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Via E-Mail - exchangeframework@hhs.gov

Don Rucker, M.D.
National Coordinator for Health Information Technology
Office of the National Coordinator
U.S. Department of Health and Human Services
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Dear Dr. Rucker:

Surescripts is pleased to respond to the request for comment by the Office of the National Coordinator (“ONC”) on the trusted exchange framework and “common agreement” — including comments specifying considerations, concerns, and success stories for the exchange of health data across networks. Our experience represents what we believe is the nation’s greatest success story in healthcare interoperability, and we draw upon our 16 year history of creating and operating the Surescripts network to provide comments for this important ONC initiative. Our comments are outlined in three specific areas: (1) Background on the Surescripts network experience; (2) Comments regarding ONC’s development of a “trusted framework”; and (3) Responses to ONC’s specific requests for comment. In the Appendix we provide background on the Surescripts network governance approach.

EXECUTIVE SUMMARY

- The government has a role to play to identify and enforce consistent and expected standards of network-to-network exchange in areas that lend themselves to commonality in order to create trust among health information exchanges and to remove factors that discourage participation of the healthcare community. Those areas that lend themselves to commonality in our view are:
 - a. identity proofing of participants
 - b. authentication of participants onto a system once properly ID proofed
 - c. matching of individuals
 - d. security standards
 - e. obligations of privacy
 - f. consistency and enforcement of trust obligations throughout the movement of information from point A to point B over multiple networks
- ONC should ensure that the framework and the “common agreement” do not disrupt current frameworks, and that the framework and “common agreement” allow market participants to continue to (i) innovate (both in business and technological advances), (ii) compete, (iii) encourage new entrants (whether commercial, governance frameworks, or otherwise) into the market, (iii) advance in product development, and (iv) develop new business models that achieve the goals of the parties and create financial sustainability for networks and their participants.

- ONC should consider the downstream effect of a trust framework or a “common agreement” on entities beyond the networks themselves. A “common agreement” among networks may include provisions that need to be imposed on entities downstream from the network, which could affect hundreds, if not thousands, of agreements.

1) Background on the Surescripts network experience

As background, today Surescripts operates the nation’s largest clinical health information network, delivering 10.9 Billion transactions in 2016, or more than 700,000 health transactions every hour, transacted both within our network and across networks with which we connect. Founded in 2001 by pharmacies and pharmacy benefit managers to establish a technology infrastructure to connect disparate technology systems across the nation to enable e-prescribing, we now connect over 99 percent of all retail pharmacies and most mail order pharmacies in the country, more than 250 EHRs and health technology vendors, representing more than 1,000,000 prescribers and hundreds of health systems. The underlying infrastructure facilitating these transactions includes a provider directory (containing the previously mentioned 1,000,000+ prescribers) and our Master Patient Index covering 230 million insured patients.

Over the past several years, Surescripts has made significant investments in leveraging the strength and unique assets of the network to deploy new services that extend beyond e-prescribing in order to enable providers to deliver the high-value care envisioned in ONC’s Shared Nationwide Interoperability Roadmap. As just one example, we are using the Surescripts network to create and operate a National Record Locator Service (NRLS) that offers providers a fast and easy way to obtain historical patient visit locations and retrieve clinical records, regardless of geography or EHR systems. NRLS already includes 230 million patients and more than 4 billion potential patient visits by referencing historical Surescripts network activity. NRLS is now live nationwide across 43 health systems and operates within the Carequality Interoperability Framework.

Our National Progress Report, which can be found at www.surescripts.com/report, provides more information about the scope of the network.

The vast majority of the health information that flows through the Surescripts network does so under the auspices of Surescripts’ governance framework for our own network. In addition, we are founding members of DirectTrust, which offers a governance and trust framework related to Direct messages. We also are founding members of Carequality, a national-level, interoperability framework for trusted exchange between and among health information networks, programs, and services. A growing number of our health information transactions are exchanged under the auspices of those frameworks.

2) Comments regarding ONC’s development of a “trusted framework”

The 21st Century Cures Act requires ONC to “build consensus and develop *or support* [emphasis added] a trusted exchange framework, including a common agreement, *among health information networks nationally* [emphasis added].” The Act expressly states that participation in any such trusted exchange framework and common agreement is voluntary. The Act also states that the trusted exchange framework and common agreement “shall take into account existing trusted exchange frameworks and agreements used by health information networks to *avoid the disruption of existing exchanges between participants of health information networks* [emphasis added].”

