



FOR IMMEDIATE RELEASE

## **SRS Response to DEA Interim Final Rule on E-Prescribing of Controlled Substances**

Caro, MI (May 26, 2010) – On March 31, 2010 the DEA published in the Federal Register an Interim Final Rule permitting the use of electronic prescriptions for controlled substances. The rule is significant in that it will finally permit DEA registrants to transmit e-prescriptions to pharmacies for Schedule II through V controlled substances, subject to state laws. An overview of the rule follows.

### **INTERIM FINAL RULE OVERVIEW**

#### **Practitioner Identity Requirements**

Before practitioners can submit a controlled substance e-prescription, they must be able to prove their identity through a federally-approved third party credential service provider (CSP) or certification authority (CA). This is known as "identity proofing." Identity proofing must meet either in-person or remote identity proofing. Institutional DEA registrants, such as hospitals, may conduct their own in-person identity proofing for any employed physician or other physician for whom the institution is granting access to issue prescriptions using the institution's e-prescribing application.

#### **Issuance of E-Prescriptions**

Each time a practitioner submits an electronic prescription, the software application must first require the practitioner to indicate that the prescription is ready to be signed. Subsequently, the practitioner must authenticate the prescription using two authentication factors. This authentication takes the place of the prescriber's signature on a hard copy prescription. The DEA rule allows the software application to use any two of the following three authentication factors: (1) a biometric factor, such as a fingerprint or iris scan; (2) a knowledge factor, like a password or response to a challenge question; and (3) a hard token, for example, a smart card or USB token. When the practitioner completes the two-factor authentication protocol, the e-prescribing application must digitally sign and electronically archive the record. The rule allows non-physician staff members to review and annotate records following practitioner authentication but before transmission. The new rule also requires that the software application automatically provide the practitioner with a monthly log of the practitioner's electronic prescribing of controlled substances.

#### **Pharmacy**

Under the rule, either the last intermediary that transmitted the prescription or the receiving pharmacy must digitally sign the prescription as received, unless a practitioner's digital signature is attached and can be verified by the pharmacy. The pharmacy is not required to periodically verify the DEA registration, but must check the registration when it has reason to suspect the validity of the registration or the prescription. The pharmacy must back up e-prescribing information daily. The rule also describes a number of technical specifications that must be included with pharmacy applications.

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## **Record Keeping**

The rule reduces the record keeping requirement of records related to controlled substance electronic prescriptions from five (5) years to two (2) years.

## **Application Providers**

The rule places a number of requirements on application providers of e-prescribing applications to practitioners and pharmacies (i.e., SRS). These include requirements for third party audits whenever software functionality related to controlled substance requirements is altered, or every two years, whichever occurs first. Alternatively, application providers can obtain certification by a DEA-approved certification organization. However, at this time, no such certification exists for either electronic prescription or pharmacy applications.

## **Liability**

The rules states that practitioners may not use existing electronic prescription applications to transmit electronic prescriptions for controlled substances until those applications are in compliance with the interim final rule. Section 1306.05 states that the practitioner is responsible for ensuring that a prescription conforms in all essential respects with the law and regulation. It also places a corresponding liability on pharmacies to ensure that only prescriptions that conform with the regulations are dispensed.

## **Conclusion**

While the DEA's Interim Final Rule is a major first step in electronic prescribing of controlled substances, a number of issues still remain. For example:

- ♦ Existing e-prescribing solutions don't necessarily contain all of the safeguards required by the rule and will require additional programming.
- ♦ E-prescribing application providers (including pharmacy software vendors) must be certified as compliant with the new standards before they can be used to create, sign, transmit, or process controlled substance prescriptions. However, no certification bodies currently exist to certify compliance.
- ♦ Providers will need to consider whether they must continue to comply with existing state laws relating to prescribing of controlled substances.
- ♦ The regulation is subject to a 60-day Congressional review period. Depending on the outcome of this review, the effective date may change.
- ♦ The DEA is accepting public comment on the rule through June 1, 2010.

While the Interim Final Rule is a move forward in allowing the e-prescribing of controlled substances, the DEA's request for public input indicates that further refinements of the standards may be forthcoming. As such, SRS will continue to monitor the final outcomes of the public comment and Congressional review periods and respond accordingly.

## **Questions?**

If you have additional questions, please contact SRS Customer Support at 1.800.673.6226.

Thank you.  
SRS Support