Davis Wright Tremaine LLP

2026 HIPAA Privacy Rule Amendments



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Introduction

- HHS announced “Regulatory Sprint to Coordinated Care” in 2018.
- HHS Office for Civil Rights (OCR) published corresponding proposed rule on Jan. 21, 2020.
- Final rule formally published in Federal Register on November 19, 2026.
- Compliance deadline of July 19, 2027. Regulated entities have until Jan. 18, 2028, to revise business associate agreements.



Right of Access

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Request for Access

"The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement. For purposes of this paragraph, in writing means that the request itself serves as documentation of the individual's exercise of the right of access, including when the request is submitted electronically or on paper." 45 C.F.R. § 164.524(b)(1)(ii).

Timeliness of Access

- The Privacy Rule currently provides 30 days and a 30-day extension for access.
- Revised deadline will be “[a]s soon as practicable, but no later than 15 calendar days after receipt of the request.”
- OCR kept the extension at 30 days rather than changing to 15 days.
- Discussions with individual about the scope, format, and other aspects of the request do not extend the deadline.
- OCR did not finalize proposal to require a policy for prioritizing urgent requests.
- If another federal or state law has a shorter deadline, then the shorter timeframe is “practicable” (i.e., “as soon as practicable” means in compliance with the other law).

“Right of Access to Direct”

- Consistent with *Ciox v. Azar*, the right to direct a copy to a third party is limited to e-copy of EHR. Does not apply to paper copies or to designated record set outside of EHR.
- A personal health app is not treated as a third party for purposes of the “right of access to direct.”
- Same timing standard applies: “[a]s soon as practicable, but no later than 15 calendar days after receipt of the request.”
- OCR did not finalize proposed requirement that covered health care providers respond to oral requests to direct records to designated persons.

Definition of Electronic Health Record

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

Form, Time, and Manner of Access

- If other federal or state law requires implementing a technology that has the effect of providing an individual with access to their PHI in a particular electronic form and format, then that form and format is “readily producible.”
- If a covered entity (CE) offers a summary in lieu of a copy of PHI, it must inform the individual that they retain the right to access the PHI, including the right of access to direct.
- CE must mail, electronically transmit PHI via email, or electronically transmit PHI to the individual’s personal health app if readily producible in such a manner.

Definition of Personal Health Application

Personal health application means an electronic application used by an individual to access health information about that individual, which can be drawn from multiple sources, provided that all of the following conditions apply:

1. Such information is managed, shared, and controlled by or primarily for the individual.
2. Such information is not managed, shared, or controlled in any of the following manners:
    i. By or primarily for a covered entity.
    ii. Primarily for another person.

Fees for Access

- Fees only may include:
  - Labor for copying PHI to electronic or non-electronic form;
  - Supplies for non-electronic copies;
  - Postage and shipping for non-electronic copies;
  - Preparing an explanation or summary of PHI.
- Fees may not include electronic media (e.g., USB) or postage for shipping electronic media.
- No charge permitted for:
  - Inspection of PHI; or
  - Electronic access to PHI using an internet-based method (that doesn't involve labor costs for copying), such as through a personal health app.
- OCR did not finalize requirement to provide individualized fee estimates upon request.

Fees Schedule

- CEs must post fee schedule on website (if it has one) and make available at the point of service.
- Fee schedule must include:
  - All types of access to PHI available free of charge;
  - Standard fees for electronic and non-electronic copies of PHI pursuant to right of access; and
  - Standard fees for copies of PHI disclosed pursuant to an authorization.



Identity Verification in Access Requests

- Prohibits CE from imposing unreasonable verification measures that cause an individual to expend unnecessary effort or resources when a less burdensome verification measure is practicable for the CE.
- Unreasonable measures include:
  - In person proof of identity
  - Wet signature rather than digital signature
  - Requiring notarization of request
  - Personal health app request through TEFCA where credential service provider verified using IAL2 and AAL2 and demographic information in token matches individual
  - Personal health app participating in Medicare App Library requesting through CMS Aligned Network
  - Requiring a HIPAA authorization rather than form with limited info needed to verify ID

Care Coordination

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Commas vs. Semi-Colons: Definition of Health Care Operations

- "Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; patient safety activities (as defined in 42 CFR 3.20); 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"

Disclosures to Non-Healthcare Providers for Care Coordination and Case Management

- A CE may disclose PHI to a social services agency, community-based organization, home and community based services provider, or similar third party that provides health or human services to specific individuals, for individual-level care coordination and case management activities (whether such activities constitute treatment or health care operations).

