



Government & External Affairs
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May 5, 2021

Xavier Becerra, Secretary
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

RE: HHS-OCR-0945-AA00, Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement published in Vol. 86 (12) Federal Register 6446-6538 on January 21, 2021.

Submitted electronically via email to <http://www.regulations.gov>

Dear Secretary Becerra:

UnityPoint Health appreciates the opportunity to provide input in response to the Department of Health and Human Services' notice of proposed rulemaking to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement. With more than 400 physician clinics, 40 hospitals, 16 home health locations, 7 Community Mental Health Centers and 4 accredited colleges, UnityPoint Health is one of the nation's most integrated health care systems. Our more than 32,000 employees provide care throughout Iowa, western Illinois, and southern Wisconsin. UnityPoint Health hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 7.9 million patient visits annually.

A. Individual Right of Access (45 CFR 164.524)

HHS proposes to amend the Privacy Rule to strengthen the individual right of access and to remove barriers that may limit or discourage coordinated care or case management among covered entities and individuals, or otherwise impose regulatory burdens. And consistent with Ciox v. Azar, HHS proposes to modify aspects of the individual's right under the Privacy Rule to direct a covered entity to transmit a copy of PHI to a third party. Specifically, HHS adds definitions for "Electronic Health Record" or EHR and "Personal Health Application"; strengthens the access right to inspect and obtain copies of PHI; modifies the implementation requirements for requests for access and timely action in response to requests for access; addresses the form of access; addressed the individual access right to direct copies of PHI to third parties; adjusts permitted fees for access to PHI and ePHI; provides notice of access and authorization fees; and adopts a technical Change for required business associate disclosures of PHI.

Request for Comments

- a. *Whether the Department's proposed definition of EHR is too broad, given the context of the HITECH Act,*

such that the definition should be limited to clinical and demographic information concerning the individual.

Comment: To ensure consistency with the proposed EHR definition, UPH would suggest that the HITECH Act definition located in part 164 definition section be similarly updated.

- b. Whether an electronic record can only be an EHR if it is created or maintained by a health care provider, or whether there are circumstances in which a health plan would create or maintain an EHR.*

Comment: It is our understanding that a health plan could have an EHR as part of the work that health plans perform for care coordination and case management of covered individuals. If health plans employ staff, we would interpretate that the definition of clinicians would apply to these staff as well.

- c. Whether the Department should instead define EHRs to align with the scope of paragraphs (1)(i) and (2) of the definition of designated record set.*

Comment: It is our interpretation that a covered entity's designated record set may include paper and electronic records, and therefore, the definition of an EHR as a designated record set would inherently extend to paper records.

- f. Should "health care clinicians and staff" be interpreted to mean all workforce members of a covered health care provider? What are the benefits or adverse consequences of such an interpretation? Does the same interpretation apply regardless of whether the provider has a direct treatment relationship with individuals, and why or why not?*

Comment: We urge the adoption of definitions which are specific to assist with implementation and compliance efforts. UPH has concerns that the addition of "and staff" is too expansive and may create ambiguity in application. In our integrated health care system, staff would include personnel providing support services such as dietary, housekeeping, patient experience advisors and the like, who all may document within the EHR. We are also concerned that the definition of "health care" continues to evolve and may impact this interpretation over time.

- i. Should the definition of EHR for Privacy Rule purposes be aligned with other Department authorities or programs related to electronic health information? If so, which ones and for what purposes?*

Comment: Yes, UPH supports the harmonization of definitions across regulations. The definition of EHR for Privacy Rule purposes should be aligned within all regulations related to electronic health information with particular attention to Centers for Medicare and Medicaid Services (CMS) authorities and programs.

- l. State laws or other known legal restrictions that might affect the ability of individuals to take photos of or otherwise capture copies of their PHI in a designated record set.*

Comment: UPH has several practical concerns related to the ability of individuals to take photos of or otherwise capture PHI within a designated record set. First, the innate format / structure of an EHR is often not conducive to photographic capture without compromising other information outside an individual's right of access. Specifically, EHRs are potentially unable to remove another patient's identifiable information from view to allow an individual to capture a photo of their information alone. This is a particular concern if the individual is video recording computer screens as patient records are accessed when navigating multiple EHR views.

