Summary of Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement

March 29, 2021

Introductory Summary

On January 21, 2021, the Office for Civil Rights, Office of the Secretary, HHS published a proposed rulemaking titled Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement. The proposed rule can be found on the Federal Register at https://www.govinfo.gov/content/pkg/FR-2021-01-21/pdf/2020-27157.pdf.

The format of the following information is intended to serve as a summary to the proposed changes and readers are encouraged to view the document in its entirety for further details.

Background

The United States Department of Health and Human Services (HHS or referred to throughout the proposed ruling as "the Department") have proposed modifications to the Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule), also referred to HIPAA Rules. The Privacy Rule according to HHS "*is one of several rules, collectively known as the HIPAA Rules that protect the privacy and security of individuals' medical records and other protected health information (PHI), i.e., individually identifiable health information maintained or transmitted by or on behalf of HIPAA covered entities (i.e., health care providers who conduct covered health care transactions electronically, health plans, and health care clearinghouses).*"

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), HIPAA Rules, included Administrative Simplifications for the establishment of national standards to protect the privacy and security of a patient's health information. The original HIPPA Rules only applied to three types of entities known as "covered entities". Originally it applied to healthcare providers who transmit patient health information electronically related to any service or interaction which HHS has adopted an electronic transaction standard, health plans, and healthcare clearinghouses. Since the initiation of the HIPAA Rules, it also now applies to the business associates of covered entities.

The reason for the proposed changes by HHS to HIPAA Rules are a result of the concern of significant regulatory barriers to covered entities to provide coordinated, value-based care. In response to this belief, HHS submitted a request for information (RFI) in 2018 which contained 53 questions on how HHS could modify HIPPA Rules, while still maintaining privacy and security, but allowing for the coordination of care and promote value-based care. Based on the feedback provided to HHS, the following is a brief summary of the key areas proposed for change related to the HIPAA Rules.

Summary of Changes

Clarifying Definitions of Terms

HHS is proposing to update/clarify the following definitions or terms used in regard to HIPAA Rules.

Electronic Health Record

"Electronic health record *means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff. Such clinicians shall include, but are not limited to, health care providers that have a direct treatment relationship with individuals, as defined at §164.501, such as physicians, nurses, pharmacists, and other allied health professionals. For purposes of this paragraph, "health-related information on an individual" covers the same scope of information as the term "individually identifiable health information" as defined at §160.103."*

The HIPAA Rules does not define the term "clinician" and HHS has not identified a uniform or consensus on the use of the term. CMS uses the definitions for "clinician" as *"The term clinician refers to a healthcare professional qualified in the clinical practice of medicine. Clinicians are those who provide principal care for a patient where there is no planned endpoint of the relationship; expertise needed for the ongoing management of a chronic disease or condition; care during a defined period and circumstance, such as hospitalization; or care as ordered by another clinician. Clinicians may be physicians, nurses, pharmacists, or other allied health professionals."*

Due to the various definitions, HHS is proposing to interpret "authorized health care clinicians and staff" as "*to at least include covered health care providers who are able to access, modify, transmit, or otherwise use or disclose PHI in an EHR, and who have direct treatment relationships with individuals; and their workforce members (as workforce is defined at 45 CFR 160.103)84 who support the provision of such treatment by virtue of their qualifications or job role."*

Right of Access Information

HHS is proposing to revise the right of access by clarifying an individual can access electronic copies of their protected health information (PHI). To fulfill the request for access, it is proposed to be completed by transmitting an electronic copy of an individual's PHI to a personal health application used by the individual. HHS is also proposing to address the use of personal health applications to access information by proposing to define personal health application in the HIPAA Rules as *"an electronic application used by an individual to access health information about that individual in electronic form, which can be drawn from multiple sources, provided that such information is managed, shared, and controlled by or primarily for the individual, and not by or primarily for a covered entity or another party such as the application developer."*

Since the personal health application is not acting on behalf of the covered entity, it would not be subject to the privacy and security requirements of the HIPAA Rules. HHS does believe and supports providing individuals with information to assist in making the best decision when selecting a personal health application or another application when not provided on behalf of the covered entity.