Surescripts has substantial experience and expertise in creating its own governance and trust framework for the operation of its own network. In the Appendix to this letter, we provide an overview of our trust framework that governs the exchange of electronic health information between and among participants within our own network. While we note that 21st Century Cures seeks to support a trusted framework “between networks,” and not among participants of a common network, we believe our experience might be illustrative of issues that the industry faces in network to network exchange (please see the Appendix).

Interoperability occurs only when data moves – moves by and among providers (including pharmacies), payers, patients (as well as their authorized family or other caregivers), public health, and/or researchers. Our experience is that trust is essential in any movement of health information – trust, among other things, (i) that the person with whom you are communicating with is who they claim to be, (ii) that the data will be secure, (iii) that the data will be used only in accordance with law, for the agreed upon purposes, and in adherence to patients’ privacy rights, and (iv) that everyone in the chain of trust is abiding by the same rules. And, this trust must exist not only between contracted parties, or between networks, but also along a sometimes long continuum of parties who touch the data as it moves from one point to its final destination.

ONC’s leadership to drive a trusted framework is to be applauded. We believe government has a role to play in establishing or supporting a framework and a common agreement that will guide, and can be used by, networks that desire to connect with one another. The 21st Century Cures Act provides the roadmap for that role by stating that the common agreement *may* [emphasis added] include: (1) a common method for authenticating trusted health information network participants, (2) a common set for rules for trusted exchange, (3) organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur, and (4) a process for filing and adjudicating non-compliance with the terms of the common agreement.

We believe that the language of 21st Century Cures gives ONC the authority and flexibility as indicated in the emphasized language above to use its discretion to ensure that the approach is just the right approach to build trust in network-to-network exchange by supporting existing frameworks and providing guidance for the creation of new frameworks in the market as needed, all without disrupting existing exchanges between participants of health information networks. Congress also was not prescriptive in what the common agreement must address – Congress stated what the common agreement may address, but makes no explicit requirements. To that end, we believe that the government has a role to play to identify and enforce consistent and expected standards of network-to-network exchange in areas that lend themselves to commonality in order to create trust among health information exchanges and to remove factors that discourage participation of the healthcare community. At the same time, it will be extremely important to ensure that the framework and the execution under the framework allow market participants to continue to (i) innovate (both in business and technological advances), (ii) compete, (iii) encourage new entrants (whether commercial, governance frameworks, or otherwise) into the market, (iii) advance in product development, and (iv) develop new business models that achieve the goals of the parties and create financial sustainability for networks and their participants.

Specifically, we would offer the following comments:

1. **Define “health information networks” and “trusted exchange frameworks”:** We recommend that ONC clearly define the entities that come within the scope of the trust framework and common agreement. While compliance with the framework and common agreement is voluntary, it will be

important to define in a normative way “health information networks” and “trusted exchange frameworks.” In the absence of a normative definition, entities may represent themselves as being a trusted exchange framework when they are not, or may seek to avoid being characterized as either a health information exchange network or a trusted exchange framework in order to avoid the requirements, albeit voluntary, of ONC’s guidance. This could lead to confusion in the marketplace. For instance, ONC highlighted seven organizations at its recent Town Hall on July 24, but it is not clear whether all of them in fact are frameworks for network-to-network exchange, whether some are operational entities offering network services, whether some are their own network, whether some are convening organizations, or whether some are hybrids. It will be important for ONC to offer normative definitions that withstand the test of time. In addition, status as a trusted framework should not be dependent on the entities actual or purported tax status under the IRS code. With the possible exception of 501(c)(3) charitable status, tax status – whether for-profit or non-profit - is not a sufficient barometer of an entity’s interests, motivations, or suitability to succeed.

2. **Provide guardrails for “Chain of Trust” Agreements:** It will be very important for ONC to consider the downstream effect of a trust framework or a “common agreement” on entities beyond the networks themselves. Exchange of health information is usually dependent on a chain of trust among many entities, reflected in agreements between and among a series of entities as information flows from a sender to a receiver. These entities could include multiple networks, providers, EHR companies, aggregators of providers, service providers, etc. This chain of trust is reflected in a series of agreements, including commercial agreements, security agreements, business associate agreements, and potentially other types of agreements. A “common agreement” among networks may include provisions that need to be imposed on entities downstream from the network, which could affect hundreds, if not thousands, of agreements. Accordingly, in considering the terms, and the specificity of the terms, of a “common agreement,” ONC must consider the burden that could be imposed by this downstream effect. To help address this issue, we would suggest that in the “common agreement” ONC suggest principles and guardrails, rather than exact legal language.

