

DEPARTMENT OF HEALTH & HUMAN SERVICES

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HIPAA Administrative Simplification Frequently Asked Questions

June 13, 2024

Subject: Statement of Enforcement Discretion for Referral Certification and Authorization Transaction Standard

Question: What is the intended purpose of the enforcement discretion?

Answer: This application of enforcement discretion is intended to promote efficiency in the prior authorization process and comes in response to public comments received on multiple notices of proposed rulemaking and extensive stakeholder outreach to CMS and HHS.

Question: Who is covered under the enforcement discretion?

Answer: All HIPAA covered entities that implement a FHIR-based Prior Authorization API as described in the CMS Interoperability and Prior Authorization final rule (CMS-0057-F).

Question: How will HIPAA enforcement discretion be exercised for covered entities that do not use the adopted X12 278 standard?

Answer: HIPAA Administrative Simplification enforcement action will not be taken against any HIPAA covered entity that does not use the X12 278 standard as part of an electronic FHIR prior authorization process that meets the requirements of the CMS Interoperability and Prior Authorization final rule (CMS-0057-F). This means that, under these specific circumstances, the use of electronic transaction standards that would otherwise be considered non-compliant will not be subject to enforcement action under the HIPAA Administrative Simplification enforcement regulations.

Question: How long will the enforcement discretion be in place?

Answer: Although there is no specified terminal date for this HHS exercise of enforcement discretion, we presently anticipate that it will be bounded by a future rulemaking.

Question: Under what circumstances would the enforcement discretion permitting use of an All-FHIR-Based Prior Authorization API in lieu of the adopted X12 278 standard for prior authorization transactions not apply?

Answer: The enforcement discretion applies only to covered entities using the FHIR-based Prior Authorization API as described in the CMS Interoperability and Prior Authorization final rule. The enforcement discretion applies to no other circumstance where HIPAA Administrative Simplification rules require covered entities to comply with the adopted version of the X12 278 standard.

Question: Can a health plan require another HIPAA covered entity to use an alternative standard to the X12 278 standard for prior authorization transactions?

Answer: No. A covered entity may elect, but may not be required, to use a FHIR-based Prior Authorization API as an alternative standard to the X12 278 as part of a prior authorization process.