May 7, 2012

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

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Regarding: Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 2 Notice of Proposed Rulemaking (CMS-0044-P)

Dear Ms. Tavenner:

Surescripts, LLC ("Surescripts") thanks you for the opportunity to provide comments on the notice of proposed rulemaking that the Department of Health and Human Services, Centers for Medicare & Medicaid Services ("CMS") published in the Federal Register, Volume 77, Number 45, beginning on page 13698 on March 7, 2012 (the "Proposed Rule").

Description of Surescripts

The Surescripts network supports the most comprehensive ecosystem of health care organizations nationwide. Pharmacies, payers, pharmacy benefit managers ("PBMs"), physicians, hospitals, health information exchanges, and health technology firms rely on Surescripts to more easily and securely share health information. Guided by the principles of neutrality, transparency, physician and patient choice, open standards, collaboration and privacy, Surescripts operates the nation's largest health information network. By providing information for routine, recurring and emergency care, Surescripts is committed to saving lives, improving efficiency, and reducing the cost of health care for all. For more information, go to www.surescripts.com and follow us at twitter.com/surescripts.

As of the end of 2011, the Surescripts e-prescribing network connects approximately 390,000 prescribers, 57,000 community pharmacies, six of the largest mail order pharmacies, and over 25

of the nation's largest PBMs for the purpose of exchanging prescription-related information in the ambulatory setting. Today, Surescripts provides access to prescription benefit and history information for more than 66 percent of patients in the United States on behalf of payers and pharmacies. Approximately 91 percent of community pharmacies in the United States are connected for prescription routing. More than 300 technology vendors' systems have been certified to connect to and access the Surescripts network.

Far more than technology is required in order to have a safe, efficient, and successful network. Other services and programs are essential components of the overall e-prescribing ecosystem such as certification, audit and compliance measures, quality improvement efforts, and e-prescribing network technology assets and capabilities such as provider directories, pharmacy directories, and patient locator services.

In 2010, Surescripts announced the expansion its nationwide e-prescribing network to support and enable the electronic exchange of all types of clinical information, including referrals and up-to-date summaries of patients' recent visits with their health care providers. The Surescripts Network for Clinical Interoperability allows healthcare providers to securely send and receive clinical information with peers locally, regionally, nationally, as well as between electronic health records ("EHRs") and across health systems and networks. The Surescripts Network for Clinical Interoperability improves clinical workflows, increases collaboration, improves quality, and lowers costs by allowing all providers involved in a patient's clinical care to make more informed decisions.

Surescripts, in conjunction with the American Hospital Association and the College of American Pathologists, has recruited hospitals to participate in a laboratory interoperability cooperative funded by a grant from the Centers for Disease Control and Prevention (the "Lab Interoperability Cooperative" or "LIC") to connect hospitals laboratories with public health agencies. Establishing this connection will enable hundreds of hospitals to engage in electronic reporting that helps public health officials act more rapidly and efficiently to control disease. During the two-year grant period, the LIC will recruit, educate, and connect to the appropriate public health agencies a minimum of 500 hospital labs - at least 100 will be critical access or rural hospitals.

General Comments

Surescripts applauds the efforts being undertaken by CMS and the Office of the National Coordinator for Health Information Technology ("ONC") to continue progress towards meeting the goals established under HITECH for advancements in health information technology.

We commend CMS on its efforts to provide a workable framework by focusing on outcomes and increased interoperability and exchange.

As a general matter, Surescripts strongly recommends that CMS recognize that various forms of exchange occur today and should be utilized by providers to achieve the goals of the meaningful use program. Exchange should not be limited to push transactions in which a provider pushes information to another provider. There is value in encouraging information to be received through query and response – pull – transactions as well. Not only should both push and pull transactions be encouraged, we also encourage CMS to allow providers to use various mechanisms for exchange. When individuals communicate in the business world, they do not communicate through only one mechanism. Rather, we all use e-mail, instant messaging, portals, and web interfaces to communicate with one another. Similarly, we believe that this concept should hold true with health information technology. The goal is to improve communication in a secure manner that results in improved care and outcomes for patients. To limit communication in one form would hamper developments made to encourage an ecosystem for exchange.

However, as advances are made with respect to both the technical capabilities for certified electronic health record ("EHR") technology ("CEHRT") and the utilization of CERHT, we urge CMS to continue evaluating the privacy and security considerations.

Ideally, all types of patient specific administrative and clinical information should be sent via secure electronic messaging. Secure messaging is critical to ensuring patient privacy and safety, and to lowering costs. Surescripts advocates that ambulatory physicians should be enabled to communicate with patients via a secure portal and encourages CMS to provide clarification on the difference between secure messaging and the sharing of electronic health records. We also urge continued coordination with ONC and other regulators to encourage best practices for identity proofing and authentication.

