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The “Regulatory Sprint to Coordinated Care”

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Overview

- The “Sprint” began in 2008!
- Amendments to Stark and Anti-kickback Regulations to promote value-based care
- ONC rules on interoperability and information blocking
- CMS rule on access to health plan data
- HHS rule on price transparency
- Proposed HIPAA amendments
- Medicaid Burden Reduction

HIPAA Privacy Rule Proposals

- Expand right of access to PHI
- Care Coordination and Case Management as part of health care operations
- Exempting CC and CM from minimum necessary use rule
- Disclosures to social services agencies
- “Good faith” rule for certain disclosures
- Disclosures to avoid harm
- NPP acknowledgement eliminated
- NPP disclosure of patient rights
- Telecommunications relay services

Right of Access

- Right of access to include right to take notes, videos or photographs of medical records
- Requirements around the request should not be “unreasonable” (e.g. notarization, only permitting requests via portal, in writing or in person all unreasonable).
- Time limit would be reduced to 15 days plus one 15-day extension.
- “Form and format” rule will apply to personal health apps that use standards-based formats.

Right of Access (contd.)

- Right to direct that copies of ePHI in an electronic health record be sent to third parties.
- Such request may be made orally, in writing or via a personal health record.
- Right to require a current provider or health plan to request ePHI from another provider or health plan that holds the requested data (15 day deadline to make request).
- Authentication not discussed.
- Invites comments on "broadcast requests."

Right of Access (contd.)

- New fee proposals: no fee permitted for access in person, via portal or via a personal health record app; the fee for all other access rights (including sending ePHI contained in an electronic health record to a third party) would be limited to a “reasonable cost-based fee” for labor involved in making copies and, if requested, preparing a summary.
- OCR seeks to avoid application of the *Ciox v. Azar* court case.

Right of Access (contd.)

- Covered Entity must post its fee schedule on line if it has a web site.
- Fee schedule also must be available on request at the point of service.
- Fee schedule must include free services, disclosures subject to recovery of copying costs, and disclosures via an authorization. The fee schedule should address all available forms and formats.
- Individualized fee estimates should be available on request.

Identity Verification

- Identity verification is required, but it must be “reasonable.”
- Specifically prohibited: notarized requests and requirements that all requests must be made in person.
- “Reasonable measures” permitted.
- Very little guidance as to what is sufficient and what is excessive.
- Comments requested.
- Significant risk factor.

Care Coordination and Case Management

- CC and CM can be performed at either an individual level or a population level.
- Providers can perform CC or CM for individuals as part of “treatment.”
- Both providers and health plans can perform CC or CM on population as part of health care operations.
- OCR proposes to amend definition to make it clear that health plans can perform CC and CM for individuals as part of health care operations.
- These activities would not be subject to “minimum necessary use” requirements.

Care Coordination and Case Management (contd.)

- Health plans and providers could disclose PHI to a third party that provides health-related social services even if the third party is not a health care provider.
- Includes entities that provide social services, food services, or sheltered housing.
- Changes are intended to eliminate ambiguity and facilitate delivery of wraparound services, including services to homeless individuals.
- Significant for MassHealth ACOs

Individuals with Substance Use Disorder

- OCR proposes changes to permit more disclosure to family members and caregivers of individuals who are being treated from substance use disorder or serious mental illness.
- OCR seeks to clarify that providers may disclose information regarding SUD and SMI based on a “good faith belief” that the disclosure is in the best interests of the patient.
- Does not amend or relax any requirements under the Part 2 rules that apply to information from SUD Programs.

Notice of Privacy Practices

- Providers would no longer be required to collect an acknowledgement of receipt of the NPP.
- NPP would need to state that the individual has a right to discuss the NPP with a person designated by the Covered Entity with location & contact information.
- New header for NPP would be required.
- NPP to include information on enhanced access rights.
- Optional to include information on the right to direct PHI to a third party.

Telecommunications Relay Services

- OCR proposes to clarify existing practice to allow use of TRS services without a business associate agreement
- This is in the nature of a clarification to avoid confusion.

Medicaid Burden Reduction

- CMS has proposed a rule that would apply to FFS Medicaid & CHIP, Managed Medicaid & CHIP, and ACA plans that are offered on Federal exchanges.
- A key purpose of the proposed rule is to facilitate the transfer of information among these plans when patients change plans.
- The NPRM contains a number of RFIs as well.
- A significant portion of the rule deals with APIs for the purpose of exchanging prior authorization ("PA") information.

Burden Reduction

- CMS proposes to “enhance the patient access API” by **requiring** the use of Implementation Guides proposed by ONC and by requiring the payers include information about pending and active PA decisions.
- The rule also would require payers to develop a process to obtain attestations from the third party apps regarding their privacy practices.
- API requests and metrics should be reported quarterly to CMS.
- CMS to establish Implementation Guides for the provider directory API
- Payer to payer data exchange will include Medicaid and CHIP FFS programs.

Burden Reduction

- Payer to Payer data exchange is to be conducted on a using HL7 FHIR-based APIs.
- Payers subject to this rule must implement a **Documentation Requirements Lookup Service** to let providers know what information must be submitted in connection with PA.
- Provider use of the API would be voluntary.
- Medicaid & CHIP programs would be required to respond to PA requests with in set timeframes.
- Medicare FFS and MA not subject to this rule.

Burden Reduction

- PA timeframes for Medicaid MCO: 14 days with one extension of 14 days, through December 31, 2022, subsequently 7 days with one extension of up to 14 days.
- PA timeframe for State Medicaid agencies: beginning January 1, 2023: 72 hours for expedited requests and 7 days for standard requests with one extension of up to 14 days.

Privacy Attestations for Apps

- CMS cannot regulate app developers.
- If a patient / member authorizes the release of information to an app, the plan would be required to request a privacy policy attestation from the app developer, in which the developer would attest to certain information.
- CMS specifies minimum standards for the attestation
- If no attestation is received, or the attestation is incomplete, the plan should notify the member.
- If the member revokes permission for the release of PHI, then no PHI should be released.
- If the member does not respond, or confirms permission, the PHI must be released.

Attestation Content

- The attestation must cover the following topics:
 - Is the privacy policy publicly available & shared with the member prior to the member granting permission?
 - Does the policy address the access, exchange or use of PHI by any other person, and its prior consent required?
 - Will the app access other information on the consumer's device?
 - How can the patient discontinue app access to their PHI
 - What is the process for disposing of the data once consent is withdrawn.
- The NRPM does not mandate the content of the privacy policy.

Privacy Issues

- The NRPM does not make the health plans responsible for the uses and disclosures by the app developers.
- The NPRM does not regulate the app developers in any way.
- As of the publication date of the NPRM (December 18, 2020) CMS has not backed away from the idea that patients will be responsible for making decisions regarding release of their PHI to app developers, even if the privacy policy is incomplete, or discloses risky uses of data.

Q&A

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