In addition, it is our experience that almost all of these agreements – commercial agreements, security agreements, business associate agreements, etc. – are highly negotiated. Negotiation is often a function of market power. ONC must consider whether the terms of a “common agreement,” considered in the context of the downstream effect noted above, will become the “state of the art” adopted and accepted by many, or whether ONC will unintentionally create a situation in which entities with less market power will accept the terms of a common agreement, but entities with market power will insist on their own unique provisions and terms, thus diluting the effect of the ONC guidance and weakening the chain of trust. To help address this issue, we would suggest that in the “common agreement” ONC suggest principles and guardrails, rather than exact legal language.

3. **Preserve Marketplace Flexibility:** Flexibility and responsiveness to change are key components of the governance of health information exchange as technology, policies, and business practices are constantly evolving, and what is current and relevant today may easily become obsolete tomorrow. As technologies, the market, and the regulatory environment evolve, networks and exchanges must have the flexibility to adapt and serve the changing needs of the stakeholders they serve.
4. **Differentiate between “network service agreements from trust networks” and “network-to-network data sharing”:** ONC should clearly differentiate network service agreements, on the one hand,

from trust frameworks for network-to-network data sharing, on the other hand. Network service agreements, for instance, address obligations of data sharing partners who subscribe to a set of services to support a particular data sharing network. A network-to-network trust framework, by contrast, serves a fundamentally different purpose: namely, to enable data sharing among networks in a manner that is technology neutral. We believe that a trust framework to enable data sharing among networks should not be focused on a particular network architecture or shared service. We believe that an interoperability framework should be technology agnostic and not rely upon a single service provider.

5. **Preserve Marketplace Ability to Sustain Multiple (current and new) Governance Organizations:** Some true network-to-network governance organizations currently exist, most notably Carequality and DirectTrust. Substantial investment has been made in these frameworks, and they are successful in advancing interoperability. As authorized by 21st Century Cures, ONC should support existing frameworks, and should strive to not disrupt that which is in place and is working. Surescripts also believes that it is appropriate to have multiple governance organizations. Governance organizations are created to solve specific problems, and it is unlikely that one organization can solve or address all problems, all forms of interoperability, or all market demands. ONC should also seek to create an environment for other governance organizations to be created and grow organically to promote innovation and to address new and evolving market demands as described above (“4. Preserve Marketplace Flexibility”).
6. **Elevate Standards:** As stated above, the network-to-network trust framework and common agreement should elevate the role of standards across the industry, across frameworks, in areas that lend themselves to commonality in order to create trust among health information exchange networks and their participants. Those areas that lend themselves to commonality in our view are:
 - a. identity proofing of participants
 - b. authentication of participants onto a system once properly ID proofed
 - c. matching of individuals
 - d. security standards
 - e. obligations of privacy
 - f. consistency and enforcement of trust obligations throughout the movement of information from point A to point B over multiple networks

3) Responses to ONC’s specific requests for comment

ONC has requested comment on certain specific areas, as follows:

1. **Standardization** - Adhere to industry and federally recognized technical standards, policies, best practices, and procedures.
 - a. Surescripts comment – Adherence to and promulgation of standards developed by Standard Development Organizations (SDOs) is fundamental to the success of interoperability. The process to set standards, however, must be open, transparent, and subject to scrutiny. There is a network of SDOs, accredited by ANSI, that meet these criteria, and ONC should support them and the processes they employ. Our own experience with federal adoption of standards is mixed. While federal recognition and adoption of standards can move the industry forward, we

have found the time that it can take for that recognition to occur given requirements imposed on the federal rule making process can lead to significant delays in recognition, and often the private sector has innovated way ahead of the government regulatory process, but is prevented from executing on that innovation. Federal recognition of technical standards, policies, best practices, and procedures properly must be process orientated, thoughtful, compliant with law, and mindful of the public interest; but it also must be timely in order to both encourage and permit innovation and progress.

2. Transparency - Conduct all exchange openly and transparently.

- a. Surescripts comment – We agree that governance must be conducted openly and transparently. We distinguish this from “all exchange must be open and transparent”; exchange is the result of technological and other advances, and the intellectual property of participants must be ensured. But we fundamentally agree with the concept that the governance process must be open and transparent. As described below, we believe an important reason behind the success of our own network governance model as described in the Appendix is openness and transparency of the process to our participants.

3. Cooperation and Non-Discrimination - Collaborate with stakeholders across the continuum of care to exchange electronic health information, even when a stakeholder may be a business competitor.

