surescripts

May 6, 2021

The Honorable Xavier Becerra
Acting Director Robinsue Frohboese
U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement NPRM, RIN 0945–AA00,
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Becerra and Acting Director Frohboese:

We appreciate the opportunity to submit comments on the "Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement" (Proposed Rule) issued by the Department of Health and Human Services (HHS) Office of Civil Rights (OCR).

Surescripts serves the nation with the most trusted and capable health information network, built to increase patient safety, lower costs, and ensure quality care. Founded in 2001 to enable electronic prescribing, today we are drawing on that experience to exchange many other kinds of actionable patient intelligence—including medication histories, prior authorizations, and other complex clinical messages. The Surescripts Network Alliance includes virtually all electronic health record (EHR) vendors, pharmacy benefit managers (PBMs), pharmacies and clinicians, plus health plans, long-term and post-acute care organizations and specialty hubs and specialty pharmacy organizations. In 2020, we transmitted 17.5 billion secure health data transactions—including 1.91 billion e-prescriptions and 1.95 billion medication histories—and connected 2 million healthcare professionals, who rely on a master patient index covering 95% of the U.S. population. Additional information about Surescripts is available at surescripts.com. For more data on how we're advancing nationwide health information exchange, please see our National Progress Report, available at https://surescripts.com/report

GENERAL COMMENTS:
Removing Regulatory Obstacles to Data Exchange for Case Management and Care Coordination

Surescripts supports HHS's proposal to clarify that case management and care coordination are among the uses and disclosures exempt from the minimum necessary requirement. Health plans and their Business Associates are increasingly becoming an essential component of *treatment* for high-risk beneficiaries (including beneficiaries at risk of opioid dependence) due to health plans' development and use of sophisticated population health tools that allow for the targeted provision of care coordination and case management.

2550 SOUTH CLARK STREET
SUITE 1000
ARLINGTON, VA 22202
T: 703.921.2121 F: 703.921.2191

920 2ND AVENUE SOUTH
MINNEAPOLIS, MN 55402
T: 866.267.9482 F: 651.855.3001

SURESCRIPTS.COM

As an example, Surescripts offers a population health product to health care providers and organizations designed to assist providers' participation in value-based payment initiatives (e.g., ACOs) that enables them to better manage high-risk patient groups within their patient panels, including patients at risk of opioid dependence. The information provided by this product would also benefit health plans by helping them identify beneficiaries who have certain medical conditions and may be at risk of non-compliance with recommended treatment. The health plan would then provide case management and care coordination support to the beneficiaries identified through the tool. The proposed rule would address any uncertainty that PHI can be shared for such purposes.

<u>Recommendation #1</u>: We commend HHS's proposal to include case management and care coordination in the list of uses and disclosures exempted from the minimum necessary requirement. This clarification will remove perceived barriers to sharing essential information for these critical purposes.

Supporting disclosures of PHI when Needed to Help Individuals Experiencing Substance Use Disorder (Including Opioid Use Disorder), Serious Mental Illness, and in Emergency Circumstances

Surescripts supports HHS' proposal to replace "the exercise of professional judgment" HIPAA standard with one permitting certain disclosures based on a "good faith belief"' about an individual's best interests. This change should better facilitate sharing of PHI among family members and caregivers in times of emergencies. Surescripts has experience assisting victims and their families during past natural disasters when access to prescription drugs and medication history was lost and we believe the proposed rule will do much to support individuals in future disaster situations.

Regarding disclosures for patients experiencing mental health illness or Substance Use Disorder (SUD), we urge HHS to accelerate efforts to align 42 CFR Part 2 (Part 2 regulations) with HIPAA.
Current Part 2 regulations create a significant barrier to care for those patients and should be modernized.

<u>Recommendation #2</u>: We support the proposal to amend the standard to permit disclosures based on a "good faith belief" about an individual's best interests and we urge HHS to accelerate efforts to align Part 2 regulations with HIPAA.

Definition of the term "personal health application" (PHA) for purposes of expanding an individual's access rights to include transmitting an electronic copy of PHI to or through a PHA.

This provision of the proposed rule signals a reversal of previous HHS policy and fails to consider the significant privacy risks associated with redefining the term "personal health application." Surescripts urges HHS to reconsider this change in course and to acknowledge that disclosures to PHA constitute disclosures to a third party which require that appropriate privacy protections be applied.

In the absence of comprehensive privacy legislation to address health information not held by HIPAA-covered entities, HHS should require PHA vendors to meet minimum privacy and security standards before

they may offer their applications to individuals, and to show that they do so through certification by independent certifying organization.