Strengthening the Access Right to Inspect and Obtain Copies of PHI

Current rules allow for individuals the right to "inspect and obtain a copy of" PHI in a designated record set. HHS is proposing to strengthen the access right to include and obtain copies of PHI as part of the updated ruling. To accomplish this, they are proposing for a covered entity to allow an individual to take notes, videos, and photographs using personal resources after arranging a time that is mutually agreed to for the individual to review the PHI in the designated medical record.

Additionally, HHS is proposing to extend and implement when PHI is readily available at the point of care in conjunction with a healthcare appointment, the covered entity (healthcare provider) is not permitted to delay the right of the individual to inspect the PHI. For example, when x-rays, ultrasounds, or lab results are part of the healthcare appointment, if the individual requests to personally inspect or review them, then it must be granted during the time of the treatment or appointment as this would be considered the convenient time to do so.

As it is not uncommon for individuals to take notes during visits, HHS explains it would be reasonable to allow the individual to also take photographs or record PHI as long as the covered healthcare provider does not experience unreasonable workflow disruptions. HHS did point out this does not mean they tend to enforce or expect a covered entity to allow for individuals to connect a personal device such as a thumb drive to the covered entity's information system, as this would and could present a non-secure mode of data transfer. Instead, the covered entity would not be permitted to create barriers to individuals who want to copy their information by creating unjustified policies which may hinder this.

Modifying the Implementation Requirements for Requests for Access and Timely Action in Response to Requests for Access

Current policy allows for a covered entity to respond to an individual's request no later than 30 days after the receipt of the request. It also allows for one 30-day extension by written explanation to the individual of when the request will be completed. HHS is proposing a few different changes, one to how requests are/can be submitted and the timeliness of response by the covered entity.

Requests for Access

Currently Section 164.524(b) of title 45 CFR requires covered entities to allow individuals that want to review or obtain a copy of their PHI in a designated record to inform them of this ability and the need to submit the request in writing. HHS is proposing to adjust the language for requirements for accessing PHI by individuals. Specifically, HHS is proposing to clarify language to ensure if a covered entity requires a request in writing to review or obtain PHI by an individual, the process to do so could not be such to create difficulty for the individual to actually obtain the information, to impede the access in any way.

To adjust the language, HHS will provide language of examples, but will be non-exhaustive, of "unreasonable measures" which covered entities are not allowed to employ for the process. In addition, HHS is proposing to also amend the HIPAA Rules to prohibit a covered entity from imposing unreasonable identity verification requirements. To do this, HHS is asking for comments from stakeholders of examples of unreasonable measures

that individuals and covered entities believe could reduce an individual's ability to obtain or access their PHI and any burdens covered entities believe these changes will create.

Timeliness

Per the current HIPPA Rules a covered entity must respond no later than 30 days from receipt of request by either providing access or a written denial per requirements. If the covered entity cannot meet the deadline of 30 days, it may increase the allowed time by one 30-day extension, if the covered entity provides within the initial 30 days written notification of the need to extend the response with a reason for the delay given.

HHS believes covered entities can provide individuals with access to their information in a shorter timeframe. Due to this, HHS is proposing to shorten from 30 days to "as soon as possible," but in no case more than 15 calendar days after receipt of the request. In addition, covered entities would need to establish a written policy for prioritizing urgent or other high priority requests (those related to health and safety) as a means to limit the need for a 15-day extension. Only one 15-day extension would be allowed and only when the covered entity has a written policy to address urgent and high-priority requests. HHS will not define what is considered urgent and high priority, it would be expected these would apply to situations where there is need for urgent medical treatment or, for example, a need for an individual with a diagnosis of severe asthma to be allowed to bring medication to school. The premise of making a change to timeliness of requests is to ensure transparency and allow individuals and healthcare providers to make better and more informed healthcare decisions for individuals.

There are several entities that require a shorter timeline for response. If there are state or other federal policies which have a shorter timeline for response, these would supersede the timeliness updates per the new HIPAA Ruling. Regardless, the changes to the timeliness of response would apply to requests from individuals for direct access to their PHI or when an individual requests an electronic copy of PHI in an EHR to be directed to a third party.

HHS is also proposing that a covered entity can discuss or ask for clarification of the request for access or copies of PHI with the individual, but this would not extend the time limit for providing access. In comments received as part of the RFI, responses indicated that many covered entities wait until the last date required to respond as a way to further delay the response. In the proposed ruling this would not be allowed, and the shortened timeline is meant to ensure requests are addressed timely and appropriately.

