National Council for Prescription Drug Programs
NCPDP

May 21, 2010

Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152
dea.diversion.policy@usdoj.gov

Re: Docket No. DEA-218

Dear Drug Enforcement Administration;

The National Council for Prescription Drug Programs (NCPDP) submits the following comments regarding the Drug Enforcement Administration interim final rule 21 CFR Parts 1300, 1304, 1306, 1311 RIN 1117-AA61.

NCPDP is a not-for-profit ANSI-accredited Standards Development Organization consisting of more than 1,550 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

NCPDP's detailed responses are provided in the subsequent pages. A summary of the most important concerns are:

1. Any time significant modifications are required to a standard that has been named in regulation (e.g. NCPDP SCRIPT) the regulatory process must be invoked which adds delays to the implementation timeframe for the industry.
2. Long Term and Post Acute Care (LTPAC) concerns
    a. Sections 1311.120, 1311.125 and 1311.170 could be interpreted as having a negative impact on the three-way communication workflow among the prescriber, the pharmacy and the nursing facility or nursing centric entity. Clarification is required.
    b. The "nurse-as-agent" is a lynchpin in the LTPAC environment. The allowance of the LTPAC three-way communication for electronic prescribing workflow requires clarification.
    c. The meaning of a "registered location", as it applies to a LTPAC setting, is undefined, and therefore unclear.
3. The digital signature option with the use of an intermediary requires clarification.
4. Has the DEA reached out to certification entities? Are certification authorities ready to proceed with this industry? What outreach has been done to vendors, prescribers, and pharmacies for how to obtain information about these entities?
5. Clarification has been given in reference to the NCPDP SCRIPT Standard, versions, and data fields.

LTPAC concerns in more detail:

1. Long Term and Post Acute Care (LTPAC) sites include skilled nursing, nursing and assisted living facilities; home health, independent and adult care environments; rehabilitation facilities; long-term acute care hospitals; and hospice. Prescribing and dispensing in the LTPAC setting involves three-way communications among the prescriber, the pharmacy and the nursing facility or nursing centric entity with the nurse serving as the lynchpin.

   During prescribing and dispensing in the LTPAC setting, the nurse is responsible for communicating vital information to the prescriber, documenting the prescriber's orders in the patient's chart and then transmitting that prescriber's orders to the pharmacy. In this manner, the nurse serves as the "agent of the prescriber," ensuring that the prescriber's orders are documented and followed. In addition, as required by federal nursing home regulations, the LTPAC facility maintains a medical record for each resident. The medical record is the central repository of all essential medical, social and legal information about each resident and includes documentation of all care and treatment including all medication orders. Electronic prescribing systems for controlled substances in LTPAC with the "nurse as agent" model promote patient safety.

   a. We are seeking clarification to the definition of "*Installed electronic prescription application"* as defined in Part 1300. The definition states "…*software that is used to create electronic prescriptions and that is installed on a practitioner's computers and servers, where access and records are controlled by the practitioner*". Does this definition include software installed at a LTPAC facility that is used by but not owned or managed by the registered practitioner?

   b. A specific concern is the IFR assumes that the electronic prescription application and related records can only be "housed" at a "registered location". The IFR uses the term "registered location" without providing the definition. It is unclear if the term "registered location" means the location must be a DEA registrant or the application must be registered with the DEA.

   c. Assuming that a DEA registrant (e.g. the facility medical director) takes responsibility for granting system access to a prescriber that is not the owner of the software but has a relationship with the facility, does the LTPAC facility itself have to be a registrant if their system is transmitting the prescription?

NCPDP detailed response encompasses aspects of Ambulatory and Long Term and Post Acute Care (LTPAC)

II. Regulatory History (page 16239) and also other references throughout

Because of the large number of electronic prescription and pharmacy applications and the current lack of a mature standard for the formatting of prescription data, most electronic prescriptions are routed from the electronic prescription or EHR application through intermediaries, at least one of which determines whether the prescription file needs to be converted from one software version to another so that the receiving pharmacy application can correctly import the data.

NCPDP response:

1. NCPDP prefers the DEA not use the terms "current lack of a mature standard" or in other places "is not yet fully functional" in the rule. The NCPDP SCRIPT Standard is mature for the functions for which it was developed. Unfortunately controlled substance electronic prescribing functionality was out of scope due to federal restrictions. Standards become mature as they are implemented and continue to evolve as business requirements do. We invite the DEA to participate in the standards development process.

2. In different areas of the rule, the function of the intermediaries cited is for converting versions. It should be noted that an important role of intermediaries is the connecting of multiple parties and the handling of network routing. Directly connecting one prescriber to the many pharmacies and payers they do business with is a daunting challenge for an office. The intermediaries play an important role in connectivity and routing transactions.

