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National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building, Suite 729D
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Washington, DC 20201

Re: Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology (RIN 0991-AB82)

Dear Dr. Mostashari,

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.

This letter is in response to the notice of proposed rulemaking that the Department of Health and Human Services, Office of the National Coordinator ("ONC") published in the Federal Register, Volume 77, Number 45, beginning on page 13832 on March 7, 2012 (the "Proposed Rule").

General Comments

Surescripts congratulates ONC for its continuous efforts within the health information technology industry and for the work that ONC has put forth towards crafting the certification criteria that certified electronic health record technology ("CEHRT") would need to meet in order to support providers to achieve meaningful use under the Medicare and Medicaid

Electronic Health Record Incentive Program. The advancements that will ultimately be achieved through this focus on achieving meaningful use of CERHT will result in better and more efficient healthcare. Surescripts is pleased to offer our comments on the proposed criteria for the 2014 Edition EHR certification criteria.

1. Proposed Transport Standards Under § 170.202(a) of the 2014 Certification Criteria

a. Recognition of the Value of Networks and Third Party Service Providers to EHR Vendors in Health Information Technology

ONC recognizes and encourages EHR technology developers "to pursue innovative ways to facilitate efficient workflows and user interactions."[1] We urge ONC to recognize the value and vital role that networks and outsourced capabilities to EHR vendors play in this industry.

Networks are, and will continue to be, a vital component of continued health information exchange in the current and near immediate environment. Networks provide essential services for exchange including, but not limited to, patient data location services and provider directories, security models, translation across multiple types of messaging, and support contractual trust frameworks and governance models. Networks add value in terms of quality control and improvement efforts. All such components are necessary for continued exchange. Many exchange issues can be systematic and a network has the capability to address such issues on a systematic level. Networks enable its participants to connect to one another and to connect to other networks in a secure manner and remain a core and foundational component of health exchange. ONC should recognize and encourage other mechanisms for exchange of health information in addition to the direct transport capabilities as an equally valid mechanism to achieve the objectives established in the EHR incentive program.

In addition to the services networks provide today, networks and third party service providers to EHR vendors also promote economies of scale. Many EHR vendors do not have the resources to develop and implement all capabilities natively.[2] As such, EHR vendor utilize third party services to reduce their burden and capitalize on areas of expertise developed by others. For example, many EHR vendors utilize third parties to provide drug databases, e-prescribing connectivity, clinical decision support, smart analytics, and drug utilization review for their EHR platforms.

[1] 77 Fed. Reg. at 13867.
[2] With respect to e-prescribing vendors, a small number of vendors control the vast majority of the market.

ONC should extend this flexible approach to implementation with respect to the transport standards specified at 45 CFR §170.202(a)(the "Directed Exchange Standards"). More specifically, we request and recommend that ONC confirm that transport capabilities can be demonstrated by a Complete EHR, Base EHR, or EHR Module itself, or through demonstration by the Complete EHR, Base EHR, or EHR Module to achieve the transport capability through integration with a service provider—such as a network or HISP. The current definition of an EHR Module permits a combination of a service and a component and we request ONC to confirm that the transport standards can be provided by a network or other third party service provider and is not required to be a native capability within the EHR module or Complete EHR. A flexible approach to transport capabilities aligns with ONC's current approach to CEHRT, evidenced by the definition of an EHR Module and current certification practices.[3]

b. Revision of the Transport Standards to Require EHR Certification to Direct (S/MIME/SMTP) and Allow for Optional Transport Standards to Include Direct (XDR/XDM), NwHIN Exchange SOAP, and a RESTful Standard for Clinical Exchange

Surescripts believes that requiring the Directed Exchange Standards as currently proposed is problematic and should be revised. While we recognize that ONC may require one or more forms of transport, we urge ONC to permit various types of standards for purposes of certification. Developments are ongoing and providers and technology partners do not rely on a single mechanism for exchange. Limiting transport to a specified standard[s] to the exclusion of other forms of transport appears to undermine the goal to improve care coordination and innovation in technology to achieve improvements in quality of patient care.