Forms of Access

Currently the HIPAA Rules require the covered entity to provide the individual with access to the PHI in the form and format requested, if readily producible in that format. If not, then in a readable hard copy form or other form and format mutually agreed to. HHS also intends for the phrase "readily producible in that form and format" to refer to how it is produced to the individual or third party as designated by the individual to receive a copy. HHS also clarifies the form and format by stating, "…*form (e.g., on paper or electronically) and format (e.g., the type of electronic file, etc.) of the PHI that is transmitted. As new forms of information and*

communications technologies emerge, the "form and format" and the "manner" of producing or transmitting a copy of electronic PHI may become indistinguishable."

HHS is also proposing if other federal or state laws require an entity (including business associates acting on behalf of a covered entity) to utilize technology or policy for providing access to PHI in a particular form and format, this would be deemed "readily producible" for fulfilling the requests for PHI. Any covered entity refusing to provide access via a secure application programming interface (API) despite the establishment of the API by the covered entity, would be a violation of the Rules. HHS is also seeking comments on whether to require a healthcare provider that has an EHR with a secure standards-based API without extra cost to implement the API; whether to require a healthcare provider to implement an API at little to no cost; and how to measure the level of cost considered reasonable for not implementing an API.

HHS is also proposing if a covered entity provides a summary in place of the actual PHI, currently allowed, the covered entity would be required to inform the individual they can receive a copy of the requested PHI if they do not agree to a summary. This would not apply when the covered entity is providing the summary because it has denied the request for access or copy of PHI based on their process and policy per the request which cannot be met.

<u>Addressing the Individual Access Right to Direct Copies of PHI to Third Parties</u>

Currently the HIPAA Rules allow for an individual to request a covered entity to transmit copies of PHI directly to another person as directed by the individual. The request must be submitted in writing, signed by the individual, and clearly identify the designated person and where to send the PHI. HHS is proposing to develop separate provisions for directing copies of PHI to a third party.

HHS is proposing only covered healthcare providers would be responsible for fulfilling an individual's request under this proposal because HHS does not believe other covered entities have an EHR as defined by the Health Information Technology for Economic and Clinical Health (HITECH) Act (i.e., an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff), but are seeking comments about this assumption.

HHS is proposing to limit copies of PHI which are requested to be sent to a third party (e.g., family member or caregiver, a health care provider, a researcher, or any other person or entity the individual (or their personal representative) chooses) be limited to electronic copies of PHI in an EHR. If requested, the healthcare provider must provide of copy of the requested PHI to the person designated by the individual. However, the Department encourages covered health care providers, when feasible, to provide copies to third parties in the electronic format requested by the individual.

HHS is also proposing requests of copies of PHI to a third party may be submitted orally or in writing (including electronic submissions). This would replace the current requirement of requests submitted in writing, signed by the individual, and clearly identifying the designated person and where to send, but allowing other means for submitting the request.

HHS is also proposing for a covered healthcare provider or health plan to facilitate an individual's request for a copy of PHI in an EHR to a third party as directed by the individual. These requests, Requester-Recipient, could be submitted orally, in writing or electronically. This would be a request initiated by the individual and differ from a covered entity requesting information on an individual for treatment or healthcare operations purposes. The Requester-Recipient request would be required to be submitted no later than 15 calendar days after receiving the individuals' direction for the information. No 15-day extension would be available in this scenario for the Requester-Recipient; however, the Discloser would be allowed one 15-day extension to answer the request, as necessary.

Adjusting Permitted Fees for Access to PHI and ePHI

Currently covered entities may charge a reasonable, cost-based fee to fulfill access to PHI requests from individuals. The fees are limited to:

- Labor for copying (whether the PHI is in paper or electronic form),
- Supplies for creating the paper copy or electronic media if requested,
- Postage, and
- Preparing any agreed-upon summary or explanation of the requested PHI

HHS is proposing to modify the access fee provisions to provide structure with two elements based on the type of access request. The first category would be requests which are always free and the second would be categories in which there would be an allowed cost. The following table outlines the proposed allowable fees.

