



PAIN & POLICY STUDIES GROUP

WHO Collaborating Center for Policy and Communications in Cancer Care

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

Re: Docket No. DEA-218P: Electronic Prescriptions for Controlled Substances

Dear Mr. Caverly,

The Pain & Policy Studies Group (PPSG) respectfully submits a series of comments to the United States Drug Enforcement Administration (DEA). These comments are in response to the DEA's anticipated modification of the Code of Federal Regulations (CFR), which is outlined in the proposed rule for "Electronic Prescriptions for Controlled Substances" and the corresponding Solicitation of Comments of June 27, 2008 (Docket No. DEA-218P).

We recognize the obligation of healthcare professionals to provide effective treatment for legitimate medical purposes while also avoiding knowingly contributing to diversion of prescription controlled substances. Alternatively, law enforcement and regulatory officials should prevent prescription medications from becoming a source of harm or abuse while ensuring that they are available for patient care. It is this principle that underlies the proposed rule; the DEA states that the planned electronic prescribing system is designed to reduce diversion through prescription forgeries and maintain a sufficient supply of controlled substances for legitimate purposes (p. 36722).

Although the proposed rule is considered an addition to, rather than a replacement for, the existing rules for prescribing, and practitioners' use of electronic prescribing is voluntary at this time, the DEA anticipates that all practitioners will eventually transition to electronic prescribing of controlled substances (p. 36761). As a result, it is essential that the authority be adequate, and that the technical and procedural characteristics of an electronic prescribing system be carefully and thoroughly vetted not only by practitioners, regulators, and law enforcement officials, but also by healthcare facility and insurance administrators and, perhaps most importantly given the nature of this electronic system, computer security experts. We do not have enough information or expertise to comment on the calculated fiscal impact or the technological appropriateness of the proposed electronic prescribing system. However, it remains unclear whether increases in registration fees will be used to cover the costs of the new system. In addition, it seems that the DEA is placing much of the responsibility for system security on practitioners and pharmacies, but does the DEA have sufficient statutory authority to do so? Does such authority to require this new responsibility lie within the Controlled Substances Act (CSA) authority to register practitioners? Further, with today's technology, would it not be more appropriate and efficient for this responsibility instead to be accomplished centrally and electronically? We appreciate the DEA's requests throughout the proposed rule for multidisciplinary feedback on various aspects of the prescribing system. Such feedback will help achieve a final electronic controlled substances prescribing system that is feasible and effective while sufficiently satisfying the DEA's objectives and concerns.

We applaud the DEA for attempting to offer an electronic controlled substances prescribing system that is designed to minimize the risk of diversion of these prescription medications while ensuring their adequate supply for legitimate medical and scientific purposes. However, there are a number of procedures and requirements within the proposed CFR regulations that demand further consideration, so that the ultimate implementation of an electronic prescribing system does not foster unintended practitioner concerns about potential federal, state, or local law enforcement oversight.

The question of balance. Despite the statement that the proposed regulations are designed to “ensure an adequate supply of controlled substances for legitimate medical, scientific, research, and industrial purposes” (p. 36722) the new rule does not seem to establish responsibility for monitoring and reporting of cases where legitimate electronic prescriptions cannot be filled in a reasonable period. The DEA should consider what system safeguards are needed to ensure an adequate supply of medications to patients with legitimate prescriptions. The obligation to ensure adequate medication availability and access should be reflected throughout the regulation, as it is in the CSA.

§ 1311.100(c) – Eligibility to issue electronic prescriptions. Under this provision, practitioners are given the broad responsibility to confirm whether an electronically-issued prescription for a controlled substance does not conform to “all essential respects to the law and regulations” (p. 36775). This requirement clearly establishes an obligation for the practitioner to be responsible for the effectiveness of the security system established by this regulation, and for verifying third-party audit reports (as in § 1311.155(f)). Of course, practitioners must remain responsible for issuing electronic prescriptions only for a legitimate medical purpose and in the usual course of professional practice, as they are with paper or oral prescriptions. However, the technological complexity of the electronic prescription system, and corresponding services, could establish for practitioners an onerous burden of oversight over a system for which they ultimately have little control. Responsibility for the efficacy and accuracy of the electronic prescribing system and security services should reasonably fall to the hardware/software manufacturers and the computer security technicians.

