HHS HIPAA Notice of Proposed Rulemaking Public Comments Guide – Davis Wright Tremaine LLP

On January 21, 2021, the Department of Health and Human Services (the Department) issued a Notice of Proposed Rule Making (NPRM) to modify the Standards for the Privacy of Individually Identifiable Health Information (Privacy Rule) under the Health Insurance Portability and Accountability Act of 1996. In the NPRM, the Department included various requests for comments seeking feedback for its proposed changes to the Privacy Rule.

Below, we outline those requests for comments. There were several requests for comments within the actual explanation of the NPRM, while some were broken out into separate "requests for comments" sub-sections. The requests for comments sub-sections were similar to, but not exactly the same as, the questions within the explanation of the proposals. The questions below are in different colors to distinguish between the two types of requests for comments:

- **Blue text: Questions/requests for comment within the explanation of the proposals**
- **Black Text: Questions within the individual Requests for Comments sub-sections**

Subsection/Topic	Request for Comment
Effective and Compliance Dates	The Department requests comment on whether the 180-day compliance period is sufficient for covered entities and business associates to revise existing policies and practices and complete training and implementation. For proposed modifications that would be difficult to accomplish within the 180-day timeframe, the Department requests information about the types of entities and proposed modifications that would necessitate a longer compliance period, how much longer such compliance period would need to be to address such issues, as well as the complexity and scope of changes and the impact on entities and individuals of a longer compliance period.
Care Coordination and Case Management Described	The Department welcomes comment on the examples and descriptions herein and on any additional definitions, examples, or scenarios that would be helpful for regulated entities and the public to understand what constitutes care coordination and case management.

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The Health Information Technology for Economic and Clinical Health (HITECH) Act and the 2013 Omnibus Rule	Consistent with the court's opinion, which the Department did not appeal, the Department takes the opportunity of this NPRM to seek public comment on proposals to: (1) narrow the scope of the access right to direct records to a third party to only electronic copies of PHI in an EHR; and (2) apply new fee limitations to the access right to direct a copy of PHI to a third party, as described more fully below.
Individual Right of Access (45 C.F.R. § 164.524)	The Department seeks comment on the scope of this proposed definition for EHR, including billing records for health care.
	The Department requests comment on the proposed definition of personal health application, including the types of activities encompassed in the terms "managed," "shared," and "controlled," and on the Department's assumptions about the use of such applications by individuals. The proposed definition of personal health application is meant to be consistent with the HITECH Act definition of personal health record (PHR), but specifically addresses certain health applications, which may or may not be PHRs.
	However, the Department requests comment on this point and examples of possible unintended consequences of the proposal. Additionally, the Department invites comments on whether covered entities should be permitted to provide copies of PHI in lieu of in-person inspection of PHI, when necessary, to protect the health or safety of the individual or others, such as during a pandemic; and if so, whether the Department should establish additional rights for individuals in such circumstances, such as the right to receive such copies for free.
	The Department seeks comment on whether to require covered health care providers to allow individuals to record PHI in this manner as part of the Privacy Rule access right; whether conditions or limitations should apply to ensure that a covered health care provider does not experience unreasonable workflow disruptions (e.g., limitations on time spent recording PHI in conjunction with a health care appointment); any potential unintended consequences of a new requirement to allow inspection of PHI that is readily available at the point of care in conjunction with a health care appointment; and how to determine when PHI is "readily available."

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	Although the Department did not solicit comment in the 2018 RFI about this section of the Privacy Rule, the Department believes it is appropriate to solicit comment on a proposal to expressly prohibit a covered entity from imposing unreasonable measures that would impede an individual's right of access. The Department believes such a proposal would support the goal of improving coordination of care for individuals, as further discussed below.
	The Department solicits comment on its assumptions, and seeks examples of unreasonable measures that individuals and covered entities believe could reduce an individual's ability to participate in the coordination of his or her own healthcare. The Department also requests comment on burdens that covered entities believe may result from this proposed change.
	The Department seeks comments on related situations: whether to require a health care provider that has EHR technology that incorporates a secure, standards-based API without extra cost, to implement the API; whether to require a health care provider that could implement such an API at little cost to do so; and how to measure the level of cost that would be considered a reasonable justification for not implementing an API.
	The Department believes that only covered health care providers would be responsible for fulfilling an individual's access request under these proposals because the Department believes other covered entities do not have an EHR as that term is defined in the 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). The Department seeks comment on this assumption.
	While Requester-Recipient might be subject to a records retention requirement under state law, its obligations, with respect to PHI, it receives as a designated third party would be no different under this proposal than its existing obligations when it receives ePHI from other health care providers, e.g., for treatment, payment, or health care operations (TPO) purposes. The Department welcomes examples and comment on this assumption.