Type of Access	Recipient of PHI	Allowable Fees
In-person inspection – including viewing and self-recording or -copying	Individual (or personal representative)	Free
Internet-based method of requesting and obtaining copies of PHI (e.g., using View-Download-Transmit functionality (VDT), or a personal health application connection via a certified-API technology)	Individual	Free
Receiving a non-electronic copy of PHI in response to an access request	Individual	Reasonable cost-based fee, limited to labor for making copies, supplies for copying, actual postage & shipping, and costs of preparing a summary or explanation as agreed to by the individual
Receiving an electronic copy of PHI through a non-internet-based method in response to an access request (*e.g.*, by sending PHI copied onto electronic media through the	Individual	Reasonable cost-based fee limited to labor for making copies and costs of preparing a summary or explanation as agreed to by the individual.

U.S. Mail or via certified export functionality)		
Electronic copies of PHI in an EHR received in response to an access request to direct such copies to a third party.	Third party as directed by the individual through the right of access	Reasonable cost-based fee, limited to labor for making copies and for preparing a summary or explanation agreed to by the individual.

Notice of Access and Authorization Fees

In order to ensure individuals are aware of the cost and fees to access copies of PHI, HHS is proposing to require covered entities to provide advanced notice of the approximate fees for copies of PHI requested under the access right and with an individual's valid authorization. To accomplish this, covered entities would be required to post a fee schedule online, if they have a website, and provide to individuals at the point of service. Formats of the fee schedule would be in paper or electronic format, at the point of care or at an office that is responsible for releasing medical records, or orally over the telephone as applicable.

The notice would be required to include the following:

- All types of access available free of charge
- Fee schedule for:
    - Copies provided to individuals under 45 CFR 164.524(a), with respect to all readily producible electronic and non-electronic forms and formats for such copies;
    - Copies of PHI in an EHR and directed to third parties designated by the individual under 45 CFR 164.524(d), with respect to all readily producible electronic forms and formats for such copies; and
    - Copies of PHI sent to third parties with the individual's valid authorization under 45 CFR 164.508, with respect to all available forms and formats for such copies.

The covered entity would also be required to provide a summary of the approximate fees to be charged to fulfill the request for PHI. This would be part of the 15-day timed response and allow for discussion and clarification of the request. Only if the 15-day extension were needed after discussion and clarification would be it allowed if the individual is notified of the needed extension. The charges and fees to fulfill the request would be required to be itemized and provided to the individual.

HHS is encouraging covered entities that charge fees for copies of PHI, to continue to exercise flexibility and assessment of requests to possibly waive fees for those individuals or scenarios where the benefit of the information outweighs the burden of the cost. For example, an individual with limited resources, inability to pay upfront, or in emergent situations.

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

Currently the HIPAA Rules require a covered entity to take reasonable steps to verify the identity of the individual requesting the PHI before it is released to the individual. HHS is proposing to make adjustments "*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." Unreasonable identity verification measures are those that require impractical means to verify an identity, such as requiring notarization of requests and instead require measures which are more convenient.

HHS is not proposing exact measures to be implemented nor impede with state and federal regulations for verification of identity but expect covered entities to employ measures which are not unreasonable, costly, or create burdens to the individual and their rights to their PHI.

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

Currently the HIPAA Rules allow for disclosure of PHI without an individual's authorization for treatment and certain healthcare operations. HHS is proposing to clarify the meaning of healthcare operations to encompass all care coordination and case management by health plans, whether individual-level or population-based. The new definition for "healthcare operations" would be as follows, *"…population-based activities relating to improving health or reducing health care costs; protocol development; case management and care coordination; contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment."*

Creating an Exception to the Minimum Necessary Standard for Disclosures for Individual-level Care Coordination and Case Management (45 CFR 164.502(b)(2))

Currently HIPAA Rules require covered entities to use, disclose, or request only the minimum PHI necessary to meet the purpose for the needed information. HHS is proposing to add an express exception to the minimum necessary standard for disclosures to, or requests by, a health plan or healthcare provider. The exception would only apply to the care coordination and case management activities at the individual level as patient privacy beyond this would be weakened.

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)

Currently HIPAA Rules do not require a covered entity to obtain an individual's consent to disclose their PHI for treatment, payment, or healthcare operations (TPO) purposes. HHS is proposing to modify language to 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. The changes would only allow health plans or covered healthcare providers to disclose PHI without authorization to a third party that provides health related services to an individual; however, the third party does not have to be a healthcare provider. The third party could be providing supportive services such as food and shelter or housing to address health risks to the individual.

