February 8, 2016

Mr. James Arnold, Chief of Policy
Office of Diversion Control
Drug Enforcement Administration
600 Army-Navy Drive
Arlington, VA 22202

Dear Mr. Arnold:

Re: Electronic Prescriptions for Controlled Substances (EPCS) Renewal Request Clarification

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,500 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

It has recently been brought to NCPDP's attention that the DEA has expressed reservations about the use of the RxRenewalRequest transaction for EPCS. We understand these reservations are related to opinions expressed by the DEA on a number of occasions about the notion of pre-population of faxed prescription refill requests that are sent from pharmacies to prescribing practitioners. Given this DEA concern, NCPDP would like to clarify that NCPDP SCRIPT Version 10.6 supports the electronic RxRenewalRequest, and we have highlighted within this letter the benefits of the NCPDP SCRIPT Standard and how its use meets EPCS requirements and better addresses concerns of diversion than the legacy prescription communication formats.

The NCPDP e-prescribing standard and all of the constituent message types have been adopted by the Centers for Medicare and Medicaid Services (CMS) for Medicare e-prescribing pursuant to the Medicare Modernization Act of 2003 (Pub.L. 108-173) as well as an EHR certification criterion adopted by the Office of the National Coordinator for Health Information Technology (ONC) pursuant to The Health Information Technology for Economic and Clinical Health (HITECH) Act under Title XIII of the American Recovery and Reinvestment Act of 2009 (Pub.L. 111–5). Accordingly, the NCPDP e-prescribing transactions are widely used within the healthcare industry with mandated use by specific state laws.

It is NCPDP's opinion that the industry's use of the electronic RxRenewalRequest does not constitute pre-population and is therefore permissible. However, to provide assurances and increased confidence to industry participants who are actively using this transaction, we have included a review of how the transaction works. The NCPDP RxRenewalRequest Transaction is explained in great detail in NCPDP SCRIPT Version 10.6, which is the current version in use by the industry, and is attached for your review.

Please note the attached NCPDP SCRIPT Version 10.6 standard is to be used for educational purposes only and is not to be distributed.

At a high level, the RxRenewalRequest transaction works by providing the prescriber the medication history record of the prescription created by the prescriber and dispensed by the pharmacy. This medication history includes patient and prescriber demographics, a copy of the prescription information transmitted to the pharmacy in the original prescription, a record of the most recent dispensing of the prescription and a record of the refills allowed and the most recent dispensing pursuant to the original prescription. The inclusion of these data elements provides important clinical dispensing information so the prescriber can quickly determine whether overuse or abuse is a concern. Other communication vehicles between pharmacies and prescribers do not consistently provide or make readily available this critical information, thereby compromising the prescriber's clinical decision process.
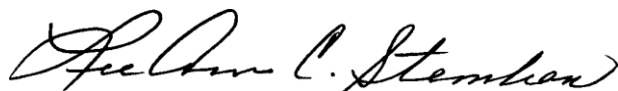
The RxRenewalRequest message cannot be returned or echoed back as an approved new prescription; rather, the prescriber must generate an RxRenewalResponse message. Much of the information in a request is different from the information in a response, which precludes using the RxRenewalRequest message itself to populate the response message (i.e.: the approved prescription). Additionally, electronic transmission of this prescription response for a controlled substance requires the safety and security measures mandated by the DEA (review and acknowledgement of all prescription elements, two-factor authentication, digital signature, etc.), thus providing strong mechanisms for minimizing diversionary activities while continuing to support efficient service to patients truly in need of continuation of these drug therapies.

In summary, NCPDP requests the DEA confirm the RxRenewalRequest message does not constitute pre-population and the use of this message type supports the DEA's mission to limit prescribing of controlled substances to circumstances of true need.

For direct inquiries or questions related to this letter, please contact
    Paul Wilson
    Technical Analyst, Standards Development
    NCPDP
    E: pwilson@ncpdp.org

Sincerely,

Lee Ann C. Stember
President
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260
(480) 477-1000 x 108
lstember@ncpdp.org

cc: NCPDP Board of Trustees