d) For a legitimate medical purpose,
- ↪ the pharmacist may fill the prescription.

4. If, after speaking with the prescribing practitioner, the pharmacist reasonably believes, in his professional judgment, that the prescription is:

- (a) Unlawful;
 - (b) Fraudulent; or
 - (c) Not for a legitimate medical purpose,
- ↪ the pharmacist shall retain the prescription and may not return the prescription to the patient.

(Added to NAC by Bd. of Pharmacy by R036-06, eff. 5-4-2006)