



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office for Civil Rights

Office for Civil Rights (OCR) Proposes Modifications to the HIPAA Privacy Rule to Empower Individuals, Improve Coordinated Care, and Reduce Regulatory Burdens FACT SHEET

General

- The Notice of Proposed Rulemaking (NPRM) solicits public comment on proposals to modify the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to improve health information sharing for more effective health care, empower individuals with their own health information, and lift unnecessary administrative burdens on covered health care providers and health plans.
- The NPRM is part of HHS Deputy Secretary Eric D. Hargan's Regulatory Sprint to Coordinated Care, initiated under HHS Secretary Alex Azar's value-based transformation agenda. The Regulatory Sprint seeks to promote value-based health care by updating federal regulations that unnecessarily impede efforts among health care providers, health plans, and other service providers to better coordinate care for individuals.
- Coordinated care is a vital piece of President Trump's vision for a patient-centric healthcare system, and regulatory reform is a key step toward promoting more coordinated care. The HHS Regulatory Sprint to Coordinated Care includes recent changes to the Confidentiality of Substance Use Disorder Patient Records regulation (42 CFR Part 2), as well as Stark Law and Anti-Kickback Statute regulatory reforms.

Proposed changes as part of this NPRM include:

Disclosures of PHI in the Best Interests of Individuals Experiencing Emergencies or Health Crises, Including Serious Mental Illness and Substance Use Disorder Crises

- The NPRM proposes to facilitate the disclosure of protected health information (PHI) needed to improve care for individuals experiencing certain health emergencies by modifying the standard for certain permitted disclosures from one based on a covered entity's "professional judgment" to one based on its "good faith" belief that a disclosure would be in the best interests of the individuals.
 - This proposed modification can help improve care coordination by expanding the ability of covered entities to disclose PHI to family members and other caregivers when they believe it is in the best interests of the individual, unless the individual objects to the disclosure, without the covered entity having undue fear of violating HIPAA.
 - This proposed modification addresses concerns that the requirement under the current rule to exercise professional judgment could be understood as limiting the permission to persons who are licensed or who rely on professional training to determine whether a use or disclosure of PHI is in an individual's best interests.

- A good faith belief may be based on, for example, knowledge of the facts of the situation (including any prior expressed privacy preferences of the individual, such as those in an advance directive) or the representations of a person or persons who reasonably can be expected to know relevant facts.
- The extent of this permitted disclosure of PHI would continue to 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.
- **EXAMPLES:**
 - Good faith would permit a licensed health care professional to draw on experience to make a determination that it is in the best interests of a young adult patient, who has overdosed on opioids, to disclose relevant information to a parent who is involved in the patient’s treatment and who the young adult would expect, based on their relationship, to participate in or be involved with the patient’s recovery from the overdose.
 - Likewise, front desk staff at a physician’s office who have regularly seen a family member or other caregiver accompany an adult patient to appointments could disclose relevant information to the family member or caregiver as a way of checking in on the welfare of the patient, when a patient misses an appointment, based on the staff’s knowledge of the person’s involvement and a good faith belief about the patient’s best interests.

Disclosures to Prevent Harm or Lessen a Threat of Harm

- The NPRM also proposes to expand the ability of covered entities to disclose PHI to avert a threat to health or safety when harm is “serious and reasonably foreseeable,” instead of the current stricter standard which requires a “serious and imminent” threat to health or safety.
 - This proposed modification seeks to prevent situations in which covered entities decline to use PHI and make disclosures of PHI that they believe are needed to prevent harm or lessen threats of harm because they are concerned that their inability to determine how imminent the threat of harm is may subject them to HIPAA penalties for an impermissible use or disclosure.
 - This proposed modification would permit covered entities to use or disclose PHI without having to determine whether the threatened harm is imminent (which may not be possible in some cases); instead, they may determine whether it is reasonably foreseeable that the threatened harm would occur.
- **EXAMPLES:**
 - Adopting a “serious and reasonably foreseeable” standard can enable a health care provider to timely notify a family member that an individual is at risk of suicide, even if the provider cannot predict that a suicide attempt is “imminent.”
 - An emergency room doctor who sees an elderly patient with COVID-19 could contact the patient’s nursing home to alert them of the potential exposure of other residents and staff based on the serious and reasonably foreseeable threat of infection with COVID-19, without delay caused by the need to assess whether the threat is sufficiently “imminent” to permit the disclosure.

Care Coordination and Exception to the Minimum Necessary Standard

- The NPRM proposes to modify the definition of “health care operations” to clarify that the term includes care coordination and case management for individuals. The current definition is sometimes read to cover only population-based activities, with the result that some entities

believe that health plans are not permitted to use and disclose PHI to coordinate care for individuals.

