Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement
(45 CFR Parts 160 and 164)

On December 10, 2020, the Department of Health and Human Services (HHS) posted a proposed rule[1] on the HHS website that would make modifications to the HIPAA Privacy Rule intended to support patient engagement in their health care, remove barriers to coordinated care, and reduce regulatory burdens on health care providers and health plans. The proposed rule has yet to be placed on public display or published in the Federal Register. **Because this rule has yet to be officially posted for public inspection by the Federal Register, it is not an official proposed rule. As a result, changes to effective dates and substantive policy could be made before the official release**. Comments will be due 60 days after the date on which the proposed rule is published in the Federal Register.

TABLE OF CONTENTS

[1] https://www.hhs.gov/about/news/2020/12/10/hhs-proposes-modifications-hipaa-privacy-rule-empower-patients-improve-coordinated-care-reduce-regulatory-burdens.htm

I. Introduction

This proposed rule modifies the Standards for the Privacy of Individually Identifiable Health Information (Privacy Rule) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA)[2] and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act). The Privacy Rule protects the privacy and security of individuals' medical records and other protected health information (PHI), 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 other health care clearinghouses).

The proposed modifications are designed to address standards that may limit or discourage care coordination and case management communications among individuals and HIPAA covered entities (including hospitals, physicians, and other health care providers, payors, and insurers) or pose other unnecessary burdens. HHS believes these regulatory burdens may impede transformation of the health care system from a fee-for-service system to a value-based system that pays for quality care.

HHS developed many of the proposals after consideration of comments received in response to the Request for Information on Modifying HIPPA Rules to Improve Coordinated Care.[3] HHS has delegated the authority to administer HIPAA privacy standards to the Office for Civil Rights (OCR).

Effective and Compliance Period

The effective date of the final rule on this issue would be 60 days after publication. HHS proposes that covered entities and their business associates would have the standard 180-day compliance period after publication of a final rule[4]; OCR would begin enforcement of the new and revised standards 240 days after publication of a final rule. **HHS requests comments 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 implement in this timeframe, HHS requests information about the types of entities and proposed modifications that would require a longer compliance period, including the additional time needed to address these issues.

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[2] Subtitle F of title II of HIPAA (Pub.L.104-191, 110 Stat. 1936 added a new part C to title XI of the SSA, Pub; L. 74-241, 49 Stat. 620 (see sections 1171-1179 of the SSA, 42 U.S.C. 1320d-8) as well as promulgating section 264 of HIPAA (codified at 42 U.S.C. 1320d-2 note), which authorizes the Secretary to promulgate regulations with respect to the privacy of individually identifiable health information. The Privacy Rule has subsequently been amended pursuant to the Genetic Information Nondiscrimination Act (GINA), title I, section 105, Pub. L, 110-233, 122 Stat 881 and the Health Information Technology for Economic and Clinical Health (HITECH)Act, Pub.L.111-5, 123 Stat 226.

[3] 83 FR 64302 (December 14, 2018)

[4] 45 CFR 104(c)(1) requires the Secretary to provide at least a 180-day period for covered entities to comply with modifications to standards and implementation specifications in the HIPAA rules.

Care Coordination and Case Management

HHS acknowledges that neither care coordination nor case management has a precise, commonly agreed upon definition and states these terms broadly refer to a set of activities aimed at promoting cooperation among members of an individual's health care delivery team, including family members, caregivers, and community based organizations. Instead of proposing a limited definition, HHS discusses a non-exhaustive list of examples for understanding care coordination and case management. **HHS requests comments on the examples provided and on any additional definitions or examples that would be helpful to understand what constitutes care coordination and case management.**

HHS' discussion includes examples from the Office of the Inspector General (OIG), Centers for Medicare & Medicaid Services (CMS), the Agency for Healthcare Research and Quality (AHRQ), the National Quality Forum (NQF), the Case Management Society of America (CMSA) and the American Case Management Association (ACMA). Highlights of some of these examples are summarized below:

- OIG finalizes a definition of "care coordination and management of care" in its final rule amending the safe harbors to the Federal anti-kickback statute[5] to mean the deliberate organization of patient care activities and sharing of information between two or more value-based enterprise (VBE) participants, one or more VBE participants and the VBE, or one or more VBE participants and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population (42 CFR Part 1001.952(ee)(14)(i)).[6]

- CMS guidance on the Medicaid benefit for children and adolescents describes "care coordination" as a range of activities that link individuals to services and improve communication flow. The guidance states that care coordination includes three key concepts: comprehensive coordination (including coordination of all services, including those delivered by systems other than the health system), patient-centered coordination (designed to meet the needs of the patient) and access and follow-up (described as ensuring the delivery of appropriate services and information flow among providers and back to the primary care provider).[7]

- NQF defines care coordination as "a multidimensional concept that includes effective communication among healthcare providers, patients, families, and caregivers; safe care transitions; a longitudinal view of care that considers the past, while monitoring present

[5] 85 FR 77748 (December 2, 2020)

[6] In this proposed rule, HHS uses the OIG's proposed definition from the proposed rule amending the safe harbors to the Federal anti-kickback statute. The OIG proposed to define "coordination and management of care" as the deliberate organization of patient care activities and sharing of information between two or more value-based enterprise (VBE) participants or VBE participants and patients, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target population (84 FR 55694, 55762 (October 17, 2019).

[7] Making Connections: Strengthening Care Coordination in the Medicaid Benefit for Children & Adolescents," CMS, page 3 (September 2014), available at https://www.medicaid.gov/medicaid/benefits/downloads/epsdt-care-coordination-strategy-guide.pdf.

delivery of care and anticipating future needs; and the facilitation of linkages between communities and the healthcare system to address medical, social, educational, and other support needs that align with patient goals."[8]

- CMSA defines case management as "a collaborative process of assessment, planning, facilitation, care coordination, evaluation and advocacy for options and services to meet an individual's and family's comprehensive health needs through communication and available resources to promote patient safety, quality of care, and cost effective outcomes."[9]

II. Background

HHS reviews the statutory and regulatory provisions pertinent to the proposed modifications to the Privacy Rule.

A. Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the HIPAA Rules

The Administrative Simplification provisions of HIPAA provide for several provisions, including the establishment of national standards to protect the privacy and security of individuals' health information and established civil monetary and criminal penalties for violations of the requirements. These provisions originally applied to three types of entities known as "covered entities": health care providers who transmit health information electronically in connection with any transaction for which HHS has adopted an electronic transaction standard, health plans, and health care clearinghouses.[10] A subsequent statute and its implementing regulations, extended some of the provisions of the Privacy Rule to directly apply to the business associates[11] of covered entities.[12] HHS has modified the Privacy Rule[13] several times to address new statutory requirements and to strengthen, refine, or add flexibility to privacy requirements in specific circumstances.[14]

The Privacy Rule protects individual's medical records and other-individually identifiable health information created, received, maintained, or transmitted by or on behalf of covered entities, collectively defined as protected health information (PHI). The Privacy Rule regulates the circumstances under which covered entities and their business associates may use or disclose PHI and requires covered entities to have safeguards in place to protect the privacy of PHI. As

[8] "Care Coordination Endorsement Maintenance Project 2016-2017," available at http://www.qualityforum.org/Projects/c-d/Care_Coordination_2016-2017/Care_Coordination_2016-2017.html
[9] "What Is A Case Manager?" CMSA (2017) available at http://www.cmsa.org/who-we-are/what-is-a-case-manager/
[10] 42 U.S.C. 1320d-1
[11] A business associate is a person, other than a workforce member, that performs certain functions or activities for or on behalf of a covered entity, or that provides certain services to a covered entity involving the disclosure of PHI to the person (45 CFR 150.103).
[12] 42 U.S.C. 17934 and HHS OCR Fact Sheet on Direct Liability of Business Associates under HIPAA, (May 2019) available at https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/biusiness-associates/index.html
[13] 65 FR 82462 (December 28, 2000)
[14] 67 FR 53182 (August 14, 2002), 78 FR 5566 (January 25, 2013), 79 FR 7289 (February 6, 2014) and 81 FR 382 (January 6, 2016).

part of these protections, covered entities are required to have contracts or other arrangements with business associates that use PHI to perform functions for or on behalf of, or provide services to, the covered entity and that require access to PHI to ensure that business associates also protect the privacy of PHI. The Privacy Rule also establishes the rights of individuals to their PHI, including the right to receive adequate notice of a covered entity's privacy practices, the right to request restrictions of uses and disclosures, the right to access their PHI, the right to request an amendment of their PHI, and the right to receive an accounting of disclosures.[15]

The Privacy Rule established the rights of individuals to access their PHI and requirements for timely action by covered entities, form and format of copies, the denial of access, and documentation. Enactment of the HITECH Act and the 2013 Omnibus Final Rule[16] expanded the requirements by covered entities and included providing individuals access to PHI in the form or format requested by the individual if readily producible and the permission for covered entities to impose a reasonable, cost-based fee for copies. Covered entity can impose a reasonable, cost-based fee limited to the costs of supplies and labor for copying; postage to mail the copy; and preparation of a summary or explanation of PHI if agreed to be the individual.

OCR has delegated authority from the Secretary to implement, interpret, and enforce the Privacy Rule, including enforcement of the Security Rule and the Breach Notification Rule.

B. The Health Information Technology for Economic and Clinical Health (HITECH) Act and the 2013 Omnibus Rule

The HITECH Act[17] promotes the widespread adoption and standardization of health information technology (health IT); subtitle D of title XIII contains amendments to sections 1176 and 1177 of the SSA designed to strengthen the privacy and security protections under HIPAA. These provisions extended the applicability of certain Privacy Rule requirements and all of the Security Rule requirements to the business associates of covered entities; required HIPAA covered entities and business associates to provide for notifications of breaches of unsecured PHI (Breach Notification Rule); established new limitation on the use and disclosure of PHI for marketing and fundraising; prohibited the sale of PHI; required consideration of whether a limited data set can service as the minimum necessary amount of information; and expanded the individuals' right to access electronic copies of their PHI in an electronic health record (EHR)[18], to receive an accounting of disclosures of their PHI, and to request restrictions on certain disclosures of PHI to health plans.

The 2013 Omnibus Rule provided that if the individual's requested PHI is maintained electronically in one or more designated record sets[19] and if the individual requests an electronic

[15] 45 CFR 164.520, 164.522, 164.524, 164.526 and 164.528
[16] 78 FR 5566 (January 25, 2013)
[17] The HITECH Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009, Pub.L,111-5, 123 Stat. 115
[18] Under Subtitle D of Title XIII of the HITECH Act, the term "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 (42 U.S.C. 17921(5)).
[19] A "Designated record set" is defined as (1) A group of records maintained by or for a covered entity that is (i) The medical records and billing records about individuals maintained by or for a covered health care provider; (ii) The

copy, the covered entity must provide the individual with access to their PHI in the electronic form and format requested by the individual if it is readily producible in such form and format or in a form and format agreed to by the covered entity and individual.[20] This rule also provides that covered entities must transmit a copy of an individual's PHI directly to a third party designed by the individual; the request must be in writing, signed by the individual, and clearly identify the designated third party and where to send the copy of the PHI.[21]

The 2013 Omnibus Rule amended 45 CFR 164.524(c)(4) to provide that fees could include, in addition to postage and preparation or explanation when application, labor for copying the PHI and supplies for creating the paper or electronic media if the individual requested the PHI in a portable format. HHS described considerations for a covered entity to include in the labor costs.

In 2016, OCR issued guidance (2016 Access Guidance) for the public about the individual's right to access PHI and clarified covered entities obligations.[22]

The U.S. District Court of Columbia, in *Ciox Health, LLC v. Azar, et al.*,[23] vacated: (1) the Department's expansion of the HITECH Act's "third party directive" beyond requests for an electronic copy of PHI in an EHR; and (2) the extension of the individual "patient rate" for fees for copies of PHI directed to third parties. The court held that 45 CFR 164.524(c)(3)(ii), as added to the Privacy Rule by the 2103 Omnibus Rule, exceeded the statutory authority in the HITECH Act which granted a limited right to individuals to direct a copy of electronic PHI (ePHI) in an EHR to a third party in an electronic format. The Court also ruled that HHS impermissibly broadened the application of the access fee limitation (also known as the patient rate) to apply to copies of PHI directed to third parties because HHS failed to subject this requirement which is stated in the 2016 Access Guidance, to notice and comment rulemaking. HHS did not appeal this decision and as discussed in this proposed rule seeks public comment on these proposals.

C. 21st Century Cures Act

The 21st Century Cures Act (Cures Act),[24] added certain provisions to the Public Health Service Act (PHSA) relating to health IT, including interoperability and information blocking.[25] HHS notes that the proposals in this proposed rule take into considerations certain provisions of the Cures Act that facilitate the exchange of health information and discusses the related final rule

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enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) Used, in whole or in part, by or for the covered entity to make decisions about the individuals. (2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes PHI and is maintained, collected, used, or disseminated by or for a covered entity (45 CFR 164.501).

[20] 78 FR 5566 (January 25, 2013)

[21] 45 CFR 164.524(c)(3)(ii)

[22] The 2016 Access Guidance is available at https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html

[23] No. 18-cv-0040-APM (D.D.C. January 23, 2020)

[24] Pub.L.114-255, 130 Stat.1033; Cures Act Title IV- Delivery amended the PHSA, 42 U.S.C. 201 et seq.