Surescripts recommends that ONC require certification of CEHRT to only one transport standard-- Secure/Multipurpose Internet Mail Extensions ("S/MIME") and simple mail transport protocol ("SMTP") and make optional other transport standards. Alternatively, we urge ONC to allow vendors to implement any one (or more) of the standards but not to the exclusion of other transport standards.

ONC should permit EHR technology to be certified, on an optional basis, to other standards for exchange of clinical information between providers or upon patient request including, but not limited to, External Data Representation ("XDR") and Cross-Enterprise Document Media Interchange ("XDM") for Direct Messaging and the Simple Objective Access Protocol

[3] ONC's Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology also supports this conclusion when describing a transport standard as a communication mechanism between systems, not as native within an EHR. 75 Fed. Reg. 2014, 2029 (Jan. 13, 2010),

("SOAP")-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0, as developed under the nationwide health information network ("NwHIN") Exchange Initiative should be optional.

Further, Surescripts requests that ONC include a RESTful implementation for clinical exchange as optional in the Directed Exchange Standards for the 2014 Certification Criteria. While we recognize that an accepted standard is still under development, we urge ONC to allow vendors to utilize existing and developing implementations until such time as a standard is adopted. Surescripts has successfully implemented a RESTful approach for our e-prescribing network and others in the industry are piloting implementations of a RESTful protocol. RESTful implementations today are scalable, workable, and secure—large parts of the internet today utilize a RESTful protocol. Such an option would enable continued innovation and growth for clinical exchange instead of stifling development moving into 2014 and beyond.

Moreover, ONC should coordinate with CMS to ensure that utilization by a provider to any of the certified transport would satisfy the objectives for providers to provide summary of care records upon transitions of care or referrals and transmissions of summary of care records upon patient request under 42 CFR §§495.6(h)(14); (l)(11) and §§ 495.6(h)(10); (l)(8), respectively.

As discussed above, we advise ONC to continue acknowledging that exchange occurs in many forms. Network support of exchange has been a valuable tool and will continue to be so as the industry progresses, ranging from support of the Directed Exchange Standards to providing additional functionalities essential to continued secure and reliable exchange.

2. Identity Proofing of Provider and Patient End Users

We support the decision of ONC to refrain from incorporating identity-proofing requirements as part of the 2014 Certification Criteria. However, as the goals of patient engagement and interoperability are realized, we suggest ONC issue guidance on best practices directed at both vendors and provider audiences regarding appropriate and sufficient processes to identity proof end users—whether the end user is an intended provider recipient or patient recipient. Such guidance should specifically include best practices regarding remote identity proofing as utilization of mobile technologies increases. Surescripts has been an active participant in the Kantara Initiative and recommends identity proofing to assurance level 3 as set forth in the Kantara Initiative Identity Assurance Framework, Service Assessment Criteria.[4]

[4] *Available at* http://kantarainitiative.org/confluence/download/attachments/41649275/Kantara+IAF-1400-Service+Assessment+Criteria.pdf?version=1&modificationDate=1272504049000.

3. Privacy and Security Certification Criteria

Surescripts concurs with ONC's proposal to limit the privacy and security certification criteria to the Base EHR and to cease requiring each EHR Module to be certified independently. Requiring certification to all components creates unnecessary and duplicative testing and certification with limited benefit. As recognized by ONC, many security functions occur within a system, and not at the level of each Module within an EHR platform or system. Additionally, some of the security requirements may not be appropriate for all services within CEHRT but would be appropriate and should be applicable to the CEHRT overall. For a specific example, please see our comments below on the proposed new certification criteria for amendments.

Additionally, Surescripts recommends that remote components providing services to a Complete EHR or EHR Module, whether or not such is a component of the Base EHR, should be secured with Transport Layer Security (or TLS) and should not be required to be separately certified to the privacy and security requirements.

4. Quality Systems and Patient Safety Events

With respect to the proposals for quality systems, Surescripts supports ONC's efforts to develop a quality management document specific to EHR technology development. In our experience, certain concepts in the ISO/NIST guides may not apply to health technology and can prove difficult to interpret and implement. Customizing guidance will be a welcome advancement and Surescripts looks forward to providing feedback to the proposed quality management document when it becomes available.