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	The Department welcomes comments on whether a Requester-Recipient should be permitted to refuse to submit a request for an individual in some circumstances (e.g., if it already has the requested information), and 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.
	The Department also seeks comments on approaches it may take to clarify that the Privacy Rule permits covered entities to use HIEs to make "broadcast" queries on behalf of an individual to determine which covered entities have PHI about the individual and request copies of that PHI. Section 164.506(c)(1) permits a covered entity to disclose PHI for its own health care operations purposes, including customer service activities, which could include forwarding an access request to other providers using a trusted exchange network. The Department is considering approaches to clarifying this permission to enhance the right of access and seeks comment on how to do so effectively.
	This NPRM proposes to place modified fee limitations in regulatory text and requests public comment on all aspects of the proposal.
	The Department requests comment on any new costs that covered entities would likely incur when providing individuals with opportunities to inspect their PHI in this manner in person at the covered entity's facility. The Department believes that access through an internet-based method likely occurs without involvement of covered entity workforce members, and thus believes that the covered entity likely incurs no allowable labor costs or expenses. The Department requests comment on its view of the costs of providing access through an internet-based method, including any internet-based methods described in the ONC Cures Act Final Rule.

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	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.
	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.
	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.
	Whether the proposed definition of EHR includes PHI outside of an electronic designated record set, whether it should, and examples of such PHI.
	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.
	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?
	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?
	Whether EHR should be defined more broadly to include all ePHI in a designated record set, and benefits or drawbacks of doing so.

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	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?
	Any other effects, burdens, or unintended consequences of the proposed definition of EHR or of including a definition for EHR in the Privacy Rule.
	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.
	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.
	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.
	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.

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	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.
	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.
	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.
	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.

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	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?
	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.
	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.
	"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.
	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.

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	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.
	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. Are there unintended consequences for covered entities or individuals of such an interpretation of health care operations?
	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.
	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?
	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)?

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	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?
	The fees (if any) that covered entities currently charge when sending records to another provider or covered entity at the request of an individual.
	What fees, if any, are charged for disclosures among covered entities made at the request of the entities?
	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.
	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.
	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.

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	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.
	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.
	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.
	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.
	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?

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	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?
Reducing Identity Verification Burden for Individuals Exercising the Right of Access (45 C.F.R § 164.514(h))	The Department assumes that a covered entity holding records of an individual in an EHR has necessarily established a treatment relationship with such individual, and therefore, imposing additional verification requirements is unnecessary. The Department seeks comments on this assumption.
	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.
	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)?
	How could or should covered entities consider the costs of implementation when evaluating whether a verification method is practicable?
	Whether the proposal would support individuals' access rights by reducing the verification burdens on individuals, and any potential unintended adverse consequences.

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	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.
	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.
Amending the Definition of Health Care Operations to Clarify the Scope of Care Coordination and Case Management (45 C.F.R § 160.103)	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.
Creating an Exception to the Minimum Necessary Standard for Disclosures for Individual-level Care Coordination and Case Management (45 CFR § 164.502(b))	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.
	Please provide examples of particular care coordination or case management activities that would be furthered or impeded by this proposal.
	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)?

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	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.
	What alternative regulatory modifications or clarifying guidance might achieve the same or greater improvements in care coordination or case management?
	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. 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?
	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?
	Please provide additional examples of circumstances in which it should be considered reasonable, or unreasonable, to rely on the representations of another entity that is requesting the minimum necessary PHI.

