



PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

George Paz
Chairman, CEO
Express Scripts, Inc.

September 25, 2008

Mark Merritt
President & CEO

Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODL
8701 Morrisette Drive
Springfield, VA 22152

RE: Docket No. DEA-218

To Whom It May Concern:

The Pharmaceutical Care Management Association (PCMA) is grateful for the opportunity to present comments on the proposed regulations issued by U.S. Drug Enforcement Administration (DEA). PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D. PBMs are at the forefront of developing and promoting e-prescribing, which promises safer and more affordable drug benefits.

PCMA appreciates the DEA's commitment in this proposed rule to guarantee controlled substances are legally prescribed and dispensed in order to create a safe, effective drug delivery system. PBMs are dedicated to these same goals for all prescription drugs—in paper or electronic prescribing systems, with the end result being that patients receive the right drug therapy at the right time.

General Comments

The safety benefits of e-prescribing to patients, providers and payors are widely known—resulting in an unprecedented law recently signed by the President that, starting in 2009, provides direct financial incentives to physicians who are e-prescribing.¹ Physicians will be able to receive financial incentives for adopting e-prescribing and face financial penalties if they do not adopt this technology in 2012. This commitment by the President and Congress will undoubtedly accelerate interest and adoption of e-prescribing among physicians and patients.

With better technology to ensure against diversion and other drug enforcement priorities, e-prescribing is fundamentally more secure than the paper process. This provides an opportunity for more collaboration with the various stakeholders that further enhances the DEA's mission. However, provisions within the proposed rule go beyond that which is needed to prescribe and dispense controlled substances, even in the less-secure paper system.

Many patients taking controlled substances have severe chronic conditions and take multiple medications, making them particularly vulnerable to the inefficiencies of paper prescribing. These

¹ Public Law 110-275, Sec.134

patients deserve the same access to the safety, savings, and security benefits offered by e-prescribing, as those who take other medications.

To encourage physicians and pharmacies to adopt e-prescribing for controlled substances, the proposed regulations must achieve the balance needed for secure prescribing and dispensing while not creating undue burdens. The risk is that burdens created in the proposed rule will be too great and physicians and pharmacies will simply “turn-off” e-prescribing for controlled substances. Unfortunately, as drafted, we believe the proposed rule cannot be effectively implemented and will not further the adoption of e-prescribing for controlled substances.

We have organized our comments to highlight the top concerns and recommendations in the proposed rule.

1. Ensuring Generic Substitution-Clarity is needed to ensure the prohibition of a pharmacy from altering a prescription during e-prescribing does not inadvertently impact generic substitution of electronic prescriptions of controlled substances.

2. Validating a Prescriber’s DEA Registration-Requiring a pharmacy to purchase and use the DEA database to validate prescriber registration in real time before dispensing an e-prescribed controlled substance is costly and ineffective. Because the database is updated by the DEA weekly and is not real-time, legitimate prescriptions from prescribers not yet included in the system will be rejected.

3. Streamlining Prescriber In-person Identity Check- Requiring prescribers to go in-person to verify their identity to: a DEA registered hospital where the prescriber has privileges, state or professional license board, or state or local law enforcement authority is cumbersome.

E-prescribing service providers offer the most streamlined manner in which a prescriber can verify their identity in-person. Service providers interact the most frequently with prescribers on e-prescribing and present a solution that does not require prescribers to leave their office to be verified.

4. Prescriber work-flow- Prescribers using the technology must benefit from improved work-flow to see the advantages of adopting e-prescribing for controlled substances. Proposed requirements such as: requiring prescribers to re-authenticate every 2 minutes on an idle system, unnecessary attestations, and duplicative prescription logs add unnecessary time and burden for the prescriber.

Ensuring Generic Substitution-

§ 1311.130 (f) Electronic prescription system requirements: Transmission of electronic prescriptions.

The contents of the prescription listed in § 1311.115(b) must not be altered during transmission. Any change to the content during transmission will render the prescription invalid. The data may be reformatted.

Comment: It is not clear that legal methods of changing prescriptions under State prescribing laws, such as a pharmacy changing a prescription to a generic, would be allowed under this rule. By not allowing generic substitution of a controlled substance that has been electronically prescribed, the proposed rule has the potential to negatively affect tools that are used to manage the pharmacy benefit. Generic substitution, the most potent tool in controlling pharmacy costs, would be limited and pharmacists would be required to request and receive a new prescription from the prescriber for many controlled substances available in generic forms, like Ambien.

Recommendation: PCMA recommends clarifying that pharmacists are allowed to change prescriptions according to State law and such change should not be considered “altering the prescription during transmission.”

Verifying DEA registration -

§1311.165(a) Pharmacy system requirements: Prescription processing.

