surescripts
The Nation's E-Prescription Network

September 13, 2010

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

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
Office of Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201
RIN 0991-AB57

Attention: HITECH Privacy and Security Rule Modifications, RIN 0991-AB57

Dear Secretary Sebelius:

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 prescription 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 notice of proposed rulemaking (NPRM) that the Department of Health and Human Services (HHS) published in the Federal Register, Volume 75, Number 134, beginning on page 40868 on July 14, 2010. Surescripts appreciates the opportunity to comment

on the proposal rules to implement certain provisions of the Health Information Technology for Economic and Clinical Health Act (HITECH) and applauds HHS and the Office of Civil Rights believing that many of the changes proposed represent significant and necessary steps towards ensuring accountability of actors in this evolving environment of health information technology.

General Comments

We applaud your efforts undertaken in the NRPM to effectuate certain provisions of HITECH. Overall, Surescripts is generally supportive of the proposed regulations and the intent to increase transparency and privacy. We have noted specific concerns, discussed below, with respect to sections of the proposed rules that have the potential to generate additional complexities and confusions within the industry.

Surescripts Comments on Specific Provisions of the Notification of Proposed Rulemaking

1. Definition of a "Business Associate"

Surescripts Comments: Surescripts applauds efforts undertaken to strengthen the rights and responsibilities that entities have when such entities are providing services on behalf of a covered entity as an overarching principle, as discussed in the NPRM. However, we have specific questions and request that HHS provide additional clarification so all parties who are involved with transactions involving the exchange or transmission of protected health information are clear on their responsibilities.

a. Umbrella term of an "HIO"

HHS: [W]e propose to modify the definition of "business associate" to explicitly designate these persons as business associates . . . we instead include in the proposed definition the term "Health Information Organization" because it is our understanding that "Health Information Organization" is the more widely recognized and accepted term . . . Further, the specific terms of "Health Information Organization" and "E-prescribing Gateway" are merely illustrative of the types of organizations that would fall within this paragraph of the definition of "business associate." We request comment on the use of these terms within the definition and whether additional clarifications or additions are necessary.

Surescripts Response: While we understand that, in some circumstances, it may be advantageous to have a single definition of a Health Information Organization (HIO), we are concerned that in other circumstances it may not be appropriate to have an umbrella term for all entities that participate in the exchange of health-related information among organizations. Not all entities should be treated the same way for all purposes. As the world of health IT evolves, we believe that HIO, as a catch-all term, could lead to conflicting obligations and confusion when taken in the context of emerging Federal and State laws and regulations.

b. When is an HIO a Business Associate?

Surescripts Comments: We request confirmation or clarification from HHS that a person providing protected health information to another person, that has obtained consent (or consent has been deemed to be provided) to pre-populate a database that could later be queried by covered entity providers is not a business associate since the database host is not acting with respect to, or on behalf of, a covered entity. We also seek further guidance on when and under what circumstances a person would be deemed to be acting "on behalf of" a covered entity as this is unclear. A vacuum exists in the chain of responsibility to a covered entity in situations where, for example, a health information exchange requests protected health information from other persons but is doing so upon the consent (or deemed consent) of an individual, but may not be requesting the information on behalf of or pursuant to the request of a covered entity.

Additionally, we request additional guidance involving situations where a person "pushes" information to another person at the request of the patient and what factors trigger a business associate relationship.

c. Inclusion of Vendors of Personal Health Records (PHRs) as a Business Associate

Surescripts Comments: Section 13408 of HITECH provides that each vendor contracting with a covered entity allow that covered entity to offer a personal health record to patients as part of its electronic health record must enter into a business associate agreement. The NPRM is a significant departure from HITECH, instead defining a person who offers a personal health record to one or more individuals on behalf of a covered entity to be a business associate. We urge HHS to provide guidance to identify the circumstances and specific triggers that would give rise to a business associate relationship.

d. Inclusion of Subcontractors as a Business Associate

HHS: We request comment on the use of the term "subcontractor" and its proposed definition.

Surescripts Response: As a general concept, we applaud and understand the importance of imparting legal responsibilities to subcontractors of business associates when the business associate is acting on behalf of the covered entity. We urge HHS to make a distinction between subcontractors who should appropriately be termed a business associate of a business associate -- a "business associate subcontractor" -- and other entities that should not be considered a subcontractor business associate. We request that HHS provide additional feedback to the industry of factors indicating that a subcontractor of a business associate is acting on behalf of the covered entity and would be a "business associate subcontractor." Additionally, we urge HHS to consider how far down the chain of contractual relationships a business associate relationship could exist.

