surescripts

June 3, 2019

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building,
Mail Stop: 7033A, 330 C Street SW
Washington, DC 20201

Re: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule

Dear Dr. Rucker:

Thank you for the opportunity to submit comments to the Office of the National Coordinator for Health Information Technology ("ONC") of the Department of Health and Human Services ("HHS") on the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program proposed rule, published in the *Federal Register* on March 4, 2019 at 84 FR 7424 (the "Proposed Rule").

Surescripts was created with the purpose of serving the nation with the single most trusted and capable health information network to help increase patient safety, lower costs, and ensure quality care. Faithful to that purpose, Surescripts built and now operates the largest and the most comprehensive clinical health information network connecting health care organizations nationwide. While founded in 2001 as an e-prescribing network, our innovation has since allowed us to expand the scope of our network to reach organizations that connect pharmacists, physicians, payers, and patients. These organizations make up the Surescripts Network Alliance.

The Surescripts Network Alliance connects our electronic health record ("EHR") vendor, pharmacy, pharmacy benefit manager ("PBM"), and clinician customers – in addition to health plans, long-term and post-acute care organizations, and specialty pharmacy organizations – with 1.61 million healthcare professionals and 258 million patients in our master patient index, covering 79% of the U.S. population and 93% of insured patients. All of these stakeholders and participants in the Surescripts Network Alliance rely on Surescripts to easily and securely share health information. In 2008, Surescripts processed 17.7 billion clinical transactions, a jump of 29% from 2017.

These clinical transactions include not only routing of prescriptions and all of the associated e-prescribing transactions, but also include delivery of medication history records, real-time prescription benefit transactions, electronic prior authorizations, clinical direct messaging, and record locator & exchange messages. For instance, our Record

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Locator & Exchange service helped bring interoperability to life for thousands of healthcare organizations in 2018, giving clinicians access to nationwide health information exchange through a single connection at the point of care. Last year, our Record Locator & Exchange service was used by over 106,000 clinicians across all 50 states and the District of Columbia, linking those clinicians to 108 million clinical documents, and allowing those clinicians to exchange 99 million care location summaries.

Please refer to our 2018 National Progress Report at https://surescripts.com/news-center/national-progress-report-2018/, which highlights the progress made last year across the Surescripts Network Alliance.

When we look at this vast exchange of actionable patient intelligence across care settings for purposes of treatment, we see interoperability in action – and in evolution. Our network strength is rooted in two core beliefs: (1) more actionable patient intelligence at critical points of care means better decisions, and (2) better decisions mean lower cost, higher quality, and increased safety. Guided by these beliefs, and further guided by our principles of neutrality, transparency, open standards, collaboration, and privacy, Surescripts is committed to saving lives, improving efficiency, and reducing the cost of health care for all.

We support and commend ONC in its commitment to fulfilling the requirements set forth by the 21st Century Cures Act, signed on December 13, 2016, by President Obama. In our experience building and operating a nationwide interoperable network, we learned that even the most efficient and sophisticated network is useless without access to adequate health information to turn into actionable intelligence. We are aligned with ONC in its mission to break down information and technology barriers to improve healthcare, and in this letter offer recommendations to better accomplish this mission to support the interoperability goals of the Nation.

Attached are our comments and recommendations for the various proposals within the Proposed Rule. Specific actionable recommendations and suggestions are underlined. We thank you again for the opportunity to share our comments and would be pleased to answer any questions you may have.

Sincerely,

Paul Uhrig

Paul L. Uhrig
Chief Administrative, Legal & Privacy Officer

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule

Comments and Recommendations

1. Deregulatory Actions for Previous Rulemakings (Section III)

1.1. Removal of Randomized Surveillance Requirements (Section III.B.1)

Surescripts supports the removal of the threshold requirement related to in-field randomized surveillance by ONC-Authorized Certification Bodies ("ONC-ACB"). This solution will help to route resources toward reactive surveillance activities.

Relatedly, we propose that ONC-ACBs have the freedom to work with health IT developers to appropriately surveil certified solutions. To that end, we recommend that ONC consider the work of The Drummond Group in its creation of the 'Interoperability Hub' that supports real-world testing. For instance, the Interoperability Hub is currently used to test Direct secure messaging. This real-world testing could be used to satisfy 42 C.F.R. § 170.315(h) by showing evidence of successful Direct messages being sent and received by the system in the production environment. The message audit data captured by most Health Information Service Providers ("HISP") will be able to create a sufficient forensic audit of real world messages without compromising patient data security while limiting the testing burden on the system under review and their customers.

1.2. Removal of the 2014 Edition from the Code of Federal Regulations (Section III.B.2)

Surescripts agrees with and supports the removal of the 2014 Edition Certification Criteria. Patient care would improve by requiring the same certification requirements across all participants of the Surescripts Network Alliance, which includes EHRs, PBMs, pharmacies, and clinicians, plus health plans, long-term and post-acute care organizations, and specialty pharmacy organizations. For example, the same certification requirements would allow our network participants to certify and support the same SCRIPT standard adopted by the National Council for Prescription Drug Programs ("NCPDP").

2. Updates to the 2015 Certification Criteria (Section IV)

2.1. The United States Core Data for Interoperability (Section IV.B.1)

Surescripts supports the transition from the Common Clinical Data Set ("CCDS") to the United States Core Data for Interoperability ("USCDI") and further supports the expanded set of data included in the USCDI. More standardized data available

through interoperable exchange will enhance the industry's ability to increase patient safety and decrease provider burden. We also support ONC's approach to include the newest version of the "minimum standard" code sets included in the CCDS within the USCDI.

2.2. Standards Version Advancement Process

We applaud ONC's proposal to create the Standards Version Advancement Process, as we agree with ONC that newer versions of standards are becoming available more quickly than ONC can address through notice and comment rulemaking. We believe that the electronic prescribing standard, NCPDP SCRIPT, is a prime example of this. Since CMS first adopted the NCPDP SCRIPT standard for electronic prescribing in 2005, CMS and ONC have only updated their selected version of the SCRIPT standard through regulation two times. Meanwhile, NCPDP has published 39 versions of the standard in the same period. As a result, the industry has not been able to timely implement the technological innovations contained in NCPDP-approved additions to the SCRIPT standard, such as new fields for prescribers to communicate allergy and substance use history to pharmacies, and to send certain specialty and compound prescriptions electronically.

We believe that the Standards Version Advancement Process proposed by ONC would be an important step in the right direction. We note, however, that under the current regulatory framework, ONC would be unable to apply the Standards Version Advancement Process to the NCPDP SCRIPT standard unless CMS first issues an interim final rule to recognize a version of the NCPDP SCRIPT standard as backwards compatible, or engaged in notice and comment rulemaking to advance the NCPDP SCRIPT standard. We believe the Standards Version Advancement Process would be more effective for electronic prescribing if it could be used to allow voluntary adoption of a new version of the NCPDP SCRIPT standard by prescribers, pharmacies, and Part D prescription drug plans without CMS rulemaking.

As a result, we recommend that the Department of Health and Human Services consider re-delegating the authority to name the standards for Part D prescription drug program electronic prescribing, medical history, and electronic prior authorization transactions from CMS to ONC. This would create a paradigm similar to the Promoting Interoperability program, where CMS would be responsible for outlining the required functionality for an electronic prescribing program, and ONC would be responsible for identifying the standards and implementation specifications for the required functionality. We feel that as between CMS and ONC, ONC is better situated to evaluate available electronic prescribing, medical history and electronic prior authorization standards, and determine the appropriate timing for adoption. Most importantly, such a change would allow the electronic prescribing industry to fully benefit from ONC's implementation of the Standards

Version Advancement Process, and receive access to much-needed innovations in electronic prescribing that have been held back due to the need for notice and comment rulemaking prior to testing and adoption.

We note, however, that while the Standards Version Advancement Process is a step in the right direction, it is not necessarily ideal because it would still require the agency to engage in notice and comment rulemaking to sunset the older version of the standard and require movement to the newer version. We are concerned that ONC may not be able to engage in notice and comment rulemaking frequently enough to keep industry current with the advancement of the NCPDP SCRIPT standard.

Additionally, we believe the Standards Version Advancement Process should only be used to allow the concurrent adoption of two versions of the NCPDP SCRIPT standard – the older version listed in the regulation, and one newer version for voluntary adoption. It would be too difficult for the electronic prescribing network to handle transactions made with more than two versions of the standard. Therefore, without timely notice and comment rulemaking following the use of the Standards Version Advancement Process to permit voluntary adoption of a newer SCRIPT standard, the industry would again be stuck at the version adopted through Standards Advancement (as adopting yet a third standard through the process would be unworkable without first moving the standards floor forward). We would prefer a solution that would allow the industry to sunset an older version of the SCRIPT standard without notice and comment rulemaking.

2.3. Electronic Prescribing Criterion (Section IV.B.2)

2.3.1. Transition to NCPDP SCRIPT version 2017071

Surescripts applauds ONC for its proposal to modify § 170.205(b) to name version 2017071 of the NCPDP SCRIPT standard as the required electronic prescribing standard for 2015 Edition Certified Health IT. As ONC noted in its proposal, this change is needed to ensure ONC's alignment with CMS's designation of NCPDP SCRIPT version 2017071 as the standard required for electronic prescribing and medication history transactions with Medicare Part D prescription drug plans starting on January 1, 2020. It will not be possible for prescribers to comply with these Part D prescription drug plan requirements on January 1, 2020 unless their Certified Health IT has adopted NCPDP SCRIPT version 2017071.

We note that unlike previous transitions to new standards, CMS has not offered a transition period for stakeholders to voluntarily adopt version 2017071, claiming that because version 2017071 is not "fully backwards compatible" with version 10.6, a transition period is not possible. As a result, all Part D plans, prescribers and pharmacies are currently required to simultaneously adopt the new version on

January 1, 2020. We are concerned that the "all jump at once" transition to SCRIPT version 2017071 will pose catastrophic operational issues for the e-prescribing network on January 1st and beyond. This abrupt switchover could jeopardize beneficiary safety, as vendors of Certified Health IT and Surescripts will be overwhelmed trying to address issues related to an update of this magnitude occurring overnight.

We ask that ONC work with CMS to create a smoother transition, whereby vendors of Certified Health IT, prescribers, pharmacies and Part D prescription drug plans could voluntarily adopt NCPDP SCRIPT version 2017071 for a period of time, such as six months, before ONC and CMS make the standard required for adoption by all stakeholders. Although the differences between versions 10.6 and 2017071 do create challenges, Surescripts has already provided guidance to make stakeholders aware of the anticipated transition and how e-prescriptions could be affected. For example, if a prescriber that has implemented SCRIPT version 2017071 sends patient instructions to a pharmacy that is still operating under SCRIPT version 10.6 and the instructions exceed version 10.6's character limits, Surescripts would not send the message, and would instead alert the prescriber to either shorten the length of the patient instructions or send the prescription manually.

Although a transition of this nature could create minor inconveniences for prescribers, these inconveniences are manageable as compared to the significant safety issues that will occur if the electronic prescribing network is forced to administer a hard cut-over to version 2017071 on midnight of January 1, 2020. A transition period is also preferable to a scenario where Certified Health IT vendors are unable to meet the January 1, 2020 deadline, making prescribers non-compliant with Part D prescription drug plans' electronic prescribing programs. We are particularly concerned about this latter scenario, as ONC may not publish a final rule until just months before the deadline – giving developers of Certified Health IT insufficient time to implement and certify their products to the new standard ahead of January 1, 2020. We ask that ONC consider these potential consequences and work with CMS to provide an appropriate transition period in advance of the January 1, 2020 deadline that would allow a safe and effective changeover.

2.3.2. New "Electronic Prescribing" Criterion

ONC proposes to adopt a new 2015 Edition "electronic prescribing" criterion that includes several transactions. Our responses to these transactions are below:

2.3.2.1. Create New Prescriptions (NewRx, NewRxRequest, NewRxResponseDenied)

We support the inclusion of the NewRx, NewRxRequest, and NewRxResponseDenied transactions. We are currently seeking early adopters of the

NewRxRequest and NewRxRequestDenied transactions, and believe that these transactions may be beneficial for e-prescribing of controlled substances as well. We note that pharmacies have expressed interest in NewRxRequest and NewRxRequestDenied transactions.