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 believes covered entities can do more to assist families and caregivers trying to address health related emergencies where an individual may be incapacitated or otherwise unable to express their privacy preference. HHS proposes to amend five provisions of the HIPAA Rules "… "*to replace the exercise of professional judgment" standard with a standard permitting certain disclosures based on a "good faith belief" about an individual's best interests."* HHS is also proposing to amend the provision which allows for a covered entity to use or disclose an individual's PHI based on "serious and imminent threat" and replace with a "serious and reasonably foreseeable threat" standard.

The five provisions addressed by HHS include:

- Disclosures to personal representatives
- Uses and disclosures requiring an opportunity for the individual to agree or object
- Identity Verification
- Uses and disclosures to avert a serious threat to health or safety
- Relevant guidance encouraging disclosures of PHI to help individuals experiencing opioid use disorder or mental illness

The following are examples provided by HHS directly from the proposed rule to illustrate the proposed good faith standard for each provision:

> *Parent or guardian who is not the individual's personal representative.* The Department proposes to amend 45 CFR 164.502(g)(3)(ii)(C) to permit a covered entity to disclose the PHI of an unemancipated minor to a parent or guardian who is not the personal representative of the individual under HIPAA if consistent with state or other applicable law and a licensed health care professional has a good faith belief that disclosing PHI is in the best interests of the individual.
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> *Facility Directories.* The Department proposes to amend 45 CFR 164.510(a)(3)(i)(B) to permit a covered entity to include an individual's name in a facility directory and to disclose, for directory purposes, the individual's location and general condition, when the individual is unable to agree or object and the covered entity has a good faith belief that the disclosure is in the best interests of the individual. For example, this change would facilitate a hospital's disclosure of directory information about an individual who is incapacitated and unable to identify family members or other caregivers involved in his or her care who are trying to locate the individual.
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> *Emergency contacts*. The Department proposes to amend 45 CFR 164.510(b)(2)(iii) to permit covered entities to disclose relevant information to a person involved in the individual's care or payment for care when the covered entity reasonably infers, based on a good faith belief, that the individual does not object. For example, under this proposal an acute care facility that lacks a written designation of an emergency contact but possesses knowledge of an incapacitated patient's designated emergency

contact could disclose PHI to that contact, based on a good faith belief that the patient does not object to the disclosure. In contrast, a disclosure of PHI by a covered entity with knowledge of an individual's advance directive that documents an objection to disclosure to a particular person would be inconsistent with a good faith belief that the individual does not object.

Emergencies and incapacity. The Department proposes to amend 45 CFR 164.510(b)(3) to permit covered entities to disclose relevant information about the individual to family members and other caregivers who are involved with the individual's care or payment for care, or who require notification related to the individual, when the individual cannot agree to the disclosure because of absence, incapacity, or emergency circumstances, and the covered entity has a good faith belief that the disclosure is in the best interests of the individual. This change would, for example, facilitate a health care provider's disclosure of PHI to a caregiver of a patient who is incapacitated by an overdose, mental health crisis, or other health emergency.

*Verifying requestor's identity***.** The Department proposes to amend 45 CFR 164.514(h)(2)(iv) to provide that a covered entity would satisfy its obligations to verify a requestor's identity if the covered entity acts on a good faith belief in making a disclosure of relevant PHI under 45 CFR 164.510, 164.512(j), and 164.514(h)(2)(iv). These disclosures are already limited in scope to the information relevant to assisting the individual with his or her health care or payment for care (45 CFR 164.510) or to the minimum amount of information necessary for the purpose (45 CFR 164.512(j)). This proposal would, for example, improve the ability of a covered hospital to disclose PHI of an individual experiencing an emergency to a person who represents that he or she is a family member or caregiver of the individual, without requiring the family member or caregiver to present documentation of the relationship with the individual, if the hospital has a good faith basis for believing the requestor and the requestor's identity.

<u>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)</u>

Currently HIPAA Rules require a healthcare provider that has a direct treatment relationship with an individual to make a good faith effort to obtain a written acknowledgement of receipt of the provider's Notice of Privacy Practices (NPP). If the provider is unable to obtain the written acknowledgement from the individual, the provider must document the good faith efforts and reason(s) for not obtaining the individual's acknowledgement and maintain the documentation for six years.

