September 30, 2009

Submitted electronically via email to:
OIRA_submission@omb.eop.gov

Carolyn M. Clancy, M.D., Director
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

Attention: AHRQ Desk Officer

RE: Proposed Project—Health IT Community Tracking Study 2009
Federal Register Vol. 74, No. 168, Pp. 45211-45214

Dear Dr. Clancy:

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.

Surescripts' role as the largest e-prescribing network in the U.S. places us in a unique position to provide AHRQ with feedback on the research methods and survey instruments

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that will be used by its contractor, the Center for Studying Health System Change (HSC), as it conducts this study over the next two years. We appreciate the opportunity to make these comments, and we hope that they will be used by AHRQ and HSC to enhance the study's procedures going forward.

General Comment

It is clearly stated in the supporting statements for this proposed study that it will be a qualitative research study of a small number of e-prescribing stakeholders that have been purposively chosen for participation, and "therefore study findings cannot be statistically generalized to the respondent universe." We appreciate the fact that AHRQ has acknowledged this limitation of this study technique throughout the aforementioned Federal Register notice as well as in Supporting Statements Parts A and B for the proposed study, and we agree that, just as is true with focus groups, "the lessons learned may be used in a variety of ways," many of which will be useful to the HIT industry. However, we are concerned that when the results of this proposed study are eventually published and disseminated one to two years from now, there will be insufficient recognition and acknowledgement of the limitations of the study, and thus there will be considerable misunderstanding within the HIT industry with respect to the limitations and applicability of the results. This is clearly what happened when the results of a previous HSC study of e-prescribing were made public (see Grossman, Joy M., et al., "Physicians' Experiences Using Commercial E-prescribing Systems," *Health Affairs*, Web exclusive, April 3, 2007 as well as the associated news release, which is attached.) We strongly encourage AHRQ and HSC to ensure that the qualitative nature of this study is emphasized both in any research reports that might issue from the study as well as any and all publicity documents and public interviews of researchers that might follow.

Comments With Respect To Interview Protocols

We have reviewed all of the interview protocols associated with the proposed study, and we found numerous questions that it is our strong opinion should be deleted from said protocols prior to initiation of the proposed study. As you will see, the general reasons that we recommend deletion of survey questions are: (1) the stakeholders being interviewed have no direct experience that would allow them to reliably answer the question and (2) the functionalities being asked about in the question have not yet been implemented by the HIT industry in the U.S., which makes the question confusing and/or misleading to the stakeholder and of questionable value to the study. The specific

questions to which we refer are listed below, as well as our specific reasons for recommending that they be deleted:

Interview Protocol 1—Physician Practice IT Administrator or Office Manager

Q.AEX.C.A.01.e. *If yes:* What vendor provides the medication history data and what is the source (e.g. adjudicated claims data, pharmacy dispensed prescriptions)? *(Surescripts Reason for Deletion: These specifics are not likely known or response by interviewee unreliable.)*

Q.AEX.C.A.01.f. *If yes:* How often is the information that the physicians see updated? *(Surescripts Reason for Deletion: Linked to invalid question above—these specifics are not likely known or response by interviewee unreliable.)*

Q.AEX.C.B.01.e. *If yes:* For what proportion of patients is this information available, approximately? Are there any groups of patients for which data are not available (e.g. Medicare, Medicaid, etc)? *(Surescripts Reason for Deletion: Not likely known or response by interviewee unreliable.)*

Q.AEX.C.B.01.f. *If yes:* What vendor provides the formulary data and what is the source? *(Surescripts Reason for Deletion: Not likely known or response by interviewee unreliable.)*

Q.AEX.C.B.01.g. *If yes:* How often is the information that the physicians see updated? *(Surescripts Reason for Deletion: Not likely known or response by interviewee unreliable.)*

Q.AEX.C.C.01.b. What vendor provides the e-prescribing system's medication database? *(Surescripts Reason for Deletion: Not likely known or response by interviewee unreliable.)*

Q.AEX.C.F.02.a. Does the practice typically receive any (other) electronic communications from pharmacies that accept electronic prescriptions (e.g. delivery confirmation, notification of whether the patient picked up the prescription, change requests)? *(Surescripts Reason for Deletion: Invalid question—the functionalities mentioned have not been implemented within the industry at this time.)*

Q.AEX.C.F.02.b. Does the practice typically use the e-prescribing system to respond to these notifications electronically via electronic data interchange (e.g. sending electronic renewal authorizations, denials, cancellations, changes)? *(Surescripts Reason for Deletion: Invalid question—some functionalities mentioned have not been implented by the industry at this time (cancellations and changes).*