2. Definition of "Marketing"

a. Face-to-Face Communications

Surescripts Comments: While not specifically highlighted by HHS in the NPRM, we urge HHS to consider publishing guidance regarding what circumstances would be considered "face-to-face," given technological advances and the advent of electronic communications.

b. Exception for Treatment of an Individual by a Health Care Provider

HHS: We are aware of the difficulty in making what may be in some cases close judgments as to which communications are for treatment purposes and which are for health care operation purposes. We also are aware of the need to avoid unintended adverse consequences to a covered health care provider's ability to provide treatment to an individual. Therefore, we request comment on the above proposal with regard to these issues, as well as the alternatives of excluding treatment communications altogether even if they involve financial remuneration from a third party or requiring individual authorization for both treatment and health care operations communications made in exchange for financial remuneration.

Surescripts Response: We support HHS' proposed exception to the definition of marketing for treatment provided to an individual by a provider as an important component of health care and believe that the disclosure of any financial remuneration is a sufficient safeguard to make individuals aware and seek further information, if desired or warranted. We also encourage HHS to provide additional guidance on the distinction between communications made for treatment purposes versus communications made for health care operations.

c. Exception for Refill Reminders

Surescripts Comments: We support your recognition that refill reminders are a significant and important component of patient care as adherence to prescribed medications impacts patient quality of care and effectiveness.

3. **Sale of Protected Health Information**

a. **Re-disclosure by a Recipient Covered Entity or Business Associate**

HHS: We also note, with respect to the recipient of the information, if protected health information is disclosed for remuneration by a covered entity or business associate to another covered entity or business associate in compliance with the authorization requirements at proposed § 164.508(a)(4)(i), the recipient covered entity or business associate could not redisclose that protected health information in exchange for remuneration unless a valid authorization is obtained in accordance with proposed § 164.508(a)(4)(i) with respect to such redisclosure. We request comment on these provisions.

Surescripts Response: We urge HHS to refrain from requiring recipients of protected health information to independently obtain authorization from an individual when the subsequent disclosure is consistent with the terms of the authorization and the individual's authorization did not specifically prohibit downstream disclosure. To require subsequent entities to obtain authorization has the potential to unduly burden the movement of health information for purposes to that the individual has explicitly agreed. Adding additional levels of authorization(s) for which authorization has already been given simply increases administrative burdens without providing a benefit to the individual in terms of increased privacy protections. If the re-disclosure by a recipient covered entity or business associates is for a different purpose than the purpose for which the authorization was given, then no authorization for the disclosure exists and the recipient would need to obtain authorization from the individual in any event.

b. Exceptions to Authorization Requirement for the Sale of Protected Health Information

HHS: In proposed § 164.508(a)(4)(ii), we set forth the exceptions to the authorization requirement of proposed paragraph (a)(4)(i). We propose the exceptions provided for by section 13405(d)(2) of the HITECH Act, but we also propose to exercise the authority granted to the Secretary in section 13405(d)(2)(G) to include an additional exception that we deem to be similarly necessary and appropriate. We invite public comment on the proposed exceptions to this authorization requirement and whether there are additional exceptions that should be included in the final regulation.

Surescripts Response: Section 164.508(a)(4)(i)(E) provides an exception to the prohibition on the sale of protected health information without an individual's authorization, "to or by a business associate for activities that the business associate undertakes on behalf of a covered entity … and the only remuneration provided is by the covered entity to the business associate for the performance of such activities." We are concerned that the general prohibition on the sale of protected health information could adversely impact the ability of persons to electronically transmit protected health information as a fee-based service if not transmitted on behalf of a covered entity.

We request that HHS clarify that the phrase "sale of PHI" does not include fees for the electronic transport of electronic protected health information and associated connectivity fees, if applicable.

Alternatively, we urge HHS to provide guidance on how entities may provide information to health information exchanges or vendors of personal health records (PHR vendor), if a health information exchange or a PHR vendor has an adopted an opt-out or other consent model that is not sufficient for purposes of individual authorization under the Privacy Rule.

Additionally, we urge HHS to consider another exception that would permit a business associate to provide protected health information to a third party for certain public health activities or other exceptions set forth under § 164.512 (even when not acting on behalf of a specific covered

entity) and that doing so would not be considered a prohibited "sale of protected health information."

For example, a State or Federal government may request certain protected health information from a business associate directly, as opposed to requesting such from multiple covered entities. Under the current proposed regulatory scheme, we do not believe that a business associate could provide this information without obtaining individual authorization.

We urge HHS to consider situations wherein a business associate could provide the information requested without obtaining individual authorization.

c. General Exception for Disclosures by Covered Entities Consistent with Applicable State Laws

HHS: We invite public comment on our proposal to include in § 164.508(a)(4)(ii)(H) a general exception for disclosures made for permissible purposes for which the covered entity received remuneration that was consistent with applicable State law.