3. NCPDP notes that there are DEA statements regarding the SCRIPT Standard, data elements, and functionality. We did not notice similar statements regarding the use of the HL7 Standard data elements in the inpatient setting. The preamble does note "Similarly, a 2008 review of studies found fewer errors with electronic medication orders, but at least 24 of the 27 studies reviewed covered only inpatient medication orders, **which DEA does not regulate"** (emphasis added). While NCPDP SCRIPT is predominantly used, the DEA will want to be consistent about HL7 data element requirements and functionality as appropriate.

(same section, same page)

SCRIPT is a data transmission standard ''intended to facilitate the communication of prescription information between prescribers, pharmacies, and payers.'' It defines transactions (*e.g.,* new prescription, refill request, prescription change, cancellation,), segments (*e.g.,* provider, patient), and data fields within segments (*e.g.,* name, date, quantity). Each data field has a number and a defined format (*e.g.,* DEA number is nine characters).

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SCRIPT provides for, but does not mandate the use of, some fields (*e.g.*, practitioner first name and patient address) that DEA requires. In addition, although the standard mandates that applications include certain fields, it does not require that those fields be completed before transmission is allowed. The SCRIPT standard is still evolving; the most recent is Version 10 Release 6.

NCPDP response:

1. NCPDP wishes to clarify the reference to the DEA number in the NCPDP SCRIPT Standard. The DEA Number is not a discrete field in SCRIPT. The data element where a provider identifier is placed is an alphanumeric 35 digit field. (This is noted correctly on page 16257 and 16268.)

2. NCPDP notes the Patient Address fields are mandatory in a new prescription transaction in SCRIPT Implementation Guide Version 10.11. Also, the prescriber's first name is mandatory on all applicable transactions. As the industry cannot adopt a version that has not been named in the Medicare Modernization Act, NCPDP has published a SCRIPT Implementation Reference

document which is to be used as industry guidance until regulations move forward. The recommendation for patient address and prescriber first name has been cited in this reference document which has been published for use in the interim.

3. The most recent version of the SCRIPT Implementation Guide is Version 10.11, currently being finalized for publication. The most recent approved version is 10.10. The industry is currently using SCRIPT Version 8.1, and moving to SCRIPT 10.6 once regulations are published.

4. NCPDP extends the offer to provide an educational session for DEA representatives about the SCRIPT Standard and/or the development process of NCPDP.

LTPAC Comments:

1. Communication of medication orders in the long-term care setting has been supported since version 10.1 of the SCRIPT Standard, and the standard is being used in nursing facilities today.

   Currently, there are prescribers who enter non-controlled substance prescriptions directly into LTPAC prescribing systems. There are also workflows in place where licensed facility nurses enter the electronic prescription on behalf of the prescriber as allowed by state pharmacy regulations (e.g., capturing telephone orders).

   In either case, it is the responsibility of the nurse to review (but not change) the medication in the context of the patient's other care, to add facility-related administration details such as specific pass times to the order, to consult with the prescriber regarding potential conflicts with other patient care, and to transmit the order to the patient's chosen pharmacy. The prescriber approves the medication order immediately (if entering it directly) or soon thereafter according to applicable regulations.

   We appreciate the DEA's recognition of the need for a controlled substance electronic prescribing rule to support the facility nurse's review and administration responsibilities, while ensuring the prescription content required by DEA regulations is not changed once signed by the prescriber. We also agree that it is necessary for controlled substance prescriptions to be signed by the prescriber before transmission to the pharmacy for dispensing.

   Comments that follow request clarification to certain aspects of the interim rule to ensure there are no obstacles to implementing the DEA's intent that LTPAC facility staff be able to add information such as pharmacy or other annotations before transmission to the pharmacy.

   Since DEA's IFR does not account for the LTPAC nurse agent role, and if the DEA does not include the nurse agent role, serious impact will occur to the industry workflow, which may include reconsideration of the economic impact. The industry will be forced to build new workflow requirements, perhaps causing federal and state regulatory modifications, as well as force a delay in the adoption of electronic prescribing. Without a modification, the practice of electronic prescribing for non-controlled substance prescriptions and **paper** for controlled substance prescriptions will continue. Furthermore, the industry would be forced to determine whether the current SCRIPT Standard will suffice or whether data fields will have to be modified or added. If changes or additions are needed, it will take time for HHS to name or mandate a new version of SCRIPT

to meet the IFR requirements in the LTPAC setting, further delaying industry adoption.

