



June 1, 2010

Submitted electronically via:
<http://www.regulations.gov>

Ms. Michele M. Leonhart, Deputy Administrator
Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

RE: Electronic Prescriptions for Controlled Substances, Final Rule; 21 CFR Parts 1300, 1304, 1306, and 1311; Docket No. DEA-218; RIN 1117-AA61

Dear Deputy Administrator Leonhart:

Surescripts is the result of the merger in June 2008 of SureScripts, LLC and Rx-Hub, LLC. SureScripts, LLC was founded in August of 2001 by the National Community Pharmacists Association (NCPA) and the National Association of Chain Drug Stores (NACDS), which together represent the interests of the 55,000 independent and chain community pharmacies throughout the United States. RxHub, LLC was founded in the same year by the nation's three largest pharmacy benefit managers (PBMs): CVS Caremark Corporation, Express Scripts, Inc. and Medco Health Solutions, Inc. RxHub's expertise in patient identification and delivering prescription drug benefit information to the physician at the point of care complemented SureScripts' focus on routing of electronic prescriptions and refill authorization requests and responses between physician offices and both community and mail-order pharmacies. The merger combines these strengths with a shared focus on greater access to patient medication history to form a single suite of comprehensive e-prescribing services. Surescripts is committed to building relationships within the healthcare community and working collaboratively with key industry stakeholders to improve the safety, efficiency, and quality of healthcare by improving the overall prescribing process. You and your staff can find more information about Surescripts at www.surescripts.com, and we would call to your attention our recent National Progress Report on E-prescribing, which can be found at: <http://www.surescripts.com/national-progress-report.aspx>.

This letter is in response to the interim final rule with request for comment that the DEA published in the Federal Register, Volume 75, Number 61, beginning on page 16236 on March 31, 2010. Surescripts appreciates the opportunity to comment on this IFR, which for the first

time allows the totally electronic transmission of controlled substance prescriptions from prescribers to ambulatory pharmacies.

General Comment

Surescripts applauds the publication of this groundbreaking IFR, which we believe is a substantial step forward from the NPRM that the DEA published in the Federal Register in 2008. The requirements of this IFR are much more responsive to the needs and concerns of the health information technology (HIT) industry, and we strongly support said requirements. There is no question that the implementation of these requirements will enhance patient safety, strengthen fraud prevention, promote systemic efficiencies, and lower healthcare costs in the United States. It is our intent to leverage the expertise in e-prescribing that we have accumulated over the last eight years to assist prescribers, pharmacies, and their application vendors in fully complying with the IFR's requirements.

Surescripts Comments on Specific Provisions of the IFR

Third-Party Audits

DEA: SureScripts/RxHub certifies pharmacy and electronic prescription applications for interoperability and compliance with NCPDP SCRIPT, but not for their internal security or other functionalities; as commenters noted, SCRIPT supports, but does not mandate, the inclusion of all the DEA-required information. In addition, SureScripts/RxHub is not a neutral third party, but was established and is run by the pharmacy industry and may have a vested interest in promoting the existing model of transmission over others. Thus, DEA believes that SureScripts/RxHub certification, while beneficial from an industry perspective, is not suitable to address DEA's requirement for a neutral unbiased third-party audit of electronic prescription and pharmacy applications.

Surescripts Comments: As we stated above, Surescripts will support the requirements of the DEA's EPCS IFR, and we believe our support will play a pivotal role in its widespread adoption and successful implementation. We have reviewed the IFR in depth, and we do not anticipate any insurmountable barriers to implementing EPCS as the DEA envisions it.

This said, we do anticipate that the implementation of the IFR's requirements will necessitate a great deal of coordination among the nation's community pharmacies, pharmacy benefit managers, mail-order pharmacies, pharmacy technology vendors, and over 300 current and emerging e-prescribing vendors serving the nation's prescribers. Surescripts operates as a large-scale, impartial broker and nationwide network committed to principles of neutrality,

transparency, open standards, efficiency, and low costs. As such, Surescripts is actively planning to take a leadership role to enable the entire HIT infrastructure to effectively support EPCS.

Surescripts will provide comprehensive support for the DEA's new rules governing the e-prescribing of controlled substances by continuing to conduct an HIT certification process of uncompromising quality that has been expanded to include the DEA's EPCS requirements. We will also be introducing a number of new informational tools and services, including an important strategic partnership that will directly support and enhance our abilities in this area. Surescripts plans to offer physicians, pharmacies, and their technology vendors a menu of services that represent the least disruptive, most cost-effective approach to EPCS rule compliance. We also plan to seek out ways to forge a closer relationship with the DEA based on our position as a transparent and neutral partner with the industry overall.

Surescripts does operate a neutral, unbiased network, which is borne out by eight years of very public policies and operations. The Surescripts network is a standards-based, impartial network serving as the backbone of e-prescribing in the U.S. Our network is open to any certified software vendor, pharmacy, PBM, or health system. From its inception, Surescripts has demonstrated a constitutional commitment to operating a neutral, transparent and open network that guarantees:

- Choice of pharmacy for patients
- Choice of medications for prescribers
- Choice of software applications for prescribers and pharmacies
- That commercial messaging of any kind is prohibited

And, having chosen from the beginning not to develop end-user e-prescribing applications, we have ensured a wide array of technology options for everybody. Further underscoring this commitment to choice, Surescripts will—in addition to offering its own services in support of EPCS—accept certification and security services provided by other third-party entities. This market-driven, proven approach will ensure the most rapid deployment of technology to support the DEA's EPCS rule.

