

February 12, 2019

Alex M. Azar II,
Secretary, U.S. Department of Health and Human Services
Office for Civil Rights
Attn: RIN 0945-AA00
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

RE: RIN 0945-AA00; Request for Information on Modifying HIPAA Rules to Improve Coordinated Care published in Vol 83, No 240 Federal Register 64302 (December 14, 2018).

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

Dear Secretary Azar,

UnityPoint Health (“UPH”) appreciates this opportunity to provide feedback on this Request for Information. UPH is one of the nation’s most integrated healthcare systems. Through more than 30,000 employees and our relationships with more than 290 physician clinics, 38 hospitals in metropolitan and rural communities and 15 home health agencies throughout our 9 regions, UPH provides care throughout Iowa, central Illinois and southern Wisconsin. On an annual basis, UPH hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 6.2 million patient visits.

In addition, UPH is committed to payment reform and is actively engaged in numerous initiatives which support population health, care coordination and value-based care. UnityPoint Accountable Care (UAC) is the ACO affiliated with UPH and has value-based contracts with multiple payers, including Medicare. UAC is a current Next Generation ACO, and it contains providers that have participated in the Medicare Shared Savings Program (MSSP) as well as providers from the Pioneer ACO Model. In addition, UPH participates in a provider-based health plan, HealthPartners UnityPoint Health, which holds a Medicare Advantage (MA) contract in Iowa and Illinois, and UPH sponsors a Program of All-Inclusive Care for the Elderly (PACE) program through Siouxland PACE for four counties in northwest Iowa.

UPH respectfully offers the following feedback on this Request for Information from the Office of Civil Rights (OCR).

PROMOTING INFORMATION SHARING FOR TREATMENT AND CARE COORDINATION

The Privacy Rule currently requires a covered entity to provide an individual with access to his or her protected health information (PHI) within 30 days after receipt of a request (with the possibility of one 30-day extension), and requires the covered entity to provide a copy of PHI to a third party, which may be a health care provider, when directed by an individual pursuant to the individual's right of access. Required disclosures of PHI are limited to (1) to the individual, pursuant to the individual's right to access, 45 CFR 164.524; and (2) to OCR for purposes of determining compliance with the HIPAA Rules. For coordination of care or managing cases, the Privacy Law contains no deadline to disclose records when requested by another health care provider or other entity; the application of the minimum necessary requirement varies; and disclosure to social services agencies and similar third parties is inconsistent. OCR seeks input on whether potential revisions to the right of access would support and promote care coordination and/or case management by enabling more timely transfer of PHI between covered entities, or between covered entities and other health care providers.

- **Comment:** UPH supports disclosure of PHI for care coordination purposes and understands that more robust record sharing has the potential to enhance medical decision making. That said, we also generally agree with the premise that covered entities are risk adverse when disclosing PHI for care coordination and/or case management beyond minimal requirements to avoid potential HIPAA violations. If OCR can provide more clarity without increasing administrative burden, UPH would support those efforts.

When an individual requests their own PHI, we complete within the 30-day timeframe and often less than a week of the request. While it is feasible to provide more rapidly than the 30-day timeframe, we must fit these requests into our daily operations. We do attempt to prioritize turn-around times for any continued care right of access requests or other urgent matters if known. We do believe that OCR could institute differentiated timeframes related to request complexity; however, we are hesitant to endorse a bright line test for EHR records, as our ability to produce results is also dependent upon the number of encounters selected; the number of scanned images; redactions included; exclusion of restricted encounters (mental health); and the delivery format (paper, CD, portal, etc.). The largest burden would just be the inconsistency of volume related to this task and managing turn-around under a shortened mandated timeframe.

OCR seeks information on the treatment of health care clearinghouses under HIPAA and their responsibility to provide PHI. Since the health care clearinghouses are subject to Business Associate (BA) agreements with covered entities, we do not believe that these contractual relationships were intended to encompass direct individual requests. That said, if the individual has set up a contractual relationship whereby the individual provides his or her records to a clearinghouse to manage, then the clearinghouse would be subject to a direct individual request for PHI.