[25] Pub.L.114-255, 130 Stat.1033; Cures Act Title IV- Delivery amended the PHSA, 42 U.S.C. 201 et seq. Cures Act sections 4003 Interoperability (amended section 3000 of the PHSA (42 U.S.C. 300jj)) and 4004 Information Blocking (amended Subtitle C of title XXX of the PHA by adding 42 U.S.C. 300jj-52).

published by the Office of the National Coordinator for Health Information Technology (ONC)[26] and proposed rule by the OIG[27] that address information blocking. The ONC Cures Act final rule also implements the Cures Act's requirement for health IT developers participating in the ONC Certification Program[28] including the requirement to publish application programming interfaces (APIs) and allow health information from such technology to be accessed, exchanged, and used without specifical effort through the use of APIs. CMS' new interoperability rule contains requirements similar to the ONC Cures Act Final Rule.[29]

Implementation of the Cures Act requirements through the ONC and CMS rules support covered entities (and their business associates) that use health information technology that enables them to respond more timely to individual requests for access to ePHI. The ONC Cures Act Final Rule requirements for certified health IT to use secure, standards-based APIs will allow individuals to more readily access their ePHI and support disclosures of PHI by covered health care providers and health plans for individual-level care coordination and case management.

III. Provisions of the Proposed Rule

As part of the HHS goal to reduce regulatory barriers that impede delivery of coordinated, value-based health care, OCR published a RFI in 2018 that included 53 questions about the need to modify the HIPAA Rules to support care coordination and case management, and promote value-based care and still preserve the privacy and security of PHI [30] The RFI was organized around three specific areas: (1) Promoting information disclosure for care coordination and care management; (2) Promoting parental and caregiver involvement and addressing the opioid crisis and serious mental illness (SMI); and (3) Notice of Privacy Practices (NPP). These comments were considered in the development of the proposals in this proposed rule.[31]

A. Individual Right of Access (45 CFR 164.524)

The Privacy Rule generally requires HIPAA covered entities (health plans and most health providers)[32] to provide individuals, upon request, with access to their PHI in one or more designated record sets maintained by or for the covered entity. HHS proposes to amend the Privacy Rule to strengthen the individual right of access[33] and to reduce barriers that may limit or

[26] ONC rule, "21st Century Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (ONC Cures Act Final Rule) 45 CFR 171.202.
[27] 85 FR 22979 (June 23,2020) Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; OIG Civil Money Penalty Rules, available at https://www.federalregister.gov/d/2020-0845/p-17
[28] In general, the HITECH Act provides the National Coordinator with the authority to establish a program(s) for the voluntary certification of health IT, and requires the Secretary to adopt certification criteria (42 U.S.C. 300jj-11.
[29] 85 FR 25510 (May 1, 2020)
[30] 83 FR 64301 (December 14, 2018)
[31] The RFI also sought information about implementing a requirement of the HITECT Act to include disclosures by a covered entity for treatment, payment, and health care operations through an EHR to an accounting of disclosures 42 U.S.C. 17935(c). HHS intends to address this requirement in future rulemaking.
[32] The third type of covered entity, a health care clearinghouse, is not subject to the same individual access requirements as covered health care providers and health plans. See 45 CFR 164.500(b)(1) for a list of Privacy Rule provisions that apply to a health care clearinghouse in its role as a business associate of another covered entity
[33] HHS states that references to the individual right of access and individual access requests include access requests by the personal representative of an individual.

discourage coordinated care or case management among covered entities and individuals. Additionally, consistent with the court's decision in Ciox v. Azar, HHS proposes to modify aspects of the individual's right to direct a covered entity to transmit a copy of PHI to a third party.

1. Adding Definitions for Electronic Health Record or EHR and Personal Health Application

Electronic Health Record. The Privacy Rule currently does not define the term "electronic health record"; the HITECH Act codifies a definition of EHR that applies to that Act's privacy and security provisions for covered entities and business associates.[34] HHS proposes to add, at 45 CFR 164.501, a definition of EHR that expands on the HITECH definition:

> *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 relationship with individuals, as defined at §164.501, such as physicians, nurse, pharmacists, and other 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.

"Authorized Health Care Clinicians and Staff". The Privacy Rule does not define the term "clinician" and HHS does not have a uniform statutory or regulatory definition; instead, there are various definitions. HHS proposes to interpret "authorized health care clinicians and staff" 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 relationship with individuals; and their workforce members[35] who support the provision of such treatment by virtue of their qualifications or job role.

HHS states an EHR would include electronic records consulted by any covered health care provider, or a workforce member of such a covered health care provider, as long as the provider has a direct treatment relationship with individuals; this proposal does not include covered health care providers who have indirect relationship with individuals. HHS defines providers with indirect treatment relationships as providers who deliver health care based on the orders of another health care provider, and they typically provide services, products, or reports to another health care provider (e.g., a provider with a direct treatment relationship with the individual).[36]

HHS notes an EHR would include electronic lab tests reports created by staff of a health system who perform lab tests and electronic billing records created by staff of a covered health provider that has a direct treatment relationship with an individual. In contrast, the term EHR would not include health-related electronic records of covered health care providers that only supply

[34] HITECH defines "electronic health record" as an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff (42 U.S.C. 1792(5).
[35] Workforce is defined at 45 CFR 160.103. In this proposed rule, HHS uses the terms "workforce member" and "staff" interchangeably.
[36] "Direct treatment relationship" is defined at 45 CFR 164.501

durable medical equipment (DME) to other providers, who then provide the equipment to individuals; the provider supplying the DME does not have a direct treatment relationship with the individual.

*"*Health-Related Information on an Individual*"*. HHS proposes to equate "health-related information on an individual" with the defined term individually identifiable health information or IIHI.[37] HHS notes that although the HITECH Act does not define "health-related information" it does define "health information"[38] consistent with the definition of the term in the Privacy Rule (45 CFR 164.501). "Health information" includes not only clinical, but billing and other data. For HIPAA purposes, HHS interprets "on an individual" to refer to information that is "individually identifiable"; health information that is de-identified is not protected by HIPAA.

HHS seeks comments on the scope of the proposed definition for EHR, including billing records for health care.

Personal Health Application (App). HHS also believes it is necessary to define, "Personal health app" in the Privacy Rule and bases the proposed definition on the definition of a personal health record in the HITECH Act.[39] HHS proposes the following definition:

> "*Personal health application (app)* is 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."[40]

HHS states a personal health app is a service offered directly to consumers and the covered entity does not manage, share or control the information, nor does the app developer manage the information on behalf or at the direction of a health care provider or health plan (e.g., through a patient "portal" that the entity uses to manage individuals' access to the PHI it maintains), or another party that collects or manages PHI for its own purposes (e.g., a research organization). Individuals (or their personal representatives) use a personal health app for their own purposes, such as requesting weight, vital signs, and other health information from their health care provider to either store in their personal health app or to direct transmission to other individuals.

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[37] 45 CFR 160.103 provides in part that IIHI is "a subset of health information, including demographic information…created or received by a health care provider, health plan, employer or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual."
[38] Section 13101 of the HITECH Act defines "health information" by reference to 1171(4) of the SSA (42 U.S.C. 300jj(4).
[39] 42 U.S.C. 17921(11). The term 'personal health record" means an electronic record of personal health record (PHR) identifiable health information (defined in section 17937(f)(2) on an individual that can be drawn from multiple sources and that is managed, shared, and controlled by or primarily for the individual."
[40] This proposed definition would not apply to or otherwise affect the requirements of the ONC Cures Act Final Rule or the CMS Interoperability and Patient Access Rule.

HHS notes that because a personal health app is not acting on behalf of, or at the direction of a covered entity it would not be subject to the privacy and security obligations of the HIPAA Rules.

HHS requests comments on the proposed definition of personal health app, including the types of activities encompassed in the terms "managed", "shared', and "controlled, and on it assumptions about the use of such applications by individuals. HHS notes that the proposed definition 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. The same software could be a personal health app under the proposed Privacy Rule definition and also be a PHR under the HITECH Act for other purposes, to the extent it meets both definitions.

2. Strengthening the Access Right to Inspect and Obtain Copies of PHI

The Privacy Rule includes a right to "inspect and obtain a copy of" PHI in a designated record set at 45 CFR 164.524(a)(1). HHS proposes to maintain the current rights and to strengthen the access right to inspect and obtain copies of PHI by incorporating a portion of the 2016 ONC Access Guidance into the Privacy Rule.[41]

HHS proposes to add a right that generally would enable an individual to take notes, videos, and photographs, and use other personal resources to view and capture PHI in a designated record set as part of the right to inspect PHI in person. HHS does not believe that an individual recording their own PHI in a designated record set through video, still camera photos, or audio recordings is subject to federal and state recording laws or intellectual property rights protections. Under this proposal, covered entities would not be able to impose a fee to provide access. **HHS requests comment on this point and examples of unintended consequences of the proposal, including unreasonable workflow disruptions.**

Additionally, HHS proposes to extend the right to inspect to mutually convenient times and places including the sites of care where PHI in a designated record set is readily available for inspection by the patient. Specifically, HHS proposes to add as part of the implementation specifications the following: "When protected health information is readily available at the point of care in conjunction with a health care appointment, a covered health care provider is not permitted to delay the right to inspect." This provision would not extend the right beyond the records maintained by or for a covered entity in the designated record set.

HHS would not require a covered entity to allow the individual to connect a personal device, such as a thumb drive, to the covered entity's information systems. Specifically, HHS proposes, "[A] covered entity is not required to allow an individual to connect a personal device to the covered entity's information systems and may impose requirements to ensure that an individual records only protected health information to which the individual has a right to access." HHS notes that a covered entity could establish policies and safeguards to ensure the individual's use

[41] HHS proposes to retain the substance of the current right at 45 CFR 164.524(a)(1), but redesignate current 45 CFR 164.524(a)(i) and (ii) as 45 CFR 164,524(a)(1)(i)(A) and (B).

of personal resources minimizes disruptions to the covered entity's operations; policies and safeguards cannot impose unjustified or unreasonable barriers to individual access.

The Privacy Rule currently does not provide covered entities with the opportunity to deny or delay (beyond 30 days plus an additional 30-day extension, discussed in the next section) the right to inspect PHI in person when necessary to protect the health or safety of the individual or others or address the ability to provide a reasonable alternative. **HHS requests comments on whether covered entities should be permitted to provide copies of PHI in lieu of in-person inspection under limited circumstances such as a public health emergency (PHE**).

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

To improve timely access to PHI, as discussed below, HHS proposes modifications to the Privacy Rule.

a. Requests for Access

Covered entities are required to permit individuals their right of access to inspect or obtain a copy of their PHI that is contained in a designated record set, and permits covered entities to require access requests in writing, provided that the covered entity informs the individual of that requirement.[42] HHS proposes to expressly prohibit a covered entity from imposing unreasonable measures that create a barrier to or unreasonably delay of an individual's right to access. Specifically, HHS proposes that an entity may require individuals to make requests for access in writing but the entity would not be permitted to do so in a way that impedes access. In addition, HHS proposes to prohibit a covered entity from imposing an unreasonable identity verification requirement on an individual exercising the right of access.

HHS proposes to include in regulatory text non-exhaustive, specific examples of reasonable and unreasonable measures that some covered entities have imposed. Examples of unreasonable measures discussed in the proposed rule include a request form containing unnecessary information, requiring notarization of the individual's signature, and requiring requests only in person at the covered entity's facility or only through the covered entity's online portal.

HHS assumes a prohibition against unreasonable measures would not result in adverse unintended consequences for individuals. **HHS solicits comments on its assumptions, and seeks additional examples of unreasonable measures.**

b. Timeliness

The Privacy Rule generally requires covered entities to respond to requests no later than 30 days after receipt by either providing access or a written denial that meets certain requirements.[43] If the covered entity is unable to provide access or a written denial within 30 days, it may extend the time by no more than an additional 30 days if the entity provides to the individual, within the

[42] 45 CFR 164.524(b)
[43] 45 CFR 164.514(b)(2)(i)

initial 30-day time limit, a written statement of the reason for the delay and the expected completion date.[44]

HHS believes that entities can provide individuals access to their information within a shorter time period and proposes to amend the individual access right provision to require covered entities to provide copies of PHI as soon as practicable, but no later than 15 calendar days (with the possibility of one 15 calendar-day extension).[45] In situations where another federal or state law requires a covered entity to provide an individual with access to the PHI requested in less than 15 calendar days, that shorter time period will be deemed practicable under the Privacy Rule. The same timeliness requirements would be applied when an individual requests direct access or when an individual requests that an electronic copy of PHI in an EHR be directed to a third party. The timeliness requirement would apply regardless of the form or format of the PHI (paper or electronic). HHS notes that at least eight states have statutory requirements to provide patients with copies of their health records in fewer than 30-days.

HHS proposes to add a requirement that a covered entity may use one 15-day extension of time for providing access to requested PHI if it has established policies to address urgent or high-priority requests. HHS does not propose to define what constitutes an urgent or high priority request and does not intend that this proposal should encourage covered entities to reveal the purposes of their requests for access. HHS notes that examples of urgent or high priority requests could include when an individual voluntarily reveals that the PHI is needed in preparation for urgent medical treatment or documentation is needed to be allowed to bring medication to school.

HHS also proposes to expressly provide that, while a covered entity may discuss aspects of the individual's access request with the individual before fulfilling the request, such clarification of the request would not extend the time limit for providing access. HHS notes this modification puts the access deadlines in the ONC 2016 Access Guidance into regulatory language.

4. Addressing the Form of Access

The Privacy Rule requires a covered entity to provide the individual with access to the PHI in the form and format requested, if readily producible in that form and format, or if not, in a readable copy form, or other form and format as agreed to be the covered entity and individual.[46] HHS intends for the phrase "readily producible in that form and format" to refer to how the PHI is produced to the individual or to a third party designated by the individual to receive a copy of the PHI and the form (e.g., on paper or electronically) and the format (e.g., the type of electronic file, etc.) of the PHI that is transmitted.