Recommendation #3: HHS should continue to treat transmission of PHI through a PHA as a disclosure to a third party, consistent with its approach in the ONC and CMS Interoperability Final Rules. HHS should permit such transmission to third-party apps not covered by HIPAA only when the third-party vendor has been certified by an independent organization as meeting minimum privacy and security standards.

Accounting for Disclosures

HHS has signaled its intention to engage in future rulemaking for the purpose of implementing a requirement to include disclosures by a covered entity for treatment, payment, and health care operations through an EHR in an accounting for disclosures. We believe that such an expansion is likely to result in a significant increase in costs and burdens for providers without creating a true benefit to patients.

Surescripts is a member of the Confidentiality Coalition which has been working on this issue for the past twelve years. Several years ago, the Coalition performed a survey of members to determine how often they receive accounting of disclosures requests. Based on the members' experience, patients are not frequently requesting an accounting. To illustrate, one health system received only 25 such requests over a 14-year period. Requiring covered entities to adopt special, expensive technology - that has yet to be developed and is not required in the most recent edition of certified EHR technology that providers are required to use in Medicare's Promoting Interoperability Program – in order to accommodate a very small number of requests would increase providers' regulatory burdens and yield little, if any, patient benefit.

Patients who do ask for an accounting of disclosures under current law often reverse course when they learn what an accounting of disclosures report would contain. Instead, what these patients typically are seeking is an investigation into whether a specific user of the EHR inappropriately viewed their record. Patients already have a right to understand how their information is used for treatment, payment and healthcare operations. Patients also have a right to know if their information has been used inappropriately through breach notification provisions. Patients additionally have recourse through the complaint process if they believe their PHI has been misused. A new requirement for Covered Entities to use EHRs to provide an accounting of disclosures would provide little or no benefit for patients while increasing burdens on health care providers.

Recommendation #4: Surescripts urges HHS to reverse course on its plan to modify the accounting for disclosures provision at 45 C.F.R. § 164.528.

COMMENTS AND RESPONSES TO SPECIFIC QUESTIONS IN THE PROPOSED RULE'S SECTION B: REDUCING IDENTITY VERIFICATION BURDEN FOR INDIVIDUALS EXERCISING THE RIGHT OF ACCESS

1. **"The Department assumes that a covered entity holding records of an individual in an EHR has necessarily established a treatment relationship with such individual, and therefore, imposing additional verification requirements is unnecessary. The Department seeks comments on this assumption."**

Surescripts Response: Although this assumption for covered entities may be correct, the same assumption may not necessarily flow down to strictly business-to-business entities like Surescripts, which operates as a business associate of covered entities, but does not establish any direct patient relationships. Despite the lack of direct relationships with patients, certain access requirements of the covered entities may flow down and similarly require verification of identity and authority of an individual for certain requests, such as the individuals' right to opt out of a Health Information Exchange. Due to the absence of direct patient relationships, the notary requirement is essential in appropriately verifying the identity of a patient before taking any action. For example, the notary confirmation can prevent a bad actor with demographic details of an individual from acting on behalf of that individual. An unauthorized opt out may affect a provider's ability to make informed care decisions, as the unauthorized opt out would result in the individuals' information no longer being available to the care provider.

2. **"The Department recognizes that due to the variety of circumstances of individuals and entities, a given measure to complete identity verification or request access, such as using an online portal, may be convenient for some individuals and burdensome for others, and practicable for some entities but not for others. Due to this variability, the Department does not propose to require that covered entities implement any measure, nor require covered entities to analyze and adopt the least burdensome measure possible for each individual. Rather, the Department would expect covered entities to avoid imposing measures that would require unnecessary effort or expense by an individual and to provide individuals with some flexibility (e.g., by accepting verification and access requests by more than one practicable measure)."**

Surescripts Response: We believe a notary that confirms the identity and authority is the least burdensome measure for individuals for entities like Surescripts, where no direct relationship exists. This method allows confirmation that actions are being made on behalf of the correct individual and prevents potential unintended adverse consequences. Although obtaining notary may have been considered "burdensome" in the past, one of the advancements during COVID is the advent of remote and electronic notarization methods that some states have instituted, thereby decreasing such burdens to individuals.

3. **"Unreasonable measures would include requiring individuals to obtain notarization of requests to exercise their Privacy Rule rights and requiring individuals to provide proof of identity in person when a more convenient method for remote verification is practicable for the covered entity. The Department would consider the application of the practicability standard for verification measures to encompass considerations related to an entity's fulfillment of its Security Rule obligations including its size, complexity and capabilities; its technical infrastructure, hardware,**

and software security capabilities; the costs of security measures related to verification and implementing measures that may be more convenient for individuals; and the probability and criticality of potential risks to ePHI in the covered entity's systems."