Our demonstrated commitment to stakeholder choice is a primary reason behind the unprecedented levels of participation on the Surescripts network by all stakeholders, not just pharmacies (levels that are unprecedented in the history of interoperable HIT):

- 193 certified prescriber applications

- 183,000 prescribers
- 54,000 chain and independent pharmacies
- Six of the largest mail-order pharmacies
- Over 30 PBMs and health plans representing 200 million patients

The secret to how Surescripts achieves neutrality is... to have no secrets. By operating transparently, Surescripts is able to balance the interests of all network participants. This is not easy, but we are committed and work hard at it. Everyone has input in how we offer services—even competing networks. Our transparency is ensured by the following Surescripts activities:

- Regular publication of a technology roadmap
- Monthly network participant information and coordination calls
- Annual technology workshops to which all network participants are invited
- Extensive participation in industry standards groups such as NCPDP and HL7
- Continual engagement with technology vendors plus physician, pharmacy, and other professional associations

Surescripts' proven commitment to neutrality, transparency, and commitment to open standards are what encouraged the Certification Commission for Health Information Technology (CCHIT) to include Surescripts in its efforts to certify electronic health records. These principles will continue with the advent of EPCS and will be key to its rapid adoption, implementation, and compliance. Our core principles, in combination with our record as a neutral and unbiased network, serve as the foundation for an extremely strong argument that Surescripts should be recognized by the DEA as an independent certification organization.

As the DEA noted in the IFR, Surescripts has had a certification process in operation for electronic prescription and pharmacy applications for nearly eight years. The time, effort, and resources we have invested in our certification process have been very significant, and as a result, we have a trained and experienced certification team that is exceptionally competent in certifying HIT applications for e-prescribing functionalities. Each and every application vendor that has connected with our network has had to go through our rigorous certification process, and a significant number of these same vendors have asked if we intend to extend the scope of our certification process to include all of the EPCS requirements in the IFR. We have told these

vendors that we agree that this would make sense and that we would raise the issue with the DEA.

There are several important reasons why we believe it would be appropriate for Surescripts to provide an EPCS certification service to industry stakeholders:

- Our technical and certification teams have an in-depth understanding of the way that physician and pharmacy applications operate, so we are well prepared to assist them in incorporating the functionalities required by the IFR into their applications and to assess their success in doing so.
- We have a thorough understanding of the design and use of the NCPDP SCRIPT Standard, and we are already playing a leadership role within NCPDP to move the standards organization toward creating the fields and data elements necessary to accommodate the special requirements of the IFR (e.g., the “indication of signature” field).
- Adding the IFR requirements to our existing network certification process will capitalize on our recognized expertise in certification and provide a very efficient and cost-effective way for application vendors to comply with the IFR.

In light of all of the facts shared above, we intend to apply to be recognized as an independent certification organization for EPCS certification purposes, and we are confident that we will meet the DEA’s requirements. We look forward to having a dialogue with DEA personnel to learn how such recognition can be attained.

Surescripts Comments in Response to DEA’s Explicit Requests for Comment

(Note: We have arranged our comments to follow the topical organization of the requests for comment made by the DEA in the IFR.)

Identity Proofing and Access Control

DEA: Because DEA has made extensive changes to the requirements related to identity proofing and logical access control, DEA is seeking further comments on these issues.

Surescripts Comments: We commend the DEA for having changed its EPCS requirements to allow either in-person or remote identity proofing, subject to NIST requirements. We also agree with the IFR’s placing on the individual practice or institution (rather than on application providers) the responsibility for checking DEA and state registration statuses and setting logical

access. Both of these changes should make these processes more efficient and user-friendly for prescribers and pharmacies.

DEA: 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.

Surescripts Comments: We agree, and Surescripts will provide guidance to our connected vendors and the industry at large as appropriate to implement solutions consistent with the IFR. In particular, Surescripts is supportive of NIST AL 3 remote identity proofing as defined by 800-63.

DEA: 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.

Surescripts Comments: We agree with this approach as it offers greater flexibility for small institutions.

DEA: All entries and changes to the logical access controls for setting the controls and for the controlled substance prescription functions must be defined as auditable events and a record of the changes retained as part of the internal audit trail. DEA is seeking comment on this approach to logical access control for individual practitioners.

Surescripts Comments: It is a good practice to track access to prescribing of controlled substances. Surescripts will be able to verify that applications have this capability during the EPCS certification process.

Third-party Auditors and Certification Organizations

DEA: 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.

Surescripts Comments: Surescripts supports the addition of CISA to the list of permissible auditors, and we recommend that the DEA also recognize CISA-equivalent auditors who are qualified to perform ISO 27001/27002, HITRUST, or EHNAC audits.

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Conclusion

Again, Surescripts is quite pleased with the DEA's EPCS IFR, and we look forward to working with the DEA and the HIT industry to implement its requirements. Should you have any questions about the information that we have shared or the recommendations that we have made, please feel free to contact either of us at: Paul.Uhrig@Surescripts.com, Ken.Whittemore@Surescripts.com, or 703-921-2121.

Sincerely,

/s/ Paul Uhrig

Paul L. Uhrig
EVP, Chief Administrative & Legal Officer; Chief Privacy Officer

/s/ Ken Whittemore Jr.

Ken Whittemore, Jr.
Senior VP, Regulatory Affairs