HHS notes that as technology evolves, the "form and format" and the "manner" of producing or transmitting a copy of electronic PHI may become indistinguishable. HHS provides an example where a covered entity or its EHR developer business associate has implemented a secure,

[44] 45 CFR 164.524(b)(2)(ii)(A) and (B)
[45] HHS proposes to explicitly refer to calendar days as the units of time. It believes that the current 30-day limit is understood to be calendar days and the ONC's 2016 Access Guidance also uses calendar days.
[46] 45 CFR 164.524(c)(2)(i)

standards-based API that is capable of providing ePHI in the form and format used by an individual's personal health application, that ePHI is considered to be readily producible in that form and format, and that is also the manner by which the ePHI is transmitted. HHS notes that if ePHI is readily producible in the electronic form and format requested by the individual, the covered health care provider must provide that access, including when the individual requests access to the ePHI through a secure, standards-based API via the individual's personal health application.

HHS also proposes to provide that if other federal or state law (e.g., a statute or regulation) requires an entity (which may include a business associate acting on behalf of a covered entity) to implement a technology or policy that has the effect of providing an individual with access to their PHI in a particular electronic form and format (e.g., if a federal law required the provision of access via secure, standards-based API), such form and format would be deemed "readily producible" for purposes of compliance with the Privacy Rule.

HHS is examining how best to address individuals' privacy and security interests when they use a personal health application that receives PHI from a covered entity. **HHS requests information about the costs and benefits of options for educating individuals in a manner that does not delay or create a barrier to access**. **HHS also seeks comments about the costs associated with a health care provider that has EHR technology that incorporates a secure, standards-based API to implement the API and how to measure the level of cost that would be considered a reasonable justification for not implementing an API**.

The Privacy Rule also allows a covered entity to provide a summary in lieu of providing access to the requested PHI, or an explanation of the PHI to which access has been provided, if the individual agrees. HHS proposes to require that when a covered entity offers a summary in lieu of access, it must inform the individual that the individual retains the right to obtain of copy of the requested PHI (or direct an electronic copy of the PHI in an EHR to a third party) if they do not agree to receive the summary. HHS notes the proposed requirement would not apply when the covered entity offers a summary because it has denied the request for a copy of the PHI; in these cases, the covered entity must implement the required procedures for a denial. HHS provides examples including an example where a covered psychologist offered to provide a summary in lieu of requested psychotherapy notes. In this example, the psychologist would be required to follow the requirements for denial of access, including providing a written denial and making other information accessible, such as mental health records that are not psychotherapy notes, as defined in the Privacy Rule.

5. Addressing the Individual Access Right to Direct Copies of PHI to Third Parties

The Privacy Rule's right of access requires covered entities to transmit a copy of PHI directly to another person designated by the individual when directed by the individual. The request must be in writing, signed by the individual, and clearly identify the designated person and where to send the copy of the PHI. The designated recipient (the "third party") may be a family member or caregiver, a health care provider, a researcher, or any other person or entity the individual (or

their personal representative) chooses.[47] HHS states the right of access does not specifically address provider-to-provider exchanges of PHI because the Privacy Rule permits such disclosures without the individual's authorization for treatment, payment, and health care operations, among other specified purposes.

HHS proposes to create a separate set of provisions for the right to direct copies of PHI to a third party that will better align the Privacy Rule with the HITECH Act. HHS believes that only covered health care providers would be responsible for fulfilling an individual's access request because it believes other covered entities do not have an EHR as defined in the HITECH Act. **HHS seeks comments on this assumption**.

HHS proposes that requests to direct copies of PHI to a third party will be limited to only electronic copies of PHI in an EHR (164.524(d)(1)). HHS believes that the *Ciox v. Azar* decision precludes a proposal to require covered health care providers to send electronic copies of PHI to third parties designated by the individual in the form and format requested by the individual. However, HHS encourages covered health providers, when feasible, to provide copies to third parties in the electronic format requested by the individual.

HHS also proposes a covered health care provider would be required to respond to an individual's request when the request is "clear, conspicuous, and specific" and the request may be orally or in writing, including electronically executed requests.[48] This proposal would replace the current requirement that a request must be in writing and signed by the individual. HHS states that an oral request that identifies the designated recipient and where to send the PHI could meet this standard.

HHS also proposes to create a pathway for individuals to direct the sharing of an electronic copy of PHI in an EHR among covered health care providers and health plans. HHS proposes to require a covered health care provider or health plan (the "Requestor-Recipient"), at the individual's direction, to submit the individual's access request regarding their own ePHI to another health care provider (the "Disclosure") requesting that the Discloser transmit the ePHI maintained by or on behalf of the Discloser in its EHR to the Requestor-Recipient.

The Requestor-Recipient would be required to submit the individual's request to the Discloser identified by the individual.[49] This requirement would apply when an individual is an existing or prospective new patient or a current member (or dependent) of Requestor-Recipient, and is limited to directing electronic copies of PHI in an EHR back to Requestor-Recipient. The individual may make the request orally if the request is clear, conspicuous, and specific. Requestor-Recipient may document and submit the oral request in writing or electronically, or if Discloser accepts oral requests for records from other health care providers or health plans, Discloser could use its established procedures for accepting and verifying such requests.

[47] 45 CFR 164.524(c)(3)(ii). HHS notes it is not enforcing the elements of this regulatory provision that apply to directing non-electronic copies of PHI or copies of PHI that are not in an EHR.
[48] HHS notes the exception to this right are parallel to the existing exceptions to the individual right of access in 45 CFR 164.542(a)(1) for psychotherapy notes and information compiled in anticipation of, or for use in, legal proceedings or unreviewable or reviewable grounds of denial.
[49] The disclosure is an entity that maintains or previously maintained an individual's PHI, so they will have had a relationship with the patient.

HHS discusses that the right of an individual to direct an electronic copy of their PHI in an EHR already exists under the HITECH Act. Under this proposal, a Requestor-Recipient would be required to assist an individual in submitting their request for Discloser to direct PHI maintained by or on behalf of the Discloser to Requestor-Recipient. HHS does not propose to change any obligations of the Requestor-Recipient once it receives the PHI. HHS notes that the Privacy Rule does not require that a covered health care provider retain PHI it receives about individuals; the Requestor-Recipient might be subject to a records retention requirement under state law. **HHS welcomes examples and comments on this assumption**.

HHS proposes to require that Requestor-Recipient submit access requests to Discloser as soon as practicable, but no later than 15 calendar days after receiving the individual's direction and any information the Requestor-Recipient needs to submit the access request to Discloser. HHS is not proposing any extension to this 15 calendar day requirement. Discloser would be required to provide the requested electronic copy to Requestor-Recipient according to the shorter time proposed for all access requests when the individual directs the information to a third party, but no later than 15 calendar days after receiving the request. HHS proposes one 15 calendar day extension under the same conditions for the Discloser fulfilling other access requests.

HHS requests comments on whether a Requester-Recipient should be permitted to refuse to submit an request for an individual in some circumstances (e.g., if it already has requested the information), and whether HHS should specify in regulatory text that if a Requestor-Recipient discusses the request with the individual (e.g., to clarify the request) such discussion would not extend the time for submitting the request.

HHS notes the Privacy Rule permits covered entities to use health information exchanges (HIE) 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. A covered entity can 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.[50] **HHS is considering approaches to clarifying this permission and seeks comments on how to do this**.

Consistent with the proposal with respect to the individual right to obtain copies of PHI, HHS proposes to require covered entities to inform individuals about their right to direct the requested electronic copies of PHI in an EHR to designated third parties when a covered entity offers to provide a summary in lieu of the requested copies of PHI. This requirement would not apply when the covered entity offers a summary because it is denying the request for a copy on unreviewable or reviewable grounds in which case the covered entity must implement the required procedures for such denial.

6. Adjusting Permitted Fees for Access to PHI and ePHI

The Privacy Rule allows covered entities to charge a reasonable, cost-based fee to fulfill access requests from individuals for copies of their PHI. Allowable fees are limited to the costs of (i) labor for copying (whether the PHI is in paper or electronic form), (ii) supplies for creating the

[50] 45 CFR 164.506(c)(1)

paper copy or electronic media, (iii) postage, and (iv) preparing any agreed-upon summary or explanation of the requested PHI. The *Ciox v. Azar* court found that HHS had improperly imposed fee limitations on the access right to direct a copy of PHI to a third party through ONC's 2016 Access Guidance instead of through notice and comment rulemaking.

HHS proposes to adjust and clarify the fees that covered entities may charge for copies of PHI by establishing a fee structure with two elements based on the type of access request. The first element describes categories of access for which covered entities cannot charge a fee, The second element describes the allowable costs that may be included when an access fee is permitted. The modified fee provisions will be separate for the individual right to inspect and obtain copies of PHI and for the right to direct electronic copies of PHI in an EHR to third parties. HHS notes the proposed approach would allow covered entities to recoup their costs for handling certain requests to send copies of PHI to third parties, while ensuring that covered entities do not profit from disclosures of PHI made at the individual's request.

The chart below (reproduced from the proposed rule) summarizes the proposed allowable access fees for different types of access and recipients of the PHI.

Proposed Allowable Access Fees		
Types of Access	**Recipient of PHI**	**Allowable Fee**
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 aa personal health application connection with 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 U.S. Mail or via certified export functionality)[51]	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.
Electronic copies of PHI in an EHR received in response to an access request to direct such copies to a third party other than an internet-based method	Third party as directed by the individual through the right of access	Reasonable cost-based fee, limited to labor for making copies, and costs of preparing a summary or explanation as agreed to by the individual.

[51] 45 CFR 179.315(b)(10) Data export functionality, as added by ONC Final Rule 85 FR 25642 (May 1, 2020)

a. No Fee Allowed

HHS believes that a covered entity does not incur labor costs for copying, and is unlikely to incur costs for supplies, when providing the individual the opportunity to inspect PHI in person and uses their own personal resources to capture the information. **HHS requests comments on the frequency of requests to inspect PHI in person and any new costs that covered entities would incur when individuals inspect their PHI in person at the covered entity's facility.**

For access through an internet-based method, HHS believes this occurs without involvement of covered entity workforce members, and thus the covered entity does not incur labor costs or expenses. HHS proposes that the term "internet-based method" would apply to portals and APIs, as well as similar successor technologies. HHS states it does not intend free access to PHI to apply to situations where the individual is simply using an online portal to submit a request for copies of PHI to be sent in a manner that would require the covered entity to incur allowable costs for supplies, postage, or labor for copying. **HHS requests comments on this proposal for internet-based access, including any internet-based method described in the ONC Cures Act Final Rule.**

b. Reasonable Cost-Based Fees

HHS proposes that when providing copies of PHI to an individual, covered entities would remain subject to the current access fee limits.[52]

HHS proposes that an access request for an electronic copy of PHI other than through an internet-based method would be a reasonable, cost-based fee that is limited to the costs of: (i) labor for making electronic copies of the PHI, and (ii) preparing a summary or explanation as agreed to by the individual. HHS states that section 13405(e) of the HITECH Act prohibits the collection of any fee for the costs of electronic media and postage for providing electronic copies of PHI by any method.

HHS proposes to limit the right of an individual to direct copies of PHI to a third party to only electronic copies of PHI in an EHR. HHS proposes to limit the allowable fee for such copies to the costs of labor for making electronic copies. Additionally, a covered entity would be permitted to charge for the costs of preparing a summary or explanation of the requested PHI to be directed to a third party as agreed to by the individual in advance. HHS acknowledges that covered entities would be restricted from recouping some costs that are allowed under the current rule, but it believes the effect of limiting the right to direct PHI to a third party to only electronic copies of PHI in an EHR would significantly reduce covered entities' burden.

HHS anticipates no fees would be charged when an individual uses an internet-based method to direct an electronic copy of PHI in an EHR to any third party when the method is fulfilled through an automated process. HHS believes there are no associated costs incurred by the

[52] 45 CFR 164.524(c)(4)

covered entity for responding to this type of specific request. **HHS requests comments on whether costs will be incurred to provide access using an internet-based method**.

HHS notes that because of the proposed limits on the right to direct transmission of electronic copies of PHI in an EHR, covered entities would be permitted to charge less restricted fees when fulfilling requests to send non-electronic copies of PHI in an EHR, or electronic copies of PHI that is not in an EHR, to third parties, because these requests would no longer be within the right of access. Such disclosures to third parties (including an individual's family member, covered entity, researcher, or any other person) would be accomplished through an individual's valid authorization, with only the Privacy Rule limitation of the fees for such copies being the Privacy Rule's provisions on the sale of PHI.[53]

HHS does not propose to change how covered entities currently charge for disclosing records to health plans and providers. HHS notes this proposal is not intended to cause covered entities to begin charging fees for such disclosures.

7. Notice of Access and Authorization Fees[54]

HHS proposes to require covered entities to provide advance notice of approximate fees for copies of PHI requested under the access right or with an individual's valid authorization. Specifically, covered entities would be required to post a fee schedule online (if they have a website) and make the fee schedule available to individuals at the point of service, upon an individual's request. The notice must include: (i) all types of access available free of charge and (ii) fee schedule for (A) copies provides to individuals under 45 CFR 164.524(a), with respect to all readily producible electronic and non-electronic forms and formats for copies; (B) copies of PHI in an EHR and directed to third parties designated by the individual under 45 CFR 164.523(d), with respect to all readily producible electronic forms and formats for such copies; and (C) copies of PHI sent to third parties with individual's valid authorization[55] under 45 CFR 164.508 with respect to all available forms and formats for such copies.