III. Discussion of the Interim Final Rule (page 16242)

As proposed, DEA is requiring in this interim final rule that the authentication credential be two-factor. Two-factor authentication (two of the following – something you know, something you have, something you are) protects the practitioner from misuse of his credential by insiders as well as protecting him from external threats because the practitioner can retain control of a biometric or hard token. Authentication based only on knowledge factors is easily subverted because they can be observed, guessed, or hacked and used without the practitioner's knowledge. In the interim final rule DEA is allowing the use of a biometric as a substitute for a hard token or a password. If a hard token is used, it must meet FIPS 140-2 Security Level 1 for cryptographic devices or one-time password devices and must be stored on a device that is separate from the computer being used to access the application. The CSPs and CAs may issue a new hard token or register and provide credentials for an existing token. Regardless of whether a new token is provided and activated or an existing token is registered for the signing of controlled substances prescriptions, communications between the CSP or CA and practitioner applicant must occur through two channels (e.g., mail, telephone, email).

However, while DEA is requiring in this interim final rule that the authentication credential be two-factor, DEA is seeking further comments on this issue. Specifically, DEA seeks comments in response to the following question:

> • Is there an alternative to two-factor authentication that would provide an equally safe, secure, and closed system for electronic prescribing of controlled substances while better encouraging adoption of electronic prescriptions for controlled substances? If so, please describe the alternative(s) and indicate how, specifically, it would better encourage adoption of electronic prescriptions for controlled substances without diminishing the safety and security of the system.

NCPDP response:

1. NCPDP heard comments from members that recommend the DEA remain flexible to other authentication options that become available for the future that can be used without a change in the rule.

(same section, page 16242)

DEA is requiring that the application display a list of controlled substance prescriptions for the practitioner's review before the practitioner may authorize the prescriptions. A separate list must be displayed for each patient. All information that the DEA regulations require to be included in a prescription for a controlled substance, except the patient's address, must appear on the review screen along with a notice that completing the two-factor authentication protocol is legally signing the prescription. A separate key stroke will not be required for this statement. Registrants must indicate that each controlled substance prescription shown is ready to be signed. When the registrant indicates that one or more prescriptions are to be signed, the application must prompt him to begin the two-factor authentication protocol. Completion of the two-factor authentication protocol legally signs the prescriptions. When the two-factor authentication protocol is successfully completed, the application must digitally sign and archive at least the DEA-required information. If the practitioner is digitally signing the prescription with his own private key, the application need not digitally sign the record separately, but must archive the digitally signed record. DEA is allowing any practitioner to use the digital signature option proposed for Federal healthcare systems. Unless a practitioner has digitally signed a prescription and is transmitting the prescription with the digital signature, the electronic prescription must include an indication that the prescription was signed.

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Because the prescription information will be digitally signed when the practitioner completes the two-factor authentication protocol, the prescription need not be transmitted immediately. Information other than the information that must be digitally signed may be added to the file (e.g., pharmacy URLs) or the prescription may be reviewed (e.g., at a long-term care facility) after it is signed and before it is transmitted to the pharmacy. After the practitioner completes the authentication protocol, the information that the DEA regulations require to be included in a prescription for a controlled substance may not be modified before or during transmission.

…

DEA has also clarified that the requirement that the DEA-required contents of the prescription not be altered during transmission applies only to changes to the content (not format) by intermediaries, not to changes that may lawfully be made at a pharmacy after receipt. Pharmacy changes to electronic prescriptions for controlled substances are governed by the same statutory and regulatory limitations that apply to paper prescriptions. Intermediaries may not convert an electronic controlled substance prescription into a fax. Once a prescription is created electronically, all records of the prescription must be retained electronically.

Unless the prescription is being transmitted with a digital signature, either the last intermediary or the pharmacy must digitally sign the prescription; the pharmacy must archive the digitally signed prescription. Both the electronic prescription application and the pharmacy application must maintain an internal audit trail that records any modifications, annotations, or deletions of an electronic controlled substance prescription or when a functionality required by the rule is interfered with; the time and date of the action; and the person taking the action. The application provider and the registrants must develop a list of auditable events; auditable events should be occurrences that indicate a potential security problem. For example, an unauthorized person attempting to sign or alter a prescription would be an auditable event; a pharmacist annotating a record to indicate a change to a generic version of a drug would not be.

Application providers must obtain a third-party audit before the application may be used to create, sign, transmit, or process controlled substance prescriptions and whenever a functionality related to controlled substance prescription requirements is altered, or every two years after the initial audit, whichever occurs first. If one or more certification organizations establish procedures to review applications and determine whether they meet the requirements set forth in the DEA regulations, DEA may allow this certification to replace the third-party audit. DEA will notify registrants of any such approvals of organizations to conduct these third-party certifications through its Web site. At this time, no such certification exists for either electronic prescription or pharmacy applications, but the Certification Commission for Healthcare Information Technology (CCHIT) has developed a program for electronic prescription applications.