Surescripts conducts quality reviews of our vendors and, in doing so, has found that the need to improve human-computer interfaces should include both a guidance component as well as a monitoring/auditing component to ensure that the improvements are actually effective. User interfaces are often used to create content, messages, or output data. The quality of such output information is directly impacted by the user interface design. Guidance should require that vendors have processes for user interface remediation if/when deficiencies in effectiveness are discovered in the desired output results.

In addition to monitoring and remediation, actual compliance is a key component of a quality system. Compliance can be achieved in a variety of ways – whether through a certification process by an external certifying body or through a public reporting process. Requiring vendor to conduct self-assessments of their processes and the results to the relevant ISO or NIST standards are a good first step. However, in order to truly achieve quality in operations, we

advocate ONC to require compliance with the quality management document – through certification or public reporting. As such, we endorse ONC's proposal to make supporting assessment documentation publicly available.

With respect to patient safety events, Surescripts favors ONC's proposal to adopt certification criteria to require EHR technology to enable a user to generate a file in accordance with the Agency for Healthcare Research and Quality ("AHRQ") Common Format. ONC should work with CMS to require reporting of all three types of events (*e.g.*, incidents, near misses/close calls, and unsafe conditions) to which the Common Format applies. Creating an output file is necessary but not sufficient to ensure that safety-related issues are reported and addressed. We urge ONC to work CMS to not only require eligible providers to submit regular reports to the appropriate authorities but also develop standards for such.

Specific Comments on the 2014 Proposed Certification Criteria
Proposed 2014 Edition EHR Certification Criteria

New Certification Criteria

a. Ambulatory and Inpatient Setting

§ 170.314(d)(4) – Amendments	
MU Objective Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.	
2014 Edition EHR Certification Criterion *Amendments*. **(i)** Enable a user to electronically amend a patient's health record to: **(A)** Replace existing information in a way that preserves the original information; and **(B)** Append patient supplied information, in free text or scanned, directly to a patient's health record or by embedding an electronic link to the location of the content of the amendment. **(ii)** Enable a user to electronically append a response to patient supplied information in a patient's health record.	
Preamble FR Citation: 77 FR 13838	**Specific questions in preamble?** *Yes*

§ 170.314(d)(4) – Amendments

Public Comment Field:

Surescripts supports ONC's proposal to limit the privacy and security certification criteria, especially with respect to the criteria regarding amendments to the Base EHR and not the CEHRT. We are concerned that the application of this criterion to EHR Modules that are not part of the Base EHR could result in conflicting and overlapping practices and result in incorrect or inconsistent information in a patient record. For example, as a downstream business associate (or business associate subcontractor) and an intermediary, Surescripts does not amend patient information. We provide notice of any requests for amendments to our upstream business associates and covered entities with whom we directly contract (in accordance with our business associate agreements and permitted under the Health Insurance and Portable and Accountability Act or HIPAA). As such, requiring an intermediary or providers of certain modules to have the capability to amend information could present confusion and should be applicable to core functionality of an EHR utilized at the provider level.

§ 170.314(e)(1) - View, download, and transmit to 3rd party

MU Objective

EPs

Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.

EHs and CAHs

Provide patients the ability to view online, download, and transmit information about a hospital admission.

2014 Edition EHR Certification Criterion

View, download, and transmit to 3rd party.

(i) Enable a user to provide patients (and their authorized representatives) with online access to do all of the following:

(A) View. Electronically view in accordance with the standard adopted at § 170.204(a), at a minimum, the following data elements:

(1) Patient name; gender; date of birth; race; ethnicity; preferred language; smoking status; problem list; medication list; medication allergy list; procedures; vital signs; laboratory tests and values/results; provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; and care plan, including goals and instructions.

(2) Inpatient setting only. Admission and discharge dates and locations; reason(s) for hospitalization; names of providers of care during hospitalization; laboratory tests and values/results (available at time of discharge); and discharge instructions for patient.