2.3.3. Change Prescriptions (RxChangeRequest, RxChangeResponse)

We support the inclusion of the RxChangeRequest and RxChangeResponse transactions.

2.3.4. Cancel Prescriptions (CancelRx, CancelRxResponse)

We support the inclusion of the CancelRx and CancelRxResponse transactions.

2.3.5. Renew Prescriptions (RxRenewalRequest, RxRenewalResponse)

We support the inclusion of the RxRenewalRequest and RxRenewalResponse transactions.

2.3.6. Receive Fill Status Notifications (RxFill, RxFillIndicatorChange)

We support the inclusion of the RxFill and RxFillIndicatorChange transactions. We note that the RxFillIndicatorChange transaction is the only way to alter the prescriber notification preferences in an ambulatory or acute setting outside of a fillable message. We further note that historically, the lack of prescriber control over notification messages may have had an impact on hindering adoption.

2.3.7. Request And Receive Medication History (RxHistoryRequest, RxHistoryResponse)

We support the inclusion of the RxHistoryRequest and RxHistoryResponse transactions.

2.3.8. Ask the Mailbox if there are any transactions (GetMessage)

We support the inclusion of the GetMessage transaction, but recommend that ONC make adoption optional for certification as this transaction is only applicable when not transacting with real time messaging.

2.3.9. Relay acceptance of a transaction back to the sender (Status)

We support the inclusion of the Status transaction.

2.3.10. Respond that there was a problem with the transaction (Error)

We support the inclusion of the Error transaction.

2.3.11. Respond that a transaction requesting a return receipt has been received (Verify)

We support the inclusion of the Verify transaction.

2.3.12. Request to Send an Additional Supply of Medication (Resupply)

We support the inclusion of the Resupply transaction, but recommend that ONC make adoption optional for certification.

2.3.13. Communicate Drug Administration Events (DrugAdministration)

We are in support of the Drug Administration transaction, but recommend that ONC make adoption optional for certification. While this transaction is applicable primarily to long term care practice settings, we note that there could be possible value of this transaction in ambulatory and acute care settings as well.

2.3.14. Transfer One or More Prescriptions (RxTransferRequest, RxTransferResponse, RxTransferConfirm)

We do not support the inclusion of the RxTransferRequest, RxTransferResponse, and RxTransferConfirm transactions are part of certification. We recommend that ONC remove the RxTransferRequest, RxTransferResponse, and RxTransferConfirm transactions from the 2015 Edition Certification Criteria as these are pharmacy-to-pharmacy transactions, and certification to these should not be required of EHRs.

2.3.15. Recertify the Continued Administration of a Medication Order (Recertification)

We support the inclusion of the Recertification transaction, but recommend that ONC make adoption optional for certification.

2.3.16. Complete Risk Evaluation and Mitigation Strategy (REMS) Transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse)

We recommend that ONC not require REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse transactions for certification until such transactions are supported by a REMS administrator.

2.3.17. Observations on Optional Transactions

While we support making transactions optional when appropriate, in our experience, we have noticed that when transactions are optional but do not necessitate optionality, it delays consistent network adoption, which may, in our experience, cause one side of the network to progress faster than another. This has the effect of reducing momentum (as one side of the network is waiting for the other to adopt), potentially lessening adoption as an organizational priority and hindering rationale for investment by organization causing delays in cross industry adoption.

2.4. Electronic Health Information Export Criterion (Section IV.B.4)

We seek further clarification on the database export criterion proposed at 42 C.F.R. § 170.315(b)(10)(2) relating to the export of electronic health information ("EHI") that health IT produces and electronically manages. We do not believe the intent of this rule is to require a HISP, certified under 42 C.F.R. § 170.315(h)(2), to have to transition data to another certified Health IT solution if the provider changes HISPs. Though EHI data may be managed as part of the operations of the network service, a HISP is neither the producer nor the responsible party for the ongoing management of the EHI that was processed through the service. We believe the inclusion of this data will cause confusion, and recommend that ONC clarify that HISPs and similar types of certified Health IT should be excluded from this requirement.

3. Modifications to the ONC Health IT Certification Program (Section V)

Surescripts' Clinical Direct Messaging service enables clinicians to electronically exchange Direct secure messages with other clinicians using different Health IT platforms. Surescripts is certified as a HISP and certified under the 2015 Edition Certification Criteria as a Health IT Module. We support the further clarification of Health IT Module Certification within this Proposed Rule. We further support the changes to the security requirements for 42 C.F.R. § 170.315(h) as these changes better align with the activities of a HISP.

4. Health IT for the Care Continuum (Section VI)

4.1. Health IT and Opioid Use Disorder Prevention and Treatment (Section VI.B)

We applaud and appreciate the focus and attention of ONC to the national opioid crisis and it's leveraging of health IT as part of the solution. We support comprehensive strategy of HHS to combat the opioid crisis using five points of focus, including the use of data. Surescripts is a leader in collection and sharing clinical data and we are encouraged that, with ONC's attention, the industry can continue to

improve and strengthen existing technology, standards, and practices to combat the opioid crisis.

We note that there is already significant existing infrastructure in place that can be used to address this problem. For example, EHRs, pharmacies, and some PDMPs already use NCPDP SCRIPT, which is the industry preferred standard for the communication of medication information. In addition, pharmacies are already required, by state law, to report opioids to state PDMPs, and providers are already required to check PDMPs. Moreover, other national medication history databases exist that can be combined with PDMPs for cross state interoperability. In other words, revising existing infrastructure, rather than creating a new national solution, will minimize costs to the healthcare system.

We believe that any new solution to combat the opioid crisis should take into account what is already in place today to avoid duplication of work, additional costs, and decreased speed to market. Moreover, it may take many years to implement a national solution, which would require national consensus, legislative change, and/or federal funding. In addition, any national solution may be hindered by the requisite technological processes and workflows necessary to make it functional. For instance, any new solution would need to work with the current health IT infrastructure, such as being built into pharmacies and EHRs. It would also require integration with the current EHR medication workflow, and would use standards that were not intended for its use, resulting in lack of critical data fields and multiple transactions to achieve the intended purpose.

4.1.1. 2015 Edition Certification Criteria (Section VI.B.1)

4.1.1.1. Transitions of Care Criterion

Per the Proposed Rule, the intent of the transitions of care criterion is to support the ability of health care organizations to transmit a summary care record to support an individual with an opioid use disorder ("OUD") upon discharge from an inpatient setting or a primary care provider to another setting for their care. While the current criterion helps to encourage the sharing of the summary care record, we note that there is not a specific field to input information for a patient with OUD. This causes the summary care record to look like any other transition of care summary document. To overcome this, we recommend a dedicated section that speaks to the unique condition of a patient with OUD.

4.1.1.2. Clinical Information Reconciliation and Incorporation Criterion

We are in support of clinical information reconciliation and incorporation criterion and note that this criterion can be met by implementation and utilization of the NCPDP Medication History standard using intermediaries such as Surescripts. To

date, billions of medication reconciliations are performed aided by our service. Further, there is substantial anecdotal evidence and peer-reviewed research demonstrating that medication reconciliation has uncovered information to help providers evaluate and treat a patient for OUD.

4.1.1.3. Patient Health Information Capture Criterion

We support the new measure within the Promoting Interoperability Programs established by CMS which is focused on verifying the existence of a signed Opioid Treatment Agreement ("OTP") for certain patients when a controlled substance is prescribed and incorporating it into the record. We agree that awareness of an existing OTP or measures that support the creation of an OTP are beneficial. For further impact, we recommend that ONC take steps to encourage a standardized, interoperable OTP template that is technologically-enabled so as to make OTPs better transferable.

4.1.1.4. Social, Psychological, and Behavioral Data Criterion

While social, psychological, and behavioral data is important, there is a gap in the system between diagnosing an OUD and Medicated-Assisted Treatment ("MAT") whereby providers are unable to quickly and easily identify treatment facilities. We recommend that ONC consider, for example, an electronic directory that is accessible by providers at the point-of-care to improve the process of identifying and making referrals to treatment facilities.

4.1.2. Revised or New 2015 Edition Certification Criteria in this Proposed Rule (Section VI.B.2)

4.1.2.1. USCDI

We support the adoption of the USCDI as proposed. The USCDI ensures that there is a common set of data classes required for interoperable exchange. As it relates to OUD, the newly added 'Clinical Notes' data class and 'Provenance' help provide clinicians with applicable context to the traditional binary type of interoperable data. In addition, some of the candidate and emerging data classes for v2 and beyond will be beneficial in the prevention and treatment of OUD, particularly 'Admission and Discharge Dates' and 'Location, Individual and Provider Goals', 'Reconciled Medication List' and other social factors like 'Alcohol Use'. Accordingly, we support and commend ONC in its proposal to adopt the USCDI.

4.1.2.2. Electronic Prescribing and PDMPs

Prescription Drug Monitoring Programs ("PDMPs") have matured and evolved to become more clinically oriented, and we believe that improving access to PDMPs is

a critical step in addressing the opioid crisis, but PDMP data needs to be seamlessly integrated into EHRs and thoughtfully merged with the other (non-controlled) medication history data to show a complete picture of the patient history.

We support moving to the new electronic prescribing certification criterion proposed at 42 C.F.R. § 170.315(b)(11), and we would like to specifically call attention to medication history transactions. The exchange of medication history is critical to the prevention and treatment of OUD. It is worth noting that while the exchange of medication history information can occur directly from a provider to a pharmacy or state PDMP, it is better suited for the industry for this be routed through an intermediary that can cleanse (e.g. de-duplication) and aggregate data from multiple sources and integrate such data into EHRs. We are aligned with the ONC in its "whole-patient" approach and believe that routing through intermediaries will allow clinicians to get the "whole" view, including information from pharmacies, state PDMPs, and other sources such as payers.

In addition, we support use by pharmacies of the Medication History transaction to query the state PDMPs directly or via an intermediary. To date, pharmacies have not adopted this transaction and are forced to access the state PDMP in a manual, inefficient, and non-integrated manner. However, we note that pharmacies are very familiar with the NCPDP SCRIPT standard due to its use in e-prescribing.

4.1.3. Emerging Standards and Innovations (Section VI.B.3)

4.1.3.1. CDS Hooks

Decision support is important in detecting, preventing, and treating OUD, and we believe clinical decision support ("CDS") Hooks has promise to standardize how we, as an industry, approach decision support. As such, we commend ONC for collaborating with the Centers for Disease Control and Prevention ("CDC") to translate the Guideline for Prescribing Opioids for Chronic Pain released by CDC into standardized, shareable, computable decision support artifacts using CDS Hooks. We recommend that this functionality be considered in the pharmacy setting to give pharmacists needed support on the frontline.

4.1.3.2. Care Plan FHIR Resource

Surescripts supports the transition from the static care plan documentation (document template in C-CDA R2.1) to a dynamic shared care plan that supports more robust care coordination, and looks forward to the work of ONC and HHS in this area.

4.1.3.3. ISA Content

We are in support of ONC's development of Interoperability Standards Advisory ("ISA") content to highlight standards and implementation specifications that support the prevention and treatment of OUD/substance use disorder ("SUD"), but suggest that ONC include within this content the degree to which these standards are adopted by various sections of the industry.

4.1.4. Additional Comment Areas (Section VI.B.4)

4.1.4.1. Integration of Health IT with PDMPs and EPCS

We believe there needs to be state-by-state legislative changes to get wider adoption of the standards, including the NCPDP SCRIPT 2017071 standard, for the exchange of PDMP data and to enable further adoption and use of Electronic Prescribing of Controlled Substances ("EPCS"). We recommend states either change their legislation to allow for this or for those states that already allow for it (e.g. Nebraska), use these standards rather than a proprietary solution. Our suggestion to ONC is to issue a policy paper on the matter. This, in addition to funding if feasible, would help formulate a nation-wide advocacy campaign to help states develop the motive and infrastructure to support the use of these standards.

