



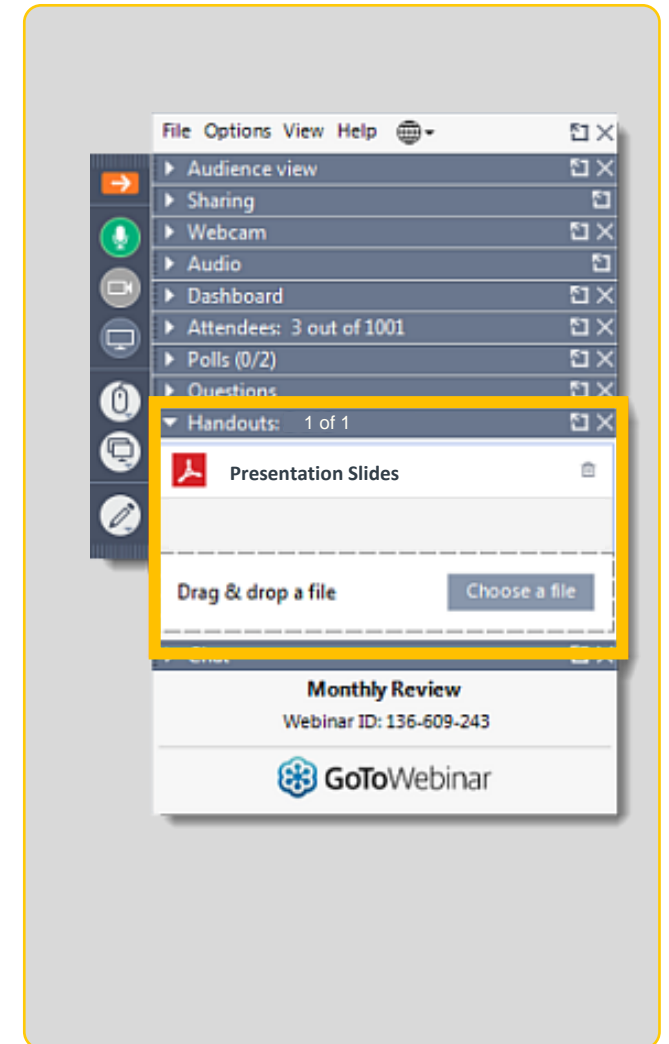
## CMS HIPAA Standards Exceptions Request Process



# Logistics

## *Presentation Slides and How to Participate in Today's Session*

- You can download the presentation slides at [www.caggh.org/core/events](http://www.caggh.org/core/events) or at [www.wedi.org](http://www.wedi.org) after the webinar.
- A copy of the slides and the webinar recording will be emailed to all attendees and registrants in the next 1-2 business days.
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# Session Outline

- Speaker Introduction
- Featured Presentation: CMS HIPAA Standards Exceptions Request Process
- Q&A
- Closing Comments

# Thank You to Our Speaker

**Daniel Kalwa**  
Policy Advisor  
CMS National Standards Group



# HIPAA Standards Exceptions Request Process



*Presentation to  
CAQH CORE and WEDI*

*Daniel Kalwa  
Policy Advisor  
National Standards Group*

*October 15, 2020*

# Regulatory Language

## ***45 C.F.R. § 162.940 Exceptions from standards to permit testing of proposed modifications.***

(a) ***Requests for an exception.*** An organization may request an exception from the use of a standard from the Secretary to test a proposed modification to that standard. For each proposed modification, the organization must meet the following requirements:

# Requirements for Consideration

***(1) Comparison to a current standard.*** Provide a detailed explanation, no more than 10 pages in length, of how the proposed modification would be a significant improvement to the current standard in terms of the following principles:

*For the full text of the requirements in context see: 45 CFR § 162.940*

# Requirements for Consideration

- (i) **Improve the efficiency and effectiveness** of the health care system by leading to cost reductions for, or improvements in benefits from, electronic health care transactions.
- (ii) **Meet the needs of the health data standards user community**, particularly health care providers, health plans, and health care clearinghouses.
- (iii) **Be uniform and consistent with the other standards adopted** under this part and, as appropriate, with other private and public sector health data standards.
- (iv) **Have low additional development and implementation costs** relative to the benefits of using the standard.
- (v) **Be supported by an ANSI-accredited SSO or other private or public organization** that would maintain the standard over time.



# Requirements for Consideration

- (vi) **Have timely development, testing, implementation, and updating procedures** to achieve administrative simplification benefits faster.
- (vii) **Be technologically independent** of the computer platforms and transmission protocols used in electronic health transactions, unless they are explicitly part of the standard.
- (viii) **Be precise, unambiguous, and as simple as possible.**
- (ix) **Result in minimum** data collection and paperwork burdens on users.
- (x) **Incorporate flexibility to adapt more easily to changes in the health care infrastructure** (such as new services, organizations, and provider types) and information technology.

# Additional Requirements

(2) ***Specifications for the proposed modification.*** Provide specifications for the proposed modification, including any additional system requirements.

(3) ***Testing of the proposed modification.*** Provide an explanation, no more than **5 pages** in length, of how the organization intends to test the standard, including the number and types of health plans and health care providers expected to be involved in the test, geographical areas, and beginning and ending dates of the test.

(4) ***Trading partner concurrences.*** Provide written concurrences from trading partners who would agree to participate in the test.

# Additional Requirements

(b) *Basis for granting an exception.* The Secretary may grant an **initial exception, for a period not to exceed 3 years**, based on, but not limited to, the following criteria:

- (1) An assessment of whether the proposed modification demonstrates a **significant improvement to the current standard.**
- (2) The **extent and length of time** of the exception.
- (3) **Consultations with DSMOs.**

# Requirements for Consideration

(c) ***Secretary's decision on exception.*** The Secretary makes a decision and notifies the organization requesting the exception whether the request is granted or denied.

(1) ***Exception granted.*** If the Secretary grants an exception, the **notification includes** the following information:

(i) The **length of time** for which the exception applies.

(ii) **The trading partners and geographical areas** the Secretary approves for testing.

(iii) **Any other conditions** for approving the exception.

(2) ***Exception denied.*** If the Secretary does not grant an exception, the **notification explains the reasons** the Secretary considers the proposed modification would not be a significant improvement to the current standard and any other rationale for the denial.

# Final Considerations

(d) ***Organization's report on test results.*** Within **90 days** after the test is completed, an organization that receives an exception must submit a report on the results of the test, including a cost-benefit analysis, to a location specified by the Secretary by notice in the **Federal Register**.

(e) ***Extension allowed.*** If the report submitted in accordance with paragraph (d) of this section recommends a modification to the standard, the Secretary, on request, may grant an extension to the period granted for the exception.

# Closing

For more information please see our *Guidance on Requests for Exceptions from Standards to Permit Testing of Proposed Modifications 45 Code of Federal Regulations (C.F.R.) § 162.940* available at:  
<https://www.cms.gov/files/document/guidance-letter-exception-process.pdf>



Questions from the public may be directed to CMS via email:

[AdministrativeSimplification@cms.hhs.gov](mailto:AdministrativeSimplification@cms.hhs.gov)

Requests for an exception may be submitted to:

[CMSAdministrativeSimplificationException@cms.hhs.gov](mailto:CMSAdministrativeSimplificationException@cms.hhs.gov)

Or:

National Standards Group  
U.S. Department of Health and Human Services  
Mailstop N1-19-21  
7500 Security Blvd  
Baltimore, MD 21244.

# Audience Q & A

# Thank you for joining us!



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