March 15, 2010

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

Ms. Charlene Frizerra  
Acting Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-0033-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

RE: CMS-0033-P

Dear Ms. Frizerra:

Surescripts, LLC (Surescripts) thanks you for the opportunity to provide comments on the Notice of Proposed Rule Making (NPRM) titled, “Medicare and Medicaid Programs; Electronic Health Record (EHR) Incentive Program,” published by the Centers for Medicare & Medicaid Services (CMS) in the Federal Register on January 13, 2010 [CMS-003-P]. Surescripts applauds this incredible undertaking by CMS and believes your work will contribute to great growth and future innovation to improve the quality of patient care in the future, as is contemplated by the American Recovery and Reinvestment Act.

I. DESCRIPTION OF SURESHEETS

As a matter of background, 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, the Nation’s E-Prescription Network™, enables physicians and other health care providers to securely access vital health information when caring for their patients through a fast and efficient health information exchange. This health information exchange, the Surescripts
network, allows health care providers to transmit electronic prescriptions and renewal requests to both retail and mail order pharmacies. In conjunction with the transmittal of such messages, Surescripts enables health care providers to access prescription-related information, including available eligibility, prescription history, and formulary coverage information. 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.

The Surescripts network’s success is grounded in its core principles, as follows:

- **Efficiency and Better Healthcare.** Surescripts’ Prescription Benefit, History, and Routing services allow pharmacies, prescribers, and payers to exchange prescription information. The result is lower costs, improved safety, and higher quality decision making.

- **Transparency and Neutrality.** The Surescripts network is designed to support patient choice of pharmacy and prescriber choice of drug therapy. In other words, no commercial messaging is allowed on the network. Plus, our choice to focus on the certification of e-prescribing software — and not its development or sale — helps ensure a wide choice of solutions for pharmacists and prescribers.

- **Certification and Interoperability.** Surescripts implements and consistently applies objective and defensible standards for certification and implementation of technology systems that promote an open, neutral network and interoperability.

- **Quality.** Surescripts seeks to improve the end-to-end quality of the entire e-prescribing process by working with customers and other stakeholders to avert potential issues in order to promote patient safety and e-prescribing effectiveness.

- **Education and a Collaborative Environment.** Surescripts works throughout the healthcare community to develop educational programs, quality initiatives, and certification standards, and to promote dialogue, to support the future growth of e-prescribing and health information technology.

Surescripts has played a leadership role across the industry in operating the e-prescribing infrastructure, serving as an expert resource to assist with national and state programs and initiatives, disseminating e-prescribing best practices, and providing education, programs, and resources to improve the safety and efficiency of e-prescribing (for example, the Electronic Prescribing Resource Center, Get Connected Program, Large Clinic Program, physician vendor account management, PBM account management, pharmacy account management, quality, technology workshops, and standards).

Surescripts enthusiastically applauds and supports the ongoing efforts being undertaken by CMS and the Office of the National Coordinator for Health Information Technology through this incentive program. The progress to be gained through this focus on achieving meaningful use of certified EHR technology and innovation will ultimately result in better quality of care and healthcare efficiency. We believe that the incentive program offers a unique opportunity to achieve these goals.
II. COMMENTS REGARDING STAGE 1 CRITERIA OVERALL

From a holistic perspective, Surescripts is concerned that the overall burden associated with achieving all the Stage 1 criteria in full, as currently proposed, may have an unintended and adverse reaction in the provider community, especially those providers in small practice office settings. Balancing driving adoption and innovation with attainability presents an extremely difficult challenge, and while we certainly believe that the NPRM attempts to reach that balance, we are concerned that even as proposed many providers may find the burden to be too much. Such challenges relate, in part, to workflow and change management experienced by eligible professionals (EPs) and eligible hospitals. The considerable amount of work involved with attaining meaningful use with respect to the Stage 1 criteria in this short time frame may be too aggressive and off-putting to the providers we are seeking to encourage. This concern can clearly be viewed in the environment of the small office practice setting. The majority of Americans receive care from small-office physicians today. Based on their limited resources and exemplified by current rates of adoption and utilization, Surescripts is particularly concerned that meeting all of the Stage 1 criteria objectives in the proposed limited time frame may be overwhelming.