4.1.4.2. Advances in Standards

As with other commenters to the 2019 Physician Fee Schedule proposed rule (83 FR 35923) and Hospital Inpatient Prospective Payment Systems proposed rule (83 FR 20528) regarding adoption of the NCPDP SCRIPT 2017071 standard to facilitate future reporting of the proposed 'Query of PDMP' quality measure, we support the use of the NCPDP Script Standard Implementation Guide Version 2017071 for medication history transactions for PDMP queries and responses. This is already widely adopted by EHRs, PBMs, and pharmacies, and has been proven to be well-tailored in communicating medication information as opposed to other standards (e.g. the Telecommunications standards or FHIR). For medication history transactions, we encourage ONC to consider and recommend the use of intermediaries to aggregate data from pharmacies, payers, state PDMPs, and other sources in the medication history response transaction in a way that becomes seamlessly integrated into the provider workflow, databases, and patient records.

Additionally, we note that there are many data sources for medication history. While some focus on converging the disparate sources into a singular source of truth, we believe that, in the short term, ensuring the existing standards are robust and encompass the necessary opioid related data fields and structure is critical. Of note is the existing and widely implemented NCPDP Medication History

(RxHistoryRequest / RxHistoryResponse) transaction, which facilitates real time request and receipt of medication data at the point of care.

Lastly, while we support the new opioid measures (Query of PDMP measure and Verify Opioid Treatment Agreement measure) included in CMS's Promoting Interoperability Programs, and agree that measures are an important drive for change, we believe that flexibility is needed in the definition of "query of PDMP". Per above, if state PDMP data is included and integrated within a medication history query and response alongside other medication data, this criteria should be considered met.

5. Conditions and Maintenance of Certification (Section VII)

5.1. Assurances: Trusted Exchange Framework and the Common Agreement—Request for Information (Section VII.B.2.d)

We encourage ONC to ensure that this rule and the Trusted Exchange Framework and Common Agreement ("TEFCA") are consistent.

Specifically, the ONC Health IT Certification Program has recognized Direct as the standard for push communication mechanisms while Draft 2 of TEFCA defines a new push-based exchange modality as a requirement in the Qualified Health Information Network ("QHIN") Technical Framework. Moreover, in addition to now including a new "push" requirement for QHINs and identifying IHE XCDR as the specified standard, TEFCA still identifies the Direct Protocol as an "alternative/emerging" standard. We believe the Direct Protocol has been thoroughly tested in the market and is already in use across multiple HIEs for message delivery; thus, it is no longer "emerging." We recommend that ONC make clear that the use of the Direct Protocol is allowed for all push-based exchange. Otherwise, confusion related to identifying which mechanism to use could be costly financially and resource-wise, and may ultimately delay or derail infrastructure work to improve data sharing through the existing, widely-adopted Direct Protocol.

Further, the Proposed Rule seeks information as to whether certain health IT developers should be required to participate in TEFCA as a means of providing assurances to customers and ONC that no actions that constitute information blocking or that may inhibit the appropriate exchange, access, and use of EHI are being taken. We support ONC's desire to provide such assurances to consumers, but we caution against making this a requirement of certification prior to the finalization of TEFCA. Surescripts recommends that ONC fully develop and finalize TEFCA and allow for additional opportunity to comment prior to making a determination as to whether to require such assurance as part of the certification process.

In the development and finalization of TEFCA, we do not believe that 42 C.F.R. § 170.315(h) should be included as part of the certification criteria for the basis for health IT developer participation in TEFCA as the industry has already come together to agree upon the DirectTrust framework.

5.2. Communications: Business Practices Related to Exchange (Section VII.B.3.b)

The Cures Act identifies a list of subject areas regarding which developers cannot prohibit or restrict communications, and within the Proposed Rule, ONC proposes that the terms used to describe the subject areas should be construed broadly. One of these subject areas is "developer business practices related to exchanging electronic health information," which would include, among other things, the following:

- the costs charged by a developer for products or services that support the exchange of electronic health information (e.g., interface costs, API licensing fees and royalties, maintenance and subscription fees, transaction or usage-based costs for exchanging information);
- the timeframes and terms on which developers will or will not enable connections and facilitate exchange with other technologies, individuals, or entities, including other health IT developers, exchanges, and networks;
- the developer's licensing practices and terms as it relates to making available APIs and other aspects of its technology that enable the development and deployment of interoperable products and services; and
- the developer's approach to creating interfaces with third-party products or services, including whether connections are treated as "one off" customizations, or whether similar types of connections can be implemented at a reduced cost.

We recommend that ONC clarify that if disclosure of certain information is prohibited by contract, the developer would not be liable for its inability to provide such information. We further recommend that ONC seek legal and policy guidance from the Antitrust Division of the Federal Trade Commission ("FTC") regarding the potential economic incentives and tradeoffs inherent in regulating the terms, prices, times, and conditions for developers to incur costs and expenses and the potential consumer benefits that would flow from creating an open ecosystem of information sharing.

5.3. Application Programming Interfaces (Section VII.B.4)

5.3.1. Proposed Adoption of FHIR DSTU 2 Standard

The Proposed Rule proposes to adopt FHIR Draft Standard for Trial Use ("DSTU") 2 (hereinafter, "FHIR Release 2") as a baseline standard conformance requirement, but notes that given FHIR Release 4's public release, the industry will begin to implement FHIR Release 4 in parallel with this rulemaking. In response to ONC's comment request as to which option ONC should pursue for a final rule, Surescripts recommends Option 2 outlined in the Proposed Rule. FHIR Release 2 and Release 3 are currently the most commonly implemented version of FHIR and FHIR Release 4 is too early in the process for formal recognition. With the introduction of the Standards Version Advancement Process, we recommend ONC take the time to vet and approve FHIR Release 4 at the discretion of the National Coordinator.

5.3.2. API Resource Collection in Health (ARCH)

Surescripts supports the proposal to include a set of specific resources required in the FHIR implementation. The API Resource Collection in Health ("ARCH") goes a long way to ensure that data is being captured and shared in a consistent, usable format. Surescripts supports the use of the Argonaut Data Query Implementation to further specify the implementation of the FHIR resources included in the ARCH. Surescripts has assisted in the development and testing of these specifications and without them, the ARCH would lead to ambiguous implementations of the FHIR resources.

5.3.3. Proposed Adoption of a New API Certification Criterion in § 170.315(g)(10): Search Support

ONC proposes in 42 C.F.R. § 170.315(g)(10)(ii) to require that the health IT presented for testing and certification be capable of responding to all of the "supported searches" specified in the Argonaut Data Query Implementation Guide Server, and notes that there is not yet a consistent, standardized specification for FHIR servers to handle searches for multiple patients. Surescripts disagrees with the approach by the ONC to require health IT developers to demonstrate multiple patient search/query capabilities in the manner the developer deems most efficient to meet this proposed certification criterion. Requiring health IT developers to demonstrate this capability without standardization will cause confusion and inconsistencies across the industry. We are concerned that this approach will limit and slow down the implementation of a consistent, standardized specification for the multiple patient searches. Instead, we recommend ONC allow industry collaboratives (such as HL7's DaVinci project or the FAST Initiative, which are both looking into this) to develop a consistent standard and adopt one such standard.

5.3.3.1. Conditions by API Technology Suppliers

In 42 C.F.R. § 170.404(a)(4)(ii)(B), ONC proposes to prohibit an API Technology Supplier from imposing any collateral terms or agreements that could interfere with or lead to special effort in the use of API technology for certain purposes, including developing products or services that are designed to be interoperable with the API Technology Supplier's health IT or with health IT under the API Technology Supplier's control; marketing, offering, and distribution of interoperable products and services to potential customers and users that would be needed for the API technology to be used in a production environment; and enabling the use of the interoperable products or services in production environments, including accessing and enabling the exchange and use of electronic health information. We are concerned that the proposed prohibition is so broad that it could have unintended consequences. For example, in the case of a HIN or HIE, although API technology can operate without implementing the directory of HIN or HIE members, requiring the API Technology Supplier to implement the HIE and HIN's directory would allow for a more efficient network. Therefore, such broad prohibition on the existence of API Technology Suppliers terms on health IT could impede the progress and potential of HIEs and HINs by disallowing the integration of a necessary tool for a well-functioning HIN or HIE. We recommend that ONC clarify that use of such directories would not be prohibited. Relatedly, we encourage ONC to clarify that requiring the inclusion of Direct addresses within a company-wide directory would not be prohibited under this regulation.

5.4. Real-World Testing (Section VII.B.5)

5.4.1. Testing Methods and Methodologies

The Proposed Rule proposes that a health IT developer submit an annual real world testing plan to its ONC-ACB via a publicly accessible hyperlink no later than December 15, of each calendar year for each of its certified 2015 Edition Health IT Modules, addressing the testing method(s) and/or methodology(ies) that will be used to demonstrate real world interoperability, including a mandatory focus on scenario and use case focused testing. Surescripts seeks clarity on the mandatory scenario and use case focused testing that will be required. Because the certification testing currently required forces a HISP to demonstrate certain activities that may never occur in a real world environment, if this testing requires the setup and execution of those scenarios, it will impose an unneeded burden on the HISP and its partners. We recommend that the HISP be able to attest to the relevant use cases and provide the proper evidence of testing associated to those scenarios. Additionally, we recommend that the submission of real world testing by a HISP be accepted for all upstream entities of that HISP who utilize their solution as "relied-upon software" for their complete EHR certifications.

5.4.2. Health IT Developers Updating Already Certified Health IT

In response to ONC's request for public comment on the minimum time prior to an anticipated implementation of an updated standard or implementation specification version update that should be considered reasonable, we recommend eighteen (18) months.

5.5. Clarification regarding Direct Messaging and Information Blocking

Within Section VII.D.5 (Effect on Existing Program Requirements and Processes), ONC uses the following example:

> ONC may receive a complaint of information blocking alleging that a health IT developer has limited the ability to receive secure Direct messages from users of a competing developer's EHR. The complaint alleges the certified health IT drops the incoming message *without alerting the user* that a message was ever received. ONC would consider the information blocking concerns (proposed § 170.401) as well as the potential safety concerns presented by dropped messages associated with certified functionality of the 2015 Edition "transitions of care" certification criterion (§ 170.315(b)(1)) and standards for the secure Direct messaging in its review. (Emphasis added.)

While we understand this is intended to be illustrative in nature, even in a non-nefarious instance, if a message fails to be received by an organization, the intended recipient is generally not notified. Rather, the sender of the message is provided notice of the failed message and is expected to take actions to correct the issue and resend the message or use alternative mechanisms to contact the recipient. This is in compliance with the Direct Protocol. We ask for clarification that the user in the italicized text is the sender and not the recipient of the message.

6. Information Blocking (Section VIII)

6.1. General Comments

Surescripts entire purpose is to facilitate interoperability. As noted in our cover letter to these comments, the Surescripts Network Alliance connects our EHR vendor, pharmacy, PBM, and clinician customers – in addition to health plans, long-term and post-acute care organizations, and specialty pharmacy organizations – with 1.61 million healthcare professionals and 258 million patients in our master patient index, covering 79% of the U.S. population and 93% of insured patients. All of these stakeholders and participants in the Surescripts Network Alliance rely on

Surescripts to easily and securely share clinical health information. Surescripts processed 17.7 billion clinical transactions in 2018.

We are aligned with ONC in its mission to break down information and technology barriers to improve healthcare. While we strongly support the policy goal of the information blocking provisions, we do not believe that any and all means by which data flow is impeded should be presumed to be improper information blocking, subject to only limited exceptions. We are also concerned that, as drafted, the Proposed Rule (as it relates to information blocking) could have significant unintended consequences on innovation and competition, and could in fact result in less, both in term of quantity and effectiveness, information sharing and interoperability. ONC should enable more flexibility for an actor to demonstrate compliance with the statutory information blocking provisions.