Specific Comments to the Proposed Changes to the Stage 1 Objectives and Measures

Proposed Modifications in 2013 to the Objective to Exchange Key Clinical Information: CMS has proposed to eliminate the objective to exchange key clinical information, effective in 2013. Given that exchange is occurring today and CEHRT meets the current certification standards at 45 CFR §§ 170.304(i); 306(f), we recommend that CMS either modify the measure to require actual transmission of summary of care documents for a real patient to another provider of care or delete the objective and require EPs to meet the objective for summary of care records

transmission. Actual exchange as opposed to a test will more appropriately serve as a basis to build upon in future stages.

Having said that, and as discussed below, we strongly suggest that CMS encourage the goal of increased exchange to improve care coordination, quality of care, and patient engagement through a wide range of tools. We do not believe the industry is ready today, at the very least, to meet the ONC 2014 proposed certification criteria for transport. Not only is the industry not ready, such standards address only one type of exchange. A number of participants in the health IT industry have made significant efforts to deploy pull models of exchange (query and response messaging systems). Multiple forms of exchange should be encouraged to continue as information and processes develop. It would be premature to limit the form of exchange in Stage 1 as well as Stage 2.

Specific Comments to the Proposed Stage 2 Objectives and Measures

1. E-Prescribing and Formulary Checks

Stage 2 Proposed Measure for E-Prescribing: Surescripts supports the proposed measure that 65% of all permissible prescriptions must be sent electronically. We recently completed a new study of providers who adopted e-prescribing in 2008 and their e-prescribing data over a four-year period, from 2008 through 2011. Based on the findings, we estimate that a significant number of active e-prescribers could meet the proposed 65% threshold – approximately one third of active e-prescribers in our study were already in a position to do so, based on their e-prescribing volume as of the fourth quarter of 2011. Furthermore, our study findings suggest that provider use of e-prescribing technology consistently increases over time, indicating that many e-prescribers who may not meet the 65% threshold today may be in a position to do so in the near future.

Additionally, should there be a concern that the use of mail-order pharmacies might impede prescribers' ability to e-prescribe, it is important to note that the percentage of mail-order prescription volume electronically transmitted today would not significantly impair a provider's capability to attain the Stage 2 proposed measure for e-prescribing. Currently, it is our understanding that Surescripts' mail-order connectivity represents approximately 60% of the volume of mail-order prescriptions. However, a small percentage of prescriptions are filled today by mail order—approximately 13% on average for the industry.[1] Thus, the net impact to e-prescribers of the electronic connectivity of mail-order volume is small—approximately 5%. As

[1] Based on information presented in the National Association of Chain Drug Stores ("NACDS") Industry Profile 2010-2011.

such, this factor should play a minor role in determining whether the 65% threshold is the appropriate measure in Stage 2.

Proposed New Exclusion: The measures for meaningful use are aimed at influencing provider behavior—to encourage providers to use CEHRT in a meaningful way. CMS has authority only over eligible providers and hospitals and lacks authority to require pharmacy participation.

CMS recognized the potential disconnect between what is required of providers and what may be supported by pharmacies with respect to e-prescribing and issued guidance to address this issue. CMS FAQ ID #10138 supports providers that practice in an area where pharmacies may not be electronically enabled. We urge CMS to continue with its current approach to influence provider practices and to reward such providers for their behavior even in areas where pharmacies may not be electronically enabled. The proposed exclusion provides questionable value in light of current guidance and practice and the exclusion's limited scope as discussed below.

If CMS opts to finalize this exclusion, CMS should make two clarifications: (1) the exclusion only applies if the location(s) from which the EP meets its 50% threshold for patient encounter requirements (under the subparagraph (3) of the definition of a meaningful EHR user at 42 CFR § 495.4) is not located within 25 miles of an electronically enabled pharmacy (and there is no pharmacy within the EP's organization); and (2) the current FAQ guidance continues to apply to EPs not eligible for the exclusion.

With respect to the first clarification, CMS should not enable EPs to utilize a practice/location that the EP does not rely on to meet the definition of a meaningful EHR user. For example, if an EP has two practice locations in which the EP practices (Location A and Location B). The EP relies on Location A to meet the requirement that at least 50% of the EP's patient encounter during the EHR reporting period occur at a practice/location equipped with CERHT. EP should not be able to utilize the exclusion if Location B is not located within 25 miles of an electronically enabled pharmacy but Location A is within 25 miles of an electronically enabled pharmacy. If an EP uses both Locations A and B to meet the 50% patient encounter requirement and one location is not within 25 miles of an electronically enabled pharmacy, then the EP could rely on the exclusion.