Subsection/Topic	Request for Comment
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)	The express permission for disclosures to these third party entities is being proposed primarily to facilitate the treatment and health care operations of the disclosing covered entities in cases where a disclosure will serve the health care or health-related needs of individuals. The Department's understanding is that, in general, the third party entities receiving PHI under this proposed permission would not be covered entities and thus, the PHI disclosed to them would no longer be protected by the HIPAA Rules. However, because some of these third party recipients of PHI may be health care providers or covered health care providers under HIPAA, which can perform care coordination and case management for their own treatment activities (and, with respect to covered health care providers, for health care operations), the Department does not propose to limit the regulatory text of the permission to disclosures made by a covered health care provider or health plan as part of the discloser's own treatment and health care operations. For example, under this proposal, a covered health care provider could expressly disclose PHI for the case management and care coordination activities of another health care provider or health plan. Such disclosures are permitted under the current rule at 45 CFR 164.506(c)(2) and (c)(4); however, the Privacy Rule currently does not address the applicability of this permission to case management and care coordination. The Department requests comment on whether such limiting language would be appropriate.
	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.
	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).

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	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?
	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?
	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.
	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?
	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?
	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?

Subsection/Topic	Request for Comment
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)	The Department does not intend with this proposal to perpetuate false and harmful stereotypes about individuals with SMI or SUD, but rather to ensure that HIPAA is not a barrier in instances when entities believe a disclosure of PHI is necessary to prevent harm to the individual or to others. Further, the Department believes that licensed mental and behavioral health professionals are among the health care providers that are most likely to have specialized training, expertise, or experience for which it is reasonable to establish a higher level of deference to their belief that a threat exists and that serious harm is reasonably foreseeable. The Department requests comment on this proposal. The Department also proposes non-substantive revisions to 45 CFR 164.512(j) to refer to preventing a harm or lessening a threat, rather than preventing or lessening a threat. These proposed revisions are intended to clarify the standard, not change it; however, the Department requests comment on whether any unintended adverse consequences may result from the revisions.
	Would the proposed change in standard from "professional judgment" to "good faith belief" discourage individuals from seeking care?
	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?

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	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?
	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?
	Would the proposed "serious and reasonably foreseeable threat" standard discourage individuals from seeking care?
	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.
	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.

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	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?
	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?
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)	Based on public comments on the 2018 RFI, the Department does not propose to create a safe harbor to deem those entities that use the model NPP compliant with the NPP. Instead, the Department requests comment on ways the model NPP could be changed to improve consumer understanding. For example, the Privacy Rule.
	Would the proposed changes to the NPP requirements have any unintended adverse consequences for individuals or regulated entities?
	Would the revised NPP content requirements improve individuals' understanding of, and ability to exercise, their rights under the Privacy Rule?
	Are there ways that OCR can improve the model NPPs to be more informative and easier to understand?
	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.

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	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?
	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.
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)	Would the proposed change achieve the anticipated effects?
	Are there any potential unintended, adverse consequences of the proposal?
	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.
	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.
Expanding the Permission to Use and Disclose the PHI of Armed Forces Personnel to Cover all Uniformed Services Personnel (45 CFR § 164.512(k))	The Department requests comments on this proposal, including on whether the proposed change would achieve the anticipated effects and any potential unintended consequences.
Public Participation	The Department seeks comment on all issues raised by the proposed regulation, including any unintended adverse consequences.

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Regulatory Impact Analysis	The Department requests comment on the estimates, assumptions, and analyses contained herein – and any relevant information or data that would inform a quantitative analysis of proposed reforms that the Department qualitatively addresses in this RIA.
	To the extent that these assumptions would impact the Department's estimate of costs, the Department welcomes comment on its assumptions, particularly those in which the Department identifies the level of workforce member (i.e., clerical staff, professional) that would be engaged in activities, and the amount of time that particular types of workforce members spend conducting activities related to this NPRM as further described below.
	For all of the proposed regulatory changes that covered entities are currently allowed to implement, consistent with its interpretive guidance, the Department seeks comment on the extent to which covered entities are already voluntarily implementing the proposed requirements, and thus would not incur additional costs or realize savings as a result of the proposed changes.
	Unless otherwise indicated, the Department relies on data about the number of businesses from the U.S. Census. The Department requests public comment on these estimates, including those for third party administrators and pharmacies where the Department has provided additional explanation. The Department additionally requests detailed comment on any situations in which covered entities other than those identified here would be impacted by this rulemaking.
	The Department requests data on costs from covered entities' data and comments on individuals' experiences when charged a fee for copies of PHI or when it is provided for free.
	The Department requests comment or examples that could assist the Department in quantifying costs or cost savings in relation to the following:

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	• Any relationship between individuals' access to medical records and improved health outcomes, including data about any health effects related to the amount of time between a request for access and the provision of access;
	• Any relationship between fees individuals pay to obtain medical records and the frequency with which the individual seeks treatment;
	• Any relationship between the ease or difficulty faced by covered health care providers and health plans to make minimum necessary determinations and health outcomes of individuals or populations;
	• Any relationship between the ease or difficulty faced by covered health care providers' and health plans' to disclose PHI based on a professional judgment standard or a good faith belief standard, and the frequency with which an individual will seek care from that provider or enroll with that plan, especially for treatment or coverage related to substance use disorders or serious mental illness.
	• The frequency with which different types of covered entities currently disclose PHI based on: o Professional judgement about an individual's best interests; and o A good faith belief that a threat or harm is serious and imminent, and the type of harm; and
	• Any relationship between improved compliance with non-discrimination laws, such as the ADA, and health outcomes of populations protected by those laws.
	The Department provides below the basis for its estimated costs and savings due to the proposed changes to specific provisions of the Privacy Rule and invites comments on the Department's assumptions, data, and calculations, as well as any additional considerations that the Department has not identified here. The Department welcomes information or data points from commenters to further refine its estimates and assumptions.

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	The Department received widely varying reports from covered entities that commented on the RFI regarding the number of access requests they receive annually and it was unclear whether the numbers included requests that are not part of the right of access, such as disclosures accompanied by a valid authorization, disclosures for purposes of treatment, payment, or health care operations, or other disclosures permitted by the Privacy Rule. In addition, while large covered entities may receive many more than two requests per year, the Department assumes that small doctor's offices, which make up the majority of covered entities, receive very few requests. The Department requests comment on these assumptions.
	Upon consideration of the instances where PHI is readily available at the point of service, such as when viewing x-rays or lab results, the Department anticipates that there may be a much greater demand by individuals for the ability to use one's own device to capture the images or other PHI as a result of this proposal. The Department anticipates this would result in individuals having better access to their medical information, leading them to potentially make better decisions about their health. The Department does not anticipate that covered entities would incur additional costs for allowing this type of access to "readily available" PHI, but requests comment on this assumption and data on potential costs.
	The Department seeks comments on the extent to which covered entities already have policies permitting individuals to photograph or otherwise capture the PHI, and how changing policies to allow such activities would increase or decrease costs to the entity or individuals. In particular, the Department seeks comments providing any quantifiable projected cost increases or decreases due to the proposed changes, including allowing individuals to photograph PHI that is readily viewable at the point of service in conjunction with a health care appointment.
	The Department projects that the ability to obtain health information faster may result in cost savings overall. The Department invites comments providing data on projected cost savings from shortening the access time limits from 30 days to 15 calendar days.

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	The Department estimates that at least 50 percent of access requests are already being fulfilled in 15 calendar days or less, taking into account those covered entities (primarily health care providers) subject to state laws with 15-day (or shorter) requirements and other covered entities that fulfill requests in 15 calendar days or less voluntarily. The Department estimates that the burden to covered entities to provide copies of PHI to individuals in half the time than currently permitted would result in increased costs for responding to access requests by 1 minute of a medical records technician's labor which can be attributed to search and retrieval activities that are not included in the allowable labor costs that may be charged to individuals. Based on an estimated 1.46 million annual total access requests for copies of PHI provided to individual at an average increased labor cost of $.75 per request, the Department calculates the total additional annual burden would be approximately $918,400. The Department requests comment on these assumptions.
	The Department anticipates that with the clear and certain path provided by this proposal to obtain ePHI from other covered health care providers (who are required to respond), covered entities may experience savings from spending less time attempting to obtain electronic copies of PHI in an EHR from other covered health care providers based on an individual's request. The Department has not quantified these cost savings, but invites comments on any projected savings to covered entities and/or individuals from this regulatory clarification.
	See Lye CT, Forman HP, Gao R, et al. "Assessment of US Hospital Compliance With Regulations for Patients' Requests for Medical Records." JAMA Netw Open. 2018;1(6):e183014, available at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2705850, citing a study evaluating the state of medical records request processes in US hospitals in which a hypothetical assumption of 200 pages per request was used. The Department requests comment and evidence regarding the actual lengths of medical records.
	The Department seeks comments on these estimates, averages, and assumptions underlying its analysis and invites comments on the number and type of access requests received by covered entities, costs incurred, and fees charged.