As a provider involved in multiple value-based, population health contracts, we urge OCR to further encourage timely sharing of PHI for treatment purposes. We do believe that covered entities should be required to disclose PHI when requested by another covered entity for treatment purposes. For disclosures to covered entities, we would suggest that guidelines related to authorized purposes be clearly established to enable staff to distinguish between treatment and health care operations. We would not support OCR creating disclosure exceptions or limitations for covered entities, as such restrictions may impact processing time and cost and also severely hinder the timeliness of providers

receiving needed PHI to provide care. We would also support a requirement for HIPAA covered entities to disclose PHI to non-covered health care providers; however, this should be more closely regulated and demonstrate a clear connection to treatment and care coordination. For these instances, it may be appropriate to require a verbal or written assurance that the request is for an accepted purpose before a potential disclosure, and if OCR is considering disclosure exceptions or limitations, we would urge more flexibility for treatment purposes as opposed to payment purposes. When considering disclosures to non-covered entities, we would support disclosures to social services agencies and community-based programs where necessary to facilitate treatment and coordination of care. We would also support disclosures to multi-disciplinary/ multi-agency teams tasked with ensuring that individuals in need in a particular jurisdiction can access the full spectrum of available health and social services.

To promote the full evaluation of treatment options and to avoid adverse outcomes, individuals should not have a right to prevent certain disclosures of PHI to the treatment team. While treatment choice is ultimately a decision of the patient, the treatment team must have full PHI to understand potential outcomes and to make recommendations related to that choice accordingly. We believe that the full disclosure of PHI should include substance abuse information (as regulated by 42 CFR part 2) and we would support revising these regulations to prevent individuals from refusing to disclose substance abuse information to health care providers for purposes of treatment. We would urge OCR not to impose additional requirements, such as an explicit affirmative authorization, before requesting PHI for treatment purposes.

Lastly, we would support increased public outreach and education on existing provisions of the HIPAA Privacy Rule that permit uses and disclosures of PHI for care coordination and/or case management, but believe that this should be conducted in conjunction with, and not in lieu of, regulatory change. While this tactic was mentioned for patients and families, it would also be beneficial for health care professionals and staff. Examples provided in handouts during intake to encourage disclosures for treatment may be helpful. This may also be reinforced directly from providers and care coordinators.

PROMOTING PARENTAL AND CAREGIVER INVOLVEMENT AND ADDRESSING THE OPIOID CRISIS AND SERIOUS MENTAL ILLNESS

The Privacy Rule allows covered entities to disclose PHI to caregivers in certain circumstances, including certain emergency circumstances. OCR would like to consider amendments to the Privacy Rule that would allow OCR to address the opioid crisis as well as facilitate parental involvement in the treatment of their children.

- ***Comment:*** In terms of addressing the opioid crisis and serious mental illness overall, perhaps the biggest obstacle is the inability of health care providers to access patient history. By allowing individuals to opt out of providing this information to providers, this does not enable providers to have all the information needed to appropriately advise on treatment options. To illustrate this, an individual involved in a car accident may be prescribed an opioid for pain by a physician who does not know of a prior addiction diagnosis / treatment. Especially for patients under value-based

arrangements, including ACO beneficiaries, Medicare Advantage enrollees with a plan participating in Value-Based Insurance Design demonstration or Dual-eligible Special Need Program, or Medicaid enrollees subject to managed care value-based contracts, care cannot be effectively managed in the absence of substance abuse disorder data. While we understand a person’s right to privacy related to PHI, we do not believe that this should apply to health care providers who are charged with medical shared decision making on behalf of the individual.

We would also take this opportunity to call out that many states have adopted more restrictive privacy rules. So, despite OCR efforts, the impact may be negligible. For instance, in both Illinois and Iowa, there are very few instances when information would be disclosed without a specific authorization. If OCR is looking to promote flexibility, we would suggest that OCR undertake a review of state laws to determine impact and, if such changes are eventually adopted, send letters to the States to encourage a similar flexibility and interpretation. If there are other more direct methods to incentivize states, we would urge OCR to consider those too.

As for promoting parental and/or caregiver involvement in treatment decisions, we would again encourage OCR to similarly review state laws to determine what impact, if any, proposed HIPAA revisions may have. State laws differ on who can grant consent for treatment and record confidentiality. In Iowa, a minor may give legal consent for voluntary treatment of drug and alcohol abuse, and information shall not be reported or disclosed to their legal guardian without the minor’s consent. This is true regardless of the subject’s age or condition. Although UPH would advocate for access by treating professionals to these records, we are not certain that disclosure of PHI to parents and/or caregivers should be provided against a patient’s desire. As such, we are not convinced that current laws are inadequate or that parents should be granted a blanket right, or even further flexibility, to obtain treatment information for their minor children in all cases. We are also concerned that this area is sufficiently complex and that more exceptions make it increasingly difficult to providers to determine who in fact has a right to receive PHI.