HHS expects that a covered health care provider would make the fee schedule upon request, in paper or electronic form, at the point of care or at an office that is responsible for releasing medical records, as well as orally (e.g., over the phone). HHS notes that this could include a customer service call center that handles requests for records.

[53] HHS states this would change the status of requests to direct non-electronic and non-EHR copies of PHI to third parties by relegating such requests to disclosures under the authorization standards at 45 CFR 164.502(a)(5)(ii)A) and 164.508(a)(4)

[54] HHS uses "access and authorization fees" to mean fees for copies of PHI provided pursuant to the individual's right of access and for disclosures made pursuant to a valid authorization, respectively.

[55] The Privacy Rule limits the fees that may be charged for uses and disclosures of PHI based on an authorization. Under the Privacy Rule's provision on the sale of PHI, covered entities generally must limit fees for disclosures pursuant to an authorization to a "reasonable, cost-based fee to cover the costs to prepare and transmit the PHI for such purpose or a fee otherwise expressively permitted by other law" or must state in the authorization that the disclosure will result in remuneration to the covered entity (45 CFR 164.502(a)(5)(ii)(B)(2)(viii).

HHS proposes to require that covered entities provide an individualized estimate to an individual of the approximate fees to be charged for the request copies of PHI, upon request. HHS expects that this information would be provided upon request and within the initial time (if not sooner) in which the covered entity has to fulfill the access request (prior to any extension time) and prior to providing the requested PHI. If more time is needs to provide the requested copies after providing an individualized estimate, a covered entity may notify the individual of its need for a 15-day extension.

HHS also proposes to require covered entities to provide, upon request, an itemization of the charges for labor for copying, supplies, and postage, as applicable.

HHS notes the Privacy Rule does not prohibit a covered entity from requiring individuals to pay a fee for copies of PHI "upfront" before receiving such copies. HHS encourages covered entities that charge fees to waive fees or provide payment flexibility for individuals who are unable to pay upfront due to an emergency or a lack of resources. HHS also encourages covered entities to waive access fees where the individual cannot pay the fee due to a demonstrated financial hardship, including when the requesting individual is a Medicaid beneficiary or homeless.

8. Technical Changes

HHS proposes technical clarifications to the Privacy Rule provision (45 164.502(a)(4)(ii) requiring business associates to disclose PHI as needed for the covered entity to fulfill its obligations under the right of access.

9. Request for Comments

In addition to the comments included in the prior discussion of the proposals, HHS seeks comments on the foregoing proposals, including any benefits or unintended consequences and delineates additional related issues for consideration. Highlights of these considerations, are summarized below. The reader is referred to the proposed rule for more specific details.

a. Proposed Definition of EHR

- Whether the 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 HHS should instead define EHRs to align with the scope of paragraphs (1)(i) and (2) of the designated record set (defined at 45 CFR 164.501).
- 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?
- Whether EHR should be defined more broadly to include all ePHI in a designated record set, and benefits or drawbacks of doing so.

b. Access Rights to PHI

- 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.
- 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. HHS seeks comment on time limits for covered entities to respond to access requests, requests to direct copies of PHI in an EHR to a third party, and requests to submit a request to another provider on behalf of the individual.
- 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.
- 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)?
- How covered entities currently calculate reasonable, cost-based fees for copies of PHI under the right of access. HHS notes that OCR's 2016 Access Guidance offered three illustrative methods for calculating allowable access fees: (1) actual labor costs; (2) average labor costs; and (3) a flat fee of $6.50 for electronic copies of ePHI, inclusive of labor, supplies, and any applicable postage. HHS requests comments on the extent entities use each of these methods and whether it should specify one or more of the three methods or another method in regulatory text as the exclusive acceptable method of calculating fees.

B. Reducing Identity Verification Burden for Individuals Exercising the Right of Access (42 CFR 164.514(h))

1. Current Provision and Issues to Address

Section 45 CFR 164.514(h) of the Privacy Rule generally requires a covered entity to take reasonable steps to verify the identity of a person before disclosing PHI to help ensure that unauthorized persons do not obtain an individual's PHI. The type and manner of the verification is at the discretion and professional judgment of the covered entity, provided the individual is not unreasonably delayed from obtaining access to their PHI. HHS has received complaints and heard anecdotal accounts of covered entities imposing burdensome verification requirements such as requiring individuals to receive their PHI in person, or obtain notarization on a written request.

2. Proposal

HHS proposes to expressly prohibit a covered entity from imposing unreasonable identity verification measures on an individual (or his/her personal representative) exercising a right under the Privacy Rule. In addition, HHS proposes to clarify that unreasonable verification

measures are those that require an individual to expend unnecessary effort or expense when a less burdensome verification measure is practicable. Unreasonable measures would include:

- Requiring individuals to obtain notarization of requests;
- Requiring individuals to provide proof of identity in person when a more convenient method for remote verification is practicable;
- Requiring individuals to provide more information than is necessary for verification of identity;
- Requiring requests for access be made only through the covered entity's online portal;
- Applying onerous or infeasible registration requirements for personal health applications such as requiring a third party that does not meet the definition of a business associate to enter into a business associate agreement with the covered entity; and
- Preventing an individual's from registering with an endpoint (e.g., API) that the covered entity makes public, absent an identified security risk to the ePHI in the covered entity's (or its business associate's) EHR systems.

HHS 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.

3. Request for Comments

HHS requests comments in specific areas such as:

- Examples of individuals facing verification barriers and of verification measures that should be encouraged as convenient and practicable.
- 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?
- Should the standards be different for an individual from a personal representative?
- Examples of state law identity verification requirements that 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.

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

1. Current Provision and Issues to Address

The Privacy Rule expressly permits certain uses and disclosures of PHI, without an individual's valid authorization, for treatment and certain health care operations, among other important purposes. The definitions of both treatment and health care operations include some care coordination and case management activities.

Some covered entities appear to interpret the existing definition of health care operations to include only population-based care coordination and case management. Such an interpretation could limit a health plan's ability to perform individual-level care coordination or case management activities. Some covered entities expressed uncertainty regarding whether the use or disclosure of PHI for a particular care coordination or case management activity is permitted as part of treatment, health care operations, both, or neither. Due to this uncertainty, they do not request or disclose PHI even when doing so would support coordinated care and the transformation of the health care system to value based care.

2. Proposal

HHS is substituting semi-colons for commas in the regulatory text to clarify that "health care operations" encompass all care coordination and case management by health plans, whether individual-level or population-based. The new definition proposed in paragraph (1) of the definition of "Health care operations" in 45 CFR 164.501 would read 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.

3. Request for Comments

HHS 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, and on any potential unintended adverse consequences.

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

The Privacy Rule generally requires covered entities to use, disclose or request only the minimum PHI necessary to meet the purpose of the use, disclosure, or request.[56] The minimum necessary standard requires covered entities to evaluate their practices and enhance safeguards as needed to limit unnecessary or inappropriate use and disclosure of PHI.[57] The minimum necessary standard generally requires covered entities to limit uses and disclosures of PHI to the minimum necessary needed to accomplish the purpose of each use or disclosure.

In the 2018 RFI, HHS requested public input on whether it should expand the exceptions to the minimum necessary standard to include uses and disclosures for additional activities related to care coordination and case management.[58] Comments varied widely, even within the general

[56] 45 CFR 164.502(b)(1)
[57] "Use" in this context refers to internal utilization and sharing of PHI within a covered entity or business associate (45 CFR 160.103).
[58] 83 FR 64302 (December 14, 2018)

categories of commenters (e.g., health care providers or consumers). Many commenters supported expanding the exceptions to allow providers to better coordinate and manage patient care across systems and delivery models. Over half of the commenters opposed adding exceptions to the minimum necessary standard and were concerned that a broader expansion would undermine patient privacy or lead to unspecified harm to patients.

After consideration of comments, HHS believes that there is room for flexibility in the application of the standard without sacrificing key privacy protections. HHS proposes to add an express exception to the minimum necessary standard for disclosures to, or requests by, a high plan or covered health care provider for care coordination and management. This exception would apply only to those care coordination and case management activities that are at the individual level. Health plan and covered health care providers would continue to be responsible for meeting all the other current requirements.[59] In addition, covered entities would continue to be able to agree to and honor an individual's request not to use or disclose information for these purposes, as provided in the Privacy Rule and the ONC Cures Act Final Rule information blocking exception for respecting an individual request.[60]

HHS believes this proposal would relieve covered entities of the requirement to make determinations about the minimum information necessary when the request is from, or the disclosure is made to, a covered health care provider or health plan to support individual care coordination and case management activities, regardless of whether such activities constitute treatment or health care operations. HHS provides several examples of how this exception would facilitate care coordination and case management. For example, when a covered health care provider contacts a health plan to coordinate potential mental health treatment referrals for a patient, the provider would not need to consider what information is the minimum necessary to disclose to the health plan for this purpose.

HHS requests comments on the proposed exception and delineates additional related issues for consideration. Highlights of these considerations, are summarized below. The reader is referred to the proposed rule for more specific details.

- Would the proposed exceptions improve the ability of covered entities to conduct care coordination and case management activities? Are there any cost or savings estimates that apply both on the entity level and across the health care system?
- Examples of particular care coordination or case management activities would be furthered or impeded by this proposal.
- Any unintended negative consequences of the proposed changes for the privacy of PHI or the health information rights and interested of individuals. Would there be any negative impact, on certain populations (e.g., people with disabilities, older adults)?
- 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 Home- and Community- Based Service (HCBS) providers?

[59] 45 CFR 164.502(b); 164.514(d)
[60] 45 CFR 164.522(a); 171.202(e)

E. Clarifying the Scope of Covered Entities' Abilities to Disclose PHI to Certain Third Parties for Individual-Level Care Coordination and Case Management that Constitutes Treatment or Health Care Operations (45 CFR 164.506(c)(6))

The Privacy Rule expressly permits a covered entity to use and disclose PHI for its own treatment, payment, or health care operations (TPO) purposes. OCR guidance[61] clarifies that covered health care providers may disclose PHI to public or private-sector entities that provide health-related social and community-based services as part of the disclosing provider's treatment activities. That guidance explains the circumstances in which the Privacy Rule permits a covered health care provider to disclose PHI about an individual to a third party when the third party is part of the broader health treatment plan, or participating in the coordination of care, for an individual. Such a treatment disclosure generally is subject to the minimum necessary standard, where the disclosure is made to a third-party entity that is not a health care provider, even though the entity is providing health-related services.

HHS believes that some covered entities are not aware that the Privacy Rule generally permits disclosure to social services agencies and community-based organizations for care coordination and case management, and others may be uncertain about the scope of the permission to disclose or about when they need a business associate agreement with the recipient.

1. Proposal

HHS proposes (at 45 CFR 164.506(c)(6)) to expressly permit covered entities to disclose PHI to social services agencies, community-based organizations, home and community-based service (HCBS) providers, and similar third parties that provide or coordinate health-related services needed for care coordination and case management for an individual. This would apply to disclosures made either as a treatment activity or a health care operations activity of a covered health care provider or as a health care operations activity of a health plan. This would not apply to disclosures for population-based activities.

A covered health care provider or health plan could only disclose PHI without authorization to a third party that provides health-related services to individuals, but the third party would not have to be a health care provider. Thus, disclosure without authorization could be made to third party entities that provide or coordinate ancillary and other health-related services when the covered entity determines that the disclosure is needed to provide health-related services to specific individuals for individual-level care coordination and case management activities that constitute treatment or health care operations.

With respect to business associates, HHS notes that some disclosures for care coordination and case management for treatment or health care operations will be made to business associates

[61] See HHS Office for Civil Rights, Frequently Asked Questions on Mental Health, Disclosures for Care Coordination (2018), available at https://www.hhs.gov/hipaa/for-professionals/faq/3008/does-hipaa-permit-health-care-providers-share-phi-individual-mental-illness-third-party-not-health-care-provider-continuity-care-purposes/index.html. A consent that a covered entity chooses to obtain consistent with 45 CFR 164.506(b) is different from an authorization obtained under 45 CFR 164.508, which is required for certain uses and disclosures of PHI.

engaged by a covered entity, such as a health plan, to provide health-related services to an individual or that relate to an individual's health care, on behalf of the plan. For these situations, the covered entity must have a HIPAA compliant business associate agreement in place to disclose PHI. Where the entity receiving the PHI provides health-related services on its own behalf, the entity is not a business associate and a business associate agreement is not required for these types of disclosures.

HHS believes that the third-party entities receiving PHI under its proposal would not be covered entities, and because of this the PHI disclosed to them would no longer be protected by the HIPAA Rules. On the other hand, some of these third-party recipients of PHI may be health care providers or covered health care providers which can perform care coordination and case management for their own treatment or health care operations activities. This is why the proposal does not limit the regulatory text to only permit disclosures made by a covered health care provider or health plan as part of the discloser's own treatment and health care operations. Under the 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. HHS notes that this type of disclosure is currently permitted (at 45 CFR 164.506(c)(2) and (c)(4)), but the Privacy Rule does not specifically apply this authority to case management and care coordination. **HHS seeks comment on whether limiting language would be appropriate.**

HHS also proposes to include examples of the third-party recipient entities in regulatory text, but it does not propose to define the care coordination and case management activities that such third parties must conduct to be appropriate recipients of PHI for these purposes.

2. Request for Comments

HHS seeks comments on its proposal generally as well as on a number of topics, including the following:

- Would the proposal improve care coordination and case management for individuals?
- Are there any potential unintended adverse consequences of the proposal?
- Does the proposal pose any particular risks to individuals for disclosures for health care operations activities of health plans?
- Should the regulation text include other third-party entities as examples? Should any particular type of organizational entity be excluded?
- Should the proposal be expanded to also include population-based activities?
- Would the proposal interact with ONC's information blocking requirement to create adverse consequences for an individual's privacy?
- Should the proposed permission to disclose be limited to services specifically identified in an individual's care plan and/or for which a social need is identified through a screening assessment?