We also have concerns with the preamble’s suggestion that individuals could ask to inspect their records during a medical visit. This places a burden on the provider who has scheduled the patient visit as the records may be incomplete at the time of the visit. Allowing real-time access does not give providers time to have a fully completed note, and not all information may be available to the individual at that time. It is common that a provider may not close out a record until additional information is obtained (e.g. pathology results, radiology results, etc.). There may be unintended consequences to allowing an individual to capture an image of a record that is not complete “dated, timed & signed”, including placing an individual at risk should they act on incomplete documentation.

Additionally, we have concerns related to image capture technology and the risk that images may be intentionally or unintentionally altered. For instance, if a photo is converted to a word processing application, there is a risk that text may not be transcribed accurately.

- n. *Whether a time limit shorter than 15 calendar days for a covered entity to submit, or respond to, an individual’s access request would be appropriate. The Department seeks comment on time limits for covered entities to respond to access requests, requests to direct electronic copies of PHI in an EHR to a third party, and requests to submit a request to another provider on behalf of the individual. The Department welcomes data on the burdens and benefits such a time limit would impose.*

Comment: UPH requests that the Department maintain the current 30-day timeframe for responding to access requests. Reducing this timeframe to 15 days fails to take into account that not all PHI being requested is contained with an EHR, or even a single EHR. Requests may require pulling paper and legacy system PHI, some of which are stored in off-site locations. Responding to requests is not as simple as running a report, and the complexity of the request grows with multiple EHRs, legacy system PHI, and extended periods of PHI records being requested. In general, the current 30-day period to complete access requests is reasonable for these complex requests, compatible with an individual’s desire to have a complete record, and aligned with the Medicare Conditions of Participation.

- o. *Whether a covered health care provider should be required to inform an individual who requests that PHI be transmitted to the individual’s personal health application of the privacy and security risks of transmitting PHI to an entity that is not covered by the HIPAA Rules. What are the benefits or burdens of different approaches? For example: Accepting the individual’s judgment without requiring covered entities to provide education, notice, or warning; requiring a covered entity to provide a warning verbally and/or electronically at the time the individual requests transmission of PHI to a personal health application; providing education about the application developer’s privacy and security policies and practices through an automated attestation and warning process; or adding information about risks to PHI disclosed to a personal health application in the covered entity’s NPP.*

Comment: UPH recommends that notification of risk should be provided by the personal health application an individual chooses to use. If an individual is asking for information to be shared, this notification burden should not shift to the covered entity to educate the individual. Instead since the individual is assuming such risk based on the personal health application for which they choose to communicate, the application developer should be required to inform the individual of any privacy and security risks. If notification will be required, we would encourage the Department to provide standard content / text for this notice.

- q. *Whether the Department should specify in regulatory text that if a Requestor-Recipient discusses the request*

with the individual (e.g., to clarify the request or explain how the request could be changed to be more useful in meeting the individual’s health needs), such discussion does not extend the time limit for submitting the request, and the benefits or drawbacks of such a provision.

Comment: UPH does not support regulatory text prohibiting time period extension as a result of Requestor-Recipient discussions. Covered entities are dependent upon individuals providing information necessary to release records in a timely manner. If clarification is sought, covered entities are dependent upon individuals to provide clarification and/or timely response to a clarification request. A blanket statement that prohibits response extension may have unintended consequences. Alternatively, UPH would instead support language that would place a pause on the response time period upon request for a Requestor-Recipient discussion until the discussion occurs and the individual clarifies and, in some cases, provides the necessary information as applicable.

- s. *Whether and how a covered entity should be required to implement a policy for prioritizing urgent or otherwise high priority access requests, so as to minimize the use of the 15-calendar-day extension. Would there be unintended adverse consequences of such a requirement—e.g., would covered entities begin to require individuals to state the purposes for their access requests even though the Privacy Rule does not make the right of access contingent on the purpose for the request? If a covered entity did impose such a requirement, would this constitute an unreasonable measure that impedes the individual from obtaining access?*

Comment: Ultimately, it should be noted that covered entities use good faith and best judgment when responding to access requests. In general, policy making requirements should facilitate discretion and flexibility in order to best meet the needs of individuals. UPH does not support covered entity mandates requiring the specific development and adoption of policies that tier access requests. The details of these policies should be left to the discretion of the covered entities, and detailing requirements may have the unintended consequence of tying hands as opposed to facilitating action. Implementing a comprehensive policy would be difficult as that would entail covered entities to account for all and varied request scenarios.