With respect to the second clarification, even if CMS finalizes the proposed exclusion, some EPs may still have difficulty fulfilling the e-prescribing measure. For example, if an EP practices in an area whose patients primarily utilize three pharmacies and only one pharmacy is electronically enabled, then the EP would not meet the conditions for the exclusion and would still face difficulty fulfilling the e-prescribing measure (assuming that the EP's patients use all

three pharmacies equally). If the current guidance remains in effect regarding intermediary computer generated faxes to pharmacies that are not electronically enabled, then this difficulty should be resolved. As such, CMS should clarify that its guidance from this FAQ would remain in effect if the exclusion is adopted in the final rule.

Electronic Prescribing of Controlled Substances in Stage 2: Surescripts supports CMS's proposal to exclude controlled substances from the e-prescribing measure in Stage 2. Electronic prescribing of controlled substances requires that providers meet NIST identity proofing standards and that technologies implement certain capabilities that are audited by a third party (a "DEA Part 1311 Audit"). Additionally, some states do not currently permit electronic prescribing of controlled substances.

Having said that, we urge both ONC and CMS to work to incorporate controlled substances into meaningful use measures in the future in order to enhance quality control, reduce abuse and diversion (in part by limiting the reproduction or forging of paper prescriptions), and improve reporting processes to the federal government and local drug monitoring programs. Providers and vendors are actively working to implement policies and procedures to enable them to begin prescribing controlled substances. The majority of states now permit electronic prescribing of controlled substances as well.[2]

CMS: However, as Stage 2 of meaningful use would not go into effect until 2014, it is possible that significant progress in the availability of products enabling the electronic prescribing of controlled substances may occur. We encourage comments addressing the current and expected availability of these products and whether the availability would be sufficient to include controlled substances in the Stage 2 measure for e-Rx or to warrant an additional measure for EPs to choose that would include controlled substance electronic prescriptions in the denominator.

Surescripts Response: In September 2011, Surescripts began the initial deployment of electronic prescribing for controlled substances (EPCS) in states where EPCS is legal.[3] In such states, there are approximately 4,000 pharmacy locations currently enabled for EPCS. While pharmacies have implemented appropriate technologies and safeguards per DEA guidance, prescriber vendors are slow to upgrade their software products to support EPCS. Prescriber vendors have been slow to update in part due to competing priorities (*e.g.*, ICD-10 or the certification criteria

[2] As of last month, 30 states permitted electronic prescribing for controlled substances for all schedules and 8 states permitted electronic prescribing for controlled substances for Schedules III through V.

[3] Additional information on Surescripts' network initial deployment of EPCS can be found at http://www.surescripts.com/news-and-events/press-releases/2011/september/sept12-epcs.aspx.

for CEHRT) and resources (EPCS certification can be costly). Incorporating EPCS into the 2014 Certification Criteria would be a great first step towards encouraging EPCS implementation by prescriber vendors.

Inclusion of Formulary Checks as Part of the E-Prescribing Workflow in Stage 2: Surescripts applauds CMS's proposal to include formulary checks as a component of the e-prescribing objective for Stage 2. This change reflects current practices today. As CMS recognized, electronic formulary checks allows providers to increase efficiency of care and reduce costs for patients.

We strongly urge CMS to encourage use of electronically available formularies that are either plan or group specific. Surescripts electronically transmits eligibility and formulary information to vendors and their end users. Formulary information is typically plan specific and, in some cases, group specific.

Patient-specific formulary information in real-time is not widely utilized at this time. However, plan level information does deliver greater utility to providers than general information including, but not limited to, providing lower-cost, therapeutically equivalent alternative medications, and coverage conditions such as prior authorization requirements, medical necessity limitations and the like.

Electronic versions of formulary information, while not perfect, delivers to providers more timely and complete information than paper formularies. Formulary information can be accessed electronically either through the Surescripts network or through other third-party service providers to vendors (such as InfoScan).

Surescripts urges CMS to finalize its recommendations to include formulary checks as part of the e-prescribing workflow and to clarify that such formulary checks should occur electronically. Based on the language in the Proposed Rule, it appears that CMS intends formulary checks to be electronic as part of the e-prescribing workflow. However, the measure itself should be revised to remove any uncertainty:

> More than 65 percent of all permissible prescriptions written by the EP are compared electronically to at least one drug formulary using Certified EHR Technology and transmitted electronically using Certified EHR Technology.

We support CMS' position that would allow providers to account for instances in which a formulary check does not return information and include such nonresponses in MU calculations.