- a. Surescripts comment – We agree that interoperability requires cooperation and putting aside parochial interests in the advancement of patient care. As described below, we believe an important reason for the success of our own network governance model is that stakeholders who compete vociferously in the market engaged in an open and transparent process to define the rules of engagement for the exchange of health information to improve patient care and outcomes, and to reduce costs in the healthcare system.

4. Security and Patient Safety - Exchange electronic health information securely and in a manner that promotes patient safety and ensures data integrity.

- a. Surescripts comment – We believe that security and patient safety is the area that lends itself to the greatest area of commonality for trust and a “common agreement.” Security and patient safety are two very different concepts, and should not be treated as the same. A system that is not secure may certainly lead to patient harm, but a secure system does not equate to patient safety. The content of messages, however secure the content may be, must be accurate and actionable to promote patient safety. Surescripts has invested substantial sums not only in its security program, but also in its quality program to ensure the accuracy of message content.

5. Access - Ensure that patients and their caregivers have easy access to their electronic health information.

- a. Surescripts comment – We agree that the technology should provide patients and their caregivers easy access to their health information through the use of APIs and other easy to use tools. Surescripts’ entire purpose is to ensure that providers and clinician caregivers have secure, easy, and efficient access to electronic health information.

6. **Data-Driven Choice** - Exchange multiple records at one time to enable identification and trending of data to lower the cost of care, improve the health of the population, and enable consumer choice.
 - a. Surescripts comment – Surescripts agrees that a goal of interoperability is to empower patients, improve outcomes, and lower costs. Our medication history and NRLS services are examples of services that aggregate information from multiple services and deliver the information to the point of care in one record. By establishing guiding principles for network to network exchange, ONC will help the Nation achieve these goals.

We thank you for the opportunity to provide comment on this important matter.

Sincerely,



Paul Uhrig
Chief Administrative, Legal, & Privacy Officer

Cc: John Fleming, M.D., Deputy Assistant Secretary for Health Technology Reform
Genevieve Morris, Principal Deputy National Coordinator for Health Information Technology
Elise Anthony, J.D., Director of Policy

APPENDIX

Background on the Surescripts network governance approach

We would like to share with ONC some of our principles in managing the governance of our own network. The governance and operation of the Surescripts network is grounded in certain core principles aligned with the areas upon which ONC has asked for comment:

- **Efficiency and Better Healthcare.** The result is lower costs, improved safety, and higher quality decision making.
- **Transparency and Neutrality.** Surescripts' network is designed to support patient choice of pharmacy and provider choice of therapy.
- **Certification and Interoperability.** Surescripts implements and consistently applies objective and defensible standards for certification and implementation of technology systems that promote an open, neutral network and interoperability.
- **Quality.** Surescripts seeks to improve the end-to-end quality of the entire e-prescribing process by working with customers and other stakeholders to avert potential issues in order to promote patient safety and e-prescribing effectiveness. In addition, we have quality programs in place and automated systems that monitor the quality of 1.5 billion scripts annually to drive continual improvements both at the transactional and clinical quality level to reduce errors and inefficiencies that risk patient safety and cost the industry hundreds of millions of dollars annually.
- **Education and a Collaborative Environment.** Surescripts works throughout the healthcare community to develop educational programs, quality initiatives, and certification standards, and to promote dialogue, to support the future growth of interoperability and health information technology.

Core to each of these principles are the concepts of privacy and security – the imperative to safeguard the privacy and security of information that is transmitted across the network.

Core to Surescripts' governance is:

- **Industry Stakeholder Participation and Feedback:** Stakeholder feedback is a vital and necessary component of governing and operating a trust framework for the exchange of health information. Feedback is required not only from the participants, but also others impacted by the network, such as consumers (*i.e.*, patients) and federal and state governments.
- **Transparency:** Clear and transparent communications with respect to the formulation and execution of operational functionality and expectations are the basis of creating trust in the governance of the network.
- **Standards Consistency:** Consistent and uniform standards based on feedback and input from industry stakeholders is crucial for intermediaries in exchange—whether the standard relates to message content (such as NCPDP Script) or organization-wide policies (such as security accreditation).

- **Flexibility and Responsiveness to Change:** Flexibility and responsiveness to change are key components of governing a network as technology is constantly evolving and what is current and relevant today may easily become obsolete tomorrow. As technologies and the regulatory environment evolve, networks and exchanges must have the flexibility to adapt and serve the changing needs of the stakeholders it serves.
- **Enforcement:** Enforcement of the rules of participation in the network is a key component to ensuring the continued interoperability and trust framework of the network. Enforcement efforts are utilized throughout our organization from contractually-required measures, certification and implementation services, our network operations guide, continued customer support and issue resolution, and our audit compliance function.