Surescripts Response: As discussed above, the assumption regarding a more practicable and/or more convenient method is based on the premise that a covered entity has a direct treatment relationship with the individual patient; however, that assumption fails when applied to a business-to-business model business associate, like Surescripts, without the same direct patient relationship. Additionally, it is unclear from the NPRM what a "more convenient" and "practical" method for remote verification would be for business associate entities like Surescripts. Without more clarity and understanding of what such alternative methods would look like, it is difficult for us to agree with the OCR's assumption or proposal. Furthermore, if notarization method for verification is prohibited, the individual patient would most likely be obligated to provide sensitive personal information to another third-party vendor, which only presents additional security risk and may contradict an individual's desire to reduce the patient's electronic footprint. For example, a patient desiring to opt out of our services may now be required to share their information with another third party to do so. With remote and electronic notarization options these days, it seems that individuals would have more control over their information by simply utilizing a notary service than relying on third parties to perform those desired requests. Contrary to OCR's assumption, verifying the identity of an individual patient via notary services is probably the most protective method for the individual to affirm their authority and identity without further disclosing personal information.

3(a). Please describe any circumstances in which individuals have faced verification barriers to exercising their Privacy Rule rights, as well as examples of verification measures that should be encouraged as convenient and practicable, in comparison to those that should be prohibited as per se unreasonable. Please also describe any circumstances related to unreasonable verification measures imposed on third parties to whom an individual directs a copy of PHI.

Surescripts Response: For the reasons mentioned above, we respectfully disagree with OCR's assumption that notarization verification is unreasonable. As discussed above, contrary to OCR's assumption, it appears to be inconsistent, and potentially more inconvenient, if a patient is forced to go through a third-party verification vendor to remove their information from our services for the purpose of reducing their electronic and online presence.

3(b). What verification standard should apply when a covered health care provider or health plan submits an individual's access request to another covered health care provider or health plan? Specifically, should the covered entity that holds the requested PHI be required to verify the identity and authority of the covered entity that submitted the request, but be permitted to rely on the requesting entity's verification of the identity of the individual (or personal representative)?

Surescripts Response: Yes; covered entities that hold the requested PHI should be the party obligated and required to verify the identity and authority of the requestor. Certain business associate entities like Surescripts do not maintain a patient's PHI, but rather transmit the PHI at the direction of the covered entity. Therefore, rather than having such business associates reverify the identity and authority of the requestor, such business associates should be able to rely on the requesting covered entity's identity and authority of the individual (or personal representative), if the covered entity has a direct relationship with the individual patient (or personal representative).

3(c). Whether the proposal would support individuals' access rights by reducing the verification burdens on individuals, and any potential unintended adverse consequences.

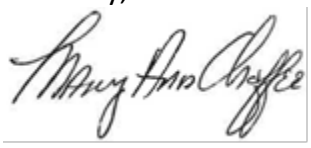
Surescripts Response: We respectfully disagree with OCR's proposal. Contrary, forbidding the use of notary as a method does not support the individual's right to "access" their information for entities with no direct relationship with individual. Again, what are the more "convenient" or "practical" methods of verifying the identity and authorization of an individual requesting sensitive information? From experience, we have identified that lesser forms of verification (i.e., electronic images of photo I.D.s, scanned or otherwise) can easily be manipulated. Also, with phishing attacks and hacking of personal accounts being prevalent and widespread, simply asking individuals to verify their identity via providing certain information (i.e., DOB; address; SSN) is no longer sufficient. These alternative methods of verifying the identity and authority of individuals, verbally or via email, have serious and unintended consequences.

Aside from disclosing PHI to unauthorized individuals who are posing as authorized individuals, lesser forms of verification may invariably allow unauthorized requestors to be opt out of services, resulting in potential unintended adverse medical events to the patient requiring such services.

Also, as mentioned above, the alternate method of using a 3rd party vendor would result in more of the patient's information being provided to another entity's information system solely for the efforts of verifying an identity, which a notary provides for with a reduced electronic and online footprint.

Once again, we thank you for the opportunity to share our recommendations on ways to strengthen the HIPAA rule. We look forward to working on ways HIT can improve care coordination and support value-based treatment.

Sincerely,



Mary Ann Chaffee
Vice President
Policy and Federal Affairs