In order to eliminate the paperwork burden and reduce confusion on this, HHS is proposing to eliminate the requirements for a covered healthcare provider with a direct treatment relationship to an individual to obtain written acknowledgement of the receipt of the NPP. In addition, if changes are finalized it would also allow the covered entity if they are unable to obtain the written acknowledgement from the individual they have reviewed the NPP, the covered entity would be able to document their good faith efforts and the reason for not obtaining the acknowledgement. The requirement for maintaining the documentation for six years would also be removed, if finalized.

HHS would require an added element to the NPP, inclusion of language to address the right to access PHI, how individuals can exercise the right to access their PHI, free of charge or with a limited cost, and the right to direct transmission of PHI by a covered entity to the EHR of a third party. An additional element would be optional but outlines to the individual how they can direct their PHI to a third party when the PHI is not in an electronic format or electronic health record. Making the individual aware of the opportunity they retain the right to have the PHI sent to a third party using valid authorization.

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 is proposing to allow for PHI to be disclosed to Telecommunications Relay Service (TRS) communication assistants by covered entities, and their business associates acting on behalf of a covered entity, to conduct covered functions. The proposed added language would cover all disclosures to TRS communications assistants relating to any covered functions performed by, for, or on behalf of covered entities and clarify for covered entities that a business associate agreement is not needed with a TRS communications assistant. HHS is proposing to exclude TRS providers from the definition of business associate. This proposal is to ensure individuals and workforce members who are deaf, hard of hearing, or deaf-blind, or have a speech disability are able to communicate easily using TRS for care coordination and other purposes.

Expanding the Permission to Use and Disclose the PHI of Armed Forces Personnel to Cover all Uniformed Services Personnel (45 CFR 164.512(k))

Currently HIPAA Rules allow for disclosure of PHI for Armed Services personnel without authorization for specialized purposes. The PHI can be disclosed to appropriate military command authorities to assure proper execution of the military mission, provided the conditions are met. HHS is proposing to expand the Armed Forces to include personnel part of U.S. Public Health Service (USPHS) Commissioned Corps and the National Oceanic and Atmospheric Administration (NOAA) Commissioned Corps, respectively. USPHS personnel must be medically fit to deploy in response to urgent and emergent public health crises and NOAA personnel are held to standards in alignment with the US Coast Guard. When personnel of USPHS or NOAA are no longer fit for duty, they are entitled to retirement pay and compensation, and once separated are entitled to receive veterans' benefits. Due to this, HHS is proposing to expand to all Uniformed Services personnel the current Armed Forces permission for covered entities to use and disclose PHI for mission requirements and veteran eligibility.

Comment Period to Proposed Rule

The release of this proposed rule to the Federal Register on January 21, 2021 included a 60-day comment period which was scheduled to end March 22, 2021; however, due to uncertainty related to the timing of the release and administration changes HHS has extended the comment period to May 6, 2021.

See the following pages for the specific comments requested of the proposed rule HHS has outlined as looking for feedback on.

Specific Questions HHS has Requested Comments

The following is the various questions HHS specifically outlined within the proposed rule for which they are seeking comment.

The Department seeks comment on the foregoing proposals, including any benefits or unintended consequences, and the following considerations in particular:

1. 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.
2. 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.
3. 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.
4. Whether the proposed definition of EHR includes PHI outside of an electronic designated record set, whether it should, and examples of such PHI.
5. Whether the proposed interpretation of "health care clinicians and staff" as it relates to the proposed EHR definition is appropriate, too broad, or too narrow, and in what respects.
6. 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?
7. Are there other health care industry participants that have access to or maintain EHRs that should be explicitly recognized in the definition of EHR or that OCR should consider when establishing such a definition?
8. Whether EHR should be defined more broadly to include all ePHI in a designated record set, and benefits or drawbacks of doing so.
9. 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?
10. Any other effects, burdens, or unintended consequences of the proposed definition of EHR or of including a definition for EHR in the Privacy Rule.
11. What types of activities should be encompassed in the terms "managed," "shared," and "controlled" in the proposed definition of personal health application, and whether other terms would improve the clarity of the definition.
12. 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.
13. The frequency with which covered entities currently receive requests to inspect PHI in person, and estimated annual costs to covered health care providers and health plans of fulfilling such requests.
14. 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.