Notice of Privacy Practices

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Notice of Privacy Practices (NPP)

- Eliminates requirement for a covered health care provider with a direct treatment relationship to seek an acknowledgment of receipt of the NPP.
  - Eliminates documentation and storage burden.
  - Removes confusion about whether acknowledgment is required for treatment.



NPP Content Changes

- NPP must state that individual has a right to discuss the NPP with a person designated by the CE.
  - "[A] covered entity could implement technology, such as super intelligence (SI), in a manner that is compliant with the Privacy and Security Rules, to receive and triage questions from individuals on its NPP, provided that individuals have the option to discuss the NPP with a workforce member knowledgeable about the covered entity's privacy practices to address their questions."
- Contact info must include email address and identify that this person or office is available to answer questions about the NPP.
- NPP's description of right of access must identify that individual can obtain a copy of their records at limited cost or, in some cases, free of charge, and the right of access to direct a CE to transmit an e-copy of PHI in an EHR to a person designated by the individual.

NPP Content Changes

- Optional: NPP may identify how an individual who seeks to send PHI to another person, when the request does not fall under Right of Access to Direct (e.g., seeks to send hard copy PHI or PHI is maintained outside of EHR), can instead: (1) obtain the PHI themselves and send to the other person; or (2) request the CE to send a copy of the PHI to the other person based on an authorization.

Current Header:

“THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.”

New Header:

NOTICE OF PRIVACY PRACTICES OF [NAME OF COVERED ENTITY, AFFILIATED COVERED ENTITIES, OR ORGANIZED HEALTH CARE ARRANGEMENT, AS APPLICABLE]

THIS NOTICE DESCRIBES:

- HOW HEALTH INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED.
- YOUR RIGHTS WITH RESPECT TO YOUR HEALTH INFORMATION.
- HOW TO EXERCISE YOUR RIGHT TO GET COPIES OF YOUR RECORDS AT LIMITED COST OR, IN SOME CASES, FREE OF CHARGE.
- HOW TO FILE A COMPLAINT CONCERNING A VIOLATION OF THE PRIVACY OR SECURITY OF YOUR HEALTH INFORMATION, OR OF YOUR RIGHTS CONCERNING YOUR INFORMATION, INCLUDING YOUR RIGHT TO INSPECT OR GET COPIES OF YOUR RECORDS UNDER HIPAA.
- YOU HAVE A RIGHT TO A COPY OF THIS NOTICE (IN PAPER OR ELECTRONIC FORM) AND TO DISCUSS IT WITH [ENTER NAME, TITLE, OR OFFICE] AT [PHONE AND EMAIL] IF YOU HAVE ANY QUESTIONS.

Miscellaneous

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- Clarification that business associate agreement (BAA) controls whether the business associate (BA) must disclose PHI to the CE, individual, or individual's designee under the Right of Access.
- CEs that are correctional institutions must provide NPPs to individuals.
- CE may disclose PHI to a telephone relay service (TRS) to conduct covered functions. TRS is not a BA when receiving PHI (including to assist a workforce member).
- Disclosure of PHI to Armed Forces personnel for activities deemed necessary by appropriate military command authorities to execute a military mission extended to Uniformed Services (which includes US Public Health Service Commissioned Corps and NOAA Commissioned Corps).
  - Also permits disclosure to VA for purposes of VA benefits.

What Did Not Get Finalized

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- “Serious and imminent threat” was not modified.
- “Professional judgment” was not modified to “good faith” (e.g., disclosures parents/guardians, disclosures to persons involved in care).
- Did not add new exemption to minimum necessary standard for individual-level care coordination and case management.
- Did not create a right to have a covered entity request designated record set on the individual’s behalf.
- Additional obligations related to an individual’s right to inspect their PHI under the right of access.

Next Steps

Next Steps

- May cease collecting acknowledgements of receipt of NPP beginning Jan. 19, 2027.
- Revise policies and procedures, especially regarding right of access, by July 19, 2027.
- Revise NPPs by July 19, 2027.
- Identify whether BAAs need to be revised (e.g., timelines for facilitating access to PHI) and revise by Jan. 18, 2028.



What's Next for HIPAA

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What's Next for HIPAA

- HIPAA Privacy Rule to Promote Individuals' Timely Access to their PHI? (listed in regulatory agenda for November 2026)
- Final Security Rule Amendments (listed in regulatory agenda for July 2027)
- NPRM regarding (1) distribution of HIPAA penalties and settlements to harmed individuals and (2) consideration of recognized security practices during HIPAA enforcement determinations (listed in regulatory agenda for November 2027)
- Health Information Privacy Reform Act?
- Health Care Cybersecurity and Resiliency Act?



For More Information





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