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	Covered entities also would need to add new access fee policies and procedures to their HIPAA training content. In its estimates, the Department includes two hours and thirty minutes of a training specialist's time for each covered entity to revise the training content for all of the proposed changes to the right of access, including fees and responding to requests for fee estimates, at an adjusted mean hourly rate of $63.12. The Department believes this estimate is reasonable, but welcomes comment and data to further inform its assumption. In total, the Department estimates 1,935,828 burden hours
	Free Access for Inspecting PHI In-Person: To the extent that covered entities are charging individuals for the copies individuals make with their own devices or resources, the covered entities would incur some loss of revenue; however, the Department anticipates that any loss would be minimal and that covered entities do not view this as a significant source of revenue, if any do charge a fee to inspect PHI in person. The Department seeks comments on the number of requests covered entities receive to inspect PHI in person and on the number of covered entities that charge fees for or prohibit individuals from making copies with their own devices or taking notes of their own PHI, and if so, the amount of fees charged for such activities.
	The Department has insufficient information to quantify the potential increased burden on individuals for these options and welcomes information and comment on these potential changes to individuals' expenditures of time and money. *[options listed starting on page 257]*
	However, the Department has no data with which to estimate the reduction in burden and welcomes comments on this change, including covered entities' experiences with the collection of access and authorization fees, the factors affecting the scope of individuals' requests for copies, and the costs to covered entities for handling fee disputes.
	The Department seeks comments on the number of covered entities that charge fees only for copies provided based on a valid authorization, no fees for fulfilling requests pursuant to the right of access.

Subsection/Topic	Request for Comment
	The Department seeks comments and data on its assumptions, and on the number of covered entities that require individuals to use an access request form and how many currently make an access and/or authorization fee schedule available to individuals, either online or through other means, such as email or telephonically.
	The Department anticipates that many covered entities are already providing access fee estimates, as recommended in OCR's 2016 Access Guidance; however, the Department seeks comments on the number of covered entities that provide estimates of access and authorization fees.
	The Department seeks comments on the number (and relative volume) of requests for the specific details of allowable charges for copies of PHI that covered entities receive from individuals or their personal representatives.
	The Department invites comment and examples of the extent to which covered entities impose measures that some may view as unreasonable and create costs for individuals when seeking to request access to PHI.
	As the Department does not have data upon which to refine its assumptions and estimates, the Department invites comments in this regard for future consideration, as well as on any costs associated with implementing the proposed changes.
	The Department lacks quantifiable data on the number of such determinations that occur in every covered entity and requests comment on the number of determinations, the type and level of workforce members making the determinations, and how such determinations are made consistent with an entity's minimum necessary policies and procedures.
	The Department does intend to illustrate that some covered entities continue to view minimum necessary determinations as burdensome and to the extent a new exception for care coordination and case management would relieve this burden, should be quantified as a cost savings. The Department requests comment on this approach.

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	The Department welcomes comments and information about its estimates and the assumptions underlying its proposed burden calculations and cost savings, including: • The level of workforce member (e.g., clerical staff, professional) responsible for making minimum necessary determinations on behalf of covered health care providers and health plans and a description of how the determination is made based on a covered entity's minimum necessary policies and procedures; • Time spent by a covered health care provider or health plan to make a minimum necessary determination; • The frequency with which a covered health care provider or health plan makes minimum necessary determinations (i.e., the number of determinations by day or month); and • The frequency with which a covered health care provider or health plan currently obtains individuals' authorizations prior to making a disclosure of PHI for care coordination or case management for that individual.
	The Department requests comments on all of the assumptions and analyses within the cost-benefits analysis. The Department also requests comments on whether there may be other indirect costs and benefits resulting from the proposed changes in the proposed rule, and welcomes additional information that may help quantify those costs and benefits.
5.G. Paperwork Reduction Act of 1995	To fairly evaluate whether an information collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that the Department solicit comment on the following issues: 1. Whether the information collection is necessary and useful to carry out the proper functions of the agency; 2. The accuracy of the agency's estimate of the information collection burden; 3. The quality, utility, and clarity of the information to be collected; and 4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Subsection/Topic	Request for Comment
	The PRA requires consideration of the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section. The Department explicitly seeks, and will consider, public comment on its assumptions as they relate to the PRA requirements summarized in this section.