- In addition, the NPRM proposes to add an express exception to the minimum necessary standard for disclosures to, or requests by, a health plan or covered health care provider for care coordination and case management for individuals.
 - Disclosures by or to covered health care providers for care coordination or case management for individuals are considered “treatment” disclosures, which are excepted from the minimum necessary standard. However, currently, when case management or care coordination is considered a health care operations activity (*e.g.*, where a health plan is performing the activity, so it is not considered treatment), it is not excepted from the minimum necessary standard.
 - This proposed exception would promote beneficial disclosures of PHI for care coordination and case management.
 - The exception would apply only to those care coordination and case management activities that are at the individual level and covered entities would still be required to meet the minimum necessary standard in other instances as outlined in the Privacy Rule.
- EXAMPLE:
 - A health plan that has care coordinators on staff to help link individuals to specialists or other health services could request PHI from a health care provider for this purpose as part of the plan’s health care operations, and the health care provider could disclose the PHI without having to make its own determination of whether the plan’s care coordinator has requested only the minimum necessary PHI to accomplish the purpose.

Disclosures to Facilitate Care with Social and Community Services

- The NPRM proposes to expressly permit covered entities to disclose PHI to social services agencies, community-based organizations, home and community based service (HCBS, which are services supported by, among other payors, state Medicaid programs) providers, or similar third parties that provide or coordinate health-related services that are needed for care coordination and case management with respect to an individual.
- This proposal is intended to clarify the ability of covered entities to disclose PHI to such third parties for individual-level care coordination and case management.
- EXAMPLES:
 - Many patients with an opioid use disorder need health-related services from a number of different agencies and community-based organizations that need to communicate among one another to provide the best care. A doctor could disclose the PHI of such a patient to a community counseling program, a nutrition assistance program, or a health care supportive housing agency, to support and coordinate care.
 - Similar situations also occur with respect to elderly individuals or individuals with disabilities who may use home health services, community health centers, and health-related social assistance programs.

Right of Individuals to Access their PHI

- The NPRM contains a number of proposed modifications to enhance individual engagement and improve individuals’ rights to access their own health information.
- The proposed modifications related to the HIPAA Privacy Rule Individual Right of Access include the following:

- Shortening covered entities' required response time to no later than 15 calendar days (from the current 30 days) after receipt of the request, with the opportunity for an extension of no more than 15 calendar days (from the current 30-day extension).
- Empowering the individual to control the sharing of PHI in an electronic health record (EHR) among covered health care providers and health plans, by requiring covered health care providers and health plans to submit an individual's access request to another health care provider and to receive back the requested electronic copies of the individual's PHI in an EHR.
 - This ensures that treating doctors can get medical records to support treatment of the individual (the Privacy Rule already permits health care providers to disclose PHI for treatment, but they are not required to do so).
 - EXAMPLE: If an individual from California was involved in an automobile accident in Virginia, and is being treated by a variety of specialists, orthopedists, neurologists, physical therapists in Virginia, the individual can send a request to one of the treating doctors in Virginia to obtain an electronic copy of the individual's records from their primary care physician in California to assist the Virginia treating physicians in providing care to the individual.
 - The Virginia doctor would be required to forward the request within 15 days and the California doctor would be required to respond to the request within 15 days (with the possibility of a 15 day extension, if the California doctor is unable to meet the 15 day deadline).
- Strengthening individuals' rights to inspect their PHI in person, which includes allowing individuals to take notes or use other personal resources to view and capture images of their PHI. Part of this is clarifying that individuals may take photos on the spot in conjunction with a health encounter.
 - EXAMPLE: An individual who is looking at their own x-ray, MRI, or sonogram while in the exam room could use their smartphone to take a photo and immediately email it to their spouse.
- Clarifying the form and format required for responding to individuals' requests for their PHI, including for electronic copies.
 - EXAMPLE: If an individual requests that a covered entity transmit PHI securely to the individual's personal health application, and the covered entity has the technical capability to so, this form and format is considered readily producible.
- Reducing the identity verification burden on individuals exercising their access rights, without adversely affecting the security of PHI.
 - EXAMPLE: Requiring an individual to obtain notarization on an access request would create an unreasonable barrier and would not be permitted under the proposed rule.
- Specifying when electronic PHI must be provided to the individual at no charge.
 - EXAMPLE: When a doctor adds a health note about an individual to their electronic system that provides view-download-transmit (VDT) capabilities for individuals, the patient cannot be charged for the costs associated with allowing access to the VDT system, because entering individual patient record information into the system as part of the normal course of providing care is not presumed to introduce any labor costs.