15. 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.
16. The Department also invites comment on whether to apply any potential education, notice, or warning requirement to only health care providers or also to health plans. Whether the Department should consider requiring a covered health care provider or health plan to provide any specific educational or advisory language to individuals who may choose to share their PHI with other individuals through applications that are not regulated by the Privacy Rule.
17. 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.
18. Whether any federal or state law time limit shorter than 15 calendar days that applies to disclosures of PHI to a third party (*e.g.*, public health agency) should be deemed a "practicable" time limit under the Privacy Rule right of access.
19. 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?
20. 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.
21. Whether there would be unintended consequences for the covered entity that has received PHI as a result of a request that was made to another covered entity by an individual.
22. "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.
23. Whether the Department should specify any bases 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.
24. 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.
25. Whether a covered health care provider or health plan that uses an HIE to make a broadcast query to identify other HIE participants that have PHI about that individual, and that requests the PHI on

behalf of an individual, should be considered to be making a permissible disclosure of PHI for customer service or other administrative or management activities that are part of the covered health care provider or health plan's health care operations.149 Are there unintended consequences for covered entities or individuals of such an interpretation of health care operations?

26. 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.
27. Whether the term "internet-based method" or alternative terms adequately describe online patient portals, mobile applications, APIs, and other related technologies. If there are unintended consequences associated with using such broad terminology, are there ways in which any unintended adverse effects could be minimized?
28. 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)?
29. 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?
30. The fees (if any) that covered entities currently charge when sending records to another provider or covered entity at the request of an individual.
31. What fees, if any, are charged for disclosures among covered entities made at the request of the entities?
32. 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.
33. 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.
34. 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.
35. Comment on whether the Department should specify one or more of the three methods listed above, or another method, in the regulatory text as the exclusive acceptable method of calculating access fees. This NPRM does not propose to require any particular method of calculation; however, the Department requests comment on the benefits and burdens of doing so. The Department also requests comment on the reasonableness of the $6.50 flat fee for electronic copies of PHI maintained electronically, and whether another flat rate would be more appropriate. Finally, the Department

requests comment on whether other methods of calculating fees should be required in regulation or offered as options in guidance.

36. 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.
37. 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.
38. 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.
39. 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?
40. 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?
41. 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.
42. 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)?
43. How could or should covered entities consider the costs of implementation when evaluating whether a verification method is practicable?
44. Whether the proposal would support individuals' access rights by reducing the verification burdens on individuals, and any potential unintended adverse consequences.
45. Whether a different identity verification standard should apply when an individual requests access, as compared to when a personal representative requests access on the individual's behalf.
46. Examples of state law identity verification requirements that apply when a covered entity provides PHI to an individual or personal representative, or fulfills an individual's request to direct a copy of PHI to a third party. Please provide input on whether any state law identity verification requirements create a barrier to or unreasonably delay an individual's exercise of the right of access in a manner that should be considered inconsistent with the Privacy Rule.
47. The Department requests comments on 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, and on any potential unintended adverse consequences.

48. 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.
49. Please provide examples of particular care coordination or case management activities that would be furthered or impeded by this proposal.
50. Please describe any unintended negative consequences of the proposed changes for the privacy of PHI or the health information rights and interests of individuals. Would there be any negative impact, in particular, on certain populations (*e.g.*, people with disabilities, older adults, rural dwellers, persons experiencing mental health conditions and/or substance use disorders or other illnesses, or others)?
51. Would the proposed changes have similar or different effects on the activities of health plans versus health care providers? Are there unintended consequences for other ancillary providers including social services agencies, community based organizations, and HCBS providers? Please describe.
52. What alternative regulatory modifications or clarifying guidance might achieve the same or greater improvements in care coordination or case management?
53. A health care provider that refused to disclose PHI would not be considered to be information blocking when a state or federal law requires one or more preconditions for providing access, exchange, or use of electronic health information and the precondition has not been satisfied.182 This proposed modification would remove one of the minimum necessary policy "preconditions" for refusing to respond to a request for an individual's PHI without violating the information blocking prohibition. How would the information blocking provisions in the ONC rule interact with these modifications, and are there any adverse unintended consequences that might result, such as covered entities requesting and receiving far more than the minimum amount of PHI necessary for individual-level care coordination and case management and using PHI for other unrelated purposes?
54. Some disclosures for payment purposes with respect to an individual's health care are related to care coordination and case management (*e.g.,* review of health care services for appropriateness of care). Disclosures for payment purposes are subject to the minimum necessary standards. Should all or certain individual-level payment activities be included in the proposed exception?
55. Please provide additional examples of circumstances in which it should be considered reasonable, or unreasonable, to rely on the representations of another entity that it is requesting the minimum necessary PHI.
56. 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.
57. Whether the proposal poses any particular risks for individuals related to permitting disclosures without authorization for individual-level care coordination and case management activities that are health care operations (i.e., those that are conducted by health plans) in addition to individual-level care coordination and case management activities that constitute treatment (i.e., those that are conducted by health care providers).
58. Would the proposed change remove perceived barriers to disclosure of PHI, as appropriate, to social services agencies, community-based organizations, and HCBS providers to better enable care coordination and case management? Are there other entities the Department should identify in regulatory text as examples of appropriate recipients of PHI under the proposed permission?