That said, if covered entities choose to adopt policies to tier requests on a voluntary basis, it would be reasonable to prioritize based on the reason for the request. For instance, priority could be based on categories (e.g., continuity of care, billing dispute, self, disability request, etc.). Requesting a stated purpose does not necessarily equate to interfering with the right of access, only the relative timing for a response. For those individuals who choose not to provide a stated purpose for the request, covered entities are left to infer request type based on best judgment, such as where the records are directed to be sent.

- t. *Any benefits or drawbacks of the proposal to require a covered entity to act on an oral access request to either direct an electronic copy of PHI in an EHR to a third party or direct a covered entity to submit such a request, provided the oral communication is clear, conspicuous, and specific.*

Comment: There are both benefits and drawbacks. In terms of benefits, oral requests do allow for more timely responses to requests. Often times covered entity staff are able to send electronic records to individuals while they are on the phone to them, which allows a dialogue and questions to occur in real-time creating a more efficient process. As for drawbacks, verifying the identity of the caller is a growing concern. Another drawback relates to the potential for directing information to an incorrect third party. As referenced in our comment to “v.” below, oral requests must also provide specific information of the third

party, including name and full address. Further clarity on the definition of “specific” would be appreciated.

If adopted, UPH would urge the Department to consider liability protections for covered entities relying in good faith that the caller is the individual representing themselves to be based upon reasonable inquiry as to patient’s identity.

- v. *“Clear, conspicuous, and specific” is a statutory standard that the Department proposes to use in place of the existing regulatory requirement that the request be signed and in writing and clearly identify the designated third party. The Department requests comment on how to interpret the phrase “clear, conspicuous, and specific,” including when the request is verbal.*

Comment: This definition is important to prevent undue burdens on covered entities. UPH urges a standard that requires the individual to provide the specific information of the third party (e.g., name, full address, etc.). Covered entities should not be expected to perform a Google search or additional fact finding if the individual only provides a third party name / facility. We would suggest that the Department define the term “specific” as its meaning is unclear.

- w. *Whether the Department should specify any basis for a Requester-Recipient to deny an individual’s request to submit an access request to a Discloser, for example, if the requested disclosure is prohibited by state or other law or if the Requester-Recipient already has the information.*

Comment: UPH would support specifying a denial of an access request when the information is not already available as a result of the Requester-Recipient relationship.

- x. *Whether there are certain types of individual requests to submit an access request to a Discloser that would place an undue burden on the Requester-Recipient, such as submitting large numbers of requests to multiple Disclosers, or other factors affecting the potential burden on or benefit to a Requester-Recipient.*

Comment: Among the types of individual requests that place an undue burden are frequent requests for “any and all records”. Often, once the individual is educated that a record abstract provides the information necessary to meet the needs of the requestor and/or recipient, the requestor and/or recipient is satisfied. For example, individuals may ask to have their entire records sent but the provider may only want a more recent history and physical.

- z. *Information from individuals and covered entities about how covered entities currently respond to “imperfect” requests to send PHI to a third party (e.g., requesting information that is not part of the access right; all the necessary elements of a right of access request are not included when an individual directs electronic PHI in an EHR to a designated third party; invalid authorizations, etc.) and the efforts made by covered entities to enhance individuals’ abilities to efficiently obtain the requested information.*

Comment: Crafting regulations sensitive to responding to “imperfect” requests is an important area, and UPH would urge the Department to enable flexibility and promote dialogue that enable the Requester and Recipient to reach agreement. Currently in order to comply with the Patient Authorization requirements, UPH requires either verbal or written communication with the individual requester on imperfect or incomplete requests, which adds a step to the process and ultimately delays the response.

- bb. *Should the Privacy Rule prohibit covered entities from charging fees for copies of PHI when requested by certain categories of individuals (e.g., Medicaid beneficiaries or applicants for or recipients of Social Security*

Disability Insurance (SSDI)), or when the copies are directed to particular types of entities (e.g., entities conducting clinical research)?

Comment: It is the individual requestor who receives the benefit of the copies. As such, the burden should not be placed on covered entities to bear the cost associated with such requests. In addition, this prohibition may disproportionately impact covered entities serving a disproportionate share of vulnerable populations.