ACCOUNTING OF DISCLOSURES

The Privacy Rule requires covered entities to provide an individual, upon request, with an accounting of certain disclosures of the individual’s PHI that were made by the covered entity or its business associate during the six years before the request. In the HITECH Act, the Department is directed to modify the Privacy Rule to require that an accounting of disclosures include disclosures made for treatment, payment, and health care operations (TPO) purposes through an electronic health record during the three years before the request. OCR requests public input on the Implementation of the HITECH Act requirement and how to ensure that individuals can obtain a meaningful accounting of disclosures that gives them confidence that their PHI is being disclosed appropriately as part of receiving coordinated care or otherwise.

- **Comment:** UPH responds to requests for an accounting of disclosures infrequently at best, with our facilities and service lines receiving none to just a handful of requests annually. This represents less than 0.01 percent of patients. Although circumstances underlying such requests vary, a frequent rationale is that individuals want to know if a specific person has entered their record. When individuals seek additional information outside the results provided, they are usually seeking to clarify who was in their record and specifically whether it was accessed by a certain person(s). Generally,

these requests for an accounting of disclosures are required to be written, which may include an electronic request. Aside from a writing, we do not have a standardized form or format for the request. After the accounting of disclosures information is pulled, the Privacy Officer reviews the HIM report along with data from other locations where disclosures may occur and combines the results in a report to be given to the individual in accordance with accounting of disclosures regulations. To produce the results, time and effort vary significantly depending upon the individual, the number of collaborating or collateral providers involved in care, the number of systems (data locations) we would need to pull from and ultimately the number of disclosures. Depending upon the level of disclosures, all requests require at least two employees and often more to ensure accuracy. Given the relative infrequency, we cannot provide an accurate estimate of time and effort beyond stating that it usually takes more than a couple hours and, in some circumstances, amounts to “work day” equivalents. These requests are fulfilled within 60 days, but average turn-around currently ranges between 15 and 30 days.

We appreciate that OCR is attempting to reconcile TPO disclosures as mandated by the HITECH Act with the potential for significant administrative burden and disincentives related to EHR adoption and interoperability. Being required to track and account for disclosures of TPO without further guidance would be an exorbitant burden and require extensive change to current processes which take away from valuable clinical and support time. We estimate that the inclusion of TPO would significantly increase, perhaps even triple, the time and effort required. This projection is based on sheer volume of disclosures that would need to be captured as well as challenges related to providing such information in a patient-friendly format. More pressing than the production of the reports, is the fact that many aspects of TPO are not currently tracked, such as internal “uses” or payer contacts. As an integrated health system, the extent to which TPO is accounted for and tracked varies by site of service (inpatient, ambulatory and home health) and EHR platform. An example of an “internal use” that would be extremely difficult to track is the data utilization by our Analytics Department. There is an abundance of analytical data being used for health care operations that would be difficult to track on a per patient basis to include on the accounting. Another challenge to tracking information is that additional treatment information may reside in documentation notes within the EHR but is not tracked for disclosure and accounting purposes. TPO records that are the most capable of being tracked relate to releases conducted through our Health Information Management department, pre- and post-pay audit requests and survey requests. Overall, the inclusion of TPO within an accounting would require additional training and infrastructure costs related to internal workflow revisions, documentation changes as well as revisions to EHRs to capture this information.

We would caution the inclusion of Business Associate (BA) disclosures within EHRs, particularly for administrative and data analytics relationships. Although we understand a desire to have comprehensive data and a centralized location for such data, we are concerned that this information is not necessarily meaningful to patients. In addition, it would add compliance responsibilities to the covered entity that do not currently exist. Generally, covered entities are not required to monitor BA compliance with the agreement, such as ensuring that BAs are accurately logging disclosures; however, this does not excuse the covered entity from action if they have knowledge of an issue. Should compliance requirements become more stringent, we are concerned about costs to covered entities related to this oversight function. To minimize administrative burden, if OCR is interested in