59. Should the proposed change be limited to care coordination and case management for a particular individual as proposed, or should it also include population-based efforts?
60. Would this permission to disclose PHI for case management and care coordination to the entities described above interact with the ONC information blocking requirement to create any unintended adverse consequences for individuals' privacy? Please explain.
61. Should the Department specify the types of organizational entities to be included as recipients of PHI in this express permission in regulation text, as well as limitations or exclusions, if any, that should be placed on the types of entities included? If yes, what types of organizational entities should be included or excluded?
62. Should the Department limit the proposed permission to disclose PHI to circumstances in which a particular service provided by a social services agency, community-based organization, or HCBS provider is specifically identified in an individual's care plan and/or for which a social need has been identified via a screening assessment? Should the Department require, as a condition of the disclosure, that the parties put in place an agreement that describes and/or limits the uses and further disclosures allowed by the third party recipients?
63. To what extent are social services agencies, community-based organizations, and HCBS providers covered health care providers under HIPAA? How many are non-covered health care providers? Are any such entities covered under HIPAA as health plans?
64. Would the proposed change in standard from "professional judgment" to "good faith belief" discourage individuals from seeking care?
65. Should the Department apply the good faith standard to any or all of the other nine provisions in the Privacy Rule that call for the exercise of professional judgment? Are there circumstances in which it would be inappropriate to apply a presumption of compliance across the other nine provisions?
66. 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?
67. When should overriding an individual's prior expressed preferences constitute bad faith on the part of the covered entity, which would rebut the presumption of compliance? Are there instances in which overriding an individual's prior expressed preferences would not constitute bad faith on the part of the covered entity?
68. Would the proposed "serious and reasonably foreseeable threat" standard discourage individuals from seeking care?
69. 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.
70. How often do mental and behavioral health professionals perceive that HIPAA constrains their ability to report such threats? Please provide specific examples, when available, including relevant state law.

71. Are there potential unintended consequences related to granting extra deference to a covered health care provider based on specialized risk assessment training, expertise, or experience when determining that a serious threat exists or that serious harm is reasonably foreseeable? Are there unintended consequences related to specifying mental and behavioral health professionals as examples of such providers?
72. 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?
73. Would the proposed changes to the NPP requirements have any unintended adverse consequences for individuals or regulated entities?
74. Would the revised NPP content requirements improve individuals' understanding of, and ability to exercise, their rights under the Privacy Rule?
75. Are there ways that OCR can improve the model NPPs to be more informative and easier to understand?
76. Should the model NPP's description of health care operations be modified? If so, please provide suggested language for modifying the description in the model NPP to reflect how your organization uses PHI for health care operations purposes.
77. Are there specific examples that should be included in a model NPP to explain to individuals how PHI can be used or disclosed for health care operations?
78. 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.
79. Would the proposed change (regarding TRS communication assistants) achieve the anticipated effects?
80. Are there any potential unintended, adverse consequences of the proposal?
81. Please share data related to the number of covered entity and business associate workforce members who are deaf, hard of hearing, or deaf-blind, or who have a speech disability and currently utilize TRS to perform their duties.
82. Please provide data on the amount of time and other resources covered entities and business associates have spent on determining whether they need a business associate agreement with a TRS provider, or actually entering into business associate agreements with TRS providers.
83. The Department requests comments on this proposal, including on whether the proposed change would achieve the anticipated effects and any potential unintended consequences. (regarding the inclusion of USPHS and NOAA to expand to all Uniformed Services personnel).