6.1.1. Regulatory Impact Analysis for Information Blocking

The regulatory impact analysis for information blocking does not appear to consider the various and substantial costs of compliance. A regulatory impact analysis must quantify and monetize the anticipated benefits and costs from the regulatory action and explain and support a reasoned determination that the benefits justify its costs.[1] Per Executive Order 12866, Section 6(a)(3)(C)(ii), the regulatory impact analysis must also consider the anticipated costs to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy and private markets including productivity, employment, and competitiveness. While the benefits of prohibiting information blocking are considered at length within the Proposed Rule, the costs are represented only as a number in Table 29: EO 12866 Summary Table without any explanation of the origin of the figures.

We believe the following very substantial costs, at a minimum and by way of example only, exist for those subject to the Proposed Rule:

- Costs of labor, process, and system development to respond to EHI and interoperable element licensing requests;
- Costs of labor, process, and system development for documentation to demonstrate compliance with information blocking rules;
- Legal costs interpreting a new regulatory framework and advice for ongoing compliance;
- Defense costs against potentially frivolous claims of information blocking instigated by private parties;
- Economic impact from loss of exclusive rights to intellectual property;

[1] https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/inforeg/inforeg/regpol/RIA_Checklist.pdf

- Impact on innovation, growth, and competition by business models limited to cost recovery and reasonable profit;[2] and
- Costs of redeveloping, modifying, and renegotiating contracts.

While we recognize that there is limited data and research available to quantify these costs, we recommend reviewing regulatory costs analyses from other industries. In listing out the specific costs above, our hope is that ONC can find research that establishes the costs of the above activities. We would also request information regarding the components and costs considered in setting the quantified costs figures in Table 29.

6.1.2. Good Faith Standard

Neither the 21st Century Cures Act nor the proposed regulations provide any protections against frivolous claims or threats of frivolous claims. We do not mean to suggest that the Government would bring frivolous claims. Rather, we envision a new environment where private parties could make threats, claims, or allegations of information blocking to enhance their position in contract negotiations or otherwise. While the Office of the Inspector General or an agency to which the claim is referred has investigative powers, without protections against frivolous allegations of information blocking, there is risk of opportunistic behavior. We recommend at a minimum that ONC impose a good faith standard on claimants. We also recommend that ONC impose penalties for frivolous claims on potential claimants.

6.2. Relevant Statutory Terms and Provisions (Section VIII.C)

ONC defines several terms used in the Cures Act. We believe that the definitions of "access," "exchange," "use," and "electronic health information" are very broad. As they interact with each other, with the definitions of the four types of actors, with the ONC descriptions and examples of information blocking practices, and with the seven exceptions, the result is an extensive and heterogeneous set of scenarios and use cases that will be subject to complex compliance and enforcement processes. We are concerned that the impact, foreseen and unforeseen, may exceed and even be inconsistent with Congress' intent to define and limit information blocking.

We are especially concerned with the implications of the very broad definition of EHI and the likely impracticality of applying the information blocking provisions to this extensive, highly situational, and largely non-standardized data set.

[2] Moreover, the Proposed Rule does not define what would constitute a reasonable profit, and in fact, notes that in some circumstances no profit may be made.

Another area of great concern is the definition of "Health Information Exchanges" and "Health Information Networks". We believe that the distinctions between these two categories are unclear. More generally, it is very important that these definitions align with congressional intent as well as common industry understanding of what these terms mean. We provide more specific commentary below.

6.2.1. Networks and Exchanges (Section VIII.C.2.c)

The Proposed Rule defines a health information network ("HIN") broadly. Given the importance of determining whether an entity is an HIN, we recommend that ONC provide additional examples of entities likely to be considered HINs. Further, we recommend that ONC clarify whether certain activities by affiliates set forth below would cause such affiliates to fall under the definition of a HIN.

The Proposed Rule states that an actor would be a HIN if it were to provide, manage, control, or substantially influence any technology or service that enables or facilities the access, exchange, or use of EHI between or among two or more unaffiliated individuals or entities. We recommend that that ONC provide clear and unambiguous definitions for terms such as "manage", "control", and "influence". We also recommend that ONC impose a materiality standard on all such factors, and not just on the "influence" criteria. Finally, we believe that many entities contract or license technology or services from third parties to enable or facilitate access, use, and exchange. For instance, many entities license servers from third parties to facilitate access, use, and exchange – this is just one of many examples. We recommend that ONC clarify that a third party would not fall within the definition of an HIN if that third party licenses, provides, or manages technology upon terms and conditions that do not otherwise give that third party material control or influence over the service that enables access, exchange, or use.

The Proposed Rule states that an actor would be a HIN if it were to substantially influence policies or agreements that define conditions or requirements that enable or facilitate the access, exchange, or use of EHI between and among two or more unaffiliated individuals or entities. Covered entities under the Health Insurance Portability and Accountability Act of 1996 and related regulations (collectively, "HIPAA") and data sources impose many requirements on the use of EHI supplied by them, and it is unclear if those requirements would cause an actor to be deemed an HIN. By way of example only, a data source may require an EHR or health system receiving EHI from it to indemnify it for claims of data misuse by the EHR or health system. As an additional example, a data source may impose limits on how long their data may be used or retained on a network. Agreeing to some of these requirements and conditions is necessary to gain the confidence of entities and incent these entities to participate in exchange of EHI. It is unclear whether these, and similar provisions, would constitute "substantial influence." We recommend

that ONC define with specificity what would constitute substantial influence of policies or agreements that define conditions or requirements that enable or facilitate the access, exchange, or use of EHI between and among two or more unaffiliated individuals or entities. Specifically, we recommend that ONC redefine "substantial influence" in this context as the ability of an actor to independently and unilaterally impose its view on policies or agreements that define *material* conditions or requirements that enable or facilitate the access, exchange, or use of EHI between and among two or more unaffiliated individuals or entities.

The Proposed Rule indicates that the definition of HIN hinges on facilitating the access, exchange, or use of EHI between and among two or more unaffiliated individuals or entities. The Proposed Rule states that two parties are affiliated if one has the power to control the other or if both parties are under the common control or ownership of a common owner. We recommend that ONC define "power to control" and "common control or ownership of a common owner." Specifically, we recommend that ONC define "power to control" and "common control or ownership of a common owner" as an entity having more than 50% of the voting power or Board control of another entity.

6.2.2. Other Entities Covered by Rule

We believe it is critical that all entities involved in the coordination or sharing of health information electronically be clearly identified as subject to the information blocking rules. We specifically make this recommendation because it does not appear that all appropriate entities fall within the purview of these rules. For instance, many health IT vendors are within the EHI exchange continuum as they act as a gateway before EHI flows to and from a provider. While we are concerned that in some respects the Proposed Rule is broad and captures entities that should not properly be within the definition of an HIN or HIE, we are equally as concerned that it may not capture entities that properly should be considered HINs or HIEs. We recommend identifying types of entities within the healthcare industry and clarifying whether each fall within one of definitions for actors or are not subject to the information blocking rules. We recommend that ONC provide clarity, by way of examples or otherwise, of other entities within the health care industry that may or may not fall within the four categories of actors.

6.2.3. Electronic Health Information (Section VIII.C.3)

6.2.3.1. Recommendation for New Category of Information

The Proposed Rule defines EHI broadly, essentially including any identifiable information that relates to an individual's health as EHI. We are concerned that the definition of EHI proposed by ONC: (1) is overly broad, (2) exceeds what was intended by Congress, (3) significantly increases the administrative complexity of

complying with the information blocking rules, and (4) improperly treats all identifiable information that relates to an individual's health as EHI as qualitatively and substantively the same.

In rolling out a new nationwide approach to data sharing under these information blocking rules that has not been done before in health care or other industries, it is important to take an incremental approach and focus on the most important problems that the information blocking rules were intending to solve. Requiring sharing of any kind of data for any purported "appropriate purpose" could dramatically affect consumer trust and innovation and may lead to a significant amount of administrative expense for health care organizations and cost to the health care system, all for sharing of data that is not focused on the patient's needs. Specifically, the information blocking rules primarily were intended to address the problem of assuring that electronic data was available for treatment of patients and that the data followed the patient. As such, we support ONC's focus on observational health information and recommend that ONC focus the roll out of information blocking rules on observational health information that is needed for purposes of treatment and facilitating patient access under HIPAA.

We believe that not all identifiable information that relates to an individual's health (the proposed definition of EHI) has the same qualitative and substantive attributes with respect to the goals of the promoting interoperability for health care treatment and patient health care management under the information blocking regulations. The goal of government should be to ensure that businesses are not blocking the exchange of observational health information, which the patient has a right to and health care providers need to provide the best care to patients and reduce unnecessary tests. Health care entities should share the observational health data itself freely for valid purposes, but should be allowed to compete on the value they bring to patients and others in the value-added services of providing that information in a usable way, including analysis and interpretation of the data. As such, we agree with ONC that there is a distinction between observational health information and transformative data, as defined in the preamble of the Proposed Rule, and that the observational health data is the category of data that should be the focus of the information blocking rule. Transformative data is employing value-added services on top of the observational health data. As such, transformative data should be carved out of the definition of EHI and should not be subject to the information blocking rules so as to ensure that these services continue to be available in the market and innovators have incentives to provide products and services that make this data helpful in providing care.

In addition, we believe that there should also be a distinction made between "observational health information" and "transactional data". "Transactional data" would include data in orders, such as an order for a lab or the ordering of a prescription, and authorizations, including messages related to the prior

authorization of medical care, by way of example only. This "transactional data" is critical for safe and cost effective care and is a value-added service. Providers and others are unlikely to block orders and other similar transactional data. As such, observational health information and transactional data are qualitatively and substantively different.

We believe that the concerns related to information blocking of observational data do not apply to "transformative data" or "transactional data." Furthermore, carving "transformative data" and "transactional data" out of the scope of the final rule would support innovation while not interfering with the underlying goal of ensuring easy availability of data by patients and providers for treatment purposes and patient needs.

Accordingly, we recommend that ONC define EHI to include only observational health information, specifically information contained in the USCDI. In the alternative, we would recommend that ONC explicitly exclude transformative data and transactional data from the definition of EHI.

6.2.3.2. Price Information

In response to whether price information should be within the scope of EHI, our thoughts are delineated below. While we have responded to the questions, we believe that price information should be characterized as transactional data and that the information blocking rules should not apply to such data unless contained in the patient's medical record as historical pricing information. We believe that the market drivers, the innovation landscape, and the value for the exchange of "transactional information" are substantially different from those for observational data, and do not believe that the information blocking rules should apply to such data. In addition, we believe that other regulatory mechanisms currently are being leveraged and can be leveraged in the future by the Government to achieve its goals of price transparency.

- Question: Should prices included in EHI reflect the amount to be charged to and paid for by the patient's health plan (if the patient is insured) and the amount to be charged to and collect from the patient (as permitted by the provider's agreement with the patient's health plan), including for drugs or medical devices?

  Response: Due to the lag between time of care, billing, adjudication of claims, and reconciliation, the amount to be charged by the health plan displayed at the point of service would be most accurate at that point in time. Charges between time of service and time of dispensary and billing may change.

- Question: Should prices included in EHI include various pricing information such as charge master price, negotiated prices, priced based on CPT codes or DRGs, bundled prices, and price to payer?

  Response: While various pricing presents a broad picture of information, usability at the time of service is crucial to ensure providers are consuming the information and using it to provide price transparency and cost sensitive recommendations to their patients. User experience testing is crucial to present not all the information, but that which is pertinent to the patient and prescriber at the point of care.

- Question: Should prices included in EHI be reasonably available in advance and at the point of sale?

  Response: Yes. Presenting actual cost at all points in a patient's care is a crucial tool for doctors, pharmacies, and care providers to provide complete transparency of price and potential alternatives to the patient and provide lower cost options when necessary to drive better medication adherence. Patients do not fill their first-time prescriptions 28% of the time, resulting in poor health and increased costs.

- Question: Should prices included in EHI reflect all out-of-pocket costs such as deductibles, copayments, and co insurance and/or include a reference price as a comparison tool such as Medicare rate and, if so, what is the most meaningful reference?

  Response: Costs such as out-of-pocket deductibles and copayments are dependent on payment processing times and there may be discrepancies at the point of care. Cash pricing options are available, but for true price transparency, full cost of care should be considered. A one-time cash payment for an episodic treatment or prescription may appear lower, but the entire cost of treatment is crucial to provide complete transparency for treating the condition.