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When a prescription is transmitted (outside of a closed system), it moves through three to five intermediaries between practitioners and pharmacies. Although prescriptions could be altered, added, or deleted during transmission, DEA is not regulating transmission. Registrants have no control over the string of intermediaries. A practitioner might be able to determine from his application provider which intermediaries it uses to move the prescription from the practitioner to SureScripts/RxHub or a similar service, but neither the practitioner nor the application provider would find it easy to determine which intermediaries serve each of the pharmacies a practitioner's patients may choose. Pharmacies have the problem in reverse; they may know which intermediaries send them prescriptions, but have no way to determine the intermediaries used to route prescriptions from perhaps hundreds of practitioners using different applications to SureScripts/RxHub or a similar service. DEA believes the involvement of intermediaries will not compromise the integrity of electronic prescribing of controlled substances, provided the requirements of the interim final rule are satisfied. Among these requirements is that the prescription record be digitally signed before and after transmission to avoid the need to address the security of intermediaries. DEA

realizes that this approach will not prevent problems during the transmission, but it will at least identify that the problem occurred during transmission and protect practitioners and pharmacies from being held responsible for problems that may arise during transmission that are not attributable to them.

NCPDP response:

1. NCPDP appreciates the ability to transmit controlled substance prescriptions with the data field.

   Currently, digital signature field(s) do not exist in the SCRIPT Standard as there has not been a business requirement brought forward.

   The IFR contains two options:
   - Digital signature
   - Field indicating the prescription was signed

   The digital signature option appears to assume there is a direct connection between the prescriber system and the pharmacy system. In interpreting further, it appears if an intermediary is involved, the prescription may not be translated/modified (especially the DEA "data") – this translation/modification would render the digital signature invalid. If the transmission is digitially signed (a wrapper), any change to the packet of information - including reformatting - makes the digital signature invalid. If an intermediary performs functions of translation, mapping, etc, we do not understand how the intermediary could perform the same functions in the digital signature scenario.

   In discussion attempting to understand the digital signature option, NCPDP wonders if the DEA was suggesting the signing of just fields the DEA stipulates (as in a packet of information within a transaction?) since the statement appears "DEA has also clarified that the requirement that the DEA-required contents of the prescription not be altered during transmission applies only to changes to the content (not format) by intermediaries, not to changes that may lawfully be made at a pharmacy after receipt." This raised the following questions.

   - Is the DEA suggesting that individual fields be digitally signed? This adds complexity for implementation. This is a significant change to the standard to sign each DEA specified field.
   - Is there any current business exchange of individual fields being signed, and of an intermediary being involved? How does this work?

LTPAC Comments:

1. We would like to confirm our understanding that an LTPAC setting may print a controlled substance medication order as long as it is clearly labeled as a copy, not valid for dispensing, for example when needed to meet the requirements of a state nursing home surveyor.
2. While the IFR indicates that the "electronic prescription application must transmit the electronic prescription as soon as possible after signature by the practitioner." (21 C.F.R § 1311.170), the DEA indicates in its comments its intent to allow flexibility for nursing facility staff to perform necessary functions prior to transmitting the prescription to the pharmacy. Those functions include reviewing the order in the context of the patient's other care, consultation with the prescriber if needed, and addition of facility administration details such as pass times and the patient's unit/room/bed location. In section 1311.170(a) (e) states transmit as soon as possible after signature which contradicts the preamble.

   We request clarification of two points regarding transmission of the prescription following these necessary steps:

a. We request the DEA provide clarification to our understanding that sufficient time would be allowed for the nursing facility to perform the steps described, which are ordinary and beneficial practices.

b. In accordance with the communication flow among the prescriber, nursing facility and pharmacy, confirm that after the prescription is signed by the prescriber, and after the nursing facility staff has performed its review and annotation, that facility staff may initiate transmission of the signed prescription to the pharmacy for dispensing.

We believe that such a process will ensure timely dispensing of the patient's medication, while protecting the security of the prescription and support patient safety.

3. The SCRIPT Standard accommodates a Prescription Change Request transaction which allows the nurse or pharmacy to inform a prescriber that the new medication order/prescription needs to be modified. The prescriber responds with a Prescription Change Response transaction either approving or denying the modification. Is there anything in the IFR that prevents the use of the transactions for these purposes?

   An example: Prescriber sends a New Prescription transaction containing Lortab® 5mg to the LTPAC facility with directions (Sig) to take every 4 to 6 hours as needed. The facility nurse sends a Prescription Change Request transaction to clarify the directions – is it every 4 hours as needed for severe pain and every 6 hours as needed for moderate pain? The prescriber responds with a Prescription Change Response transaction with clarification.