In our experience, the foregoing factors are interrelated and co-dependent underlying features that are essential to the successful governance and operation of our network to exchange health information.

Surescripts' governance model consists of a web of contractual chains of trust and governance, certification and implementation requirements, on-going compliance and enforcement activities, and continued flexibility and responsiveness to industry needs. This governance model has served us well with promoting interoperability and quality of communications across the Surescripts network.

At the heart of the governance of a network are the rules of participation – in short:

1. Who can connect to, and transact business on, the network;
2. What are the prerequisites and conditions for connectivity, including, but certainly not limited to, security and privacy measures and processes in place
3. How – what are the standards by which – Participants connect to the network;
4. What message types can be transmitted; and
5. What are the conditions of continued participation?

The Surescripts governance model has processes and procedures to:

1. Establish the rules of participation;
2. Disseminate the rules of participation;
3. Require compliance with the rules of participation;
4. Monitor compliance with the rules of participation; and
5. Take enforcement action in the event of a breach of a rule of participation.

As Surescripts constructed its network to facilitate health information exchange, we began with our principles – we should operate a secure and neutral network in which all stakeholders meeting our certification and implementation requirements could participate with the assurance that their information would be transmitted accurately, timely, and securely. We ensure the security of our network by adhering to our policies and procedures (which are audited and accredited by multiple third parties). We also require secure connectivity by Participants through authentication of Participants (each are granted a unique identifier and password) and encryption of data in transit.

Surescripts has played a leadership role across the industry in establishing a governance mechanism and trust framework for a nation-wide interoperability infrastructure, serving as an expert resource to assist with national and state programs and initiatives, disseminating best practices, and providing education, programs, and resources to improve the safety and efficiency of electronic exchange.

Establishing the rules of participation in an open and transparent manner is critical. Surescripts utilizes industry-developed standards as the basis for creating our certification and implementation guides for Participants to employ when operating on our network. Our guides are developed based on published standards including National Council of Prescription Drug Programs (“NCPDP”), Health Level Seven (“HL7”), Accredited Standards Committee (“ASC”) X12 for various message types so that the messages are transacted between Participants in the same format.

Surescripts takes an active role in providing feedback to Standards Development Organizations (“SDOs”). Standards development is typically an open and collaborative process amongst a wide expanse of stakeholders in the health information technology industry—ranging from prescribers, pharmacies, PBMs, and software vendors. From its inception, Surescripts recognized the importance in collaborating and utilizing such standards and, as such, became and remains active with several SDOs including but not limited to, the NCPDP, HL7, ASC X12, American National Standards Institute (“ANSI”), and the Health Information Technology Standards Panel (“HITSP”).

We engage Participants and other stakeholders through multiple outlets including our annual Customer Forum, periodic Participant calls, Participant questionnaires and surveys, and our advisory councils. And every network participant is assigned an account manager that serves as their point of contact. Participant input is a critical and required component for Surescripts finalizing current versions of our rules of participation—our guides.

In addition the annual Customer Forums, we also receive input via our quarterly Participant calls. These calls are open to all Participants and cover a wide range of topics, with opportunities for Participants to pose questions, review changes to any rules of participation, and provide feedback to Surescripts in a timely manner. The calls cover a wide range of governance topics from legal/regulatory updates to technical and product developments and review of feedback (received as a result of questions, reports, or Surescripts-conducted surveys).

Once the rules of participation are vetted through the various open and collaborative processes described above, Surescripts establishes and memorializes the “rules of the road” in our certification, implementation, and network operation guides. Once established, Surescripts disseminates its rules of participation to all Participants on our network.

Our certification process tests each system connecting to our network to ensure that all Participants appropriately comply with the guidelines and requirements set forth in our implementation guides and our qualitative application requirements. All certification requirements must be met -- regardless of the identity of the Participant and other relationships in the industry -- to ensure neutrality and quality. All certification decisions are made by a committee of representatives from different company departments to determine, based on the certification team recommendations, whether certification should be granted and to provide appellate processes to ensure due process to all parties seeking to become a Participant on our network.