- Question: For the purpose of informing referrals for additional care and prescriptions, should future rulemaking by the department require health IT developers to include in their platforms a mechanism for patients to see price information, and for health care providers to have access tailored to priced information, tailored to an individual patient, integrated into the practice or clinical workflow through APIs?

  Response: Native integration into the workflow is crucial to allow providers to quickly and easily access price information during the point of care. Patient specific pricing is the most accurate and dependable way to provide

patients with a clear snapshot of their cost of care, and for providers to find the most cost effective therapies to meet the need of the patient and encourage adherence to the care plan. It is critical to patient care and wellness to not just deliver costs, but to also deliver alternative therapies for the treatment that could cost less for the patient and lead to improved medication adherence and health outcomes.

We note that Surescripts has the capability to send patient specific prescription price and benefit information at the point of care in the provider workflow today. This service is available and live today and will eventually be based off of the NCPDP Real-Time Prescription Benefit standard. Thus far, the data on the value of real-time benefit tools ("RTBT") to patients has been impressive. Entities using the Surescripts Network Alliance have found that, for prescriptions written by physicians using RTBT and filled by the member:

- when a lower-cost therapeutic alternative was available, prescribers switched to that alternative 40% of the time, leading to an average savings for the patient of $130 per prescription filled;

- when the original drug was not covered, prescribers switched to a covered drug 75% of the time; and

- there are multiple examples of significant savings to patients whose providers used our technology. In one instance reported, a prescriber selected an appropriate therapy to treat a patient's ulcerative colitis. Leveraging our RTBT, the prescriber learned the requested medication would cost the patient $1361.40, but that a generic therapeutic alternative was available through the patient's pharmacy benefit plan for just $4. The prescriber changed the order, saving the patient $1357.40.

- Question: How would price information vary based on the type of health insurance and/or payment structure being utilized, and what, if any, challenges would such variation create to identifying the price information that should be made available for access, exchange, or use?

  Response: By way of example, Surescripts has robust connectivity with PBMs to provide patient-specific price information to providers. The NCPDP standard for Real-Time Prescription Benefit will improve the speed and accuracy of information. However, we have found that challenges exist training individuals in using the system, and that differences in EHR interfaces could make information harder to access.

Question: Are there electronic mechanisms/processes available for providing price information to patients who are not registered (i.e., not in the provider system) when they try to get price information?

Response: By way of example, the Surescripts patient matching dataset (discussed further in Section 7 below) is populated by a combination of payers, pharmacies, EHRs, and health systems. Maximizing the number of patients in it requires contractual agreement and a secure technical connection capable of capturing patient data. Surescripts can find and match 95% of the insured population using our Master Patient Index. For the U.S. population who cannot be found and matched with their insurance prices, medication cash price options are available. This service is available today.

- Question: What technical standards currently exist or may be needed to represent price information electronically for purposes of access, exchange, and use?

  Response: The NCPDP standard for Real-Time Prescription Benefit is in process to deliver greater uniformity across the industry on how prescription price data is accesses, exchanged, and shared.

- Question: Are there technical impediments experienced by stakeholders regarding price information flowing electronically?

  Response: Adoption by EHR systems to include real time prescription price transparency varies based upon age of system and prioritization of technical work. An NCPDP standard would speed adoption. Additionally, prescriber use is dependent on better training and usability of EHR systems.

- Question: If price information is included in EHI, could that information be useful in subsequent rulemaking that the Department may consider in order to reduce or prevent surprise medical billing?

  Response: By way of example, prescription costs are currently available to providers and care workers in their EHR through Surescripts' Real Time Prescription Benefits service. We do believe that subsequent rulemaking by the Department addressing price information may be helpful in order to reduce or prevent surprise medical billing, but we do not believe that the Information Blocking regulation is the appropriate vehicle.

6.2.4. Proposed Exceptions to the Information Blocking Provision (Section VIII.D)

6.2.4.1. Not Meeting an Exception as *Per Se* Violation

The Proposed Rule states that an actor must demonstrate that an exception is applicable and that the actor meets all relevant conditions of the exception at all relevant times. The statute defines information blocking as "[w]hen the provider knows, or the health IT developer, exchange or network, knows or should know, that the practice is unreasonable and will likely interfere with, prevent, or materially discourage, access, exchange, or use of electronic health information." Given that the 21st Century Cures Act forbids only conduct that an actor engaged in "knowingly," it would be against Congressional intent to state that there is a *per se* violation if an activity does not fall into an exception. Moreover, the Proposed Rule discusses documentation and/or standardized methods to demonstrate compliance with the conditions of each exception. We recommend that ONC provide examples on how an actor can demonstrate that it did not knowingly engage in information blocking. We also recommend that ONC clarify that if an entity acts reasonably in developing policies to comply with these rules, any practice that may later be determined to interfere with, prevent, or materially discourage access, exchange, or use of EHI will not be a "knowing" violation on the part of an actor.

6.2.4.2. HIN and HIE Fees for Access, Exchange, or Use

The Proposed Rule suggests that actors who control the access, exchange, or use of EHI should not be able to charge fees for providing such electronic access, exchange, or use of patients' EHI other than reasonable, cost-based fees. Our concern is that the Proposed Rule does not make it clear that this prohibition is not intended to displace the HIN or HIE revenue model. HINs and HIEs are generally designed solely to facilitate exchange of protected health information between and among various healthcare entities. Our concern is that this language may be inadvertently interpreted to prevent HINs and HIEs from being able to charge for their facilitation of the exchange of information and we recommend clarifying that this is not ONC's intent.

6.2.5. Preventing Harm (Section VIII.D.1)

We believe the conditions for the prevention of harm exception are too restrictive and recommend that the prevention of harm exception apply whenever an actor reasonably believes that a practice will directly and substantially reduce the likelihood of harm to a person.

6.2.6. Promoting the Privacy of EHI (Section VIII.D.2)

It is difficult for entities to assess whether compliance with certain provisions of HIPAA would mean non-compliance with information blocking rules. For example, Surescripts is contractually restricted from sharing protected health information for purposes other than those set forth in service agreements or a business associate agreement with covered entities who are the sources of data. Generally, these purposes are limited to treatment or limited to merely providing the services under the service agreement. Because Surescripts aggregates information from several sources and provides that information in a usable format, Surescripts frequently receives requests from organizations to make this information available to them for non-treatment purposes or for uses not contemplated in the service agreements or the business associate agreements. Due to language in our service and business associate agreements, Surescripts is often compelled to reject such requests. These situations do not appear to fit squarely into any of the privacy sub-exceptions. As such, we recommend clarification on the application of the information blocking regulations to situations when an entity receives a request for EHI but is unable to comply due to contractual limitations for information that otherwise may be disclosed under applicable state and federal laws, or when an entity is disclosing information for permitted purposes such as treatment or patient access. We recommend clarifying that an entity will not be in violation of the information blocking rules if it does not make EHI available because the source of the data, usually the covered entity, has limited the business associate's rights in sharing or disclosing the information often due to the scope of services being provided. We further recommend advising that the burden on ensuring that a practice is not information blocking is on the covered entity, and not the business associate, if the covered entity imposes any restrictions.

We are concerned that the requirement that the actor "[d]id all things reasonably necessary within its control to provide the individual with a meaningful opportunity to provide the consent or authorization" is too rigid a requirement. If even one possible action was not done, the exception would not apply. Moreover, for an HIN that does not have operational control over or visibility into the detailed decision-making of its participants, it would not be possible to apply or validate this test. We recommend that ONC explicitly indicate that an actor such as an HIN does not have the obligation to review or confirm that the actions of its participants meet this or other exception tests that do not involve direct decisions by the HIN.

A key issue for a nationwide HIN, for example, is that the terms of its trust agreement, may (out of necessity) provide reasonable discretion for the network participants. One such example is enabling participants to accommodate variations in privacy laws across states as necessary. Doing so could also be potentially construed as enabling decisions that implicate information blocking. It is essential,

therefore, that ONC focus on direct HIN decisions rather than the actions of its participants, which may or may not have been enabled by the HIN's trust agreement.

The Proposed Rule states, "[i]f the precondition that an actor purports to have satisfied relies on the provision of a consent or authorization from an individual, it is a condition of this sub-exception that the actor must have done all things reasonably necessary within its control to provide the individual with a meaningful opportunity to provide that consent or authorization." We recommend modifying this requirement so that an actor that does not have a direct relationship with patients is not required to obtain patient consent or authorization. For actors who do not interact with patients, such as business associates, this would be a significant organizational burden and would result in extraordinary additional administrative costs to have a large team responsible for seeking patient consent. We suggest that ONC clarify that the entity with a direct relationship to the patient – e.g. the covered entity – or the entity requesting the information is the one responsible for ensuring patient consents and/or authorizations are obtained. We believe it should suffice that an actor who does not have direct interaction with the patient has not discouraged or otherwise created an undue burden on the individual to provide consent or authorization.

Given the significant overlap between entities subject to the information blocking provisions and those subject to HIPAA, we also recommend clarity on the interaction between this provision and HIPAA regulations. For example, HIPAA permits, but does not require, covered entities to use or disclose protected health information for treatment, payment, or health care operations. Technically there is generally no "precondition" for a covered entity to disclose information for these purposes. We therefore seek clarity on whether the information blocking regulations would require disclosures in these circumstances. If that is the case, we would recommend that this be addressed as a modification of HIPAA and not through the information blocking regulations in order to avoid confusion -- given that the HIPAA framework has been in place for almost two decades -- and to avoid significant administrative and legal expense as entities attempt to understand the connection of these two regulations.

6.2.7. Promoting the Security of EHI (Section VIII.D.3)

We are pleased that ONC has created an exception that would permit actors to engage in practices that are reasonable and necessary to promote the security of EHI. We agree that it is important, as an industry and a company, to have a defined set of security standards and requirements that need to be met before sharing EHI.

However, we urge ONC to note that if actors are concerned about being in violation of the information blocking rules, they may relax their security protocols. This, in tandem with increasing ease of EHI availability, could increase the number of data

breaches and security incidents in the healthcare industry. To address this, we recommend adding a subexception whereby actors are allowed time for adequate diligence into organizations that are requesting access to EHI. This is especially concerning in an environment of bad actors purporting to have proper intention for EHI; we believe actors should have the necessary time to make sure that the privacy and security of EHI will not be compromised.

With regard to implementation of policies in a consistent and non-discriminatory manner, we recommend that discrepancies among customer organizations based on a risk-based approach would not be considered "inconsistent" so as to be information blocking. As an example, a company could offer stronger forms of encryption for connections (e.g., Transport Layer Security 1.2) and insist all new customers use that encryption, while at the same time providing existing customers a period of time to make the changes to meet the new standard. Likewise, using a risk-based approach whereby high-risk customers are encouraged to add or modify security requirements first is standard among the industry. We recommend that ONC state that approaches such as these would not be construed as information blocking.

Specifically, we recommend that ONC confirm that an organization can use security policies that exceed what is required by law or regulation based on their assessment of the threat environment, without violating this exception.

The Proposed Rule mentions the NIST Cybersecurity Framework as a consensus-based standard and best practice guidance upon which it can evaluate the reasonableness of a particular security control for this exception. We recommend that ONC expressly expand this to additionally include Health Information Trust Alliance ("HITRUST") and Electronic Healthcare Network Accreditation Commission ("EHNAC") as acceptable standards and/or guidance.

Understanding the importance of this exception, we recommend that ONC provide additional guidance and more examples of "unreasonably broad" and "onerous" practices that only purport to promote security. We would also like information on the criteria upon which ONC is relying to assess the size of the institution. We recommend using employees and/or financial resources of the institution when considering size. Lastly, throughout this exception, there are formal documentation requirements and we recommend that ONC provide more guidance on what specific information this documentation should contain.