   In the example above, can the facility staff add the additional clarification to the signed electronic prescription prior to transmission to the pharmacy? We need clarification as to what can be added to the prescription and what is allowed to be modified.

4. The SCRIPT Prescription Change Response transaction supports the prescriber modifying the new prescription. Per the DEA, changes to dosage form, strength, quantity, etc. are allowed. Does the Prescription Change Response transaction need to meet the same requirements as a New Prescription transaction (two-factor authentication, the sign field, etc.)?

5. The unit, room and bed must be added to the medication order by the nurse; NCPDP would like to request clarification that unit, room and bed are not considered to be part of the resident's address.

IV. Discussion of Comments

I. Identify proofing (page 16245)

DEA Response. In view of the comments, DEA has revised the requirements for identity proofing to adopt an approach that does not involve parties discussed in the proposed rule. As suggested by some commenters, for individual practitioners in private practice (i.e., those practitioners not seeking access to an institutional practitioner's applications), DEA will use existing certification authorities (CAs) and similar credential service providers (CSPs) that have been approved by a Federal authority. These organizations conduct identity proofing and issue digital certificates and other identity credentials as part of their existing businesses. The standards they use to conduct identity proofing and issue credentials are established in documents (e.g., Certificate Policies, Certificate Practice Statements, and Assurance Frameworks) that are reviewed and approved by Federal authorities and subject to third-party audits for their implementation. DEA is specifying that the identity proofing must meet NIST SP 800-63-1 Assurance Level 3 although a CA or CSP may impose higher standards.
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For remote identity proofing, Level 3 requires a valid government-issued identification number and a financial account number. These numbers must be confirmed via record checks with either the issuing agency or institution or through credit bureaus or similar databases. The check must confirm that the name, address, date of birth, and other personal information in the records are consistent with the application and sufficient to identify a unique individual. The address or telephone number must be confirmed by issuing the credential in a manner that confirms the ability of the applicant to receive communications at the listed address or number. DEA notes that CAs and CSPs

may conduct more extensive remote identity proofing and may require additional information from applicants. DEA believes that the ability to conduct remote identity proofing allowed for in Level 3 will ensure that practitioners in rural areas will be able to obtain an authentication credential without the need for travel. DEA expects that application providers will work with CSPs or CAs to direct practitioners to one or more sources of two-factor authentication credentials that will be interoperable with their applications. DEA is seeking comment on this approach to identity proofing.

NCPDP response:

1. NCPDP vendor members thank the DEA for removing vendors from this process.

(same section, page 16246)

Under the rule, the institutional practitioner may issue the two-factor authentication credentials itself or obtain them from a third party, which will have to be a CSP or CA that meets the criteria specified above. In the latter case, the institutional practitioner could have each practitioner apply for the two-factor credential himself, which would entail undergoing identity proofing by the CSP or CA. Alternatively, the institutional practitioner can serve as a trusted agent for the third party. Trusted agents conduct part of the identity proofing on behalf of the CSP or CA and submit the information for each person along with a signed agreement that specifies the trusted agent's responsibilities. DEA emphasizes that institutional practitioners are allowed, but not required, to conduct identity proofing. If an institutional practitioner (e.g., a small hospital or clinic) decides to have each practitioner obtain identity proofing and the two factor authentication credential on his own, as other individual practitioners do, that is permissible under the rule. DEA is seeking comment on this approach to identity proofing by institutional practitioners.

NCPDP response:

1. This recommendation is an improvement over the identity proofing process suggested in the NPRM. NCPDP appreciates the DEA efforts to provide flexibility so as to not be a deterent to adoption of electronic prescribing.

C. Authentication Protocols (page 16251)

Because the use of biometrics and the standards related to their use were not discussed in the notice of proposed rulemaking, DEA is seeking further comment on these issues. Specifically, DEA is seeking comments in response to the following questions:

- What effect will the inclusion of biometrics as an option for meeting the two factor authentication requirement have on the adoption rate of electronic prescriptions for controlled substances, using the proposed requirements of a password and hard token as a baseline? Do you expect the adoption rate to significantly increase, slightly increase, or be about the same? Please also indicate why.
- Is there an alternative to the option of biometrics which could result in greater adoption by medical practitioners of electronic prescriptions for controlled substances while also providing a safe, secure, and closed system for prescribing controlled substances electronically? If so, please describe the alternative(s) and indicate how, specifically, it would be an improvement on the authentication requirements in this interim rule.