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

HHS states that it seeks to remove the fear of HIPAA penalties from the decision-making of covered entities in determining whether to share information with family members, caregivers, and friends who are trying to help an individual with a health-related emergency, substance use disorder (SUD), serious mental illness (SMI) and other instances where the individual is incapacitated or otherwise unable to express a privacy preference.

A number of provisions of the Privacy Rule permit a covered entity to make certain unauthorized uses and disclosures of PHI when doing so is in the best interests of the individual using the "exercise of professional judgment" standard. HHS proposes to substitute a more flexible "good faith belief" standard in five provisions of the Privacy Rule described below. The Department explains that the professional judgment standard presupposes that a decision is made by a health care professional, such as a licensed practitioner, whereas good faith may be exercised by other workforce members who are trained on the covered entity's HIPAA policies and procedures and who are acting within the scope of their authority.

HHS also proposes to add to the regulations a presumption that a covered entity has complied with the good faith requirement, absent evidence that the covered entity acted in bad faith.

1. Replacing Professional Judgment with Good Faith in Sections 45 CFR 164.502(g)(3)(ii)(C), 164.510(a)(3), 164.510(b)(2)(iii), 164.510(b)(3), and 164.514(h)(2)(iv)

HHS is concerned that the current requirement to use professional judgment in the regulations listed above could be interpreted as limiting this permission to persons who are licensed or who rely on professional training to determine whether use or disclosure of PHI is in an individual's best interests. It seeks to broaden this authority to let other members of a covered entity's workforce who do not have specialized education or professional experience (such as front desk staff) disclose an individual's PHI based on a good faith belief that it is in the best interests of the individual.

HHS explains that a good faith belief may be informed by knowledge of the facts of the situation; however, it expects the covered entity or workforce member to exercise a degree of discretion appropriate for its role when deciding to use or disclose PHI, and to comply with any other conditions contained in the applicable permissions. Further, the extent of the PHI disclosure would be limited to the level of involvement of the family member or caregiver of which the staff is aware, consistent with the covered health care provider's policies and procedures for disclosures of PHI by workforce members. HHS acknowledges its proposals raise concerns about disclosure of sensitive information to family members or caregivers about individuals who are at risk of or experience abuse from those family members or caregivers; covered entities would have to take those concerns into account when deciding whether to make a disclosure.

a. Parent or guardian who is not the individual's personal representative (45 CFR 164.502(g)(3)(ii)(C))

HHS 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 a licensed health care professional has a good faith belief that disclosing the PHI is in the best interests of the individual. Additionally, the disclosure would have to be consistent with state or other applicable law. This change would permit a covered health care provider to disclose PHI of an un-emancipated minor experiencing SUD in a state or jurisdiction where applicable law does not treat the minor's parent as a personal representative if the provider believes that disclosing information to the parent could improve the care and treatment of the minor.

b. Facility Directories (45 CFR 164.510(a)(3)(i)(B))

Under the proposal, a covered entity would be permitted 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. This authority would only apply insofar as the covered entity has a good faith belief that the disclosure is in the best interests of the individual.

c. Emergency contacts (45 CFR 164.510(b)(2)(iii))

Covered entities would be allowed 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 would not object. Thus, when a facility knows an emergency contact of an incapacitated individual but does not have a written designation of the person as an emergency contact, the facility would be able to disclose PHI to the emergency contact if the facility has a good faith belief the individual would not object to disclosure of PHI to that contact.

d. Emergencies and incapacity (45 CFR 164.510(b)(3))

Under this proposal, in the case where an individual cannot agree to the disclosure because of absence, incapacity, or emergency circumstances, covered entities would be allowed 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. The covered entity would be required to have a good faith belief that the disclosure is in the best interests of the individual. HHS notes that the Privacy Rule does not include a definition of incapacity, but the Department does not propose to define the term.

e. Verifying requestor's identity (45 CFR 164.514(h)(2)(iv))

Generally, before making a disclosure of PHI, a covered entity must verify the identity of a person requesting the PHI and the authority of that person to have access to the PHI. Currently, this requirement may be satisfied if the covered entity relies on the exercise of professional

judgment in making a use or disclosure under §164.510 or acts on a good faith belief in making a disclosure under §164.512(j). HHS proposes to substitute the good faith belief standard for the verification requirement generally for the requirement to rely on the exercise of professional judgment for uses or disclosures under §164.510. Under the proposal, a hospital could disclose PHI of an individual experiencing an emergency to persons who represent themselves as family members or caregivers, without requiring those persons to present documentation of the relationship with the individual; this would be a permissible use or disclosure only if the hospital has a good faith basis for believing the persons requesting the PHI and the identity of those persons.

f. Presumption of compliance with good faith standard (45 CFR 164.502(k))

With respect to each of its proposals described above to substitute a "good faith" standard for the exercise of professional judgment, the Department proposes to add a presumption of compliance. The presumption of compliance would apply when covered entities make a disclosure under the circumstances of those five provisions based upon a belief that the disclosure is in the best interests of the individual.

2. Changing "serious and imminent" to "serious and reasonably foreseeable" (45 CFR 164.512(j))

Section 164.512(j) of the Privacy Rule permits a covered entity to use or disclose PHI, consistent with applicable law and standards of ethical conduct, if the covered entity has a good faith belief that the use or disclosure is necessary to prevent or lessen a "serious and imminent threat" to the health or safety of a person (including the individual) or the public. These threats of harm envisioned range from harm to the individual or others to threats of mass violence, such as acts of terrorism. The recipient of the PHI must be reasonably able to prevent harm or lessen the threat, or the use or disclosure of PHI must be necessary for law enforcement to identify or apprehend an individual.

HHS proposes to clarify that the Privacy Rule allows covered entities to address threats of harm; specifically, it proposes to replace the "serious and imminent threat" standard in §164.512(j)(1)(i)(A) with a "serious and reasonably foreseeable threat" standard. The goal is to prevent situations in which covered entities decline to make uses and disclosures they believe are necessary to prevent harm or lessen threats of harm because they may not be able to determine precisely how imminent a threat of a harm is. Under the proposal, covered entities would not be required to make a determination that a threat is imminent; rather, they would only have to determine whether the threatened harm is reasonably foreseeable.

The Department proposes to define reasonably foreseeable using a reasonable person standard in a new paragraph (5) of §164.512(j). The reasonable person standard considers whether a similarly situated covered entity could believe that a serious harm is reasonably likely to occur. There would be no need to determine whether a majority of covered entities could have such a belief.

It also proposes to establish in regulation (in a new paragraph (6) of §164.512(j)) an express presumption that certain health care providers with specialized training, expertise or experience (such as licensed mental or behavioral health professionals) would be deemed to have met the reasonably foreseeable standard when they make a disclosure related to facts and circumstances for which the providers have specialized training, expertise or experience.

Section 164.512(j) of the Privacy Rule currently specifies the circumstances in which a covered entity will be presumed to have acted in good faith in using or disclosing PHI to prevent harm or lessen a threat; HHS does not propose any changes to that presumption. It notes that this existing good faith presumption combined with its proposed changes could afford a covered entity the benefit of two presumptions: (1) a presumption that the serious harm the covered entity identified was reasonably foreseeable, and (2) a presumption that the covered entity believed the use or disclosure was necessary to prevent harm or lessen a threat.

HHS also proposes to make what it describes as non-substantive changes to the regulation text in §164.512(j) to refer to preventing a harm or lessening a threat in lieu of the current references to preventing or lessening a threat.

3. Request for Comments

HHS seeks comments on its proposal generally as well as on a number of topics, including the following:

- Would the proposed change in standard from "professional judgment" to "good faith belief" discourage individuals from seeking care?
- Should this proposed change also be made in other provisions of the Privacy Rule that use the professional judgment standard?
- 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?
- When should overriding an individual's prior expressed preferences constitute bad faith on the part of the covered entity?
- Would the proposed "serious and reasonably foreseeable threat" standard:
    - Discourage individuals from seeking care?
    - Improve a covered entity's ability to prevent potential harm?
- Would granting extra deference to health care providers based on specialized risk assessment training, expertise, or experience result in any unintended consequences?
- Should HHS, as an alternative, establish a specific permission for mental and behavioral health professionals to disclose PHI when in their view the disclosure could prevent serious and reasonably foreseeable harm?

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

Section 164.520 of the Privacy Rule requires a covered health care provider that has a direct treatment relationship with an individual to make a good faith effort to obtain a written acknowledgment of receipt of the provider's Notice of Privacy Practices (NPP). If the provider is unable to obtain the written acknowledgment, the provider must document its good faith efforts and the reason(s) for not obtaining an individual's acknowledgment; that documentation must be retained for six years.

A number of stakeholders identified the requirement for covered entities to make a good faith effort to obtain an individual's signed acknowledgement of receipt of the NPP as unduly burdensome and confusing to patients and health care workers; some believe it causes a barrier to treatment because patients think they must sign the acknowledgement as a condition to get treatment. Other commenters to the 2018 RFI objected to eliminating the requirement because the acknowledgement helps ensure individuals are aware of their HIPAA rights. Comments also raised issues with the required content of NPPs. HHS notes that ONC and OCR developed several model NPPs which are available to the public on the OCR website; some commenters suggested creating a safe harbor to protect covered entities that used one of those model NPPs.

1. Proposal to Substitute an Individual Right To Discuss NPPs for the Written Acknowledgement Requirements (45 CFR 164.520(b)(1)(iv)(G), 164.520(c)(2)(ii), 164.520(e))

HHS proposes to eliminate NPP written acknowledgement requirements for covered health care providers with a direct treatment relationship to an individual as follows:

- It would eliminate the requirement to obtain a written acknowledgment of receipt of the NPP.
- It would eliminate the requirement to document good faith efforts to get a written acknowledgement if the covered provider was unable to obtain the written acknowledgment from the individual.
- It would eliminate the requirement to retain copies of such documentation for six years.

To ensure individuals understand and make decisions based on the information in the NPP, in lieu of the written acknowledgement requirements, HHS proposes to require covered entities to designate a person to be available to discuss the NPP with individuals who may have questions. It would establish this as a patient right.

2. Changes to NPP Content

In response to concerns about patient awareness of HIPAA rights, HHS proposes a number of changes to the required content of NPPs.

a. Changes to the required header

The regulations include specific requirements for language used in the header to an NPP. The following changes are proposed to that language:

- The header would specify that the NPP provides information to individuals about (1) how to access their health information; (2) how to file a HIPAA complaint; and (3) individuals' right to receive a copy of the notice and to discuss its contents with a designated person.
- The header would specify whether the designated contact person is available onsite and include a phone number and email address individuals can use to reach the designated person. (HHS notes this requirement would apply to all covered entities without regard to any direct treatment relationship.)

The Department believes this information will be more helpful to individuals with questions about or the need to exercise their HIPAA rights.

b. Right of access to inspect and copy PHI

This current right would be modified to describe how individuals can exercise their rights of access to obtain a copy of their records at limited cost or, in some cases, free of charge, and add the right to direct a covered health care provider to transmit an electronic copy of PHI in an EHR to a third party.

c. Option to include information on directing PHI to a third party

HHS proposes to add an optional element to the NPP. Under the proposal, a covered entity could include in its NPP information about how an individual who wants to direct PHI to a third party, when the PHI is not in an EHR and/or is in a non-electronic format. The individual may instead obtain a copy of PHI directly under §164.524 and send the copy to the third party themselves, or may request the covered entity to send a copy of PHI to a third party using a valid authorization under §164.508.

HHS does not propose to create a safe harbor for covered entities that use a model NPP developed by OCR and ONC.

3. Request for Comments

HHS seeks comments on its proposal generally as well as on a number of topics, including the following:

- Would the proposed NPP changes have unintended consequences for individuals or covered entities?
- Would the revised content requirements improve understanding of HIPAA rights?
- How can OCR improve the model NPP? Should the model NPP description of health care operations be modified? Or provide specific examples of how PHI may be used for operations purposes?

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

Telecommunications Relay Service (TRS) facilitates telephone calls between individuals who are deaf, hard of hearing, or deaf-blind, or who have a speech disability, and others. Communications assistants transliterate conversations or interpret them using American Sign Language; information including PHI is relayed between a person using text or video and another person who may be communicating by voice or who may also be using TRS. Under a longstanding FAQ issued by OCR, a covered entity may disclose an individual's PHI to a TRS communications assistant when communicating with the individual, without the need for a business associate agreement with the TRS provider. TRS is used not only to connect patients and providers; it assists communications among workforce members of covered entities and business associates. Stakeholders asked HHS to address the use of TRS by members of the covered entity or business associate workforce to share PHI with other workforce members or outside parties as needed to perform their duties.

1. Proposal 45 CFR 164.512(m)

HHS proposes to amend its regulations to expressly permit covered entities (and their business associates, acting on the covered entities' behalf) to disclose PHI to TRS communications assistants as is necessary to perform covered functions. This authority would cover all disclosures to TRS communications assistants relating to any covered functions performed by, for, or on behalf of covered entities. The proposal would also clarify that a business associate agreement is not needed with a TRS communications assistant.

The definition of business associate (at 45 CFR 160.103(4)) would also be amended to exclude TRS providers. The exclusion would apply regardless of whether the workforce member is an employee, contractor, or business associate of the covered entity.

The Department believes these proposals would help ensure that workforce members and individuals who are deaf, hard of hearing, or deaf-blind, or who have a speech disability may communicate easily using TRS for care coordination and other purposes.