Interview Protocol 2—Physician Practice Medical Director or Physician User

Q.AEX.C.A.01. Do physicians have access via the e-prescribing system to information on patient medication history from a third-party vendor, such as Surescripts, at the time they are writing a prescription? *(Surescripts Reason for Deletion: These specifics are not likely known or response by interviewee unreliable.)*

Q.AEX.C.A.01.e. *If yes:* What vendor provides the medication history data and what is the source (e.g. adjudicated claims data, pharmacy dispensed prescriptions)? *(Surescripts Reason for Deletion: Linked to invalid question above—these specifics are not likely known or response by interviewee unreliable.)*

Q.AEX.C.B.01.f. *If yes:* What vendor provides the formulary data and what is the source? *(Surescripts Reason for Deletion: Not likely known or response by interviewee unreliable.)*

Q.AEX.C.C.01.b. What vendor provides the e-prescribing system's medication database? *(Surescripts Reason for Deletion: Not likely known or response by interviewee unreliable.)*

Q.AEX.C.C.01.c. How often is the information that the physicians see updated? *(Surescripts Reason for Deletion: Not likely known or response by interviewee unreliable.)*

Q.AEX.C.F.02.a. Does the practice typically receive any (other) electronic communications from pharmacies that accept electronic prescriptions (e.g. delivery confirmation, notification of whether the patient picked up the prescription, change requests)? *(Surescripts Reason for Deletion: Invalid question—the functionalities mentioned have not been implemented within the industry at this time.)*

Q.AEX.C.F.02.b. Does the practice typically use the e-prescribing system to respond to these notifications electronically via electronic data interchange (e.g. sending electronic renewal authorizations, denials, cancellations, changes)? *(Surescripts Reason for Deletion: Invalid question—some functionalities mentioned have not been implemented by the industry at this time (cancellations and changes).*

Interview Protocol 3—Pharmacy Pharmacist-In-Charge

Q.AEX.H.04. Do you typically send other types of electronic messages besides renewal authorization requests to practices with e-prescribing (e.g. delivery confirmation, change requests)? *(Surescripts Reason for Deletion: Invalid question—the functionalities mentioned have not been implemented within the industry at this time.)*

Q.AEX.H.04.a. *If yes:* How does pharmacy staff use this feature? *(Surescripts Reason for Deletion: Linked to invalid question above.)*

Q.AEX.H.04.b. *If yes:* How frequently is this feature used? *(Surescripts Reason for Deletion: Linked to invalid question above.)*

Q.AEX.H.05. If a prescription is written for a brand-name medication when therapeutically-equivalent generic medications are available and "Dispense As Written" is not indicated, does the pharmacy typically make a generic substitution or consult the prescribing physician about the possibility of a substitution? *(Surescripts Reason for Deletion: This is a general pharmacy regulatory issue not specifically linked to e-prescribing. Thus, it is not relevant in the context of this study.)*

Q.AEX.I.01.a. Which local, regional and national retail pharmacy chains have the largest share of the pharmacy market in [site]? Do any of those stand out as having particularly high or low rates of e-prescribing? *(Surescripts Reason for Deletion: Not likely known or response by interviewee unreliable. There is no reason that an individual pharmacist would know the e-prescribing rates in other local pharmacies. Any answer supplied would be completely speculative.)*

Q.AEX.I.01.c. What are the reasons some pharmacies are not accepting prescriptions electronically via electronic data interchange? *(Surescripts Reason for Deletion: Not likely known or response by interviewee unreliable. It is not appropriate to ask one pharmacist to suggest why other pharmacies are not accepting e-prescriptions. A*

pharmacist can only give a reliable answer as to why his or her pharmacy does or does not accept e-prescriptions.)

Interview Protocol 4—State Pharmacy Association Representative

Surescripts has great respect for the valuable work done by the various state pharmacy associations, and we have good working relationships with the vast majority of these associations. This said, by virtue of our familiarity with the state pharmacy associations, we know that it is exceedingly unlikely that representatives of these associations will have direct knowledge of, or experience with, either pharmacy or physician e-prescribing applications. However, many of the questions in this attachment presume that state pharmacy personnel participating in this study have such direct and intimate knowledge and experience. This calls into question the validity and reliability of including state pharmacy association representatives as participants in this study.