§ 1311.105(b)(2 & 3) – Electronic prescription system requirements: Identify proofing. Among other requirements, practitioners who wish to prescribe controlled substances electronically must submit to in-person identify proofing conducted either by the state professional or licensing board, state controlled substances authority, or a state or local law enforcement agency. This is a practice requirement that has few if any precedents with other, non-law enforcement, professionals, and the healthcare community likely will perceive this as a criminalization of medical practice. Research and published reports demonstrate that healthcare practitioners historically have avoided engaging in prescribing practices associated with greater law enforcement scrutiny, such as with state triplicate prescription monitoring programs. The prospect of practitioners acquiring identify proofing through local law enforcement agencies could significantly impede the widespread adoption of electronic prescribing. Given these considerations, we recommend that the requirement of in-person identity proofing, if maintained, be satisfied solely through the use of non-law enforcement organizations.

§ 1311.140(b) – Electronic prescription system requirements: Providing log of prescriptions to practitioner. A practitioner using an electronic prescription system seems required to review, and indicate review of, monthly logs of all electronic prescriptions issued by the practitioner during the previous month using that system. When describing this provision in the Section-By-Section Discussion of the Proposed Rule (p. 36754), the DEA does not detail the practitioner’s ultimate responsibility to review and approve the information in the logs, the manner and

timeframe in which the review must be completed, or the practitioner's liability for failing to review the log. This obligation, as well as the other requirements detailed above, seems to create a new practice standard that places more responsibility, and thus increased liability, for proper implementation of the law on practitioners. In addition, there is a need to specify the confidentiality of all such records, including who has access and under what circumstances.

§ 1311.165(a) – Pharmacy system requirements: Prescription processing. Pharmacists have a corresponding responsibility for the proper prescribing and dispensing of controlled substances (§ 1306.04(a)). This proposed provision requires the pharmacy, or “the prescribing practitioner’s service provider or one of the intermediaries” to verify the validity of a practitioner’s DEA registration prior to dispensing; if the prescription is not determined to be valid for any reason, the pharmacy must reject the prescription – “A pharmacy that fails to check the validity of controlled substance prescription before dispensing is legally responsible if the prescription is invalid” (p. 36740). Under current federal law, pharmacists are not required to verify a practitioner’s DEA registration before every controlled substance prescription, paper or oral, is dispensed, but are given guidance about how to verify practitioner registration, when there is a reason to do so, in the DEA’s *Pharmacist Manual* (April, 2004). Although this new requirement could be considered simply an extension of the “corresponding responsibility” requirement of § 1306.04(a), the language could be viewed as creating an additional legal and practice standard which may add an additional compliance burden for pharmacies and may even become part of state pharmacy boards’ requirements .

Again, we agree with the DEA’s objective of proposing an electronic controlled substances prescribing system that reduces medication harm and risk of diversion while maintaining availability for legitimate medical and scientific purposes; given this objective, the new regulation should require the DEA to submit an annual report concerning various aspects of the system operation, including the prevalence of system errors that reduce patient access and how these are corrected. However, the proposed system of checks and balances seems likely to create a cumbersome and overly strict system that, if implemented as currently designed, would result in an enormous burden of oversight for practitioners and pharmacies. We anticipate that concern about law enforcement actions resulting from failure to comply with the complex regulatory requirements will be a substantial reason for practitioners and pharmacies deciding against voluntarily engaging in these procedures. Since practitioners currently have the option of issuing electronic prescriptions, such profound disincentives would argue against electronic prescribing becoming a feasible practice, thereby undermining the program intent. We urge the DEA to consider the issues above, as well as those involving sufficiency of authority, fiscal impact, and system and security technology, when modifying the proposed rule before issuing the final regulations.

Sincerely,

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