(B) Download. Electronically download:

(1) A file in human readable format that includes, at a minimum:

(i) Ambulatory setting only. All of the data elements specified in paragraph (e)(1)(i)(A)(1).

(ii) Inpatient setting only. All of the data elements specified in paragraphs (e)(1)(i)(A)(1) and (e)(1)(i)(A)(2).

(2) A summary care record formatted according to the standards adopted at § 170.205(a)(3) and that includes, at a minimum, the following data elements expressed, where applicable, according to the specified standard(s):

§ 170.314(e)(1) - View, download, and transmit to 3rd party

(i) Patient name; gender; date of birth; medication allergies; vital signs; the provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; care plan, including goals and instructions;
(ii) Race and ethnicity. The standard specified in § 170.207(f);
(iii) Preferred language. The standard specified in § 170.207(j);
(iv) Smoking status. The standard specified in § 170.207(l);
(v) Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);
(vi) Encounter diagnoses. The standard specified in § 170.207(m);
(vii) Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3);
(viii) Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g);
(ix) Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed;
(x) Medications. At a minimum, the version of the standard specified in § 170.207(h); and
(xi) Inpatient setting only. The data elements specified in paragraph (e)(1)(i)(A)(2).

(3) Images formatted according to the standard adopted at § 170.205(j).

(C) Transmit to third party. Electronically transmit the summary care record created in paragraph (e)(1)(i)(B)(2) or images available to download in paragraph (e)(1)(i)(B)(3) in accordance with:
(1) The standard specified in § 170.202(a)(1); and
(2) The standard specified in § 170.202(a)(2).

(ii) Patient accessible log.

(A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A)-(C), the following information must be recorded and made accessible to the patient:
(1) The electronic health information affected by the action(s);
(2) The date and time each action occurs in accordance with the standard specified at § 170.210(g);
(3) The action(s) that occurred; and
(4) User identification.

(B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) if it is also certified to the certification criterion adopted at § 170.314(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

Standard(s) and Implementation Specifications

§ 170.204(a) (Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance); § 170.205(a)(3) (Consolidated CDA); § 170.205(j) (DICOM PS 3—2011); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT® International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release); § 170.202(a)(1) (Applicability Statement for Secure Health Transport) and § 170.202(a)(2) (XDR and XDM for Direct Messaging); and § 170.210(g) (synchronized clocks).

Preamble FR Citation: 77 FR 13838-41	**Specific questions in preamble?** *Yes*

Public Comment Field:

Transport Standards: *See* Surescripts comments above under General Comments, Section 1, "Proposed Transport Standards Under § 170.202(a) of the 2014 Certification Criteria."

Consolidated CDA Support: Surescripts supports ONC proposal to change the certification criteria for summary of care records from a CCD or CCR record (HL7 CDA Release 2, CCD Implementation

§ 170.314(e)(1) - View, download, and transmit to 3rd party
Specifications: HITSP Summary Document for CCR and Adjunct to ASTM or ASTM E2369 Standard Specification of CCR and Adjunct to ASTM E2369) to a Consolidated CDA record (Implementation Guide for Clinical Document Architecture, Release 2.0 (Consolidated CDA) (US Realm), Draft, September 2011) because CCDAs includes additional metadata and improves interoperability of such records.

§ 170.314(g)(4) - Safety-enhanced design	
MU Objective N/A	
2014 Edition EHR Certification Criterion Safety-enhanced design. User-centered design processes must be applied to each capability an EHR technology includes that is specified in the following certification criteria: § 170.314(a)(1); § 170.314(a)(2); § 170.314(a)(6); § 170.314(a)(7); § 170.314(a)(8); § 170.314(a)(17); § 170.314(b)(3); and § 170.314(b)(4).	
Preamble FR Citation: 77 FR 13842-43	**Specific questions in preamble?** *Yes*
Public Comment Field: *See* Surescripts comments above under General Comments, Section 4, "Quality Systems and Patient Safety Events."	