NCPDP response:

1. NCPDP notes that as biometrics are in limited use in healthcare, they may not impact electronic prescribing transaction volume at this time. There should be a wide variety of products to allow flexibility as the industry matures in use and technologies to achieve the NIST level requirements specified. From the questions proposed by the DEA in this section, it appears that more analysis and experience is needed.

3. Indication that the Prescription Was Signed (page 16256)

DEA Response. DEA is not specifying by regulation how the field indicating that a prescription has been signed could be formatted, only that such a field must exist and that electronic prescription applications must indicate that the prescription has been signed using that particular field. As DEA noted in the NPRM, the field indicating that the prescription was signed could be a single character field that populates automatically when the practitioner ''signs'' the prescription. DEA is not requiring that a signature be transmitted. The field is needed to provide the pharmacy assurance that the practitioner in fact authorized the prescription. Although most existing applications may not transmit the prescription unless the prescription is approved or signed, and DEA is making that an application requirement, the pharmacy has no way to determine whether the electronic prescription application the practitioner used to write the prescription meets the requirement absent an indication that the prescription was signed. The prescription application's internal audit trail is not available to the pharmacist who has to determine whether he can legally dispense the medication. If a pharmacy receives an electronic prescription for a controlled substance in which the field indicates that the prescription has not been signed, the pharmacy must treat this as it would any written prescription that does not contain a manual signature as required by DEA regulations.

NCPDP response:

1. An interim solution is being built for the current regulated SCRIPT version 8.1 to denote the prescription was signed. An interim solution is also being built (which may be the same) for SCRIPT version 10.6 which is going through the HHS regulatory process. A long term solution is also being analyzed for a future version of SCRIPT. Any time significant modifications are required to a standard that has been named in regulation (e.g. NCPDP SCRIPT) the regulatory process must be invoked which adds delays to the implementation timeframe for the industry.

4. Other Prescription Content Issues (page 16257) and 6. Other Pharmacy Issues (page 16268) – same topic

The problem with special codes for individual practitioners prescribing controlled substances using the institutional practitioner's registration and the DEA-issued identification number for certain substances used for detoxification and maintenance treatment is that SCRIPT does not currently have a code to identify them. Codes exist that identify DEA numbers and State authorization numbers; the fields are then defined to limit them to the acceptable number of characters. The general standard for the identification number field, however, is 35 characters. It should, therefore, be possible for NCPDP to add a code for an institution-based DEA number that allows up to 35 characters, with the first nine characters in the standard DEA format; the remaining characters should be sufficient to accommodate most institutional coding systems until DEA and the industry can standardize the format. Similarly, NCPDP should be able to add a code for the identification number for maintenance of detoxification treatment. Free text fields may also need to be used to incorporate other information required on certain prescriptions; for example, part 1306 requires that prescriptions for gamma hydroxybutyric acid the practitioner must indicate the medical need for the prescription; for certain medications being used for maintenance or detoxification treatment, the practitioner must include an identification number in addition to his DEA number.

NCPDP response:

1. The Data 2000 Waiver ID was added as a valid value in the January 2010 publication of the NCPDP External Code List and is available for use in SCRIPT now. The Data 2000 Waiver ID is a unique identification number that must be on the prescription in addition to the DEA Number. The NCPDP standards development process is very responsive to the requested needs of the industry.

2. A free text field may also be used to incorporate other information required on certain prescriptions once electronic prescribing is allowed for controlled medications; for example, the medical need. Part 1306 requires that on prescriptions for gamma hydroxybutyric acid the practitioner must indicate the medical need for the prescription.

3. NCPDP would have appreciated the DEA discussing these statements via a call with NCPDP to accurately report them in the rule. **The size of the Reference Number field that holds the prescriber identifier is not the concern. Nor is any "code" the industry may wish to include. Nor is stuffing the field with any other information.** As NCPDP and industry have stated in their response to the ANPR 74 FR 46396, the inclusion of **institution-based suffixes cannot be verified via a commercially available resource**. Yes, the DEA number (first nine characters) can be verified to be a DEA number. **Any suffixes cannot be verified**. The DEA wants validation of the prescriber. While the pharmacy can verify the DEA number is an appropriate DEA number, **the prescriber cannot be verified because the individual actually prescribing does not have a *unique DEA number***. Who the suffix is assigned to is only known at the institution. If each prescriber is to be verified, **each prescriber must have a unique DEA number**.

(same section)

On the issue of the inability of pharmacies to validate the special code assigned by an institutional practitioner to individual practitioners permitted to prescribe controlled substances using the institution's DEA registration, DEA notes that the ''validation'' that some pharmacy applications conduct simply confirms that the DEA number is in the standard format and conforms to the formula used to generate the DEA registration numbers. The validation does not confirm that the number is associated with the prescriber listed on the prescription or that the registration is current and in good standing. To confirm the actual validity of the DEA number, the pharmacy would have to check the DEA registration database using the Registration Validation tool available at the Office of Diversion Control Web site (*http://www.DEAdiversion.usdoj.gov*). If a pharmacy has reason to question any prescription containing special identification codes for individual practitioners, it must contact the institutional practitioner.