Rather than direct knowledge of e-prescribing, it is far more likely that state pharmacy association representatives would have indirect information with respect to e-prescribing. Unfortunately, unless the state pharmacy associations involved in this pilot were allowed to survey their members about e-prescribing extensively prior to their participation in this study, any indirect information with respect to e-prescribing applications that they might have would be highly anecdotal in nature, and thus also be of questionable value to a study such as this.

Further, with regard to either direct or indirect information that state pharmacy association representatives might have with respect to e-prescribing, at most it might be in reference to two or three pharmacy and/or physician applications from a universe of approximately 40 of the former and well over 100 of the latter. This being the case, the information that might be collected from the state pharmacy association representatives could in no way be considered to be representative or even reasonable examples of e-prescribing applications. This further compounds the questionable value of including this information in a study such as this.

In summary, the validity of results obtained from many questions asked of state pharmacy association representatives in this study requires that at least one of the following two conditions are met: (1) state pharmacy association representatives that are interviewed have direct knowledge of e-prescribing gained through extensive, hands-on

experience using e-prescribing applications, or (2) state pharmacy association representatives that are interviewed have extensive knowledge of e-prescribing that has been gained through a systematic collection and analysis of data from a representative sample of their member pharmacists who are users of e-prescribing. If neither of these conditions is met, the results must be considered anecdotal, as the opinions expressed are likely influenced by personal bias and/or the opinions of a small number of vocal constituents. *In light of these concerns, Surescripts recommends that a significant number of the survey questions on Protocol 4—State Pharmacy Association Representative be deleted. These questions are:*

Q.AEX.I.01. Approximately what proportion of the retail pharmacies in [site] have pharmacy management systems that support the electronic receipt of prescriptions from physician practices' e-prescribing systems via electronic data interchange (e.g. via the Surescripts exchange) rather than by computer-generated faxing?

Q.AEX.I.01.a. Which local, regional and national retail pharmacy chains have the largest share of the pharmacy market in [site]? Do any of those stand out as having particularly high or low rates of e-prescribing?

Q.AEX.I.01.b. Which mail order pharmacies operate in this site? Do these pharmacies' pharmacy management systems support the electronic receipt of prescriptions from physician practices' e-prescribing systems via electronic data interchange (EDI) rather than by computer-generated fax?

Q.AEX.I.01.c. What are the reasons some pharmacies are not accepting prescriptions electronically via electronic data interchange?

Q.AEX.I.01.e. What fees, if any, do pharmacies pay for enabling and using e-prescribing features?

Q.AEX.I.02. To what extent are physicians in this market adopting and using e-prescribing systems to write prescriptions? To what extent are these practices sending prescriptions electronically via electronic data interchange?

Q.AEX.H.01. Could you briefly walk us through how pharmacy staff would receive new prescriptions generated from physician e-prescribing systems, enter them into the work queue and fill them? Please indicate the ways in which computer generated

prescriptions are handled differently from non-computer generated prescriptions.

Q.AEX.H.01.a. How does the process for handling prescriptions generated from physician e-prescribing systems vary for renewals?

Q.AEX.H.01.b. How does staff, including temporary workers and floaters, learn how to receive and process electronic prescriptions?

Q.AEX.H.03.b. Approximately what proportion of all renewal requests to physician practices with e-prescribing are sent electronically via electronic data interchange? Approximately what proportion of responses to those electronic renewal requests is sent back electronically via electronic data interchange from those physician practices to the pharmacy?

Q.AEX.C.F.03.a. How do reasons for communications about computer generated prescriptions differ from non-computer generated prescriptions?

Q.AEX.C.F.03.b. When a prescription that has been sent electronically via electronic data interchange is not received at the pharmacy, what, if any, procedure is used to identify and resolve the transmission problem? [Probe on whether the pharmacy communicates with the e-prescribing system vendor and with the electronic e-prescription routing service provider such as Surescripts (e.g. via the Surescripts website link they provide to report problems).]

Q.AEX.D.02. What have been the perceived effects of using electronic prescribing on pharmacy operations and patient care? Probe if necessary on:

Q.AEX.D.02.a. Overall pharmacy efficiency?

Q.AEX.D.02.b. Pharmacist and technician efficiency?

Q.AEX.D.02.c. Volume and type of phone communications with physician practices about new prescriptions and renewals?

Q.AEX.D.02.d. Physician prescribing behavior including prescribing of generics and medications on formulary?

Q.AEX.D.02.e. Prescribing safety and quality?

Q.AEX.D.02.f. Patient satisfaction and medication use?