b. [Intentionally Omitted]

c. Inpatient Setting

§ 170.314(b)(3) - Electronic prescribing	
MU Objective Generate and transmit permissible discharge prescriptions electronically (eRx).	
2014 Edition EHR Certification Criterion Electronic prescribing. Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with: **(i)** The standard specified in § 170.205(b)(2); and **(ii)** At a minimum, the version of the standard specified in § 170.207(h). **Standards** § 170.205(b)((2) (NCPDP SCRIPT version 10.6) and § 170.207(h) (RxNorm February 6, 2012 Release).	
Preamble FR Citation: 77 FR 13844-45	**Specific questions in preamble?** *No*

§ 170.314(b)(3) - Electronic prescribing
Public Comment Field: *See* Surescripts comments below under Specific Comments, "§ 170.314(b)(3) – Electronic Prescribing."

Revised Certification Criteria

a. Ambulatory and Inpatient Setting

§ 170.314(b)(1) - Transitions of care - incorporate summary care record; and (b)(2) - Transitions of care - create and transmit summary care record
MU Objective The EP, EH, or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.
2014 Edition EHR Certification Criteria (1) Transitions of care – incorporate summary care record. Upon receipt of a summary care record formatted according to the standard adopted at § 170.205(a)(3), electronically incorporate, at a minimum, the following data elements: Patient name; gender; race; ethnicity; preferred language; date of birth; smoking status; vital signs; medications; medication allergies; problems; procedures; laboratory tests and values/results; the referring or transitioning provider's name and contact information; hospital admission and discharge dates and locations; discharge instructions; reason(s) for hospitalization; care plan, including goals and instructions; names of providers of care during hospitalization; and names and contact information of any additional known care team members beyond the referring or transitioning provider and the receiving provider. (2)Transitions of care – create and transmit summary care record. (i) Enable a user to electronically create a summary care record formatted according to the standard adopted at § 170.205(a)(3) and that includes, at a minimum, the following data elements expressed, where applicable, according to the specified standard(s): **(A)** Patient name; gender; date of birth; medication allergies; vital signs; laboratory tests and values/results; the referring or transitioning provider's name and contact information; names and contact information of any additional care team members beyond the referring or transitioning provider and the receiving provider; care plan, including goals and instructions; **(B)** Race and ethnicity. The standard specified in § 170.207(f); **(C)** Preferred language. The standard specified in § 170.207(j); **(D)** Smoking status. The standard specified in § 170.207(1); **(E)** Problems. At a minimum, the version of the standard specified in § 170.207(a)(3); **(F)** Encounter diagnoses. The standard specified in § 170.207(m); **(G)** Procedures. The standard specified in § 170.207(b)(2) or § 170.207(b)(3); **(H)** Laboratory test(s). At a minimum, the version of the standard specified in § 170.207(g); **(I)** Laboratory value(s)/result(s). The value(s)/results of the laboratory test(s) performed; **(J)** Medications. At a minimum, the version of the standard specified in § 170.207(h); and **(K)** Inpatient setting only. Hospital admission and discharge dates and location; names of providers of care during hospitalizations; discharge instructions; and reason(s) for hospitalization. (ii) Transmit. Enable a user to electronically transmit the summary care record created in paragraph (i) in