DEA recognizes that revisions to the SCRIPT standard to accommodate identification codes for individual practitioners prescribing controlled substances using the institutional practitioner's registration, identification numbers for maintenance or detoxification treatment, and dates before which a Schedule II prescription may not be filled may not occur immediately as they have to be incorporated into a revision to the standard that is subject to the standards development process. Application providers will then have to incorporate the new codes into their applications.

NCPDP response:

1. See response immediately above.

(same section, page 16268)

These prescriptions must be dated on the day they are signed and marked to indicate the earliest date on which they may be filled. All of these requirements can (and must) be satisfied when a practitioner elects to issue multiple prescriptions for Schedule II controlled substances by means of electronic prescriptions. At present, it is not clear that the SCRIPT standard accommodates the inclusion of these dates or that pharmacy applications can accurately import the data. As noted in the previous response, until applications accurately and consistently record and import these data, applications must not be used to handle these prescriptions.

NCPDP response:

1. If asked, NCPDP would have been able to respond to this question and provide an answer to the DEA before including the question in a rule. On a new prescription, the date written is a required field. As each new prescription is a new message transmitted, each new prescription is required to have the date written. (The date written field is a different field than the transmission date.)

I. Third Party Audits (page 16269)

Finally, DEA has expanded the kinds of third-party auditors beyond those who perform SysTrust, WebTrust, or SAS 70 audits to include certified information system auditors (CISA) who perform compliance audits as a regular ongoing business activity. The CISA certification is sponsored by the Information Systems Audit and Control Association (ISACA) and is recognized by the American National Standards Institute under ISO/IEC 17024. The certification is required by the FBCA for third-party auditors and by the Federal Reserve Bank for its examiners and is approved by the Department of Defense. DEA believes that allowing other certified IT auditors will provide application providers with more options and potentially reduce the cost of the audit. DEA is seeking comments on the addition of CISA to the list of permissible auditors.

NCPDP response:

1. NCPDP appreciates the DEA expanding auditor choices for the industry. Questions were raised about whether expertise from certification or audit entities includes healthcare settings? Has the DEA reached out to these entities? Are they prepared to begin certifying this industry, as the effective date is June 1, 2010? Will the DEA provide information to vendors, pharmacies, prescribers about these entities? (Re section: § 1311.300 Application provider requirements - Third-party audits or certifications.)

The Interim Final Rule Analysis (page 16294)

DEA has determined that this interim final rule is an economically significant regulatory action; therefore, DEA has conducted an analysis of the options. The following sections summarize the economic analysis conducted in support of this rule. DEA is seeking further comments on the assumptions used in this revised economic analysis and is especially interested in any data or information that commenters can provide that would reduce the many uncertainties in the estimates as discussed below and improve the options considered in the analysis of a final rule.

Options Considered

DEA considered three options for the electronic prescribing of controlled substances:

Option 1: The interim final rule as described in this preamble.

Option 2: The interim final rule with the requirement that one of the factors used to authenticate to the application must be a biometric.

Option 3: No additional requirements for electronic prescription or pharmacy applications, but a callback for each controlled substance electronic prescription.

Universe of Affected Entities

The entities directly affected by this rule are the following:

- DEA individual practitioner registrants who issue controlled substance prescriptions or individual practitioners who are exempt from registration and who are authorized to issue controlled substance prescriptions under an institutional practitioner's registration.
- Hospitals and clinics where practitioners may issue controlled substance prescriptions.
- Pharmacies

In addition, application providers are indirectly affected because their applications must meet DEA's requirements before a registrant may use them to create or process controlled substance prescriptions. The practitioners who prescribe controlled substances are primarily physicians, dentists, and mid-level practitioners. Hospitals and clinics will be affected if practitioners working for or affiliated with the hospital or clinic use the institutional practitioner's application to issue prescriptions for persons leaving the institution (inpatient medical orders are not subject to these rules). Several thousand institutional practitioner registrants (e.g., prisons, jails, veterinarians, medical practices, and Federal facilities) are not included either because they are unlikely to have staff issuing prescriptions, are already counted in the practitioner total, or, in the case of Federal facilities, already comply with more stringent standards. Table 4 presents the estimates of entities directly affected and estimated growth rates, which are based on recent trends. As the number of hospitals and retail pharmacies have been declining, DEA did not project growth (or decline) for these sectors.