EPs and eligible hospitals could ultimately determine that the costs (financial and time considerations) outweigh their benefits from seeking incentives during Stage 1. Adopting a more flexible approach could simultaneously shift the cost-benefit analysis and generate significant strides towards the full achievement of the Stage 1 objectives and goals of meaningful use as currently proposed while simultaneously rewarding and encouraging meaningful gains made by providers. We hope that CMS will consider adopting a more flexible approach that could be achieved through either a materiality standard for all or some of the proposed objectives and/or a phasing approach within the payment year structure.

III. COMMENTS REGARDING SPECIFIC STAGE 1 CRITERIA

Surescripts supports the Stage 1 objectives with respect to e-prescribing and believes that the use of the following objectives in conjunction allows prescribers to realize the maximum benefit of e-prescribing: implementation of drug-drug, drug-allergy, and drug-formulary checks; generation and transmission of permissible prescriptions electronically; maintenance of an active medication list; and the performance of medication reconciliation at relevant encounters and each transition of care; capability to exchange key clinical information among providers of care and patient authorized entities electronically; and protecting electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.

We generally agree with CMS that measures can and should be aggressive for these objectives but request specific modifications and clarifications and, as such, we have provided the following comments for your consideration.
A. Objective for EPs: Generate and Transmit Permissible Prescriptions Electronically

Surescripts strongly supports the Stage 1 objective of generating and transmitting permissible prescriptions electronically (i.e., true electronic data interchange or EDI). Routing of prescriptions electronically by means of true EDI via the Surescripts network grew from 68 million in 2008 to 191 million in 2009, an approximate 181% increase.\(^1\) The number of prescribers routing prescriptions electronically grew by approximately 156% in the last year, which represents approximately 25% of all office based prescribers.\(^2\)

We encourage CMS’ efforts and continue our strong support of this objective, believing that NCPDP SCRIPT compliant messages are a critical component to improving patient safety and efficiency.

Although many prescribers active on the Surescripts network could achieve the 75% threshold and a certain population today are meeting this threshold, we still believe that the proposed measure that EPs must send at least 75% of all permissible prescriptions electronically is too high of a measure and unattainable for the vast majority of EPs in their first payment year (if occurring before 2013) during Stage 1, especially for those EPs who are not currently e-prescribing but are beginning to do so. Currently, about 12% of permissible prescriptions are currently sent electronically.\(^3\) This is a significant increase from approximately 4% of permissible prescriptions being sent electronically in 2008.\(^4\) Surescripts estimates that, of the prescribers currently active on the Surescripts network, approximately 2/3 of such prescribers are sending permissible prescriptions electronically less than 50% of the time. These figures indicate that 75%, while attainable in the future, is too aggressive by 2011 or 2012 for a significant majority of EPs who are active e-prescribers, notwithstanding those EPs which will need to begin e-prescribing. However, as the technology improves and EPs become educated on the use of e-prescribing, we believe that EPs would be able to achieve this measure.

We urge CMS to reconsider the measure of a 75% threshold for e-prescribing and recommend the following:

- With respect to a first payment year occurring in 2011 or 2012, reduce the threshold measure to require that 50% of all permissible prescriptions written by the EP must be generated and transmitted electronically using certified EHR technology;

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\(^1\) This figure represents the number of new prescription messages and renewal responses.


\(^3\) By December 2009, approximately 18% of eligible prescriptions were being sent electronically via the Surescripts network.

\(^4\) This calculation is based on the 190 million new prescriptions and renewal responses electronically transmitted in 2009 and the 1.63 billion new prescriptions and renewals eligible for electronic routing in 2009 in the United States, according to NACDS. This calculation does not include DEA controlled substances or preauthorized refills on existing prescriptions, as they do not require communication between a physician and a pharmacist.
• By CY 2013, increase the threshold measure to require that 75% of all permissible prescriptions written by the EP must be generated and transmitted electronically using certified EHR technology; and
• Clarify that electronic transmission means transmission via true EDI, as required by NCPDP SCRIPT Standards; where possible.