2. Request for Comments

HHS seeks comments on its proposal generally as well as on whether the proposal would achieve the anticipated effects and whether there are any potential unintended, adverse consequences of the proposal.

It also seeks data on the following:

- 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 who currently use TRS to perform their duties; and

- 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.

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

Consistent with the requirements of §164.512(k), a covered entity may use and disclose the PHI of Armed Services personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission by ensuring the medical readiness of members of the Armed Services. Unless a member of the Uniformed Services personnel in the U.S. Public Health Service (USPHS) Commissioned Corps and the National Oceanic and Atmospheric Administration (NOAA) Commissioned Corps are actively assigned to the Armed Services, a covered entity may not use and disclose the PHI of such Commissioned Corps personnel for the same purposes as is permitted for the Armed Services (i.e., to ensure medical readiness for duty and potential deployment).

HHS proposes to expand the regulation at §164.512(k)(1) to permit covered entities to use and disclose the PHI of individuals serving in the USPHS and NOAA Commissioned Corps (referred to in the regulation text as the Uniformed Services) for mission requirements and for determinations of veteran eligibility. **It seeks comment on the proposal.**

IV. Public Participation

HHS seeks comment on all issues raised by the proposed regulation. It is especially interested in unintended adverse consequences of any of its proposals. Comments submitted by fax or email, or submitted after the end of the comment period, will not be accepted.

V. Regulatory Impact Analysis

A. Overall Costs and Savings

This proposed rule is deregulatory. HHS has estimated net savings of $3.182 billion over five years as shown in Table 1 below. However, there are first year net costs of $116 million. First year costs are $996 million attributable to covered entities revising or developing new policies and procedures, at a cost of $696 million; revising training programs for workforce members, at a cost of $224 million; and additional administrative tasks, at a cost of $76 million. HHS estimates these first-year costs would be partially offset by $880 million of first year savings.

For years two through five, estimated annual costs of $55 million are attributable to ongoing administrative costs, primarily related to improvements to the right of access to PHI. However, there will be net savings of $825 million annually in years two through five attributable to eliminating the NPP acknowledgment requirements (cost savings of $537 million) and clarifying the minimum necessary standard ($343 million).

Covered entities would experience an average net savings of approximately $1,065 per entity in years two through five after expending costs of $150 per entity in the first year. HHS estimates that the private sector would bear approximately 60 percent of the costs, with state and federal health plans bearing the remaining 40 percent of the costs. All of the savings experienced from the first year through subsequent years would benefit covered entities.

HHS has identified three general categories of costs arising from these proposals which mostly relate to activities by HIPAA covered entities, particularly health care providers and health plans: (1) administrative activities (first-year and ongoing); (2) revising or creating policies and procedures, the NPP, and an access fee schedule; and (3) revising training programs for workforce members.

Table 1 below shows the aggregate net savings figures over 5 years (in millions):

Estimated Five-Year Costs and Cost Savings, Undiscounted, in Millions	
Costs	**Amount**
Revise Training	$224
Revise Policies and Procedures	$696
Administrative Costs	$297
Capital Costs	$1
Total Costs	**$1,218**
Cost Savings	
Eliminate Notice of Privacy Practices Acknowledgement	$2,685
Clarify Minimum Necessary Standard	$1,715
Total Cost Savings	**$4,400**
Net Total (negative=savings)	**-$3,182**

HHS estimates that the proposed adjustments to costs that can be charged to individuals for copies of PHI in an EHR on electronic media would result in a transfer of those expenses from individuals to covered entities in a total estimated amount of $1.4 million. HHS also estimates that the proposed changes to the right to direct the transmission of copies of PHI to a third party and to allowable access fees would result in an annual transfer of $43 million in costs incurred by covered entities to individuals for directing copies of PHI to third parties. The net result of these proposals likely would be a transfer of an estimated $41.6 million in costs from covered entities to individuals and some third-party recipients of PHI in the form of higher fees for copies of PHI.

The proposed changes to the right of access, acknowledgment of the NPP, and several use and disclosure permissions would result in net economic cost savings of approximately $3.2 billion over five years as shown in Table 2 below.

B. Assumptions Underlying Estimates

Health Care Encounters

HHS based its assumptions for calculating estimated costs and benefits on a number of publicly available datasets, including data from the U.S. Census, the U.S. Department of Labor, Bureau of Labor Statistics (BLM), CMS, and the Agency for Healthcare Research and Quality (AHRQ). All calculations using mean hourly wages include benefits and overhead by multiplying the mean hourly pay for an occupation by two. HHS relies on the annual number of U.S. health care encounters as reported by the AHRQ, 2.46 billion, for some of its calculated estimates. Table 3 below summarizes these assumptions:

Annual U.S. Health Encounters	
Type of Encounter	**# of Visits or Days in Residence (in millions)**
Physician Office Visits	923
Hospital Outpatient	803
Nursing Home Days	500
Hospice Days in Residence	120
Home Health Visits	117
Total Annual	2,463

Business Establishments Affected

HHS estimates to be 774,331 business establishments that are covered entities that will be affected by this rule. Approximately 2/3 are the offices of practitioners. Table 5 of the proposed rule provides the details.

Individuals Affected

HHS believes that, by having some contact with a HIPAA covered entity, a large proportion of the 329 million individuals in the United States would be affected by this proposed rule. The widespread effect on individuals would be due primarily to the proposed changes to the right of access, notice of access and authorization fees, access and authorization fees that could be charged, ability to disclose PHI to an individual's family, friends, and others, disclosures for care coordination and case management to third parties and HCBS providers. HHS believes the persons most affected by the proposed changes to the rule permitting certain disclosures based on "good faith" would include individuals who are unable to agree or object to the use or disclosure of PHI due to incapacity or who are at risk of harming themselves or others and loved ones and caregivers of such individuals.

C. Overall Costs/Benefits

HHS describes many of the provisions of the rule as having costs or savings that cannot be estimated or one-time costs that will serve a deregulatory function where neither the costs or subsequent savings are estimable. Similarly, benefits are also inestimable and HHS uses the impact section to describe how the many provisions of the rule can impart benefit upon those

affected. **In some of these areas, HHS requests comment or examples that could assist in quantifying costs or costs savings. In all of the areas—whether quantified or not—HHS requests comments on its assumptions and estimates.**

In a long section titled "qualitative analysis of non-quantified benefits," HHS repeats its many proposals and describes how it believes each of the provisions is burden reducing or will benefit affect parties. This discussion is duplicative of the individual proposals or would follow from the preamble discussion of the proposed changes.

D. Specific Provisions Where HHS Quantified Costs/Benefits

For each of these sections. HHS describes the proposal and then its assumptions underlying the estimates and then the cost or savings estimate itself.

Savings and costs from adding a definition of EHR. No costs or savings.

Savings from changes to the right to inspect PHI. HHS lacks sufficient data about the number of inspection requests received by covered entities to make a reasonable estimate of the projected savings.

Costs from changes to the right to inspect PHI. To the extent that covered entities are currently prohibiting individuals from notetaking, photographing, or other ways of capturing PHI using their own devices, they would incur costs involved in changing the existing policy for in-person access: 25 minutes of lawyer time and approximately 322,638 hours for total costs of approximately $45 million. Revising the related training content would incur average costs for 20 minutes of a training specialist's time for each covered entity, resulting in increased hours of 258,110 and a total cost of approximately $16 million.

Savings from shortening access time limits. HHS lacks sufficient data to quantify any potential cost savings to covered entities resulting from this proposal; however, the receipt of PHI more rapidly from other covered entities may create efficiencies throughout the entire health system and contribute to improved health outcomes and decreased treatment costs.

Costs from shortening access time limits. One 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 $0.75 per request, HHS calculates the total additional annual burden would be approximately $918,400.

Costs and cost savings from addressing the form and format of access. HHS lacks sufficient information to quantify the potential costs or cost savings from these proposals and requests information about how these proposals would affect covered entities, business associates, and individuals.

Savings from addressing individual access right to direct copies of PHI to Third Parties. Covered entities may incur some labor costs for requests by individuals under the right of access to direct electronic copies of ePHI to a third party and estimates that costs may increase for 25 percent of the estimated annual 615,000 such requests (153,750) in the amount of 2 minutes of labor at the hourly wage of a medical records technician ($44.80) or $1.49 per request that cannot be charged to the individual as an allowable fee for copies.

In recognition that covered entities are unlikely to recoup costs for requests by individuals under the right of access to direct electronic copies of ePHI to health plans and health care providers (as opposed to other third parties), HHS estimates that costs may increase for 25 percent of the estimated annual 615,000 of such requests (153,750) in the amount of 4 minutes of labor at the hourly wage of a medical records technician ($44.80) or $2.99 per request. This is greater than the uncompensated burden estimate for copies sent to other third parties because HHS understands that health care providers and health plans may not routinely charge any fees for disclosures to other covered entities.

Additionally, HHS considers that a signed, written request and use of a personal health application are both examples of means that an individual may use that meet the condition that the request be clear, conspicuous, and specific, and that a signature may be provided in electronic form.

HHS 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. HHS has not quantified these cost savings.

Costs from addressing individual access right to direct copies of PHI to Third Parties. HHS estimates that covered entities may incur some one-time costs for changing their policies and procedures and revising their training program for employees who handle access requests, as well as initial implementation costs for adjusting to the revised policies and procedures. Covered entities will incur 30 minutes of a lawyer's time to revise policies and procedures related to the changes to this part of the right of access and 20 minutes of a training specialist's time to incorporate the newly revised policies and procedures into the covered entity's existing HIPAA training program.

HHS estimates that covered entities, primarily providers, would incur some costs from the proposed new requirement to submit requests for access on behalf of individuals who are seeking to direct the transmission of electronic copies of PHI in an EHR from another health care provider ("Discloser") to the requesting entity ("Requester Recipient"). The proposed requirement would increase costs for 15 percent of the 615,000 annual requests to direct copies of ePHI to health plans and providers (92,250) by 3.5 minutes per request at the adjusted labor rate of a medical assistant for a total of 5,381 burden hours at a total annual cost of $184,792.

The small proportion of covered entities or business associates who are not already fulfilling individuals' access requests to transmit ePHI to health care providers or health plans may

experience a small increase in costs resulting from their current noncompliance: 25 percent of these requests (153,750 total) would result in transmitting an electronic copy of ePHI via a non-internet based means, at a labor cost of 4 minutes of a medical records technician's adjusted hourly rate of $44.80, for a total annual cost of $459,200. Overall, HHS believes that, for covered health care providers and health plans, any costs to fulfill requests made under this proposal would be counterbalanced by the increased responsiveness from other covered entities that would transmit records to them, when requested, on a timelier basis, which would improve care and contribute to cost reductions.

Savings and cost transfers from changes to access fees. Of an estimated 2.46 million annual access requests, HHS assumes that one half (1.23 million) are for individuals to directly access PHI, 25 percent (615,000) direct copies to health care providers or health plans, and the remaining 25 percent (or 615,000) direct copies to other third parties. Of the 615,000 requests directed to other third parties, assuming an average record size of 200 pages, HHS assumes 100 pages are electronic copies and 100 pages are non-electronic copies (a "hybrid" records request) because it lacks sufficient data to estimate the average length of a record that is requested by an individual.

Covered entities would be disallowed from charging for certain expenses that the Privacy Rule currently allows when providing copies to an individual and when directing an electronic copy of PHI in an EHR to a third party under the right of access. The non-chargeable expenses would be the portion of costs attributable to emailing, mailing, or shipping the electronic copies and the costs of electronic media requested by individuals. Estimated additional costs are shown below:

Estimated Allowable Fee for a 200-page Hybrid Record Under the Current Rule	Estimated Allowable Fee for a 200-page Hybrid Record Under State Law
$25.23	$133.50

Estimated Allowable Fees for 100 Nonelectronic Pages under State Law	Estimated Allowable Fees for 100 Electronic Pages under State Law	Estimated Allowable Fees for 100 Nonelectronic Pages under the Current Rule	Estimated Allowable Fees for 100 Electronic Pages under the Current Rule	Estimated Allowable Fees for 100 Electronic Pages under the Proposed Rule
$88.16	$76.70	$16.74	$8.49	$1.41

- Allowable Fees under Proposed Rule for Sending an Electronic Copy of PHI in an EHR to a Third Party. The estimated average allowable fee under the proposed rule (100 pages in electronic format) is $1.49 per request (estimating 2 minutes for labor). In developing its estimated costs and cost benefits HHS employed several methods to arrive at a range of costs and cost benefits and average estimated costs and cost benefits for the proposed adjustments to the allowable access fees.

Under the first method, HHS estimates savings of the proposed changes to the access right to direct an electronic copy of PHI in an EHR to a third party and allowable fees for directing copies of PHI to third parties, would range from $53 to $108 per request.

Under the second method, HHS estimates costs for covered entities would increase for the estimated 307,500 requests that are accepted (for electronic copies of PHI in an EHR) by an estimated $7 per request in supplies and postage they would no longer be able to recoup in fees, for a total estimate of $2,152,500 annually. Savings for covered entities would accrue for the estimated 307,500 requests that are no longer within the right of access (for non-electronic copies or electronic copies not in an EHR) by an estimated $108.27 for a total estimate of $33,293,025 annually. This estimation method would result in an estimated net cost savings for covered entities of $31,140,525 annually ($33,293,025 minus $2,152,500).

- Summary Results of the Department's Estimated Costs and Cost Savings for Proposed Fee Adjustments. Under the several methods for calculating estimated fees for copies of PHI, HHS estimates total annual cost savings for covered entities ranging from $31 million to $67 million, or an average of $43 million. However, HHS estimates that all of these cost savings on the part of covered entities would be transferred to individuals and/or their third-party designees as costs. HHS estimates that 50 percent of these costs savings would be transferred as an additional cost imposed on individuals and the other 50 percent would be transferred to the third parties to whom the PHI is directed. For each of the estimated 615,000 requests that would have been made under the current rule to direct the transmission of copies of PHI to a third party under the right of access, the allowable fee for copies would increase by an estimated average of $70 ($43 million in estimated annual cost savings divided by 615,000 requests).