Prior to providing access to our network and as an overall wrapper for our trust infrastructure, all Participants must enter into a services agreement, including a business associate agreement where appropriate, which establishes the legal chain of trust we have developed to ensure and protect all impacted parties. As part of this contractual chain of trust, Participants must agree to certain requirements, on behalf of themselves and downstream entities with whom they provide services. We believe that this process ensures that our network is governed properly and in a trusted environment without unduly burdening related and downstream parties with multiple contractual relationships (similar to how the proposed HIPAA regulations have structured business associate relationships). For example, we require that all vendors agree to certain core principles including, but not limited to:

- Authenticate end-users of the Participant's system that such end-user is duly authorized to receive and transmit protected health information under all applicable law;
- Prohibit advertising and commercial messages through the network, permit and protect patient and physician choice of pharmacy and medication therapy;
- Limit uses and disclosures of the data transmitted via the Surescripts network to the uses and disclosures to provide the services under the agreement only;¹
- No modifications shall be made to the software (either by the Participant or any user of the product) as certified without first providing advance written notice to Surescripts and being re-certified, if required;
- Continued compliance in accordance with all Surescripts' guides (the certification guide, implementation guide, etc.); and
- Compliance with applicable state and federal laws including, but not limited to, such laws and regulations governing privacy, security of information, and breaches of information.

Surescripts requires compliance with our rules of participation not only through our contractual relationships and certification processes, but also through our ongoing compliance function. We believe that compliance is an integral part of Surescripts' work and the value we bring to the e-prescribing industry. The Certification Policy and Compliance function is focused on the following core Foundational and Guiding principles:

- **Objectivity:** As defined by the following Foundational Principles:
 - Patient Safety / Quality of the end-to-end Surescripts network;
 - Efficiency of the end-to-end Surescripts network; and
 - Cost effectiveness of the Surescripts network.
- **Neutrality:** Requirements that are based on furthering interoperability as a whole.
- **Transparency:** Requirements are published and provided to Participants during implementation. Participants can view the requirements process.
- **Auditability:** Requirements are based on testable events.
- **Legality:** Requirements are aligned with government mandates, laws, and regulations.

Patient safety, end-to-end reliability, efficiency, and quality and reliability in message transmission are primary concerns of Surescripts. As such, special emphasis is placed on reviewing previously certified applications to validate that Participants continually comply with our requirements.

¹ Except that this restriction does not govern the use of information or data once it has become part of a patient's permanent medical record.

Surescripts' compliance team conducts both regularly scheduled and ad-hoc compliance checks as needed on all the Participants on our network. Ad-hoc compliance checks are initiated based on issues identified during daily operational monitoring of the Surescripts network and issues brought to Surescripts' attention by others. Regularly-scheduled compliance checks are based on pre-established criteria to determine the Participant to be audited. The compliance team internally determines the scope of the compliance check and notifies the impacted Participant. Compliance checks may focus on any number of requirements from our implementation and certification requirements, our network operations guide, the Participants' contract with Surescripts, and the like.

Depending on the scope of the compliance check, Surescripts may review transaction audit logs and error notifications and transaction formats for all message types and validate that the application requirements are being met and that the Participant is meeting the commercial messaging rules. Any additional issues discovered during a compliance check will also be reviewed and addressed.

Components of a compliance check include:

- Execution of compliance checks;
- Creation of Participant compliance reports;
- Out of compliance notification;
- Development of remediation plans;
- Distribution of Participant Certificates of Compliance;
- Execution of a decertification process and removal from the Surescripts network based on Participant's failure to meet a remediation plan; and
- Execution of a reinstatement process on the Surescripts network when all compliance requirements are met.

In the event that Surescripts determines that a Participant breached a rule of participation, then Surescripts will take appropriate action. If the breach does not implicate patient safety, privacy, or security issues, then Surescripts will work with the Participant to develop an appropriate remediation plan and time frame for coming into compliance with that plan. Certain remediation plans will require a Participant's system to undergo a recertification process to resume operating on our network. If the Participant fails to execute on the remediation plan or does not pass the recertification process, the Participant will be de-certified and cannot transact on our network.

Surescripts specifically reserves the right to immediately suspend services and decertify a Participant under certain circumstances. The decision to take this action generally depends upon whether a patient safety, privacy, or security issue is involved, whether the Participant is unresponsive or evasive, and other such types of behavior. Surescripts has designed an internal process to immediately and swiftly address the any potential patient safety, privacy, or security issues. After decertification for any reason, a Participant must go through Surescripts reinstatement process (including a full certification of their system) to transact on our network.

We hope that this description of the governance of our own network is helpful to ONC as it continues on its journey to support a network-to-network trust framework and establish a "common agreement."