6.2.8. Recovering Costs Reasonably Incurred (Section VIII.D.4)

ONC states they interpret the definition of information blocking to include any fee that is likely to interfere with the access, exchange, or use of EHI. However, ONC also notes that "this interpretation may be broader than necessary to address

genuine information blocking concerns and could have unintended consequences on innovation and competition." Surescripts agrees that prices and rent-seeking should not be used as a tool for information blocking. We are concerned, however, that this exception is overly broad, will be administratively burdensome, and will have the feared unintended consequences on innovation and competition. In this section in particular we reiterate our prior comment that there are qualitative and substantive differences between observational data, on the one hand, and transformative and transactional data, on the other hand, and again recommend that ONC distinguish between these data types with respect to information blocking.

Under the Proposed Rule, the method for recovering costs must be "reasonably related" to the actor's costs. This suggests that there should be some proportionality between costs and prices charged. But for many actors, costs are dynamic and frequently fluctuate due to factors that are completely outside the actor's control, such as costs for technology or number of customers or partners. It would be impractical to require actors to change prices whenever costs change or to anticipate these changes in advance. We recommend that ONC address how prices would be calculated in an environment of ever changing costs.

It appears that in order to fall within this exception an actor would be required to engage in cost accounting. This would impose a significant burden on actors, and we believe this would add sufficient cost and burden that it would be a barrier to data exchange and dissuade new entrants into the market. Such expenses could be prohibitive for non-profit HIEs that have weak business models. We also recommend that ONC clarify whether this provision would require entities to do cost accounting, which would impose a significant burden on actors.

Under the Proposed Rule, the method for recovering costs must be "reasonably allocated among all customers to whom the technology or service is supplied, or for whom the technology is supported." The Proposed Rule adds that a reasonable allocation of costs would require allocating costs between those customers that either cause the costs to be incurred or benefit from the technology. We believe ONC should provide further guidance on the reasonable allocation requirement and how such arrangements would fit under the exception. In addition, customers generally are not static. It would be impractical for many actors to allocate costs among customers when the number of customers is constantly changing. We recommend that ONC provide guidance on how costs can be allocated among customers when costs are constantly changing, innovative market services are constantly changing or being enhanced, and the number of customers using a service is in almost constant flux, especially in a thriving and expanding market.

We recommend that ONC clarify which costs would be recoverable. For instance, and only by way of example and not a limitation:

1. Many actors must incur large up-front labor or systems development costs to respond instantly to EHI requests -- will all such incremental up-front compliance expenditures be recoverable in a per-EHI-transaction price?
2. If an actor must create or install systems for tracking its costs (e.g., labor hours) for either building EHI-response capabilities or fulfilling EHI requests -- are such rule-imposed "system creation" regulatory compliance costs recoverable in any per-EHI-transaction price?
3. An actor's costs may vary according to the nature of the request. We request clarification that an actor may make adjustments to fess charged based upon the nature of the request.

Calculation of reasonable charges by its nature will require an actor to estimate the expected number of requests for EHI that it anticipates during a defined time period in order to allocate appropriately. Actors should be protected against enforcement action if it makes a good faith estimate of the expected number of requests proves to be incorrect. For instance, by way if example, an actor may estimate that it will receive one million requests for EHI over an annual period, and develops charges that would constitute cost recovery with a reasonable profit for those based on that estimate. If the actor in fact received two million requests for EHI and charge for those transactions, the actor could be subject to a claim even though it acted in good faith in anticipating volume, costs, and revenue. We recommend that ONC include safeguards so that an actor may recover any shortfall if the actor's best forecast of the number of requests is too high, compared to its actual number of requests, and its fees are too low, meaning its costs are under-recovered. We recommend that ONC apply a good faith exception so that if an actor in good faith makes estimates regarding its costs that later prove to be incorrect, the actor may still avail itself of this exception.

The proposed exception would also appear to prohibit business models that are legitimate and prevalent in the market. For instance, volume discounts are a prevalent and accepted pricing mechanism. Generally, the marginal cost of engaging in an additional transaction when there is a large volume is lower than the marginal cost of an additional transaction when the volume is low. Another example is subscription pricing. Our experience is that many entities prefer subscription pricing because it provides more predictable costs. Given that volume may fluctuate, this may not be strictly tied to costs nor should it be as the HIN or HIE may be taking some risk about the volume and must price accordingly. We recommend that ONC not only allow, but encourage, multiple business models, including but not limited to, volume discounts and subscription pricing.

We believe this exception should not apply to all actors in the same way due to differences in business models among the types of actors. Regulating cost and price margins in this one-size-fits-all manner creates poor incentives for investment, and

allowing ONC to decide what is the "right" amount by sector and/or function is, respectfully, arbitrary. For example, we believe this exception would disproportionately disadvantage an entity that is primarily in the business of health information exchange as opposed to an actor where information exchange is a secondary service, and that actor is in a position to simply charge more for other products and services. The limitations on cost recovery make more sense in the latter situation than the former, where the stand up HIN makes substantial investment in development, which must be in line with larger health policy goals. This is a difficult operating environment with conflicting incentives and a multiplicity of actors, all with mixed incentives. We do not believe that this exception, in its current form, creates the correct incentives to stand up HIEs or HINs in the face of operational and policy uncertainty.

The Proposed Rule states that costs recoverable under this exception could include a "reasonable profit." We request clarity on what constitutes a reasonable profit for purposes of this exception. It is often the opportunity for profit that drives many to start new companies, to enter new markets, and to invest resources in developing either novel and disruptive technologies or enhancements to current technologies. We believe imposing limitations on, or creating uncertainty in, an actor's ability to profit from its risk taking, development, and intellectual property could discourage, rather than encourage, innovation and competition.

We also request clarity on how actors are generally expected to demonstrate a profit is reasonable. For example, are actors expected to hire third-party consultants to certify that profits are reasonable, similar to how many health care providers hire consultants to provide fair market value determinations for fraud and abuse purposes? We note that this would be a significant expense and administrative burden that will slow down arrangements for exchange of health information, counter to the goal of this regulation.

Regulatory rules for the recovery of "reasonable" costs and reasonable profit have been developed and studied in other industries. We recommend that ONC engage in an analysis of regulatory cost recovery rules that have been applied to other industries to determine best practices and pitfalls that other industries have experienced. For example, this review would seek to identify whether and how the issues discussed above have been resolved in other settings, particularly in connection with the recovery of costs and rates of return for new or incremental investments or activities.

While we have provided specific recommendations to this exception as drafted, we strongly recommend that ONC revisit this exception in its entirety. We are concerned that as drafted it will have significant unintended consequences on innovation and competition, especially at a time when the government is seeking innovation, disruption, and increased choice and competition in the market. It is

often the opportunity for reasonable rate of return that drives many to start new companies, to enter new markets, and to invest resources in developing either novel and disruptive technologies or enhancements to current technologies. We believe imposing limitations on, or creating uncertainty in, an actor's ability to enter into economic arrangements and/or reasonable rate of return from its risk taking, development, and intellectual property could discourage, rather than encourage, innovation. We strongly encourage ONC to consider rulemaking that is targeted to specific problem areas that ONC has identified, rather than rulemaking that will be broad in its application and have adverse consequences. For instance, a proposal that would require free API access to an individual who requests access to their EHI through a consumer-facing application would be a targeted proposal that would meet an identified policy goal.

6.2.9. Responding to Requests that are Infeasible (Section VIII.D.5)

We are very concerned that this exception is too vague, with many undefined terms (e.g., timely, burdensome, etc.). This vagueness will create uncertainty as to whether claiming this exception will ultimately be validated by regulators and therefore lessen the benefit of this important exception.

We recommend that ONC address potential conflicts between valid contracts, such as HIPAA Business Associate Agreements, and requests for data access that are inconsistent with these contracts. To what extent does the need to honor (as opposed to the desire to enforce) contractual obligations meet the infeasibility exception? For instance, Surescripts has negotiated and entered into numerous contracts whereby the other party, usually a Covered Entity (as the originators of certain health information), limits our ability to share such information beyond providing our services. We, accordingly, cannot comply with some requests for such information. In the Proposed Rule, ONC identifies certain legitimate practical challenges beyond an actor's control that may limit its ability to comply with requests for access, exchange, and use of EHI, including not having the requisite technological capabilities, legal rights, financial resources, and other means necessary to comply to such request. But ONC indicates in multiple places that actors cannot enforce certain contracts that are contrary to the provisions in this rule but does not address corresponding contractual obligations to honor contracts; this gap is very problematic, especially as application of these provisions will often require case-by case, fact-based evaluations. We recommend further clarifying that a contractual restriction on use of health information that limits an actor's ability to comply with a request for access, exchange, and use of EHI would additionally fall within this exception.

Surescripts does not maintain a designated record set and does not currently provide patients with their medical records. Our Business associate Agreements with HIPAA-Covered Entities account for this and allow us to redirect patients to

their provider for medical records. Providing patients with their medical records is not feasible for us because we move health information in real-time and do not maintain a copy of this health information in an accessible manner that can be parsed out by patient. We recommend that ONC clarify that entities that do not maintain a designated record set and are unable to easily parse out information by patient will not be engaged in information blocking if a patient or their designee requests their health records from such an entity.

We further request that ONC specify that any requests must be properly made to an individual employed by an actor with the authority and ability to respond to such requests. In the event a request is infeasible and a written explanation is necessary, we recommend that such explanation need not contain detailed technical information.

We recommend that ONC recognize that honoring specific requests for information can be infeasible if the cost to meet that request, for example researching whether a patient has provided consent, is prohibitive.

We recommend that ONC confirm that infeasibility could include not having the technical capability in production to meet a request (e.g., not having technical means to support a specific type of exchange, access, or use, for example to enable write access to the EHR), when the cost of acquiring such capabilities are excessive and could reduce the ability to meet other project plans and customer commitments.

We recommend that ONC allow an actor to determine that a request is infeasible if there is another widely accepted alternative for performing the same or comparable action.

We recommend that ONC clarify that information blocking is not implicated if, per the regulatory language, the actor works "with the requestor in a timely manner to identify and provide a reasonable alternative means of accessing, exchanging, or using the electronic health information".

6.2.10. Licensing of Interoperability Elements on Reasonable and Non-Discriminatory Terms (Section VIII.D.6)

The Proposed Rule states that actors could be deemed to be engaged in information blocking if they refuse to license interoperability elements, and defines "interoperability element" broadly as any means by which EHI can be accessed, exchanged, or used, and clarifies that the term encompasses technologies, services, policies, and other conditions necessary to support uses of EHI. We believe that this requirement and this definition have the effect of mandating the licensing of any patented technology necessary for the access, exchange, or use of EHI. We believe that this could have the unintended consequence of impeding patent holders'

statutory right to choose not to license their patented technology.[3] Similarly, the requirement and definition would additionally mandate the licensing of trade secrets, and the Uniform Trade Secret Act has clarified that a trade secret ceases to exist when it is common knowledge within the industry that stands to profit from the trade secret.[4] This may have the effect of disincentivizing innovation and investment within the health information technology industry.

In light of the breadth of the definitions of interoperability elements and access, exchange, and use of EHI, we recommend that ONC define with specificity the reach of this exception and the intent behind this exception. The Proposed Rule suggests that the licensing exception is not intended to dictate a licensing scheme and actors may choose to comply with the information blocking provision in another way, such as by developing and providing alternative means of accessing, exchanging, and using EHI. However, having to develop and/or provide such alternative means every time an actor wishes to license a technology could be unduly burdensome and impractical, making licensing the only viable option. We recommend that ONC make clear that there are other ways for actors to be in compliance with the information blocking rules besides licensing interoperability elements to all requestors, particularly in instances where a requestor is simply attempting to commercialize their own product rather than facilitate the exchange of EHI for treatment purposes, and include examples to provide more clarity for industry.

We recommend that ONC expand the licensing exception by: (1) removing the requirement to offer an appropriate license upon receipt of a request; and (2) expressly allowing actors to assess on a case-by-case basis whether licensing the technology is appropriate given their statutory or other legal rights to the technology and the purposes of the disclosure. If an actor determines that licensing is not appropriate, ONC can require that the actor document the reasoning for such decision with that documentation available for governmental review.