We also urge ONC to adopt certification criteria to enable electronic formulary checking through the CERHT.

2. Medication Reconciliation

Proposed Objective for Medication Reconciliation in Stage 2: CMS defines "medication reconciliation" as the "process of identifying the most accurate list of all medications that the patient is taking, including name, dosage, frequency, and route, by comparing the medical record to an external list of medications obtained from a patient, hospital, or other provider."[4]

CMS then states that it is not requiring electronic exchange of information for medication reconciliation even though it recognizes that electronic exchange of information following the transition of care of patient is the most efficient method for performing medication reconciliation.

Medication reconciliation is a key component to providing quality care and avoiding medication errors due to omissions, duplications, dosing errors, or adverse drug interactions. Accordingly, Surescripts applauds CMS's proposal to include this objective in the core set of objectives in Stage 2.

Medication Reconciliation and Electronic Medication History: In addition to performing a comparison of a patient's medical record to an external list, Surescripts strongly recommends that CMS incorporate electronic exchange of information as a component of the medication reconciliation workflow in Stage 2 (or alternatively, require medication history messaging as a menu objective in Stage 2) in order to improve data quality.

When a patient consents to share their medication history, Surescripts enables providers to access ambulatory patient medication history (typically up to one year of medication history) based on data from pharmacies as well as patient medication claims history from payers and PBMs -- both in the ambulatory and acute care settings. Electronic medication history from Surescripts is currently accessed for approximately 1 out of every 3 office visits. Medication history is currently electronically accessible and being accessed by providers working in acute-care environments to support transitions in care. In between 2009 and 2011, the number of medication history messages delivered to providers more than quadrupled.[5]

[4] 77 Fed. Reg. at 13721.
[5] Additional information is available at http://www.surescripts.com/about-e-prescribing/progress-reports/national-progress-reports.aspx.

Not only are medication histories being delivered today, medication history can provide information to supplement patient interviews. By itself, neither a patient interview nor an electronic exchange of information is sufficient. However, when providers conduct a patient interview and request electronic medication history from Surescripts, one study found that the accuracy and completeness of the patient's medication history is significantly improved (in addition to increasing efficiency by reducing the time needed for patient interviews).[6] One study indicated that 46% of patients experience medication errors upon admission; 85% of those errors originated from the patient's medication history. [7] Improvements in medication reconciliation accuracy from electronic exchange of medication history could significant reduce the percentage of patients experiencing a medication error upon hospital admission, improving quality of care while reducing costs. As such, we urge CMS to require an electronic exchange of information from available resources to providers. Requiring such will enable providers to more completely and meaningfully reconcile the patient's medical record in order to receive clinical decision support.[8]

Furthermore, CMS should require medication reconciliation not only upon transitions of care and referrals, specifically during patient admission to and discharge from a hospital. Patient admissions and discharges are relevant encounters and should be included as mandatory. When patients receive medication as an inpatient, the medication is covered under the patient's medical coverage (and, thus, not included in claims data). As such, critical information regarding medication a patient took during the hospital say or received upon discharge could be omitted from information that the patient's primary care physician or other treating provider receives (based on claims data information). If providers conduct medication reconciliation, then the patient's subsequent providers in the ambulatory setting will receive a more accurate medication history.[9]

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[6] A study conducted by Butler Memorial Hospital and Health Monitoring Services found that medication history was 95.4% accurate when supplemented with electronic medication history as compared to a 72.7% accuracy rate when a patient was interviewed only without electronic medication history. More information on the study design can be found in the 2010 Surescripts National Progress Report.

[7] Bluml BM. Definition of medication therapy management: development of a professionwide consensus. J Am Pharm Assoc. 2005;45:566-72.

[8] An additional benefit of electronic exchange of information is that the information delivered includes accurate drug descriptions and dosages.

[9] "One in five patients discharged from hospitals suffers an adverse event, 72% of which are related to medications." Publication titled "Improving Care Transitions: Optimizing Medication Reconciliation," American Pharmacists Association and American Society of Health-System Pharmacists (March 2012), available at: http://www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=28022 (citing Forster AJ, Murff HJ, Peterson JF, et al., "*The incidence and severity of adverse events affecting patients after discharge from the hospital*," Ann. Intern. Med. 2003; 138:161-7).

Proposed Measure for Medication Reconciliation: We also encourage CMS to increase the measure for performing medication reconciliation from 65% to 100% in Stage 2 when a provider believes an encounter is relevant. CMS specifically and intentionally granted providers a great deal of flexibility for determining when an encounter is relevant. If a provider believes an encounter is relevant, then medication reconciliation should occur in all instances—not just 65% of the time.