Again, we recommend the deletion of all nineteen of the questions highlighted in blue above, and in addition, as was true with previously mentioned protocols, we also share the following comment on with regard to:

Q.AEX.H.04. Do pharmacies typically send other types of electronic messages besides renewal authorization requests to practices with e-prescribing (e.g. delivery confirmation, change requests)? *(Surescripts Reason for Deletion: Invalid question—the functionalities mentioned have not been implemented within the industry at this time.)*

Interview Protocol 5—Pharmacy IT Vendor Representative

Q.AEX.H.04. Do pharmacies typically send other types of electronic messages besides renewal authorization requests to practices with e-prescribing (e.g. delivery confirmation, change requests)? *(Surescripts Reason for Deletion: Invalid question—the functionalities mentioned have not been implemented within the industry at this time.)*

Q.AEX.H.04.a. *If yes:* How would pharmacy staff use this feature? *(Surescripts Reason for Deletion: Linked to invalid question above.)*

Q.AEX.H.04.b. *If yes:* How frequently is this feature used? *(Surescripts Reason for Deletion: Linked to invalid question above.)*

Q.AEX.C.F.03. What are the most common reasons physicians and pharmacists communicate about prescriptions that are computer-generated, whether sent electronically via electronic data interchange or by other means? [For physicians and vendors, probe on how these reasons differ for retail and mail-order pharmacies.] *(Surescripts Reason for Deletion: Not likely known or response by interviewee unreliable—interviewee would not have direct knowledge or experience with which to answer this question.)*

Q.AEX.H.08. What, if anything, do you hear from physician practices about the benefits or challenges of e-prescribing? *(Surescripts Reason for Deletion: Not likely known or response by interviewee unreliable—interviewee would not have direct knowledge or experience with which to answer this question.)*

Interview Protocol 6—E-prescribing System Vendor Representative

Q.AEX.C.F.01.e. What are the most common reasons for using methods to send prescriptions other than electronic transmission? *(Surescripts Reason for Deletion: Not likely known or response by interviewee unreliable—interviewee would not have direct knowledge or experience with which to answer this question.)*

Q.AEX.C.F.02.a. Does the practice have the ability to receive any (other) electronic communications from pharmacies that accept electronic prescriptions (e.g. delivery confirmation, notification of whether the patient picked up the prescription, change requests)? *(Surescripts Reason for Deletion: Invalid question—the functionalities mentioned have not been implemented within the industry at this time.)*

Q.AEX.C.F.02.b. Does the practice have the ability to use the e-prescribing system to respond to these notifications electronically via electronic data interchange (e.g. sending electronic renewal authorizations, denials, cancellations, changes)? *(Surescripts Reason for Deletion: Invalid question—some functionalities mentioned have not been implemented by the industry at this time (cancellations and changes).*

Q.AEX.C.F.03. What are the most common reasons physicians and pharmacists communicate about prescriptions that are computer-generated, whether sent electronically via electronic data interchange or by other means? [For physicians and vendors, probe on how these reasons differ for retail and mail-order pharmacies.] *(Surescripts Reason for Deletion: Not likely known or response by interviewee unreliable—interviewee would not have direct knowledge or experience with which to answer this question.)*

Q.AEX.C.F.03.a. How do reasons for communications about computer generated prescriptions differ from non-computer generated prescriptions? *(Surescripts Reason for Deletion: Not likely known or response by interviewee unreliable—interviewee would not have direct knowledge or experience with which to answer this question.)*

Interview Protocol 7—E-prescribing Connectivity and Content Vendor Representatives

The types of companies that this attachment might refer to are so divergent that it is difficult to evaluate this particular attachment. We would, however, have the same

concerns about questions that appear on other attachments that are coded and worded the same on this attachment.

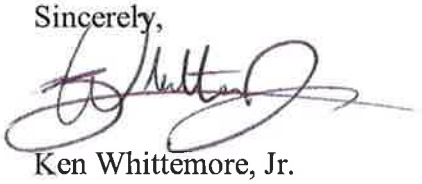
Interview Protocol 8—Other E-prescribing Experts

We have no comments to offer with respect to this protocol.

Conclusion

In summary, we appreciate the opportunity to share our perspective with respect to this proposed study and to offer to AHRQ and HSC our thoughts regarding how it should be conducted so as to maximize its credibility and utility to policymakers, prescribers, pharmacists, the HIT industry and other interested stakeholders. Should you have any questions about the recommendations that we have made, please feel free to contact me at Ken.Whittemore@Surescripts.com or 703-921-2114.

Sincerely,



Ken Whittemore, Jr.
Senior VP, Clinical Practice Integration

Attachment