NCPDP response:

1. The NCPDP SCRIPT Standard is available for use in these settings. Industry organizations will provide more detail on practitioners who prescribe in these settings.

LTPAC Comments:

1. In response to the DEA request to the economic analysis of the IFR the DEA states "Several thousand institutional practitioner registrants (e.g., prisons, jails, veterinarians, medical practices, and Federal facilities) are not included either because they are unlikely to have staff issuing prescriptions, are already counted in the practitioner total, or, in the case of Federal facilities, already comply with more stringent standards." There are many instances in which the long-term and post acute care (LTPAC) pharmacy providers service prisons, jails, and Federal facilities using their own DEA registration not the prisons', jails', or Federal

facility's registration. It is recommended that the DEA reconsider the economic analysis to include these situations.

PART 1300 – DEFINITIONS

1. The authority citation for part 1300 continues to read as follows: AUTHORITY: 21 U.S.C. 802, 821, 829, 871(b), 951, 958(f).
2. Section 1300.03 is added to read as follows: **§ 1300.03 Definitions relating to electronic orders for controlled substances and electronic prescriptions for controlled substances.**

For the purposes of this chapter, the following terms shall have the meanings specified:

Installed electronic prescription application means software that is used to create electronic prescriptions and that is installed on a practitioner's computers and servers, where access and records are controlled by the practitioner.

NCPDP response:

LTPAC Comments:

1. We are seeking clarification to the definition of "Installed electronic prescription application means software that is used to create electronic prescriptions and that is installed on a practitioner's computers and servers, where access and records are controlled by the practitioner".

2. A specific concern is the IFR assumes that the electronic prescription application and related records can only be "housed" at a "registered location." The term "registered location" is mentioned multiple times in the IFR but is not defined.

   For example, in section 1311.125 what is meant by the term "registered location"? If a LTPAC facility's EHR with electronic prescribing capabilities meets all the requirements outlined in 1311.120 can they transmit a controlled substance electronic prescription as outlined in 1311.170? If the prescriber uses the LTPAC facility's EHR that has electronic prescribing capabilities does this mean the LTPAC facility's EHR becomes a registered location?

3. In section 1311.125 of the IFR, it appears to require that signed electronic prescriptions be stored on a CPOE/electronic prescribing system that belongs to or is at least controlled by the prescriber. Considering the sections 1311.120, 1311.125 and 1311.170 is the following workflow acceptable?

   > Dr. Smith is a physician who has been granted practice privileges by Shady Rest Nursing Home, a Medicare certified skilled nursing facility. He maintains a private practice separate from the facility, but also cares for patients at Shady Rest. The facility maintains an electronic health record that includes CPOE/electronic prescribing functionality that meets all the requirements detailed in the DEA IFR. The facility is not a DEA registrant, but the medical director is a registrant, and is one of the two people that control the granting of prescribing rights in the EHR system. After meeting all requirements of the IFR (e.g., identity proofing), Dr. Smith is granted prescribing rights that include controlled substances. During a visit to the facility, Dr. Smith determines the need to prescribe morphine for one of his patients. He logs into the facility CPOE system, writes the order, and appropriately signs the order using his approved two-factor authentication. The signed order is stored in the facility system and is transmitted electronically to the long term care pharmacy provider.

   Key facts:

   1. The prescriber is a DEA registrant authorized to prescribe controlled substances.
   2. The nursing home is not a DEA registrant.
   3. The CPOE/EHR/electronic prescribing system is owned and controlled by the nursing home, not the prescriber.
   4. The medical director of the nursing home is a registrant and one of the two people that would control prescribing rights in the facility.
   5. Signed orders are stored in the facility system.

> If the above scenario is not acceptable, implementation of electronic prescribing of controlled substances in LTPAC could be delayed by several years. Serious impact will occur to the industry workflow, which may include reconsideration of the economic impact. The industry will be forced to build new workflow requirements. This may cause collision or even non-compliance with federal and state regulatory modifications, as well as force delay in the adoption of electronic prescribing. Without a modification, the practice of electronic prescribing for non-controlled substance prescriptions and **paper** for controlled substance prescriptions will continue. Furthermore, the industry would be forced to determine whether the current SCRIPT Standard will suffice or whether data fields will have to be modified or added. If changes or additions are needed, it will take time for HHS to name or mandate a new version of SCRIPT to meet the IFR requirements in the LTPAC setting, further delaying industry adoption.

NCPDP appreciates the opportunity to respond.

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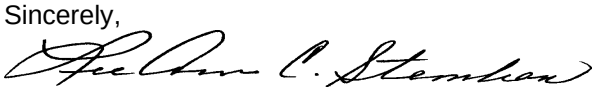
Sincerely,



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