§ 170.314(b)(1) - Transitions of care - incorporate summary care record; and (b)(2) - Transitions of care - create and transmit summary care record	
accordance with: **(A)** The standards specified in § 170.202(a)(1) and (2). **(B)** Optional. The standard specified in § 170.202(a)(3). **Standards** § 170.205(a)(3) (Consolidated CDA); § 170.207(f) (OMB standards for the classification of federal data on race and ethnicity); § 170.207(j) (ISO 639-1:2002 (preferred language)); § 170.207(l) (smoking status types); § 170.207(a)(3) (SNOMED-CT® International Release January 2012); § 170.207(m) (ICD-10-CM); § 170.207(b)(2) (HCPCS and CPT-4) or § 170.207(b)(3) (ICD-10-PCS); § 170.207(g) (LOINC version 2.38); § 170.207(h) (RxNorm February 6, 2012 Release); and § 170.202(a)(1) (Applicability Statement for Secure Health Transport); § 170.202(a)(2) (XDR and XDM for Direct Messaging); and § 170.202(a)(3) (SOAP-Based Secure Transport RTM version 1.0).	
Preamble FR Citation: 77 FR 13848-49	**Specific questions in preamble?** *Yes*
Public Comment Field: Transport Standards: *See* Surescripts comments above under General Comments, Section 1, "Proposed Transport Standards Under § 170.202(a) of the 2014 Certification Criteria." Consolidated CDA Support: Surescripts supports ONC proposal to change the certification criteria for summary of care records from a CCD or CCR record (HL7 CDA Release 2, CCD Implementation Specifications: HITSP Summary Document for CCR and Adjunct to ASTM or ASTM E2369 Standard Specification of CCR and Adjunct to ASTM E2369) to a Consolidated CDA record (Implementation Guide for Clinical Document Architecture, Release 2.0 (Consolidated CDA) (US Realm), Draft, September 2011) because CCDAs includes additional metadata and improves interoperability of such records.	

§ 170.314(b)(4) - Clinical information reconciliation	
MU Objective The EP, EH, or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.	
2014 Edition EHR Certification Criterion Clinical information reconciliation. Enable a user to electronically reconcile the data elements that represent a patient's active medication, problem, and medication allergy list as follows. For each list type: (i) Electronically display the data elements from two or more sources in a manner that allows a user to view the data elements and their attributes, which must include, at a minimum, the source and last modification date. (ii) Enable a user to merge and remove individual data elements. (iii) Enable a user to review and validate the accuracy of a final set of data elements and, upon a user's confirmation, automatically update the list.	
Preamble FR Citation: 77 FR 13849	**Specific questions in preamble?** *Yes*

Public Comment Field:

Medication reconciliation should include electronic exchange of medication history in order to provide the most complete and accurate information to providers and improve quality care. At least one study found that electronically received medication history not only increases workflow efficiencies by reducing patient interview time, it also results in a significantly more complete medication history than simply reconciling information received from a patient and inputted in the patient's record.[5]

Given the benefit derived from medication history electronically available, we are urging CMS to include electronic exchange of medication history as part of the medication reconciliation workflow. Correspondingly, we urge ONC to include certification criteria to enable this workflow and recommend that ONC specify the content exchange standard for medication history as both the NCPDP SCRIPT Version 8.1 and the NCPDP SCRIPT Version 10.6.[6]

§ 170.314(b)(5) - Incorporate laboratory tests and values/results	
MU Objective Incorporate clinical laboratory test results into Certified EHR Technology as structured data.	
2014 Edition EHR Certification Criteria Incorporate laboratory tests and values/results. (i) Receive results. (A) Ambulatory setting only. (*1*) Electronically receive clinical laboratory tests and values/results formatted in accordance with the standard (and implementation specifications) specified at § 170.205(k) and, at a minimum, the version of the standard specified in § 170.207(g). (*2*) Electronically display the tests and values/results received in human readable format. (B) Inpatient setting only. Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such tests and values/results in human readable format. (ii) Display test report information. Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7). (iii) Incorporate tests and values/results. Electronically incorporate a laboratory test and value/result with a laboratory order or patient record. **Standards and Implementation Specifications** § 170.205(k) (HL7 2.5.1 and HL7 Version 2.5.1 Implementation Guide: Standards and Interoperability Framework Lab Results Interface, Release 1 (US Realm); and § 170.207(g) (LOINC version 2.38).	
Preamble FR Citation: 77 FR 13849-50	**Specific questions in preamble?** *Yes*

[5] 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.

[6] Surescripts is in the process of transitioning its operations to NCPDP SCRIPT Version 10.6 but the transition for medication history will not be complete until the first quarter of 2014 (anticipated).

§ 170.314(b)(5) - Incorporate laboratory tests and values/results
Public Comment Field: *See* Surescripts comments below under Specific Comments, "§ 170.314(f)(5) – Reportable laboratory tests and values/results; and (f)(6) – Transmission of reportable laboratory tests and values/results."

