
2021 HIPAA Privacy Rule: Proposed Changes

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“... support individuals’ engagement in their care, remove barriers to coordinated care, and reduce regulatory burdens on the health care industry.”

- The Regulatory Sprint to Coordinated Care
 - promotes care coordination and facilitates a nationwide transformation to value-based health care
- The CMS Interoperability Final Rule
- The ONC Information Blocking Final Rule
- Updates to the Confidentiality of Substance Use Disorder Patient Records regulation (42 CFR Part 2)
- New Stark Law regulations
- New Anti-Kickback Statute regulations
- OCR Right of Access enforcement activities

- *Ciox Health, LLC v. Azar et. al.*
 - On January 23, 2020, the district court vacated:
 - HHS’s expansion of the HITECH Act’s “third party directive” beyond requests for an electronic copy of PHI in an electronic health record (“EHR”), and
 - the extension of the “patient rate” for fees for copies of PHI directed to third parties.

- Right of Access
 - Timeframe for responding to access requests
 - No later than 15 calendar days (currently 30)
 - Can extend for additional 15 days (currently 30)
 - Prohibits unreasonable identity verification measures
 - Clarifies readily producible
 - Includes secure, standard-based APIs such as a “personal health app”
 - Right of the individual to take notes, photographs, videos and use other such personal resources
 - Direct access to 3rd parties
 - Electronic transmission to another covered entity required
 - Request no longer must be in writing

- Fee structure
 - Free-of-charge when accessing in person or via Internet
 - Fees for copying allowed as well as for electronic transmission to a 3rd party
 - Covered entity must provide notice of estimated fee schedules on website
 - Must also provide individualized estimates upon request

- Permitted disclosures for care coordination
 - Amends definition of health care operations to include both population-based care coordination and individual-based activities (treatment)
 - Exception to minimum necessary
 - Applies to activities related to treatment and health care operations
- Expressly permits disclosures to telephone relay services (TRS) providers
 - Would be excluded from definition of Business Associate

- Notice of Privacy Practices (NPP)
 - Eliminates requirement for written acknowledgement of NPP
 - Includes required and detailed header
 - Instructive in nature
 - How to access health information
 - How to file a HIPAA complaint
 - Individuals' right to receive a copy and discuss its contents with a designated person

- Disclosures of PHI
 - Disclosure to certain 3rd parties including community-based organizations *without authorization*
 - Encourages broader disclosure in instances of substance abuse disorder, serious mental illness, or emergencies
 - Allows for “good faith belief” rather than “professional judgement”
 - Allows for “serious and reasonably foreseeable” rather than “serious and imminent” threat

- The HITECH Act requires covered entities to include in an accounting of disclosures those disclosures for treatment, payment, and health care operations through an EHR.
- OCR previously issued a proposed rule addressing the accounting requirement and later withdrew it
- OCR “intends to address [the accounting of disclosures] requirement in future rulemaking.”

- Comments are due 60 days from date published in *Federal Register*

- Should HHS modify the proposed definition of EHR? If so, how?
- Should the time limit for a CE to submit or respond to an individual's access request be shorter than 15 days?
- Should a CE be required to inform an individual of the privacy and security risks of transmitting PHI to a personal health app (especially apps not subject to HIPAA)?
- How should HHS interpret the phrase “clear, conspicuous, and specific” for verbal requests?

- Should the Privacy Rule prohibit CE's from charging fees for copies of PHI when requested by certain categories of individuals?
- Should the Privacy Rule prohibit CEs from denying requests under right of access when individual is unable to pay? How to determine if individual is unable to pay?
- How do CEs currently calculate reasonable, cost-based fees for copies of PHI?
- Should HHS specify a method as the exclusive method to calculate reasonable fees?

- Should OCR narrow the scope of the access right to direct records to a third party to only electronic copies of PHI in an EHR?
- Should OCR apply new fee limitations to the access right to direct a copy of PHI to a third party?
- Examples of convenient and practicable verification methods and those that are per se unreasonable

- Verification standard when a CE submits an individual's access request to another CE?
- How do the ONC information blocking provisions interact with proposed changes to “minimum necessary”? Any unintended consequences?
- Should HIPAA be revised to allow a CE to disclose PHI of individual who has capacity to a friend/family member contrary to individual's known privacy preferences?

Questions:

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