- cc. *Whether the Privacy Rule should prohibit covered entities from denying requests to exercise the right of access to copies of PHI when the individual is unable to pay the access fee. If so, how should a covered entity determine when an individual is unable to pay?*

Comment: UPH agrees that access should not be denied to an individual for their inability to pay for their own record for their own use. Covered entities should have the discretion to determine if the individual qualifies for such records free of charge. In doing so, discretion should include the provision of records in the most cost efficient solution as agreed upon with the individual.

- dd. *The fees (if any) that covered entities currently charge when sending records to another provider or covered entity at the request of an individual.*

Comment: UPH does not currently charge for records needed for continuing care when requested by the individual or an entity authorized by the individual.

- ee. *What fees, if any, are charged for disclosures among covered entities made at the request of the entities?*

Comment: UPH does not currently charge for records needed for continuing care when requested by other covered entities.

- ff. *How covered entities currently treat access requests that involve converting non-electronic PHI into an electronic format, the fees that are charged for such requests, and how that compares to fees charged for similar requests for copies of PHI made by a third party with an individual's valid authorization.*

Comment: At UPH, if necessary, paper records are scanned to a PDF to make them electronic. We do not charge for this conversion.

- gg. *How the proposals to narrow the access right to direct PHI to third parties to electronic copies of PHI in an EHR will affect fees for copies of PHI.*

Comment: While this doesn't necessarily affect the charge for fees, we anticipate that there may be confusion on split billing, such as when an EHR portion of requested PHI is billed one way and the non-electronic PHI portion is billed differently.

As for fee setting, we would encourage the Department to not impose fee limits for requests directed to third parties outside of care coordination/case management purposes. For example, attorneys will use an individual-directed request to obtain records for a lawsuit, and not for continuity of care. It is our experience that a majority of requests for "any and all" records are related to legal requests – these are large record requests, are not necessarily targeted and pull unnecessary records, and require significant work effort. By continuing to charge for attorney requests, attorneys are more sensitive to the overall cost and target requests to avoid an unnecessary volume of records as well as multiple requests for the same records.

In terms of operational implications, the Privacy Rule does not prohibit covered entities from requiring individuals to pay an upfront fee for a PHI request. We would support a requirement that, if a covered entity demands an upfront payment, the regulatory response time period should be satisfied upon notification of payment request or invoicing.

- hh. *How covered entities currently calculate reasonable, cost-based fees for copies of PHI under the right of access. For example, OCR’s 2016 Access Guidance offered three illustrative methods for calculating allowable access fees: (1) Actual labor costs for copying, plus supplies and postage; (2) average labor costs for copying, plus supplies and postage; and (3) a flat fee of \$6.50 for electronic copies of ePHI, inclusive of labor, supplies, and any applicable postage. The Department requests comment on the extent to which entities use each of these methods. For entities using the average costs option (2), the Department requests comment on what data is being used to calculate the average. It also seeks comment on how covered entities calculate fees for “hybrid” access requests—that is, requests for copies of PHI that encompass both electronic and non-electronic PHI.*

Comment: UPH charges a flat rate of \$6.50 for patient right of access. For “hybrid” access requests, UPH calculates fees utilizing a Work Comp rate for paper records, a reduced half rate for electronic records, or when applicable, a state-specific fee schedule.

- jj. *Whether the Department should establish in regulation a separate required timeframe for covered entities to respond to individuals’ requests for access fee estimates or an itemized list of charges, and what timeframe(s) would be appropriate, and whether the time to respond to a request for access should be tolled pending an individual’s confirmation that it desires the requested information given the fee estimate.*

Comment: These requests can be time consuming and required timeframes should take into account the number of systems accessed and the total pages required to provide an estimate. Although many may be performed in a shorter period, we would support a 15-day timeframe for both the estimate as well as an itemized list of charges, if requested.

- kk. *Whether there should be a legal consequence to covered entities for the bad faith provision of an incorrect estimate of fees for access and authorization requests, and if so, what actions should be considered evidence of bad faith sufficient to subject a covered entity to potential penalties.*

Comment: UPH would reiterate that we believe covered entities use good faith and best judgment when responding to access requests. Establishing consequences with the assumption that bad faith actions are occurring becomes a legal exercise and may lead to unintentional consequences for clerical errors. Instead we would recommend that the Department encourage the use of disclaimers of fee estimates. While clerical errors can occur, they should be resolved by the covered entity and requestor acting in good faith.