§ 170.314(d)(2) - Auditable events and tamper-resistance; and (d)(3) - Audit report(s)	
MU Objective **Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.**	
2014 Edition EHR Certification Criteria **(d)(2) Auditable events and tamper-resistance.** **(i) Enabled by default. The capability specified in paragraph (d)(2)(ii) must be enabled by default (i.e., turned on) and must only be permitted to be disabled (and re-enabled) by a limited set of identified users.** **(ii) Record actions. Record actions related to electronic health information and audit log status in accordance with the standard specified in § 170.210(e).** **(iii) Audit log protection. Actions recorded in accordance with paragraph (d)(3)(ii) must not be capable of being changed, overwritten, or deleted.** **(iv) Detection. Detect the alteration of audit logs.** **(d)(3) Audit report(s). Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the elements specified in the standard at § 170.210(e).** **Standards** **§ 170.210(e) Record actions related to electronic health information, audit log status, and encryption of end-user devices.** **(1) When EHR technology is used to record, create, change, access, or delete electronic health information, the following information must be recorded:** **(i) The electronic health information affected by the action(s);** **(ii) The date and time each action occurs in accordance with the standard specified at § 170.210(g);** **(iii) The actions(s) that occurred;** **(iv)Patient identification; and** **(v) User identification.** **(2) When the audit log is enabled or disabled, the following must be recorded:** **(i) The date and time each action occurs in accordance with the standard specified at § 170.210(g); and** **(ii) User identification.** **(3) As applicable, when encryption of electronic health information managed by EHR technology on end-user devices is enabled or disabled, the following must be recorded:** **(i) The date and time in accordance with the standard specified at § 170.210(g); and** **(ii) User identification.**	
Preamble FR Citation: 77 FR 13853-54	**Specific questions in preamble?** *No*
Public Comment Field: ONC should revise § 170.314(d)(2)(iii) to permit deletion of audit logs in accordance with applicable law.	

§ 170.314(d)(7) - Encryption of data at rest	
MU Objective **Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.**	
2014 Edition EHR Certification Criterion **Encryption of data at rest. Paragraph (d)(7)(i) or (d)(7)(ii) must be met to satisfy this certification criterion.** **(i) If EHR technology manages electronic health information on an end-user device and the electronic health information remains stored on the device after use of the EHR technology on that device has stopped, the electronic health information must be encrypted in accordance with the standard specified in § 170.210(a)(1). This capability must be enabled by default (i.e., turned on) and must only be permitted to be disabled (and re-enabled) by a limited set of identified users.** **(ii) Electronic health information managed by EHR technology never remains stored on end-user devices after use of the EHR technology on those devices has stopped.**	
Preamble FR Citation: 77 FR 13854-55	**Specific questions in preamble?** *No*
Public Comment Field: Surescripts supports the revisions as proposed as a positive step towards protecting health information and increasing security measures to align with best practices.	

b. Ambulatory Setting

§ 170.314(b)(3) - Electronic prescribing [Note: this is a revised certification criterion for the ambulatory setting and why this table appears twice, see page 7]	
MU Objective **Generate and transmit permissible prescriptions electronically (eRx).**	
2014 Edition EHR Certification Criterion **Electronic prescribing. Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with:** **(i) The standard specified in § 170.205(b)(2); and** **(ii) At a minimum, the version of the standard specified in § 170.207(h).** **Standards** **§ 170.205(b)(2) (NCPDP SCRIPT version 10.6) and § 170.207(h)(RxNorm February 6, 2012 Release)**	
Preamble FR Citation: 77 FR 13856	**Specific questions in preamble?** *No*
Public Comment Field: SCRIPT Standard: Surescripts endorses the proposed recommendation that, starting in 2014, EHRs should be certified to NCPDP SCRIPT Version 10.6 only. The Surescripts network currently is migrating to this version of the standard and expects said migration will be complete by the end of 2013. RxNorm: Surescripts requests that ONC clarify what the use of RxNorm as the source vocabulary would entail. Would this be RxNorm as a drug description or a drug qualifier? We urge ONC to use RxNorm as a drug qualifier, specifically via the use of RXCUIs, similar to how NDC numbers are currently being used. In general, RxNorm drug descriptions are not always end-user friendly, which is a primary reason	