Costs arising from changes to access fees. One-time costs of 3 hours at $139.72 per hour for a lawyer to review the new HIPAA provisions and evaluate the entity's fee structure based on changes to allowable access fees; 2,322,993 total hours, for approximately $325 million in lawyers' costs related to the proposed changes to the right of access. Two hours and thirty minutes at $63.12 of a training specialist's time to revise the training content; 1,935,828 hours and costs of approximately $122 million. An average seven-minute increase for time spent in training on the proposed right of access changes in the first year of implementation; total estimate of 90,339 hours at an estimated cost of $4 million.

- Free Access for Inspecting PHI In-Person: To the extent that covered entities are charging individuals for the copies they make with their own devices or resources, the covered entities would incur some loss of revenue; however, HHS 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.

- Free Internet-Based Access: Because covered entities do not incur additional costs for labor, supplies, or postage for this method of providing access and because it only applies to covered entities that choose to use this method, HHS does not anticipate an increased burden for expressly requiring entities to provide such access for free.

- Reducing the Expenses Included Access Fees Copies of PHI in an EHR on Electronic Media: HHS proposes to disallow covered entities from charging individuals for the costs of electronic media and postage when providing access by mailing copies of PHI in an EHR on electronic media. It estimates that the costs of electronic media may range from $1 for a CD to $4 for a USB drive and the postage may range from $1 to $3, resulting in a range of estimated increased costs of $2 to $7 per request of this type or an average estimated increase of $4.50. HHS estimates that one-half of the 2.46 million total estimated annual access requests (or 1.23 million) would be made by individuals to obtain copies of PHI for themselves, and that half of those requests would be for non-electronic copies of PHI (or 615,000), one-fourth would be for internet-based access (or 307,500), and one-fourth would be subject to the proposed fee limitations for sending copies on electronic media (or 307,500). Total cost equals $1,383,750 but it would be a cost transfer from individuals to covered entities

- Narrowing Scope of Requests to Direct PHI to Third Parties Subject to the Access Fee Limits: Allowing covered entities to charge higher access fees than currently permitted when directing non-electronic copies of PHI or electronic copies of PHI not in an EHR to third parties based on a valid authorization rather than an access request would reduce the covered entity's burden for directing copies of PHI to a third party, and shift the costs to the individuals or to the third parties to whom the responses to such requests are directed. HHS has insufficient information to quantify the potential increased burden on individuals for these options.

Savings from requiring covered entities to provide access and authorization fee information. HHS believes that the benefits of changing covered entities' access procedures to incent individuals to make more targeted access requests and inform them of fees in advance would counterbalance the burdens on covered entities. However, it has no data with which to estimate the reduction in burden.

Costs requiring covered entities to provide access and authorization fee information. HHS estimates the potential burden on all covered entities (774,331) as the cost of 10 minutes of a web developer's time for a total labor cost of approximately $10 million. Although HHS assumes that 35 percent of covered entities have already posted an access and authorization fee schedule, it recognizes that all covered entities may need to post an updated fee schedule. In addition, HHS estimates that all covered entities will incur first-year and ongoing capital costs for making the fee schedule available at a cost of $0.10 for paper and printing or a total of $232,299. This assumes each covered entity prints an average of three copies of the fee schedule as a separate document.

- Providing the individual, upon request, with advanced notice of access/authorization fee: HHS assumes that three percent of 2.46 million total access requests, or 73,800, would result in a request for a fee estimate at a cost per request of three minutes of a medical records technician's time for a total new labor cost of approximately $165,312. HHS estimates that 15 percent of 73,800 requests for an access fee estimate (or 11,070) would need to be printed and mailed, at a total estimated capital expense of $7,638 at a cost of

$0.69 per estimate.

- Providing an itemized list of access/authorization charges for labor, copying, and postage: HHS estimates the potential labor costs as one minute of a medical records technician's time at the hourly rate of $44.80 for an estimated 24,600 annual requests for an itemized list of access charges, or a total of 410 burden hours and $18,368 in total costs. HHS estimates that covered entities would incur capital costs for printing one sheet of paper at a cost of $0.10 per request for an itemized list of charges and no additional postage because the itemized list of charges would be included with the copies of PHI sent to the individual, for a total cost of $2,460 annually.

Cost savings from changes to the verification requirements. Because HHS assumes that most entities do not impose unreasonable barriers to individual access, HHS anticipates that the total cost savings will be modest, but they may be significant for any particular affected individual.

Costs from changes to the verification requirements HHS estimates that 5% of covered entities (38,717), and any business associates that fulfill requests for access on their behalf, would need to modify their verification policies and forms and update related HIPAA workforce training content. HHS estimates that these covered entities would incur costs for 30 minutes of a lawyer's time (or $69.86) to revise these policies and procedures, and costs for 10 minutes of a training specialist's time (or $10.52) to update the HIPAA training content on this provision for a total of approximately $80.38 per covered entity.

Savings from adding an exception to the minimum necessary standard for care coordination and case management for individuals. HHS expects to achieve significant cost savings from this proposal but lacks quantifiable data on the number of such determinations that occur in every covered entity. HHS estimates that each covered health care provider and health plan would save 25 minutes per month in time currently spent considering requests for care coordination and case management disclosures, to determine whether the information requested could be provided consistent with its internal minimum necessary policies, and to follow the requisite procedure for doing so.

For purposes of calculating burden, HHS assumes that minimum necessary determinations generally are made outside of a patient encounter by workforce members at a registered nurse level, although HHS believes workforce members at a variety of levels in an organization may apply a covered entity's minimum necessary policies and procedures to routine disclosures of PHI. HHS proposes to adopt the mid-range estimate of burden reduction, which is 4 hours per covered entity per year for an annual reduced total of 3,097,324 burden hours and $342,997,660 in total annual projected cost savings.

HHS estimates that the cost savings from its proposed changes with respect to uses and disclosures in connection with care coordination and case management would equal 25 minutes of burden reduction for each covered entity for a total annual burden reduction of 4 hours per covered entity, resulting in remaining annual burden for complying with the minimum necessary requirement of 14 hours on average.

Costs arising from adding an exception to the minimum necessary standard for disclosures for individual-level care coordination and case management. HHS estimates that changes to policies and procedures for minimum necessary and disclosures for care coordination and case management would require 75 minutes of lawyer time at an adjusted mean hourly rate of $139.72, and revisions to training content would require one hour of training specialist time (including related training for care coordination and case management definitions and disclosures to third parties, such as social services agencies, community based support programs, and HCBS providers) at an adjusted mean hourly rate of $63.12.

Savings from changing "professional judgment" to "good faith" and "imminent" to "reasonably foreseeable." HHS does not have data sufficient to estimate the reduction in professional time spent analyzing the risk of harm; however, HHS believes this change would result in cost savings to covered entities, in addition to the cost savings from improved patient safety and treatment outcomes, as well as, potentially, the decreased costs due to avoided public safety incidents.

Costs from changing "professional judgment" to "good faith" and "imminent" to "reasonably foreseeable." One hour of a lawyer's time to update policies and procedures (for a total of 768,169 burden hours at a cost of $107,328,573) and 40 minutes of a training specialist's time to update related HIPAA training content (for a total of 512,113 burden hours at a cost of $32,324,552).

Savings from eliminating the acknowledgment of receipt of the NPP. HHS acknowledges the uncertainty and wide variability in how different covered health care providers disseminate the NPP acknowledgement and make a good faith attempt to obtain the signed acknowledgement and then store and maintain it. HHS is estimating a range from 30 seconds to 2 minutes and 55 seconds, taken to disseminate the NPP acknowledgement, request the patient's signature, explain what the acknowledgement consists of, wait for the patient to sign, complete the check-off or other procedure applied when the patient is unable or unwilling to sign, file the acknowledgement documentation, and store the documentation for six years. HHS utilizes the mid-range estimate of 17,879,169 reduction in burden hours for an annual cost savings of $537,090,228 associated with the proposal to eliminate the requirements associated with the good faith attempt to obtain acknowledgment of receipt of the NPP.

HHS also assumes that eliminating the related requirement to maintain documentation of the acknowledgment of the NPP for six years would result in significant cost savings to direct treatment health care providers in the form of a reduction of one page (electronic or paper) of each patient's record, and reduced space needed for one page of medical records (if that is where such documentation is stored) per patient or reduced electronic storage space for systems that store these notices electronically; however, HHS has not quantified the potential savings.

Costs from eliminating the acknowledgment of receipt of the NPP. HHS anticipates no costs for eliminating the requirement for direct treatment providers to make a good faith effort to obtain an individual's signed acknowledgment of receipt of the NPP and to maintain related documentation.

Savings from changes to the NPP content. HHS does not anticipate quantifiable cost savings to covered entities from making the required changes to the NPP; however, the improvements to individuals' right of access may contribute to improvements to health care delivery and the health of patients overall.

Costs from changes to the NPP content. HHS estimates that the proposal to update and revise the language in the NPP (including drafting the language in the header) would require one hour of professional legal services. There are no new costs for providers associated with distribution of the revised notice other than posting it on the entity's website (if it has one), as providers have an ongoing obligation to provide the notice to first-time patients. HHS estimates approximately 613 million first time visits with health care providers annually. HHS further estimates the cost of posting the revised NPP on the covered entity's website would be ten minutes of a web developer's time. HHS assumes that about 1% of an estimated 613 million new patients will ask for further discussion with the designated contact person. HHS therefore estimates that 6,130,000 individuals may ask for a discussion on the NPP as a result of OCR's media campaigns as well as through general awareness of individual privacy rights under HIPAA. HHS estimates that its proposal to require covered entities to make available a person who may be contacted for further information on the covered entity's privacy practices would add $8.69 in burden per request for information or $53 million (or 715,167 burden hours) total per year. HHS assumes each discussion between the contact person and individual will last an average of 7 minutes as individuals ask questions and receive answers, at the adjusted mean hourly rate for a registered nurse.

Savings from adding a permission to disclose PHI to a TRS communications assistant. HHS lacks sufficient data to quantify the cost savings of this proposed change

Costs from adding a permission to disclose PHI through TRS communications assistant. HHS has not identified any additional costs to covered entities arising from the proposed change other than changes to policies and procedures and training, as TRS is provided without charge to the user.

HHS summarizes quantifiable costs and savings detailed above in the below tables:

Quantifiable Cost Savings Estimates			
Cost Item	**Burden Count**	**Multiplier**	**Savings (Millions)**
Clarifying Minimum Necessary	4 hours of health manager time X $110.74 = $442.96	Total CEs (774,331)	$343
Eliminating NPP Acknowledgment	1 minute 45 seconds (.0292) of clerk/receptionist time X $30.04 = $.877	613,000,000 1st time encounters	$537
Total Annual Cost Savings			**$880**
Total Cumulative Cost Savings (5 Years)			**$4,400**

Quantifiable Costs to Covered Entities			
One-Time Costs	**Burden Count**	**Multiplier**	**Total Administrative Cost**
Post access fee schedule online	10 min. X web developer ($79.20) = $13.20	Total covered entities (774,331)	$10
Post revised NPP online	10 min. X web developer ($79.20) = $13.20	Total covered entities (774,331)	$10
Total One-Time Administrative Burden			**$20**

The following tables show ongoing costs based on an individual's request and include providing copies of PHI and ePHI under the right of access within a shorter time, providing an estimate of access and authorization fees, providing an itemized list of allowable access charges, discussing privacy practices with individuals, and submitting requests for copies of PHI to health care providers or health plans.