- ll. *More information from covered entities and individuals about their experiences with records requests (including when made at the direction of the individual or with an individual’s valid authorization) and any unintended consequences that may result from the Department’s proposals.*

Comment: The primary purpose of PHI access is to engage individuals in their health care. In our experience, attorneys frequently use a “patient directed letter” to request PHI. Providing records to a third party for reasons other than care, care coordination, or care management run afoul of the right to direct records to a third party. We urge the Department to provide clarification on this process and how this is to be prioritized with other PHI requests. As described in our narrative to item “gg”, these “any and all” requests

are very burdensome and should be subject to a separate schedule for priority and charges.

mm. What are commonly available electronic forms and formats that covered entities and business associates generally provide to individuals or third parties? How many requests per month for electronic copies of PHI on electronic media do covered entities and business associates receive from individuals? How many requests per month are received for electronic copies provided through internet-based methods? How long does it take to fulfill each type of request?

Comment: UPH commonly responds to PHI requests by individuals and third parties via a PDF on CD or a PDF sent through email or file transfer. We also release records to patients through our self-service portal. As a large integrated health care system, the volume of requests per month as well as the time period to fulfill these requests varies, which underscores the need for regulatory flexibility.

nn. Do individuals or third parties ever receive requested PHI in unreadable electronic forms and formats? What are those forms and formats, and do covered entities or business associates provide another form and format if they are told the first copy of PHI they provided is unreadable or unusable?

Comment: In our experience, issues related to electronic access most commonly include (1) not being able to open CDs, (2) not being able to unzip files, and (3) not being able to open CD files due to encrypted passwords, which creates extra steps to access files upon receipt. In some cases, there is program incompatibility with operating systems or not have programs properly installed. While this is not frequent, we do work with requesters when files are unreadable, and solutions or work arounds vary.

B. Reducing Identity Verification Burden for Individuals Exercising the Right of Access (45 CFR 164.514(h))

HHS proposes to expressly prohibit a covered entity from imposing unreasonable identity verification measures on an individual (or his or her personal representative) exercising a right under the Privacy Rule and to clarify that unreasonable verification measures are those that require an individual to expend unnecessary effort or expense when a less burdensome verification measure is practicable for the particular covered entity.

Request for Comments

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.

Comment: UPH agrees that the Department should prohibit covered entities from imposing unreasonable identity verification measures. UPH does support reasonable verification measures that include requesting a copy of a photo ID as well as verifying a signature, if one is not on file. In addition, we support verification of identification when PHI is requested by a patient representative, such as a guardian or power of attorney. As for requiring certification of signature, we do not believe this is necessary.

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

Comment: UPH seeks clarification on how the Department will address requests from family members. We are concerned that covered entities acting in good faith may rely on family members (acting in bad faith) to verify an individual's identification and ultimately records are directed to third parties not authorized by the

individual. A similar scenario could exist for a written authorization request which includes a forged signature. We would recommend the Department consider imposing penalties on requestors acting in bad faith.

C. Amending the Definition of Health Care Operations To Clarify the Scope of Care Coordination and Case Management (45 CFR 160.103)

HHS proposes to clarify the definition of health care operations to encompass all care coordination and case management by health plans, whether individual-level or population-based.

Request for Comments

- a. *What are the benefits and costs of clarifying the definition of health care operations, including information on how, if at all, this clarification would affect covered entities' decision-making regarding uses and disclosures of PHI for these purposes?*

Comment: As providers focus on population health and are being encouraged by the CMS to transition from fee-for-service to value, barriers to care coordination and care case management should be removed. UPH is an early adopter of population health care delivery and has participated in Medicare accountable care organization (ACO) models since 2012. In addition, UPH is part owner of a health plan, HealthPartners UnityPoint Health, which has offered a Medicare Advantage plan since 2017. To enable care to be consumer/patient driven, UPH supports this clarification for health plans (as selected by consumers/patients) to assure holistic care coordination.

D. Creating an Exception to the Minimum Necessary Standard for Disclosures for Individual-Level Care Coordination and Case Management (45 CFR 164.502(b))

HHS proposes to add an express exception to the minimum necessary standard for disclosures to, or requests by, a health plan or covered health care provider for care coordination and case management. The exception would apply only to those care coordination and case management activities that are at the individual level.