§ 170.314(b)(3) - Electronic prescribing [Note: this is a revised certification criterion for the ambulatory setting and why this table appears twice, see page 7]

that Surescripts has not seen any significant adoption to date. In addition, as acknowledged by the National Library of Medicine (the creators and maintainers of RxNorm), some drug descriptions are over 105 characters in length. The NCPDP SCRIPT standard limits drug descriptions to 105 characters, which means that transmission of some e-prescriptions that include RxNorm drug descriptions would not be possible. As such, we believe that certification criteria for RxNorm should be limited to use of this standard for drug qualifiers only.

Additionally, we caution that RxNorm is not yet a complete drug compendium, RxNorm qualifiers are not available for all prescriptions that currently are sent electronically (e.g., medical supplies), and the database might not be completed by 2014. As such, we urge ONC to clarify that the transition to the certification criteria in 45 CFR § 170.314(b)(3)(ii) would not preclude use of other drug databases and qualifiers if circumstances require it.

Since most EHR vendor systems use proprietary commercial drug databases for their clinical terminology needs, there is a critical and urgent need for RxNorm RXCUI mappings to proprietary drug database codes to be made readily available to the industry by either drug database companies or a third party in order to foster the adoption of RxNorm.

Electronic Prescribing of Controlled Substances: 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 recommend that 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.[7]

Beginning steps could be to include certification criteria mapping to the DEA's EPCS requirements contained in 21 CFR §§ 1300, 1304, 1306, and 1311 as optional in the 2014 Certification Criteria.

ONC ought to encourage the development and/or implementation of strong authentication credentials that are exclusive to a provider, not the provider's organization or software. In order to reduce the burden on providers and encourage early adoption and improve workflows, we urge ONC to work with NIST or

[7] 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.

§ 170.314(b)(3) - Electronic prescribing [Note: this is a revised certification criterion for the ambulatory setting and why this table appears twice, see page 7]
other appropriate parties on the development of best practices for individual-specific credentialing that can be utilized in a wide variety of healthcare settings and across multiple platforms.

c. [Intentionally Omitted]

Unchanged Certification Criteria

a. [Intentionally Omitted]

b. Unchanged Certification Criteria Without Refinements

§ 170.314(a)(10) - Drug-formulary checks	
MU Objective **Implement drug-formulary checks.**	
2014 Edition EHR Certification Criterion **Drug-formulary checks. Enable a user to electronically check if drugs are in a formulary or preferred drug list.**	
Preamble FR Citation: 77 FR 13859	**Specific questions in preamble?** *No*
Public Comment Field: Surescripts recommends that ONC adopt standards to enable electronic formulary checking through the CERHT. We recommend that the 2014 Certification Criteria for formulary checks include the NCPDP Formulary and Benefit Standard Implementation Guide, Version 3.0, or alternatively, at a minimum, the NCPDP Formulary and Benefit Standard Implementation Guide, Version 1.0.	

§ 170.314(d)(9) - Accounting of disclosures	
MU Objective **Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.**	
2014 Edition EHR Certification Criterion **Optional – accounting of disclosures. Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in §170.210(d).**	
Preamble FR Citation: 77 FR 13859, 13871-72	**Specific questions in preamble?** *Yes*
Public Comment Field: Surescripts supports ONC's proposal to retain as optional the privacy and security certification criterion regarding the accounting of disclosures. As the HIPAA proposed rule regarding accountings of disclosures received significant industry feedback and the revisions of the proposed rule are unclear and an accounting, as it is currently defined under HIPAA, requires more input than can be obtained solely from an audit log, Surescripts urges ONC to maintain its position on the optionality of this criterion.	

Conclusion

We thank ONC 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,

/s/ Paul Uhrig

Paul L. Uhrig
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/s/ Kelly Broder

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