Ongoing Costs			
Ongoing Costs	**Burden Hours & Pay**	**Multiplier**	**Total Annual Administrative Cost (Millions)**
Access for Individuals ―Search and retrieval within shorter times	1 min. X records technician time ($44.80) = $.75	50% of 2,460,000 access requests = 1,230,000	$0.9
Sending copies of ePHI to third parties other than covered entities―Non-internet-based method	2 min. X records technician time ($44.80) = $1.49	25% of 615,000 access requests = 153,750	$0.230
Sending copies of ePHI to health plans and providers under the right of access―Non-internet methods	4 min. X records technician time ($44.80) = $2.99	25% of 615,000 access requests = 153,750	$0.459
Providing good faith fee estimates upon request	3 min. X records technician time ($44.80) = $2.24	3% (.03) of 2,460,000 access requests = 73,800	$0.165
Providing itemized list of access and authorization fees upon request	1 min. X records technician time ($44.80) = $0.75	1% (.01) of 2,460,000 access requests = 24,600	$0.018

Ongoing Costs			
Ongoing Costs	**Burden Hours & Pay**	**Multiplier**	**Total Annual Administrative Cost (Millions)**
Discuss privacy practices with individuals upon request	7 min. X registered nurse time ($74.48) = $8.69	1% (.01) of 613 million 1st time encounters = 6,130,000 requests	$53
Submitting access requests to providers & plans for individuals	3.5 min. X medical assistant time ($34.34) = $2.00	15% (.15) of 615,000 access requests = 92,250	$0.185
Total Ongoing Annual Administrative Burden			$55

Capital costs associated with fee estimates for copies of PHI provided under the right of access and with a valid authorization

Increased Capital Costs				
Fees Estimates Section	**Proposed Regulatory Requirement**	**Number of Pages to be Printed**	**Average Cost**	**Total**
164.525	Printing itemized list of copy charges	24,600	$0.10	$2,450
Total Capital Costs				$242,398

Additional costs for revising policies and procedures:

Revising Policies and Procedures			
Revising Policies and Procedures	Time (mins)	Covered Entities	Burden Hours
Minimum Necessary, Disclosures for Care Coordination & Disclosures to Social Services Agencies & CBOs	75	774,331	967,914
Right of access (multiple provisions, including fee schedule)	180	774,331	2,3223,93
Disclosures to family & friends of individual; Disclosures to prevent harm	60	768,169 (providers)	768,169
Revise NPP	60	774,331	774,331
Disclosures for Uniformed Services & TRS	10	774,331	129,055
Simplify verification & revise form	30	5% of 774,331 covered entities = 38,717	19,358
Total Burden Hours			4,981,820
Total Costs			$696 million

HIPAA Training Programs			
Training Content to be Revised	**Time (Mins)**	**Covered Entities Affected**	**Burden Hours**
Minimum Necessary, Disclosures for Care Coordination, & Disclosures to Social Services Agencies & CBOs	60	774,331	774,331
Changes to Access Times, Changes to Access Procedures, Submitting PHI to Providers & Plans, and Fees and Estimates	150	774,331	1,935,828
Disclosing PHI to Family & Friends; Uses and Disclosures to Prevent Harm	40	768,169 Providers	512,113
Disclosures for Uniformed Services; Telecommunications Relay Services	15	774,331	193,583
Right to Discuss NPP	5	774,331	64,528
Verification of Identity	10	5% of covered entities = 38,717	6,453
Total Time to Update Training Content			**3,486,834**
Total Costs for Updating Training Content			**$220 million**

First Year Training Costs: Medical Records Technician					
Staff in Training	**Hourly Wage**	**Time (mins)**	**Covered Entities Affected**	**Burden Hours**	**Costs (Millions)**
Medical Records Technician	$44.80	7	774,331	90,339	$4.047

Total Estimated Training Costs		
Cost Item	**Burden Hours**	**Cost (Millions)**
Updated Training Content	3,486,834	$220
Increase Time in Training	90,339	$4
Total New Training Costs	**3,577,173**	**$224**

Cost/Benefit Analysis

HHS expects the benefits of the proposed rule to outweigh any costs because covered entities will save costs each year after the first year, having experienced initial higher costs related to implementation of proposed changes. The following tables summarize the Department's analysis of costs and benefits:

Cost Item	Costs	Savings
Revised Training	$224	
Revising P&P	$696	
Administrative Costs	$76	
Capital Costs	$0.242	
Eliminating NPP Acknowledgement		$537
Clarifying Minimum Necessary		$343
Total	**$996**	**$880**
Net Savings/Cost – First Year		**$116**

Ongoing Estimated Quantifiable Annual Costs/Costs Savings to Covered Entities (In millions, years 2 – 5)		
Cost Item	**Costs**	**Savings**
Access & Administrative Costs	$55	
Capital Costs	$0.242	
Eliminating NPP Acknowledgement		$537
Clarifying Minimum Necessary		$343
Total	**$55**	**$880**
Net Costs Savings – Years 2-5		**$825**

Estimated Transfers (millions)		
Cost Item	Amount of Costs Transferred (Transferor)	Amount of New Costs Incurred (Transferee)
Decreased fees for providing electronic copies in an EHR on electronic media to individuals	$1.4 (individuals)	$1.4 (covered entities, primarily providers
Additional fees for authorizing copies of nonEHR PHI to a third party	$43 (covered entities, primarily health care providers); 615,000 access requests X $70 average estimated increased fee	$21.5 (individuals) $21.5 (third party recipients)

Non-Quantifiable Costs/Benefits for Covered Entities and Individuals		
Regulatory Changes	**Costs**	**Benefits**
Changing from "professional judgment" to "good faith" and from "imminent" to "reasonably foreseeable"	Potential increased complaints to OCR from individuals who did not want their PHI used or disclosed; potential to chill some	Improved care coordination and case management; increased harm reduction; likely increase in adherence to treatment and increased service utilization

Non-Quantifiable Costs/Benefits for Covered Entities and Individuals		
Regulatory Changes	**Costs**	**Benefits**
	individuals' willingness to access care	
Changing verifications		Improved access to PHI
Adding permission to disclose to TRS and excluding TRS providers from the definition of business associate		Improved employment conditions and opportunities for workforce members who are deaf, hard of hearing, or deafblind, or who have a speech disability; improved compliance with nondiscrimination laws
Adding right to discuss covered entity privacy practices, eliminating NPP acknowledgment requirement & changes to NPP		Improved understanding of individuals' rights & covered entities' privacy practices; improved access to care
Better enabling individuals to direct the transmission of electronic PHI in an EHR among providers and plans as part of the right of access		Improved care coordination and case management; increased individual control over directing ePHI for health-related purposes
Strengthening right of access (free online access; shorter access times; right to inspect; access fee information)	Increased burden on individuals to directly obtain lower cost copies of non-EHR PHI and send it to third parties to avoid paying higher fees under an authorization	Improved access to PHI by individuals—receiving PHI twice as fast; improved access to ePHI by providers & plans; reduction in access fee disputes/improved collection of access fees; increased certainty about allowable fees; increased adoption and utilization of EHR technology
Restricting the right to request that a covered entity direct the transmission of certain PHI to a third party	Increased burden on individuals to submit two forms: an access request and an authorization, when seeking to send a complete medical record to a third party	Improved clarity and certainty for covered entities;
Adding an optional element of the NPP for covered entities to provide information about alternate ways to obtain PHI directly or		Increased knowledge by individuals of their rights to access and their options for accomplishing their information sharing goals.

Non-Quantifiable Costs/Benefits for Covered Entities and Individuals		
Regulatory Changes	**Costs**	**Benefits**
have it sent to a third party, for certain requests to direct the transmission of certain PHI to a third party		

Uncertainty Analysis

HHS estimates total costs of implementation over a five-year period ranging from a low of approximately $0.8 billion to a high of approximately $4 billion and a range of five-year cost savings of approximately $1.2 billion to $7.5 billion. The proposed rule details the range of estimates for many provisions of the proposed rule.

E. Consideration of Regulatory Alternatives

HHS considered not proposing this rule at all and just increasing outreach and education but decided that pursuing this rule is consistent with its regulatory burden reduction objectives as well as improving the Privacy Rule. Despite extensive outreach efforts, HHS remains concerned that covered entities remain fearful of incurring HIPAA penalties for using and disclosing PHI. For this reason, HHS is pursuing rulemaking to expressly permit beneficiary disclosures that currently are not permitted, or are burdensome to complete under the existing Privacy Rule

Right of Access

Changing the Right to Direct Electronic Copies of EHR to a Third Party and Form and Format for Such Requests. HHS considered creating two new unreviewable grounds to deny an access request to direct a copy of PHI to a third party: 1) if the requested copy was for PHI not contained in an EHR; and 2) if the request was for a copy of PHI not in electronic format. As part of the response to the written denial a covered entity would have been required to provide information about how the individual could access the requested PHI directly or how to request it with a valid authorization. HHS also considered a simplified approach, which would have required a covered entity to inform the individual about other options to obtain PHI, but without creating new grounds for denying the request.

HHS also considered requiring covered health care providers to provide the electronic copies to third parties in a readable form and format as agreed to by the individual and the covered entity. As raised in the 2018 RFI, HHS considered whether to require covered entities to disclose PHI to other covered entities for purposes of treatment, payment, or health care operations and variations on that idea, such as limiting the requirement to health care providers or limiting such required disclosures to treatment purposes only. HHS also considered how much individual control should be permitted for disclosures between covered entities, such as an opt-in or opt-out mechanism or some type of express permission. However, HHS rejected these ideas because of concern about judicial precedent *(Ciox vs. Azar)* or privacy concerns raised by commenters in response to the 2018 RFI.

Access Time Limits. HHS considered the feasibility of changing the access time limits by requiring covered entities to provide copies of electronic PHI within a shorter time period than non-electronic PHI but rejected this idea as it would create unnecessary complexity and add to covered entities' burdens.

HHS also considered whether to modify the Privacy Rule to require covered entities to disclose PHI for continuity of care or medical emergencies within a shorter time than required under the access right. Instead, HHS proposed to require entities to adopt a policy addressing the prioritization of access requests as it believes most covered entities are doing anyway.

HHS also considered whether to change the access time limits overall to a period shorter than the 15 calendar-day proposed time and did not pursue this approach because that is more stringent than many of the short time limits contained in state access laws and may overly burden covered entities and affected business associates.

Access Fees. HHS considered retaining the existing access fee structure without change but decided it needed to be responsive to comments on the 2018 RFI that multiple, voluminous access requests to direct copies of PHI to third parties is burdensome and interferes with addressing other disclosure requests. HHS also considered allowing covered entities to charge no more than the limited access fee amounts for directing non-electronic copies of PHI to a third party for any treatment, payment, and health care operations purposes, while permitting higher fees for directing non-electronic copies of PHI to a third party for any other purposes. It rejected this approach because it would open the door for covered entities to inquire into individuals' purposes in directing their own PHI to third parties.

Verification of Identity. HHS considered modifying the individual right of access provision to prohibit burdensome paperwork requirements for individuals without also changing the identity verification provisions. However, HHS determined that changing both would help covered entities and individuals understand how the access and verification provisions interact. HHS also considered applying the proposed prohibition against unreasonable measures only to identity verification related to access requests, which would be more narrowly tailored to situations HHS has seen in complaints filed with the Department. However, HHS does not see a meaningful distinction between the access right and the other individual rights under HIPAA that would justify treating them differently with respect to verification of identity.

Exceptions to the Minimum Necessary Standard. HHS considered limiting the new exception to the minimum necessary standard to disclosures to and requests by covered health care providers for all health care operations purposes. This would have relieved the burden on covered health care providers who conduct population-based care coordination and case management of needing to assess the minimum necessary PHI when exchanging information with other covered health care providers. Limiting the exception to health care providers also would have addressed the concerns of commenters who opposed an exception for disclosures to health plans due to concerns that the plans may use the information against patient interests. HHS rejected this option, however, because health plans collaborate with health care providers, other health plans and other entities, including public health agencies, to improve patient health through care coordination and case management activities.

Disclosures to Third Parties such as Social Services Agencies, Community Based Organizations, and HCBS Providers. HHS considered proposing to clarify in the definition of treatment when a covered health care provider's disclosure to a social services agency, community-based organization, or HCBS provider are considered part of that covered health care provider's treatment activities, without adding an express disclosure permission. HHS also considered limiting the proposed disclosure permission to only covered entity health care providers and excluding health plans from the proposed policy. Ultimately, HHS rejected that option and proposed a permission for covered health care providers and health plans to encourage beneficial information sharing that would support care coordination and case management for individuals.

"Professional Judgment" and "Good Faith"

Replace the professional judgment standard with the good faith standard throughout the Privacy Rule. HHS considered applying a presumption of good faith to all fourteen provisions in the Privacy Rule that allow covered entities to use or disclose PHI based on the exercise of professional judgment. However, HHS intends this proposed modification to carefully expand the ability of covered entities to use or disclose PHI to facilitate the involvement of family and caregivers in the treatment and recovery of people experiencing the impacts of the opioid crisis, serious mental illness, and health emergencies. HHS believes the remaining nine provisions would be beyond the scope of this goal. HHS further believes there likely could be unintended consequences if it replaced the exercise of professional judgment standard with a good faith standard across all fourteen provisions, including those provisions not rooted in emergency circumstances.

Apply a presumption of compliance to all Privacy Rule provisions referencing professional judgment without changing the professional judgment standard to a good faith standard. HHS considered proposing to apply a presumption of compliance to all existing provisions that permit covered entities to make decisions about uses and disclosures of PHI based on the exercise of professional judgment, without replacing the standard with a good faith standard. However, HHS intends not only to presume compliance with existing permissions, but to broaden the circumstances in which covered entities will use or disclose PHI in order to help address the needs of individuals experiencing opioid use disorder and other similarly situated individuals.

Replace the professional judgment standard with a good faith standard only in specified provisions of 45 CFR 164.510. HHS considered replacing the professional judgment standard with a good faith standard in limited circumstances (in the individual's best interest because of the individual's incapacity or emergency circumstances, reasonably infer the individual does not object to disclosure to family, relatives, or close friends, or when the individual is not present but disclosure is in his/her interest) but decided that would encourage the disclosure of information only to family members, friends, caregivers, and other involved persons and only in the circumstances addressed at 45 CFR 164.510. HHS intends through this proposal to carefully broaden the permissible uses and disclosures of PHI by covered entities in circumstances that relate to the opioid crisis, serious mental illness, and health emergencies, to ensure that covered entities are able to share information as needed to care for individuals and protect the public.

Define "imminent" instead of replacing the term with "reasonably foreseeable." The Privacy Rule does not define the term "imminent," although common understanding of the term conveys that an event will happen soon. Instead, HHS proposes to create a standard based on reasonable foreseeability because HHS believes it would provide needed flexibility for covered entities to address serious threats to health and safety that are likely to occur.

NPP and Acknowledgment of Receipt. HHS considered requiring the online posting of the NPP by all covered entities, including those that do not currently have a website. However, HHS believes the burden of creating a website solely to post the NPP for those few covered entities without a website outweighed the benefits to individuals of such a requirement.

Telecommunications Relay Service (TRS)

HHS considered an alternative proposal to categorize TRS providers as "conduits" because of their temporary access to PHI and thus deem them not to be business associates. However, this alternative would not have precluded them from disclosing information in a variety of appropriate circumstances. Thus, HHS believes it is necessary to propose an express permission to disclose PHI to TRS communications assistants without a business associate agreement.