3. Provide Summary of Care Records upon Transitions of Care and Referrals

Proposed Measure in Stage 2: Surescripts supports the proposal to require electronic transmission of summary of care records upon the transition of care of a patient or referral of a patient to another provider as a critical step in achieving interoperability to improve patient care.

Given that CEHRT is capable of electronically receiving, displaying, and transmitting summary of care records today, the 10% proposed measure for Stage 2 for this objective is the appropriate threshold.

While we support the threshold of 10% for this measure, Surescripts requests that CMS reconsider the measure limitations that the provider transmits a summary of care record using CERHT to a recipient (1) with no organizational affiliation; and (2) using a different CEHRT vendor than the sender.

First, it is unclear what constitutes an "organizational affiliation" or an "organization." Is an organization a legal entity? Is it a network? Is it an accountable care organization ("ACO")? In addition to confusion with the phrase "organizational affiliation" itself, this requirement would undermine other government initiatives to improve patient care and reduce costs—one example being ACOs (in addition to state-designated or other health information exchange initiatives).

The Shared Savings Program is intended to promote accountability, coordinate services to patients, and encourage investment in infrastructure and redesigned care for high quality and efficient service delivery, whether through an ACO consisting of providers in a group practice, hospital and professional joint venturers, or other arrangements.[10] One of the goals of ACOs is to coordinate care across and among primary care providers, specialists, and acute and post-acute providers. Similarly, many states have instituted innovative care networks to improve patient care. The proposed measure requiring provider to refer or transition patients outside of an organizational affiliation to become a meaningful user defeats the purposes of the EHR Incentive

[10] Section 3022 of the Affordable Care Act.

Program while undermining other programs advancements to achieve greater coordination in care. The unintended consequences of this limitation outweigh the intended benefit CMS seeks to achieve.

Second, requiring providers to ensure that referrals or transitions of care occur between providers using different technology vendors is also problematic as providers have little or no control over whether another provider utilizes a different vendor. Tracking such information could also be quite difficult. However, it is our belief that only approximately 30% of referrals would be between providers using the same vendor. As such, a 10% threshold would be achievable.

Transport Standards: We urge CMS to coordinate with CMS and continue to allow providers to achieve electronic transmission through any transport standard as noted in the Proposed Rule preamble. We further suggest that CMS clarify the measure at 42 CFR §§ 495.6(h)(14)(ii); (l)(11)(ii) to clarify that any of the transport standards to which CEHRT may be certified in addition to other forms of exchange. Robust exchange to improve care coordination is supported by a number of forms of exchange today and we urge CMS to encourage utilization of such—essentially, to recognize function over form.

4. Public Health Objectives—Reporting to Public Health Agencies and Registries

Surescripts supports CMS's continued requirement that public health reporting should be submitted in accordance with applicable law and practices. However, we are concerned that the proposed phrase "except where prohibited" could result in confusion and conflicting provider obligations. We recognize CMS intends this language "to encourage EPs, eligible hospitals, and CAHs to submit electronic immunization data, even when not required by State/local law." However, HIPAA authorizes covered entities (and business associates acting on behalf of a covered entity) to submit information to public health agencies without first obtaining patient consent only where required by law. To require ongoing submission where not prohibited but also not required would have the unintended impact of requiring patient consent. As such, we recommend that CMS remove this language.

Certification for Public Health Reporting: CMS should not impose certification requirements upon intermediaries providing public health reporting submission services. States require a wide range of submission requirements—ranging from the timing to the format of such submission.

Testing and certification of intermediaries to a particular standard—such as HL7 2.5.1 for laboratory reporting—has limited value here. The purpose of requiring certification is to inform providers that the product or service they are using has the necessary capabilities to support the

provider's attainment of meaningful use. Given the wide range of public health reporting requirements, testing and certification to a single standard that may not be relevant fails to accomplish the intended purpose associated with certification of EHR technology. Rather, such arrangements are best addressed through contractual obligations between providers, vendors, and any intervening health information exchange organizations.

Clarification of the Term "Ongoing Submission": Surescripts urges CMS to clarify that the term "ongoing submission" means submission in accordance with the applicable reporting timeframes mandated by the state or registry. In cases where a registry or public health agency does not specify frequency of reporting, CMS should clarify what would constitute "ongoing submission."

Conclusion

We thank CMS for the opportunity to comment on the Proposed Rule. Should you have any questions about the information we share herein or our recommendations, please feel free to contact either of us at: Paul.Uhrig@Surescripts.com or 703.921.2179 or Kelly.Broder@Surescripts.com or 703.921.2119.

Sincerely,

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