Surescripts Response: We urge HHS to expand this exception also be applicable to business associates under certain circumstances. *See* discussion above in Section 3(b).

4. Right to Request Restriction on Uses and Disclosures

HHS: Due to the myriad of treatment interactions between covered entities and individuals, we recognize that this provision may be more difficult to implement in some circumstances than in others, and we request comment on the types of interactions between individuals and covered entities that would make requesting or implementing a restriction more difficult. For example, an individual visits a provider for treatment of a condition, and the individual requests the provider not disclose information about the condition to the health plan and pays out of pocket for the care. The provider prescribes a medication to treat the condition, and the individual also wishes to restrict the health plan from receiving information about the medication. Many providers electronically send prescriptions to the pharmacy to be filed so that the medication is ready when the individual arrives to pick it up; however, at the point the individual arrives at the pharmacy, the pharmacy would have already sent the information to the health plan for payment, not permitting the individual an opportunity to request a restriction at the pharmacy. A provider who knows that an individual intends to request such a restriction can always provide the individual with a paper prescription to take to the pharmacy, allowing the individual an opportunity to request that the pharmacy restrict the disclosure of information relating to the medication. However, this might not be practical in every case, especially as covered entities begin to replace paper-based systems with electronic systems. We request comment on this issue, and we specifically ask for suggestions of methods through which a provider, using an automated electronic prescribing tool, could alert the pharmacy that the individual may wish to request that a restriction be placed on the disclosure of their information to the health plan and that the individual intends to pay out of pocket for the prescription.

Surescripts Response: We support encouraging the development of a uniform means of notification of a disclosure restriction when protected health information is transmitted electronically. We also urge HHS to develop clear guidelines for the communication of such restrictions to avoid communication gaps in carrying out the individual's request when transmitting information electronically between different types of entities (health information exchanges, e-prescribing gateways, pharmacies, PBMs, etc.) and how far down the chain such restrictions should be applied. In considering these questions, we urge HHS, the National Institute of Standards and Technology, or other related entities to provide guidance on the segregation of such restricted protected health information not only with respect to the initial transaction but also within the context of a electronic health record and separate transactions impacted by such restrictions (e.g., a prescription history request by the original treating provider with whom the restriction was filed or by a subsequent provider seeking information on the patient).

The following comments relate solely to the e-prescribing transaction. In order to electronically transmit the individual's restriction on the use and disclosure of their protected health information, two items would have to be communicated clearly to pharmacies within the electronic transaction: (1) that the pharmacy should not adjudicate a claim to the individual's insurance, and, that cash will be paid instead; and (2) that the individual does not want information about this prescription shared with the health plan (via medication history type services, etc.). We would suggest that both items (1) and (2) should be specified because the inclusion of only one would not automatically guarantee or require the other. With respect to the indication that the pharmacy should not adjudicate the claim via the individual's health plan and will pay cash, difficulties are present in that adjudication transactions occur quickly upon receipt of the transaction so the message should clearly indicate to the pharmacy software that such information should not be shared. We believe that the same would hold true in the case of a faxed prescription as well. All indicators should be very specific and targeted to meet the individual's requested restriction.

Current standards do not clearly support such an indication but could be modified to do so. For example, the COO segment in SCRIPT 8.1 standard could be utilized or expanded to electronically indicate that an individual has restricted the use or disclosure of his or her protected health information. The patient consent field could be expanded with respect to new prescriptions refill requests to indicate the individual's limitation. Another option could be to consider a plan service code (2Ø1Ø Cash Retail-Payments made by patients to a drug dispenser (retail pharmacy)) that indicates that the individual paid the full cost of the prescription at the point of sale in the external 8.1 code set. Please also be aware that formal changes to the SCRIPT standard can be a lengthy process that would need to be implemented across the board for electronic exchanges of prescription information indicating individual restrictions on the use and/or the disclosure of their protected health information or, alternatively, the code set could be extended without requiring a new version of the standard to be issued.

HHS: Additionally, we request comment on the obligation of covered health care providers that know of a restriction to information other health care providers downstream of such restriction.

For example, a provider has been treating an individual for an infection for several months pursuant to the individual's requested restriction that none of the protected health information relating to the treatment of the infection be disclosed to the individual's health plan. If the individual requests that the provider send a copy of his medical record to another health care provider for treatment, what, if any, obligation should the original provider have to notify the recipient provider (including a pharmacy filling the individual's prescription) that the individual has placed a restriction upon much of the protected health information in the medical record? We request comment on whether a restriction placed upon certain protected health information should apply to, and the feasibility of it continuing to attach to, such information as its moves downstream, or if the restriction should no longer apply until the individual visits the new provider for treatment or services, requests a restriction, and pays out of pocket for the treatment. In addition, we request comment on the extent to which technical capabilities exist that would facilitate notification among providers of restrictions on the disclosures of protected health information, how widely these technologies are currently utilized, and any limitations in the technology that would require additional manual or other procedures to provide notification of restrictions.