Request for Comments

- a. *Would the proposed exceptions improve the ability of covered entities to conduct care coordination and case management activities? Why or why not? Please provide any cost or savings estimates that may apply both on the entity level and across the health care system.*

Comment: As providers focus on population health and are being encouraged by CMS to transition from fee-for-service to value, barriers to care coordination and care case management should be removed. UPH is an early adopter of population health care delivery and has participated in Medicare accountable care organization (ACO) models since 2012. In addition, UPH is part owner of a health plan, HealthPartners UnityPoint Health, which has offered a Medicare Advantage plan since 2017. To enable care to be consumer/patient driven, UPH supports this clarification for health plans (as selected by consumers/patients) or covered health care providers to assure holistic care coordination.

E. Clarifying the Scope of Covered Entities' Abilities to Disclose PHI to Certain Third Parties for Individual-Level Care Coordination and Case Management That Constitutes Treatment or Health Care Operations (45 CFR 164.506)

HHS proposes to expressly permit covered entities to disclose PHI to social services agencies, community based organizations, HCBS providers, and other similar third parties that provide health-related services to specific individuals for individual-level care coordination and case management, either as a treatment activity of a covered

health care provider or as a health care operations activity of a covered health care provider or health plan.

Request for Comments

- a. *Whether the proposal to create an express permission to disclose PHI to certain third parties for individual level treatment and health care operations would help improve care coordination and case management for individuals, and any potential unintended adverse consequences.*

Comment: As providers focus on population health and are being encouraged by CMS to transition from fee-for-service to value, barriers to care coordination and care case management should be removed. UPH welcomes clarification that leads to more appropriate and easy sharing of information for care coordination and case management.

F. Encouraging Disclosures of PHI when Needed to Help Individuals Experiencing Substance Use Disorder (Including Opioid Use Disorder), Serious Mental Illness, and in Emergency Circumstances (45 CFR 164.502 and 164.510–514)

HHS intends to encourage covered entities to use and disclose PHI more broadly in scenarios that involve SUD, SMI, and emergency situations, provided that certain conditions are met. In particular, HHS proposes to amend five provisions of the Privacy Rule to replace “exercise of professional judgment” with “good faith belief” as the standard pursuant to which covered entities would be permitted to make certain uses and disclosures in the best interests of individuals.

Request for Comments

- a. *Would the proposed change in standard from “professional judgment” to “good faith belief” discourage individuals from seeking care?*

Comment: No, UPH does not anticipate that this would discourage individuals from seeking care. We would support this proposed change.

- c. *Should 45 CFR 164.510(b)(3) be revised to permit a covered entity to disclose the PHI of an individual who has decision making capacity to the individual’s family member, friend, or other person involved in care, in a manner inconsistent with the individual’s known privacy preferences (including oral and written expressions), based on the covered entity’s good faith belief that the use or disclosure is in the individual’s best interests, in any situations outside of an emergency circumstance? Put another way, are there examples in which the totality of the facts and circumstances should or would outweigh an individual’s preferences, but do not rise to the level of posing a serious and reasonably foreseeable threat under 45 CFR 164.512(j)? Are there examples related to individuals who have regained capacity after having been formerly incapacitated, such as where an individual recovering from an opioid overdose leaves the hospital against medical advice or leaves a residential treatment program?*

Comment: UPH supports the proposed disclosures of mental health information by covered entities to family members and others based on the “best interest of the individual” when done in good faith. Today, a lot of information vital to the health and care of an individual is not shared with an adult’s family because a release has not been signed. Commonly there are instances when individuals present at Emergency Departments for services, but providers are restricted in what can be discussed with the family. This disclosure should balance keeping the individual’s best interests in mind, and the requirement of a good faith belief for covered entities seems reasonable.

- e. *Would the proposed “serious and reasonably foreseeable threat” standard discourage individuals from*

seeking care?

Comment: No, UPH does not anticipate that this would discourage individuals from seeking care. We would support this proposed change.

- f. *Would the proposed standard improve a covered entity's ability to prevent potential harm, such that the benefits of the change would outweigh potential risks? Please provide examples.*

Comment: UPH supports the proposed disclosures by covered entities to prevent harm or lessen a threat of harm. In our business, the best predictor of future behavior is past behavior, and this seems to provide covered entities with this flexibility based on experience with the individual and using our professional judgement to disclose information. In Iowa, a recent modification to state law started down this path by allowing some additional communication with law enforcement officials, although this disclosure is still fairly restrictive.