pursuing this we would encourage that these disclosures be limited to compliance audits and accreditation/complaint surveys. As an alternative, OCR seeks input on whether individuals should make direct requests to BAs. While providing individuals with direct contact information for BAs appears at first blush to resolve issues for covered entities, we believe that burdens would outweigh the benefits. While UPH would benefit by narrowing the scope of our accounting results and thus being able to produce a timelier accounting, we are uncertain about the capacity of our BAs as well as the associated infrastructure costs (which may be passed through to us and ultimately patients) related to this function. Specifically, some of our BAs do not have access to electronic data, and for those that do, our BA agreements often do not require them to produce audit/access logs nor require their capacity to receive and respond to direct individual requests. An additional limitation would be the fact that we would not have a simple way to determine each BA that had handled an individual's data. This would also create a tremendous burden on the individual requesting the accounting of disclosures, as they would have to be directed to multiple different organizations to make requests.

In terms of mechanics, we are pleased that OCR has asked questions to understand the current state of EHR capabilities in recognition that there are associated costs as well as go live timeframes that accompany changes to regulations. Our EHR systems do not have the ability to distinguish between "uses" and "disclosures." Since this may be used by OCR to lessen regulatory burden, we request that OCR seek stakeholder input when crafting these definitions. Additionally, our integrated health system has not fully converted to one EHR and we have numerous platforms outside Epic (our largest EHR) that contain PHI. Presently each platform varies on how its record for access is formatted as well as the length of time that this information is retained. We do have an audit plan in place to assure that routing proactive audits are being performed and that we are in overall compliance. The existence of multiple platforms, even within one health care system, is a reality that ORC must account for in the proposed rules and their implementation timeframe.

As for the accounting of disclosures requirement itself, we agree that OCR should revisit the purpose of the accounting requirement and assure that it produces results that are meaningful for the individuals making these requests. We would suggest that access audit information not be included in the accounting of disclosures. "Disclosure" is when PHI goes outside the covered entity. If an internal workforce member is accessing the information, it should not meet the definition to be included in the accounting of disclosures. Current regulations require an accounting to include the name of the entity or person who received the PHI and, if known, the appropriate address. Additional data elements for potential inclusion could be: Dates/timeframes of the disclosure being reported; medical record number; patient first and last name; brief description of PHI disclosures; and brief statement of purpose of the disclosure. If TPO is required for the accounting of disclosures that is not contained with the EHR, we would request at least 60 days to complete such investigation and report within our normal day-to-day operations. When such an investigation is conducted, we would suggest including a brief statement regarding the scope of the review. This would include a high-level description of the systems reviewed and timeframe.

NOTICE OF PRIVACY PRACTICES

The Privacy Rule requires covered providers and health plans to develop a Notice of Privacy Practices (NPP)

that describes individuals' health information privacy rights and how their health information may be used and disclosed by the covered entity. The Privacy Rule also specifies the format and means by which the NPP is provided to individuals, including rules applicable to direct treatment providers. OCR seeks public input on whether the signature and recordkeeping requirements should be eliminated and how the NPP requirements might be modified in other ways to alleviate covered entity burden without compromising transparency regarding providers' privacy practices or an individual's awareness of his or her rights.

- **Comment:** UPH supports a reduction in administrative burden related to the NPP acknowledgement and recordkeeping. The function to obtain an individual's written acknowledgment of the NPP receipt is well-established and embedded in our face-to-face intake process along with all other forms of consent and authorization to bill payers. If an individual refuses to acknowledge receipt of the NPP, the declination is noted by staff. Because this process is embedded, costs are relatively low and associated with intake time to explain and obtain the signature (average of 60 seconds) as well as printing costs. We estimate that we are unable to obtain a written acknowledgement for less than 10 percent of patients across all service lines and sites of care. The reasons that acknowledgements are not signed vary but include individuals under a court committal, brought in by law enforcement or otherwise do not agree with need for treatment; patient state, such as unresponsive or other condition, and without authorized family or representative; individuals that do not want to acknowledge responsibility for payment of the services provided; individuals that disagree with the form / substance of the NPP, such as its length or complexity, the lack of time to review, and a general philosophical disagreement with some of the accesses and disclosures that are allowable by HIPAA; and general suspicion by individual resulting in reluctance to sign any document.