Surescripts Response: Please see our comments above. Additionally, we suggest that not only should covered health care providers be required to provide information on a restriction to other health care providers but that this restriction should also be communicated to business associates of a covered entity in order to allow such business associate to comply with the restriction when communicating with other covered entities and third parties.

HHS: At this time, we would consider the lack of a restriction with respect to the follow-up treatment to extend to any protected health information necessary to effect payment for such treatment, even if such information pertained to prior treatment that was subject to a restriction. We encourage covered entities to have an open dialogue with individuals to ensure that they are aware that protected health information may be disclosed to the health plan unless they request an additional restriction and pay out of pocket for the follow-up care. We request public comment on this issue.

Surescripts Response: We support HHS' suggestion that covered entities should have an open dialogue with individuals requesting restrictions on uses and disclosures of their protected health information and potential problems associated with so doing. For example, when an individual requests restrictions on the uses and disclosures of their protected health information, if the individual's original or subsequent provider requests medication history on the individual, this information could either be absent from the history or could be disclosed, depending on the reach of the individual's restriction.

5. Access of Individuals to Protected Health Information

a. General Comments

Surescripts Comments: We request that HHS provide clarification to the NPRM that a business associate must provide requested information to the covered entity in the form and format

requested by the individual, if possible, but not to the individual directly. It is unclear whether HHS proposes to extend the requirement that covered entities provide access to an individual's protected health information to their business associates. We agree that business associates should provide such information to the covered entity in the appropriate form and format, if readily producible in that format, or if not, in a different electronic format that has been agreed to by the covered entity and the requesting individual.

If HHS intended to require business associates to provide protected health information to individuals, we urge HHS to reconsider this position for several reasons. First, this requirement appears to be an expansion of the HITECH requirement. Second, requiring business associates to provide access to protected health information would be contradictory to Congressional intent of strengthening privacy protections since, by doing so, the number of access points for protected health information would be substantially increased and could present significant security risks. The increase in access points would likely not have additional, corresponding benefit to individuals since access would continue to be provided via covered entities. Third, the purpose of allowing individuals access to their protected health information is not advanced or improved. The purpose in providing access to an individual's protected health information is to allow the individual to request corrections of his or her information. Even if a business associate provided access, the individual would still need to contact the covered entity to amend or otherwise correct the accessed protected health information. Fourth, the administrative burden on business associates would be significant (*e.g.*, additional personnel to process such requests and liability to authenticate the requestor) and many business associates may not have the resources to handle such requests (either from a volume perspective or a security perspective (*i.e.*, authentication of the individual and/or the individual's designee).

As a technical note, we suggest modifying the regulations at 45 CFR § 164.502(a)(2)(ii) should include a reference to the individual's designee as well as the individual.

b. Costs Associated with Searching for and Retrieving Requested PHI

HHS: In response to section 13405(e)(2) of the HITECH Act, we propose to amend § 164.524(c)(4)(i) to identify separately the labor for copying Protected Health Information, whether in paper or electronic form, as one factor that may be included in a reasonable cost-based fee. While we do not propose more detailed considerations for this factor within the regulatory text, we retain all prior interpretations of labor with respect to paper copies—that is, that the labor cost of copying may not include the costs associated with searching for and retrieving the requested information. With respect to electronic copies, we believe that a reasonable cost based fee includes costs attributable to the labor involved to review the access request and to produce the electronic copy, which we expect would be negligible. However, we would not consider a reasonable cost-based fee to include a standard ''retrieval fee'' that does not reflect the actual labor costs associated with the retrieval of the electronic information or that reflects charges that are unrelated to the individual's request (e.g., the additional labor resulting from technical problems or a workforce member's lack of adequate training). We invite public comment on this aspect of our rulemaking, specifically with respect to what types of

activities related to managing electronic access requests should be compensable aspects of labor.

Surescripts Response: We urge HHS to reconsider the costs associated with fulfilling requests for access to protected health information in the electronic world. Many of the costs associated with providing such access occur as sunk costs in the form of obtaining and maintaining necessary software to conduct the search (*e.g.,* patient locator systems) and to ensure the security in the storage and transmission of such information. Additionally, costs for secure connectivity should also be considered.

Conclusion

We thank you for the opportunity to comment on the above-noted commendations and concerns. If you have any questions, please feel free to contact either of us at: 703.921.2179 or Paul.Uhrig@Surescripts.com; or 703.921.2119 or Kelly.Broder@Surescripts.com.

Sincerely,

/s/ Paul Uhrig

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

/s/ Kelly Broder

Kelly L. Broder
Associate Counsel