- i. *As an alternative to the existing proposal, should the Department establish a specific permission for mental and behavioral health professionals to disclose PHI when in the view of the professional, the disclosure could prevent serious and reasonably foreseeable harm or lessen a serious and reasonably foreseeable threat to the health or safety of a person or the public? What would be potential unintended consequences of such an alternative?*

Comment: UPH is also open to this alternative proposal, as opposed to doing nothing at all. Currently, the hands of mental and behavioral health professionals are tied by HIPAA, prioritizing privacy before health, safety and wellbeing.

G. Eliminating Notice of Privacy Practices Requirements Related to Obtaining Written Acknowledgment of Receipt, Establishing an Individual Right To Discuss the NPP With a Designated Person, Modifying the NPP Content Requirements, and Adding an Optional Element (45 CFR 164.520)

HHS proposes to eliminate the requirements for a covered health care provider with a direct treatment relationship to an individual to obtain a written acknowledgment of receipt of the NPP and, if unable to obtain the written acknowledgment, to document their good faith efforts and the reason for not obtaining the acknowledgment. HHS also proposed to remove the current requirement to retain copies of such documentation for six years.

Request for Comments

- a. *Would the proposed changes to the NPP requirements have any unintended adverse consequences for individuals or regulated entities?*

Comment: UPH wholeheartedly supports the elimination of these requirements. Overall, the signature and record keeping requirements are not meaningful to individuals and are an administrative burden to covered entities without relative consumer benefit. In addition, it is costly for covered entities to print these notices as well as to implement NPP workflows.

- b. *Would the revised NPP content requirements improve individuals' understanding of, and ability to exercise, their rights under the Privacy Rule?*

Comment: UPH supports and provides education on Privacy Rule rights; however, incorporating this into the NPP adds little value. In our experience, very few individuals read the notice, and many find it cumbersome.

- c. *Are there ways that OCR can improve the model NPPs to be more informative and easier to understand?*

Comment: UPH would recommend that the Department not target NPPs as the vehicle to communicate rights to individuals. The complexity of health care organizations and the legal standards for privacy practices are difficult to reduce to an informative, yet easily understandable handout. While we understand the initiative, time has proven that this is not effective and is basically disregarded as a nuisance by individuals receiving treatment services.

- f. *Specific examples of amounts spent and any other costs incurred by a covered entity to comply with the requirements relating to the acknowledgement of receipt of the NPP, when the covered entity fulfills the requirements using paper-based or electronic forms, signatures, or document filing systems.*

Comment: There is general confusion on implementation of the current requirement where some organizations resort to an annual signing of the NPP, which is not required. This practice causes confusion for individuals seeking treatment who sometimes believe they are authorizing treatments versus acknowledging receipt of NPP. Additionally, requiring a “designated person” to be available to speak with someone upon request about the NPP is extremely burdensome. It is unclear when this person must be available and how response timeliness is measured. This results in workflow and cost implications, including on call availability after regular business hours as well as staff limitations at smaller clinic/hospital locations where staff may be responding to patients at the same time as an explanation is requested.

H. Permitting Disclosures for Telecommunications Relay Services for People Who are Deaf, Hard of Hearing, or Deaf-Blind, or Who Have a Speech Disability (45 CFR 164.512)

HHS proposes to expressly permit covered entities (and their business associates, acting on the covered entities’ behalf) to disclose PHI to TRS communications assistants to conduct covered functions and to expressly exclude TRS providers from the definition of business associate.

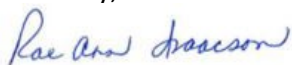
Request for Comments

- a. *Would the proposed change achieve the anticipated effects?*

Comment: UPH supports this change as current language is not clear that TRS providers are not business associates. When evaluating this service, the user may be an employee rather than an interaction directly involving a patient where opt out permission could be obtained. UPH encourages the Department to provide clarification on the issue for health care organizations that have employees using TRS.

UPH is pleased to provide input on this notice of proposed rulemaking. Aside from our specific feedback provided above, UPH is also a member of the American Hospital Association and is in general support of their formal comment letter dated March 10, 2021 on RIN 0945-AA00. To discuss our comments or for additional information, please contact Cathy Simmons, Government & External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,



RaeAnn Isaacson, BSN, MBA, CHP
System Privacy Officer



Cathy Simmons, JD, MPP
Executive Director, Government & External Affairs