Aside from the NPP, there are numerous other state and federal laws, guidelines and standards as well as payor contractual requirements that need a patient acknowledgment or signature on a document on their first visit. These documents vary by payer and state accreditation, and our intake personnel have checklists to provide and explain these documents and to obtain signatures as required. Generally, all visits require consent to treat and authorization to bill payers / insurance. Other documents include Notification of Financial Assistance; Important message from Medicare and Tricare forms; Patient rights; Advance Directives; Confidentiality; Financial responsibility; and Appeals and grievance procedures. It is standard practice that the NPP is bundled with these other documents at intake and are often referenced as an admission packet or pamphlet. While each service line is different, the NPP is typically several pages in length and the length of the total pamphlet is approximately 10 pages. Aside from documents required by payers and accreditation, some service lines also include other information during the initial visit. For instance, our home health and hospice service lines include full admission materials which may include welcome to the program overview and service description, contact information, emergency and safety planning, bereavement information, and more.

NPP training is part of our required education completed at orientation for appropriate staff members. In addition, we have annual privacy and compliance training which includes these concepts. Overall the costs for training is relatively low for maintaining the acknowledgement, there are costs associated with printing the admission pamphlets and for updating NPP materials required to be posted in a clear and prominent location in each facility.

As for our “use” of the signed NPP forms, these are maintained as part of the permanent record and verify that this information has been provided to the patient or responsible party. Bottom line, this acknowledgement demonstrates our compliance with the regulatory requirement that we document receipt. We are not aware that UPH has ever received a complaint or concern where an individual alleged that they were not provided a NPP. If OCR removes the written acknowledgment on the first visit, the benefits are one less item for the patient to sign, which may make the process more efficient. The potential adverse consequences are that some patients may not understand their privacy rights to the extent they may have if they were required to sign an acknowledgement and it may be difficult to verify that this information has been received by the patient.

To lessen administrative burdens while preserving transparency about privacy practices and promoting individual awareness of privacy rights, we would encourage OCR to streamline notice provisions. First, OCR may either remove the signature requirement or encourage electronic acknowledgements when possible. Second, OCR could revisit the format of the NPP to shorten its length to basic elements of what it is about and who to contact if questions or concerns. Third, OCR may eliminate duplicative notices. For instance, we would recommend that providers be given a choice of providing such notice either through NPP posters or through intake documentation. We believe that the posting of materials is an unnecessary expense involving additional costs and staff resources with each notice revision. Fourth, OCR could consider eliminating both the NPP intake documentation and NPP posting and replacing them with notice through a website. Given the prevalence of technology, we believe notice would be sufficiently provided by pointing patients to a website and responding to specific patient requests to receive a copy as opposed to universally providing copies and collecting signatures.

ADDITIONAL WAYS TO REMOVE REGULATORY OBSTACLES AND REDUCE REGULATORY BURDENS TO FACILITATE CARE COORDINATION AND PROMOTE VALUE-BASED HEALTH CARE TRANSFORMATION

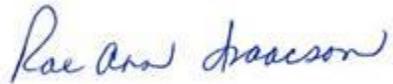
OCR seeks public input on ways to modify the HIPAA Rules to remove regulatory obstacles and decrease regulatory burdens so as to facilitate efficient care coordination and/or case management and promote the transformation to value-based health care, while preserving the privacy and security of PHI.

- **Comment:** Our suggestions related to improving care coordination and/or care management include:
 - Require sharing of mental health and substance abuse information for treatment purposes regardless of consent. If OCR would consider relaxing 42 CFR part 2 requirements, we are hopeful that states will follow suit.
 - Review impact of HIPAA rules on EMR integration and Conditions of Participation. We would encourage stronger statements about the interrelationship of HIPAA and site-specific Conditions of Participation. As an example, home care and hospice regulations require their records to be locked down to only those clinicians that work in home care or hospice, and any treatment of records otherwise equates to an inability to keep records confidential, which is a condition level deficiency. This does not encourage home care and hospice agencies to engage in the disclosure of information for treatment or promoting activities that involve a shared or interoperable EMR.

- Clarify when and how information is to be disclosed to other health care providers (covered entities) as well as non-covered entities involved in care coordination. Integrated systems have access to patient information (regardless of the setting) when it is seen to benefit the patient in care coordination / case management. While we are encouraged by this RFI, we would recommend that the proposed rules permit broad authority accompanied by a preamble that provides illustrative examples of how these provisions should be implemented.

We are pleased to provide feedback on this request for information and its impact on our patients and integrated healthcare system. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President, Government & External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,



RaeAnn Isaacson, RN, BSN, MBA, CHP
Corporate Privacy Officer



Sabra Rosener, JD
VP, Government & External Affairs