- Requiring covered entities to post estimated fee schedules on their websites for right of access requests and for valid authorization disclosures and, upon request, provide individualized estimates of fees for an individual's request for copies of PHI, and itemized bills for completed requests.
 - This will help ensure that covered entities are charging reasonable cost-based fees for right of access requests, and for requests using an authorization, the individual knows what the costs will be in advance.
 - EXAMPLE: An individual who wants to request copies of their record can find out in advance what different copy formats (*e.g.*, electronic, paper) will cost and, if they wish, take the estimated fees into consideration in requesting particular formats.

Notice of Privacy Practices (NPP)

- The NPRM proposes to eliminate the requirement for a covered entity to obtain an individual's written acknowledgment of receipt of a direct treatment provider's NPP, and the associated requirement to retain copies of such documentation for six years. This proposal will result in a significant reduction of administrative burden for covered health care providers.
 - Eliminating this requirement will reduce paperwork and time spent away from the care of individuals. It will also eliminate confusion, as some individuals believe they are entering into a contract or waiving their rights under HIPAA, and improve access to care, as OCR has received complaints where individuals were denied treatment after declining to sign the acknowledgment.
 - EXAMPLE: An individual receives their health care provider's NPP when arriving at an appointment. The front office staff will not have to take the time to ask for a signature of receipt, explain why they need it (which the staff, as well as the individual, may not understand), and file and maintain the acknowledgment – or the documentation of their attempt to obtain a signed acknowledgment – for six years.
- The NPRM also proposes to modify the content requirements of the NPP to clarify for individuals their rights with respect to their PHI and how to exercise those rights.
 - The required header of the NPP would inform individuals that the notice provides information about how to access their health information, how to file a HIPAA complaint, and their right to receive a copy of the notice and to discuss its contents with a designated person.
 - Proposes to modify the required header to also specify whether the designated contact person is available onsite and include a phone number and email address the individual can use to reach the designated person.
 - Providing this information at the beginning of the NPP would improve individuals' awareness of their Privacy Rule rights, what they can do if they suspect a violation of the Privacy Rule, and how to contact a designated person to ask questions.
 - Consistent with the proposed required header language, and to ensure that individuals are fully informed of their access rights, proposes to modify the required element of an NPP that addresses the access right to describe how an individual can exercise the right of access to obtain a copy of their records at limited cost or, in some cases, free of charge,

- and the right to direct a covered health care provider to transmit an electronic copy of PHI in an EHR to a third party.
- EXAMPLE: An individual who receives their health care provider's NPP will immediately see how to exercise their right to request records at a reasonable fee, to report suspected violations to OCR, and how to get answers from the provider about the use and disclosures of their PHI under HIPAA.

Telecommunications Relay Service (TRS)

- Telecommunications Relay Service (TRS) facilitates telephone calls for individuals who are deaf, hard of hearing, deaf-blind, or have a speech disability. TRS facilitates such telephone communication by using a communications assistant who transliterates conversations (or, in some cases, interprets using ASL).
- The NPRM proposes to expressly permit disclosures to TRS communications assistants, and to modify the definition of business associate to exclude TRS providers.
- Currently, the HIPAA Privacy Rule permits covered entities to disclose PHI to TRS communications assistants to facilitate communication with individuals (patients or beneficiaries) who are deaf, hard of hearing, deaf-blind, or who have a speech disability, but does not address the situation where members of a covered entity's or business associate's workforce might be deaf, hard of hearing, deaf-blind, or have a speech disability and need TRS communications assistants to help them communicate.
- EXAMPLE: A hospital nurse who is deaf can use a TRS communications assistant to facilitate a call with a health plan representative about pre-authorization for a patient's procedure, or to coordinate post-discharge care for an individual with another health care provider, without obtaining the individual's authorization and without the hospital having a business associate agreement with the TRS provider.

Uniformed Services

- Currently, a covered entity may use and disclose the PHI of Armed Forces personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, provided certain required conditions are met.
- This NPRM proposes to extend the permission to disclose PHI of Armed Forces personnel to that of U.S. Public Health Service (USPHS) Commissioned Corps and the National Oceanic and Atmospheric Administration (NOAA) Commissioned Corps. These Services are considered part of the Uniformed Services but are not considered part of the Armed Forces.
- EXAMPLE: A covered entity could disclose to USPHS command authorities the results of a fitness-for-duty examination of an individual who is a member of USPHS Commissioned Corps, without the individual's authorization, when needed to assure the proper execution of the USPHS mission.