If ONC decides to retain the requirement to offer an appropriate license, we recommend that ONC consider extending the proposed response period of 10 business days to allow for a response within "a reasonable period of time given the nature of the request, the volume of requests received, the ability of the actor to respond to immediately respond to such a request, and any other reasonable criteria". We believe that, given the broad definition of an "interoperability element," the nature of the request is a significant factor. Preparing an offer to license the infrastructure of a network would take substantially longer than putting together an offer to license a policy document. Moreover, we believe a 10-day time

[3] *See* 35 U.S.C. § 271(d)(4).
[4] Uniform Trade Secrets Act With 1985 Amendments, § 1 ("The language 'not being generally known to and not being readily ascertainable by proper means by other persons' does not require that information be generally known to the public for trade secret rights to be lost. If the principal person persons who can obtain economic benefit from information is are aware of it, there is no trade secret").

period is inconsistent with industry practice and grossly underestimates the time to both negotiate with the requestor and offer a license and to consult with counsel to ensure compliance with legal requirements. In addition, if ONC is wishes to prescribe a set number of days to respond, we recommend setting forth how and to whom a request should be made. As an example, if a request is sent to an individual that is no longer employed by the actor to a defunct email address, the requestor may claim that the actor engaged in information blocking without any fault of the actor.

Lastly, depending on the interoperability element being licensed, licensing itself is not a hands-off activity. The licensor may need to work with the licensee to ensure technical compatibility and operational safety and additionally aid in preventing against security implications and patient care issues. All of this would further require financial and personnel resources. While the exception allows for a royalty, we suggest allowing actors to charge for the costs of these activities.

6.2.11. Maintaining and Improving Health IT Performance (Section VIII.D.7)

While we are generally in agreement with this exception, we recommend that ONC recognize that it is unlikely that actors would make a system unavailable as part of deliberate information blocking. Actors have strong incentives to keep systems up and to respond quickly maintenance needs or to unplanned outages.

We recognize that system unavailability due to prevention of harm or security risks would fall under those exceptions and not this one. At the same time, subjecting urgent system downtime needs to the far-reaching requirements associated with any of these exceptions seems unwarranted.

Scheduling downtime is very complex even within an organization; the need to gain the assent of external parties affected by the downtime is impractical and infeasible. Consider for instance a system that is used by hundreds or thousands of users -- would the actor be unable to initiate needed maintenance if even one of these users did not agree? We agree that it is desirable for service level agreements ("SLAs") to address maintenance downtime but requiring agreement by users for any downtime should not be required. We are concerned that if ONC makes needed system maintenance and upgrades more difficult to accomplish, overall system quality will be threatened.

We recommend that ONC eliminate the requirement for prior agreement of planned downtime, and instead allowing for unilateral notice to organizations at least 10 days prior to scheduled maintenance.

As drafted, the Proposed Rule does not address unplanned downtime, and thus unplanned downtime would be considered information blocking. Unplanned downtime does occur, and will almost always only occur when the actor initiating the downtime is unable to control such situations. We recommend that ONC expand the exception to allow for unplanned downtime, without notice.

6.2.12. Recommendation for Another Exception

In order to ensure that the information blocking rules support standard business practice, sound operations, innovation and improvements in data sharing, we recommend that ONC allow flexibility in the rules through an exception that allows an actor to otherwise show that a practice is, among other things, reasonable and necessary. Moreover, because the 21st Century Cures Act imposes a "knowingly" standard, even if an activity does not fall into an exception, there might not be a *per se* violation of the information blocking rules. In this instance, an actor should be allowed to demonstrate that the actor did not knowingly engage in information blocking.

There are many examples of long-standing and sound practices that would not fall within an exception as drafted in the Proposed Rule. Citing just some examples by way of example applicable to Surescripts:

1. Some state laws require e-prescribing applications to be licensed by the applicable state. Surescripts retains the right to suspend the access of any e-prescribing application that fails to meet such a legal requirement. Such an action would be considered information blocking under the Proposed Rule.
2. The Drug Enforcement Agency's Interim Final Rule on the prescribing of electronic substances ("EPCS IFR") requires that any EHR engaged in electronic prescribing of controlled substances be certified by a third party as being in compliance with all of the requirements of the EPCS IFR. Surescripts retains the right to suspend the access of any e-prescribing application so certified. Such an action would be considered information blocking under the Proposed Rule.
3. Almost all transactions that flow through the Surescripts network are pursuant to standards adopted by Standard Development Organizations such as NCPDP. In fact, some such standards, such as the e-prescribing standards, are adopted and mandated by CMS. Surescripts retains the right to suspend the access of any health IT vendor that is not in compliance with the applicable standards. Such an action would be considered information blocking under the Proposed Rule.
4. In order to maintain the integrity of the network and preserve patient choice of provider and provider choice of therapy, Surescripts does not permit commercial messaging on its network. Surescripts retains the

right to suspend the access of any health IT vendor that uses the network for purposes of commercial messaging. Such an action would be considered information blocking under the Proposed Rule.

5. There are bad actors in today's environment – on occasion we have become aware that a clinician's identity has been stolen and a third party is attempting to use the network for improper purposes. Surescripts retains the right to suspend that clinician's or purported clinician's access to the network under such circumstances while it investigates the matter. While such an action perhaps would fall under the privacy or security exceptions, we envision scenarios where a circumstance may not fall within the strict confines of those exceptions.
6. One can envision a circumstance where a governmental entity, whether law enforcement or otherwise, requests that a network suspend the access of an individual or an entity to transmit EHI on that network. If that network were to comply with that governmental request or order, such an action would be considered information blocking under the Proposed Rule.

Accordingly, we recommend that ONC adopt a general exception whereby an actor be allowed to demonstrate that the actor did not knowingly engage in unreasonable information blocking. For an actor to qualify for this additional exception, we recommend that an actor:

(a) implement an organizational policy addressing how the actor will assess whether a practice is reasonable;
(b) document that an individualized assessment was conducted for each practice or category of practices in accordance with the organizational policy; and
(c) demonstrate within this documentation that each practice was reasonable.

We believe that this would account for the knowledge standard and allow for further flexibility as needed. We believe it is fair to require actors maintain this policy and documentation so as to qualify for this exception.

6.3. Conclusion on Information Blocking Rules

We recommend that ONC institute a period of enforcement discretion and educating and promoting voluntary compliance to help stakeholders learn, as was done with HIPAA enforcement. We recommend that OIG not take any enforcement action for a period of two years after finalization of this NPRM to allow actors to develop the policies and infrastructure to comply with these provisions. Further, to help stakeholders adjust to the new information blocking provisions and new definitions, we recommend a period of enforcement discretion that would have OIG require

corrective action plans – rather than levy fines which would likely lead to litigation – where claims of information blocking are found to be warranted. We recommend that this period should last no less than five years from finalization of this NPRM and all claims – substantiated and unsubstantiated – should be made publicly available for stakeholders to study.

We recommend that ONC "grandfather" any economic arrangements that exist two years from date of the finalization of this NPRM. We believe that it is unfair to ask parties that negotiated and entered into agreements before the final rule issued by ONC to comply with requirements that were unknown at the time. These agreements should be considered valid and effective as they are mutual agreements entered into by two parties informed by what was known at the time of their execution. Requiring the multitude of entities that will be subject to the information blocking rules to renegotiate what no doubt will be thousands upon thousands of contracts will disrupt the ecosystem and cause actors to focus on renegotiation of contracts rather than taking steps to drive interoperability and innovation.

Surescripts supports the intent behind the information blocking provisions. However, we strongly encourage ONC to consider the various issues and concerns raised within this letter. We particularly encourage ONC to consider the costs of compliance, the varying degree of risk based on the type of health information, and the expectations for recoverable costs. We additionally urge ONC to assess the inadvertent impact the information blocking regulations may have on stifling innovation, disruption, and competition.

7. Patient Matching Request for Information (Section X)

For patient matching, Surescripts utilizes a Master Patient Index ("MPI"), which is a collection of all patient demographics from information data suppliers (e.g. PBMs, pharmacies, EHRs, and health systems) connected to the Surescripts network. The demographic data is compiled and segmented into databases and used to associate requests for patient information from providers through their EHR with a corresponding data record using custom configured patient matching algorithms. For further information, please refer to Sections 7.1.1 and 7.8 below.

7.1. Data Quality

We agree that data quality standards are a critical component of patient matching and our MPI.

There are many ways to increase patient matching data quality, and which solution to pursue depends on the area one is seeking to improve. Most require collaboration across organizations and ongoing technical investment. For example, Surescripts' patient matching dataset is populated by a combination of payers, pharmacies,

EHRs, and health systems. Maximizing the number of patients within our MPI requires contractual agreement with our data suppliers and a secure technical connection capable of inserting patient data. Making sure sufficient demographic fields are populated requires agreement on minimum data population standards and intervention when those standards are not met. Even when a field is populated, it must be monitored to ensure the content quality is sufficient to accurately match the patient.

Additionally, comparison algorithms must be robust enough to deal with data which is not properly formatted. For example, much of Surescripts data originates from older systems that cannot be easily modified to produce data which conforms to standards. We, therefore, have to deal with poorly formatted data. As such, tools which can recognize and correct this data are critical.

Accordingly, we use the following framework for data quality in patient matching when utilizing our MPI.

7.1.1. Surescripts' Framework

By way of background, we assess quality in two types of datasets: (i) dataset that require the initiation of a patient match (Dataset A) and (ii) dataset upon which matching is occurring (Dataset B).

(i) Assessing quality of datasets that require the initiation of a patient match (Dataset A):
  (a) Is the data formatted in a manner which can be processed by the matching engine?
  (b) Does the data address population and quality related aspects on incoming transactions (NCPDP, X12, HL7, etc.)?
  (c) Are all demographic data fields available?
  (d) On the data fields available, are they populated with real data rather than dummy data, such as 0s and 9s?
  (e) Basically, are all fields available and useful?

(ii) Assessing quality of the data set upon which matching is occurring (Dataset B):
  (a) Is the data formatted in a manner which can be processed by the matching engine?
  (b) Does the patient in Dataset A exist in Dataset B?
  (c) If the patient exists in Dataset B, is there sufficient demographic information populated on that patient in Dataset B?
  (d) If the patient exists in Dataset B and there is sufficient demographic information populated in Dataset B, is the content quality of the information sufficient to match with Dataset A?

Within this framework, we believe it is important to maintain quality on an ongoing basis by monitoring increases or decreases in quality to make sure that any quality issues are regularly resolved. For example, we define minimum data standards (such as required fields) and generate errors anytime a data supplier fails these standards.

To give specific examples, the following tools, utilized in various industries could be beneficial for improving data quality in patient matching:

(i) Architect an MPI such that it is:
  (a) tracking patient information over the course of a patient's life (e.g. historical addresses);
  (b) consolidating all known information about each patient across all sources; and
  (c) differentiating between patients with similar demographics which can cause false positives;
(ii) Data standardization tools such as those used within Melissa Data by the U.S. Postal Service; and
(iii) Optimal algorithm tuning based on the demographic type and weighing of the demographic to accommodate multiple types of demographics.

7.1.2. Data Standardization

The concept of data standardization can be further divided into three distinct categories: (i) actual standardization, (ii) validation, and (iii) augmentation. Actual standardization is the standardizing of information in the original dataset, data validation involves using external sources to validate the data, and augmentation is the process of using external sources to fill in missing information in the original dataset.

For data standardization, some types of standardization may be more beneficial than others. As an example, we believe it is valuable to further standardize addresses such as changing 'NW' to Northwest or 'LN' to Lane. This is a very valuable piece of the patient matching puzzle and should be a standard for the industry.

If the data is already of high quality, we find that data validation is not as valuable but conversely, if the data is of poor quality, data validation is much more valuable and necessary. We find that data validation, such as checking the existence of the address, is not useful for high quality data because of the limited variability within that data. For instance, if a record has '123 RollingHills' as the address, data validation here would involve checking that 'RollingHills' is a valid street. In this example, 'RollingHills' should in fact be 'Rolling Hills' but validation does not know this. We do not find this type of validation to be useful in patient matching

capabilities as a sophisticated matching algorithm such as ours is able to perform this type of capability during the actual matching process, rather than necessitating a prior data validation process.