(a) The pharmacy system must verify that the practitioner’s DEA registration was valid at the time the prescription was signed. The pharmacy system may do this by checking the DEA CSA database or by having the prescribing practitioner’s service provider or one of the intermediaries check the DEA CSA database during transmission and indicate on the record that the check has occurred and the registration is valid. The CSA database may be cached for one week from the date of issuance.

Comment: Currently, the DEA’s Pharmacist Manual guides the professional judgment of the pharmacist with the verification of practitioner registration by outlining the structure of a DEA number, how it is derived, and what it must contain. Pharmacists review the practitioner’s written order and use their professional judgment as to whether further inquiry is required as to the validity of that practitioner’s registration. Adding an extra layer to this process essentially replaces the professional judgment of the pharmacist

The DEA offers the option to purchase a costly CSA registration database. An annual subscription to the database as updated weekly costs as follows: for up to 5 concurrent users -- \$4,400; Up to 10 concurrent users --\$7,288; 11+ concurrent users \$14,025. A subscription based on weekly updates is not real-time and therefore does not insulate the pharmacy from liability if a change to the database has been made in the interim, nor does it accomplish the DEA’s objective. If a new prescriber was not yet entered in the system, pharmacies would be forced to reject his or her prescriptions. Similarly, the DEA system may not register every DEA number that has been suspended or revoked – since it is not real-time - and a pharmacy could be held liable for filling a prescription including a valid DEA number according to DEA’s own database.

Recommendation: Although the proposed rule does permit pharmacy reliance on the intermediary to validate the prescriber’s DEA registration, we are concerned that this would result in increased costs for service. Moreover, such reliance would not shift ultimate liability for compliance from the pharmacy, as the DEA states at 21 CFR 36745 and elsewhere in the proposed rule.

Prescriber in-person identity proofing

§1311.105(a) and (b) Electronic prescription system requirements: Identity proofing.

Comment: In order to begin e-prescribing for controlled substances, the proposed rule requires prescribers to go verify in-person: their identity, valid medical license, and DEA authority to prescribe controlled substances. They can do this at any of the following locations: a DEA registered hospital where the prescriber has privileges, state or professional license board, or state or local law enforcement authority.

The process contemplated creates a burden that is onerous and unnecessary, and that does not result in the security and assurances that the DEA seeks to achieve. This is a completely new practice from that which exists for prescribers today, requiring significant time out of their day to go to one of these locations. This is particularly difficult for rural and small practices to accomplish since they would have less flexibility and would have to travel longer distances.

In addition, since it is not required that any of these three entities envisioned support this identification process, there is no guarantee that a prescriber would have the ability to get verified. Some entities, such as a hospital, may need to charge a fee for this service in order to cover the costs of maintaining an identity verification process.

We also note that the proposed rule establishes that a letter or other correspondence is given to prescribers who are identity proofed, which will then be given to the service provider, attesting to his identity. In a rule and in a process in which we are trying to promote electronic communications, we believe it is counter-intuitive for the process to then be dependent upon the provision of a written document, especially a letter or other correspondence that is easily forged. Service providers will have no basis for knowing whether a letter presented by prescriber is original.

Recommendation: PCMA recommends service providers be allowed to verify a prescribers identification in-person.

Since service providers interact with the prescriber the most frequently on matters dealing with e-prescribing, and the proposed rule already requires prescribers to demonstrate to service providers that they are verified, this recommendation would eliminate an extra step and provide the guarantees needed.

Prescriber Work-flow

§ 1311.110 Electronic prescription system requirements: Authentication.

(c) The system must require reauthentication if the practitioner does not use the system for more than 2 minutes.

Comment: Requiring that practitioners reauthenticate if their system remains idle for more than 2 minutes is unreasonable and does not recognize the workflow demands of medical practice. In the commercial world, such timeouts are normally in the 15 to 20 minute range. Freestanding e-prescribing devices and EMRs are typically under much closer scrutiny and supervision than are commercial information technology systems, and 2 minute timeouts would serve as potent barriers to the implementation of e-prescribing for controlled substances.

Recommendation: PCMA recommends that the time lapse for reauthentication be revised to 15 minutes.

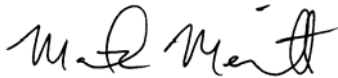
§ 1311.125(b) Electronic prescription system requirements: Signing the prescription.

Comment: All of the affirmations that are contained in the proposed rule statement are implicit in the act of signing a prescription. In addition, the proposed attestation statement is too lengthy and will take up a page (screen) of PDA space. Requiring a prescriber to indicate agreement with the attestation prior to every transmission likely will result in the prescriber ignoring the statement. This onerous requirement will act as yet another drag on practitioner workflows, which will serve to further impede e-prescribing adoption and utilization.

Recommendation: PCMA recommends deleting this provision.

On behalf of PCMA, thank you for considering our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Merritt". The signature is fluid and cursive, with the first name "Mark" and last name "Merritt" clearly distinguishable.

Mark Merritt
President and Chief Executive Officer