Additionally, we request that CMS clarify that prescribers who send prescriptions electronically will not be penalized if a prescription cannot be delivered to pharmacies electronically due to factors outside of the prescriber’s direct control. More specifically, we encourage CMS to clarify that prescribers who generate and transmit prescriptions electronically via certified EHR technology will not be penalized for the following (but not by way of limitation): (i) pharmacies that are not electronically enabled; (ii) applicable law that prohibits the electronic transmission of prescriptions (including but not limited to DEA regulation of controlled substances, state regulations with respect to “dispense as written” prescriptions, etc.); (iii) patient-imposed limitations (e.g., a request that a prescription be printed and given to the patient); and (iv) communication failures impacting the ability to generate and transmit prescriptions electronically (i.e., power outages, temporary system failures, down time due to maintenance, etc.).

We urge CMS to continue promoting true EDI transmissions of prescriptions in order to improve quality of patient care, reduce errors, and improve workflow between prescribers and dispensers. Many prescriber applications work in the same manner, from the prescriber’s perspective, regardless of whether the prescription is sent via true EDI or via computer-generated facsimile. Additionally, it is our understanding that an upgrade to enable true EDI transmissions is already included in the cost of the EHR technology. CMS should clarify that prescribers must either activate the true e-prescribing feature or upgrade the certified EHR technology in order to satisfy this Stage 1 objective of sending prescriptions electronically via true EDI, where possible.

B. Objective for EPs and Eligible Hospitals: Implement Drug-Drug, Drug-Allergy, Drug-Formulary Checks

In addition to the routing of prescriptions electronically, Surescripts works directly with payers and PBMs to provide EPs participating in the Surescripts network patients’ formulary information at the point of prescribing. The provision of formulary information is required under the Medicare Improvement for Patients and Providers Act of 2008 (MIPAA) for an e-prescribing system to be qualified for incentives thereunder. Electronic requests for prescription benefit information – which includes both formulary and eligibility information – grew from 79 million in 2008 to 303 million in 2009. This represents a rise from approximately 8% of patient visits that involved one of the requests in 2008 to 30% in 2009.5

Because we believe that e-prescribing is more effective and efficient when providers have formulary information available, we urge CMS to consider aligning the requirement for drug-formulary checks in conjunction with the e-prescribing objective. In other words, we recommend that drug-formulary checks should be part of the same meaningful use criterion as

5 The average response rate to requests for prescription benefit information was approximately 62% in 2009.
electronic transmission of prescriptions. We recommend this because drug-drug and drug-allergy checks support the clinical decision-making process. In contrast, drug-formulary checks are administrative in nature as a function of prescription benefit plans. Further, drug-formulary checks are more appropriately aligned with e-prescribing because of the nature of the transaction itself. A drug-formulary check, similar to e-prescribing, relies on external communications (i.e., formulary data must be downloaded prior to every clinical encounter) whereas most clinical decision support checks, such as drug-drug and drug-allergy, primarily rely on processes and data which are internal to certified EHR technology.

In order to provide relevant information to prescribers at the point of care, we also urge CMS to clarify that such drug-formulary checks should be plan specific. For example, a PBM may create a generic national formulary for that PBM but will also create formularies for particular health plans which the PBM services (as well as formularies specific to particular patients or groups of patients receiving benefits under a particular health plan). Surescripts strongly believes that requiring drug-formulary checks to provide plan and patient-specific formulary information, where available, provides a significantly more relevant exchange of information than simply providing generic information which is of little practical use to the prescriber and/or the prescriber’s patient.

C. Objective for EPs and Eligible Hospitals: Incorporate Clinical Lab-Test Results into EHR as Structured Data

Surescripts supports the Stage 1 objective and measure with respect to incorporating lab test results as structured data into an EHR 50% of the time for all lab tests ordered whose results are capable of being reported in a positive/negative or numerical format. We believe the input of lab test results will result in improved quality, safety, and efficiency in patient care and support a meaningful exchange of information sought in further stages of meaningful use and beyond. To that end, Surescripts has recently announced a collaboration with Quest Diagnostics to pioneer the formation of an integrated service to make laboratory information broadly and easily accessible to physicians and other appropriate healthcare providers, along with prescription and prescription-related information that we currently provide. We believe that this streamlined process will assist providers to have access to efficient, low-cost communications to further improve patient safety and positive health outcomes.
We thank CMS 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
General Counsel; EVP, Legal & Finance; Chief Privacy Officer

/s/ Kelly Broder

Kelly L. Broder
Associate Counsel