Lastly, data augmentation is a vital component of high quality data for us. It allows us to, for example, auto generate the city and state of an individual based on their zip code, decreasing variability and errors.

7.2. Additional Data Elements

In addition to the standards named in the Interoperability Standards Advisory, we recommend the usage of other IHE and FHIR standards to discover patients. To do so, all standards should include the same broad set of demographic fields within the transaction so that the type of patient search (e.g. FHIR patient search, PIX/PDQ or XCPD to request patient discovery) would not matter.

Incomplete or outdated demographic data in patients' records can prevent accurate matching. We recommend using referential matching by leveraging data from different sources to build a more complete profile of each patient over time. For us, referential matching began with a minimum viable dataset without which accurate patient matching is not possible. Beyond that minimum viable dataset, we added more information from our data suppliers to allow for referencing matching. Such addition and utilization of referential matching in general requires (i) proper tuning of the underlying algorithm; (ii) trustworthy sources of data of sufficient quality; and (iii) agreement by and capability of such sources of data to provide it in a secure structured format at acceptable business terms.

7.3. Requirements for Electronic Health Records

In setting requirements for EHRs to assure data used for patient matching is collected accurately and completely, we recommend requiring EHRs to establish a minimum viable matching dataset that includes the "transitions of care" certification criterion (specifically, first name, last name, middle name, suffix, date of birth, address, phone number and sex) and allowing for other data categories that would be beneficial to have (such as previous name, previous address, medical record number, etc.). We further recommend requiring EHRs to inquire about updates and updating such information after each patient encounter. As patient information is updated after each patient encounter, EHRs should be required to communicate the update to other organizations with which they are interfacing for patient matching.

Relatedly, we suggest efforts to harmonize industry standards for the electronic exchange of information with required information for patient matching. As an example, the X12 270/271 v5010 standard for eligibility benefit requests and responses, frequently used by EHRs, does not include phone number as an available

field in the request transaction and therefore, information from these transactions limit patient matching capabilities.

Lastly, standards should be designed with flexibility in mind. They must allow for generic values or label attributions to add data elements in the future. This is more effective and efficient than re-writing a standard if a data element needs to be added in the future.

7.4. Pediatric Record Matching

The biggest barrier to pediatric matching is lack of data upon which to match. We recommend that ONC make strides to require making birth records more easily available in a structured format, differentiated from their parents, and consumable by technology providers (*i.e.*, for download) would improve the accuracy of pediatric matching.

7.5. Involving Patients in Patient Matching

We do not recommend involving patients in patient matching, and we believe that there are reasons to be skeptical of this. Any efforts to involve patients in patient matching must provide protection against inadvertent and intentionally incorrect information and further, protection from identity theft.

Moreover, significant resources would be required to develop and introduce a solution that allows for patients to view their information, provides adequate protection from potential abuse, and allows for integration of the resulting modifications into the healthcare ecosystem. We recommend reviewing the summary and analysis from the recent RAND study, "Defining and Evaluating Patient-Empowered Approaches to Improving Record Matching," which states, "it is likely that no patient-empowered solution is a 'silver bullet,' and improvements in record matching will require a constellation of solutions".[5]

7.6. Standardized Metrics for the Performance Evaluation of Available Patient Matching Algorithms

Examples of metrics we recommend for the evaluation of patient matching algorithms include: (i) match rate, (ii) false positive rate, (iii) duplicate record rate, (iv) allocation of match types, (v) percentage of demographic information used by the algorithm, and (v) percentage of near matches. We specifically recommend near matches so as to help recognize opportunities for improving match rates and match accuracy.

[5] Robert Rudin et al., RAND Corporation, *Defining and Evaluating Patient-Empowered Approaches to Improving Record Matching* (2018), available at https://www.rand.org/pubs/research_reports/RR2275.html.

That said, measuring industry performance should take into account the many different patient matching use cases and patient matching models. As an example, duplicate rate is an effective indicator of matching during the hospital patient intake process but does not work for organizations who are matching to enable real-time record location services.

Above all, it is important to remember that automated data comparison, such as patient matching, has inherent risks of false positives and false negatives. Any metrics would require defining the correct balance between false positive and false negative matches, which can vary by the patient matching model and the use case. For example, the consequences for an incorrect patient match when checking a patient's benefits information is different from consequences when patient's medication history is correctly matched or when hospital records are merged.

We recommend that ONC grade or certify patient matching algorithms and prior to doing so, provide the industry with criteria and examples of known false negatives or false positives for patients that is to be used as unbiased testing criteria for grading algorithms, defining false negatives as the occurrence of an incorrect match and false positives as the match that exists but is not found.

7.7. Transparent Patient Matching Indicators

We agree that the current lack of consensus, adoption, and transparency of patient matching indicators makes communication, reporting, and comparison of patient matching near impossible. Adding to the difficulty is that patient matching best practices and performance indicators differ based on the use case and the patient matching model.

Having said that, lack of transparent patient matching indicators does not prohibit us from decision-making nor does it impede progress and innovation in this area. Rather, it just requires us to develop tailored indicators for our business. To illustrate, at Surescripts, we offer solutions that match almost every patient within the U.S. to their corresponding medical information, such as benefit information, drug history, and clinical documents. For the use case of benefit information (our measure), we have found valuable: (i) total insured patients, (ii) total unique patients, and (iii) duplicate patients against the total insured population in the U.S. accounting for dual coverage. Our general steps for this measurement are as follows:

Population of the United States ["Population"]	328,630,000
Population removing uninsured and closed network health systems	310,866,216

Population removing uninsured and closed network health systems taking into account dual coverage ["Insured Population"]	307,135,821
Number of unique patients in Surescripts' MPI	XX million
Actual match rate for Insured Population removing network errors ["Actual Match Rate"]	XX%
Delta between expected match rate based on number of patients in MPI and Actual Match Rate (e.g. our opportunity to decrease false negatives)	XX%

Please note that this is a unique model and our metrics may not be useful or applicable to other industry members.

7.8. Surescripts Approach to Patient Matching

Surescripts' MPI consists of demographic information of approximately 310 million individuals within the United States, sourced from PBMs, pharmacies, EHRs, and health systems. This information is used to uniquely match patients 2.52 billion times per year, enabling us to offer several healthcare solutions within the provider EHR workflow including finding a patient's (i) formulary and benefit information to inform prescribing, (ii) medication history information to inform medication reconciliation, and (iii) medical record to inform care decisions.

Surescripts uses a probabilistic algorithm for patient matching. However, without additional sophistication built in, patient matching is fundamentally limited by the quality and completeness of the underlying patient demographic data being relied upon to compare. In our opinion, conventional patient matching technologies are fundamentally limited and no conventional matching technology can match two records if either record contains out of date or mismatching information. We have found that using referential matching dramatically improves patient matching with minimal disruption to quality of service.

While matching accuracy can be improved with better standardization and algorithmic improvements, there are limitations to a purely algorithmic approach to matching, such as the inability to use artificial intelligence and machine learning. To illustrate, we offer two examples:

- Bill Adams moves to another state and changes his address, insurance, and physicians. An algorithm would not be able to definitely state the initial record for Bill Adams and the new record after his move are a match.

- Alexis Jones and Alexia Jones are twins, still living with their parents. An algorithmic approach would not be able to inform if the records for Alexis and

Alexia should be matched as siblings, rather than identified as the same person.

In both these cases, the missing element is further information, and any attempts to use this information for artificial intelligence or machine learning would be hindered by this missing information. Moreover, those methods would not solve the underlying data problem.

7.8.1. Names, Addresses, and Household Information

In the same fashion, ability to identify and incorporate other external information such as name or address changes and household information would be beneficial. These can be obtained from databases housing credit information, U.S.P.S. databases, and other locations. Equally important is ensuring that such data is machine-readable. As we note in Section 7.4, making birth records available and readable would improve the accuracy of pediatric matching.

7.8.2. Biometric Data

Use of biometric data may also be beneficial. However, because utilization of biometric data for identification is still in its infancy in healthcare, further work is necessary encourage adoption to establish standards and procedures related to collection, exchange, and comparison of such data before it can be impactful.

7.8.3. Unique Identifiers

We share the perspective of the Pew Research Center and the Sequoia Project in their recently published white papers[6] on the challenges associated with unique identifiers, and do not recommend the use of unique identifiers as the sole method for identifying a person. We believe unique identifiers pose many challenges that make them a poor option for a standalone solution.

First, a unique identifier does not forego an identity proofing or authentication process. Those processes need to additionally occur to ensure that a patient is who they claim to be. Additionally, some care may be anonymous or pseudo-anonymous, and use of unique identifiers may make receipt of such care difficult.

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[6] The Pew Charitable Trusts, *Enhanced Patient Matching Is Critical to Achieving Full Promise of Digital Health Records* (2018), https://www.pewtrusts.org/-/media/assets/2018/09/healthit_enhancedpatientmatching_report_final.pdf; Seth Selkow, Eric Heflin & Sid Thornton, The Sequoia Project, *Successful Patient Matching without a Unique ID: A Framework for Cross-Organizational Patient Identity Management* (2016), https://sequoiaproject.org/wp-content/uploads/2016/03/TheSequoiaProject-CCC-HIMSS16-PATIENT-MATCHING-Final.pdf

Second, there is potential risk of assigning a unique identifier to two different patients. Once such identifier is in public use, users will associate and link information for the two patients to the same unique identifier. This is particularly problematic as the associated information would relate to the health of the patient, and any combined or missing health information could have detrimental effects to the health and safety of the patient. Once this is recognized as a false positive, it can be very difficult, sometimes impossible, to properly split the data. If a unique identifier is lost, information corresponding to that identifier may also be lost if the unique identifier is used as a standalone option.

The problem of false positives may become even more problematic when a third party vendor is tasked with allocating or distributing unique identifiers. For instance, two records may contain the same last name, address, phone number, and date of birth, but both may only have a first initial "M." When unique identifiers are introduced by a vendor, they may unknowingly combine these two records using the unique identifier, resulting in a false positive. The entities relying on these unique identifiers are unlikely to have insight into the vendor's matching engine to gauge whether there is risk of a false positive. Relatedly, there may additionally not be any visibility into changes to the vendor's matching engine or allocation of unique identifiers by entities relying on the unique identifiers.

There is further risk that any importance placed on the unique identifier may occur at the expense of a tuned matching algorithm. For instance, in cases where records represent the same person but contain differing data (e.g. maiden name and previous address in one record and married name and current address in another record), the unique identifier would need to be weighted heavily in order to automatically merge records together. However, weighting unique identifiers so heavily would increase the chances of creating more false positives, as well as contradict the philosophy of using the unique identifier to push matching decisions over the cliff.

In each of the aforementioned instances of false positives, there is now insidious data introduced into records causing data quality issues. Without visibility into vendor allocation of unique identifiers and a mechanism to identify false positives, it is very difficult to assess how and why information within records was put together – was it organically included in the record at the time of care or did a third party's unique identifier force the information together?

Beyond this, there are several logistical issues with unique identifiers. If one is lost or misplaced, a process needs to be in place to replace the lost or misplaced identifier and retrieve information associated with the lost or misplaced identifier. Moreover, prior to unique identifier allocation, the vendor would need to have a complete and accurate enterprise master patient index so as to avoid inadvertently

linking or associating (or inaccurately failing to link or associate) records to the same unique identifier.

Lastly, the healthcare industry currently does not have infrastructure for unique identifiers. Such infrastructure needs to be developed, including laws to protect the privacy of unique identifiers and laws to prevent against fraud related to the unique identifier. This will need a substantial amount of resources, funding, and buy-in from legislators. To this point, we note that Congress has explicitly prohibited the use of federal funds to investigate or create unique patient identifiers within the Omnibus Appropriations Act of 1998.

For these reasons, we do not recommend the exclusive use of unique identifiers in patient matching. In certain scenarios they can be useful but as an input alongside other demographic variables. There will always be a need for probabilistic solutions that take into account all variables and demographics in relation to each other, and the exclusive use of unique identifiers without supplemental probabilistic techniques would likely create more problems to patient matching that it would solve.