

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850



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Guidance**
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AND TRANSPARENCY

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Subject: Guidance on Requests for Exceptions from Standards to Permit Testing of Proposed Modifications

45 Code of Federal Regulations (C.F.R.) § 162.940

The National Standards Group (NSG) on behalf of the Department of Health and Human Services (HHS) is issuing this guidance letter to clarify the process for requesting and conducting an exception to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) transaction and code set standards.

Background

The August 17, 2000 Transactions and Code Sets Final Rule (65 FR 50369) codified the process that entities may use for requesting the opportunity to test new or modified standards, and for conducting such a test.

HHS encourages innovation in the development and implementation of standards that promote Administrative Simplification. The criteria for requesting and conducting an exception to the use of adopted standards and testing of modifications are specified at [45 C.F.R. 162.940](#).

This guidance document discusses the five stages of the exception process:

1. Request for the exception;
2. Basis for granting an exception;
3. The Secretary's decision on exception;
4. Organization's report on test results; and
5. Requests to extend the exception.

1. Request for Exception and Testing

Any organization may request an exception to an adopted standard and permission to test a modification.

What to include in the request

A request for an exception to compliance with an adopted standard, and permission to test a modification to that standard, should include the following elements:

- a. A comparison of the proposed standard to the current adopted standard that includes an explanation (no more than ten pages) of how the proposed modification would be a significant improvement to the current adopted standard in terms of the ten principles listed in the Appendix to this letter.
- b. Specifications of the proposed modification, including any additional system requirements.
- c. An explanation 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, the geographic areas affected, and the beginning and ending dates of the testing (no more than five pages).
- d. Written concurrences from trading partners who agree to participate in the test.

Where to send the request

Requests may be submitted by mail to:

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

Requests may also be submitted electronically to the following e-mail address:

CMSAdministrativeSimplificationException@cms.hhs.gov.

The subject line in these communications should read "HIPAA Transaction Exception Request." This will help ensure that the request is promptly directed to the appropriate staff.

2. Basis for Granting or Denying an Exception

Criteria for Evaluation

The following criteria may be considered in evaluating the request for exception:

- An assessment of whether the proposed modification represents a significant improvement to the current standard;
- The extent and length of time of the exception testing;
- Consultations with Designated Standards Maintenance Organizations (DSMOs).

The [Transactions and Code Sets final rule](#) specifies the DSMO organizations designated by the Secretary of HHS which are the three standard setting organizations – Health level Seven (HL7), the National Council on Prescription Drug Programs (NCPDP) and X12. The rule also specifies the three data content committees: National Uniform Billing Committee (NUBC), National Uniform Claim Committee (NUCC) and the Dental Content Committee (DeCC).

3. The Secretary's Decision

Notification of Decision

Upon completion of the review and evaluation, the requesting organization will receive a notification letter stating whether the exception request has been granted or denied.

If granted, the notification will include:

- The length of time for which the exception applies;
- The trading partners and geographical areas that have been approved for testing; and
- Any other conditions for approving the exception.

For requests that have been denied, the requestor will receive a notification that includes an explanation of why the Secretary considers that the proposed modification would not be a significant improvement to the current standard, and/or any other reasons for the denial.

Public Availability of Approved Exception Requests

Following approval of an exception request, the full request and the Secretary's response will be made publicly available through the Administrative Simplification website.

4. Report on Test Results

Within 90 days of completing the test, the organization must submit a report of its results, including a cost-benefit analysis, to NSG. The report should be sent to one of the addresses specified in step one above.

A notice regarding the report will be published in the Federal Register and will include the location where the full report may be viewed. This notice of the report will be available on www.regulations.gov.

5. Requests to Extend the Exception

Following submission of the report of test results, the organization may request that the Secretary extend the period of time during which the exception is granted. Requests for an extension should be sent to the addresses specified in step one above. Upon receipt of a request for an extension and review of the final report, a written notice of approval or denial of the extension will be sent to the requestor.

An extension of time for operating under an exception does not alter any other conditions of the exception, such as the trading partners participating, or other elements originally approved, or any expansion or modification of the original request.

It is important to note that the Secretary's permission to extend the exception time period does not mean that the new standard will be adopted. Such a change can only take place if a DSMO submits the standard to the National Committee on Vital and Health Statistics (NCVHS) to obtain industry consensus and the NCVHS then recommends that the Secretary adopt the standard. If the Secretary accepts the recommendation, the adoption takes place only through notice and comment rulemaking. It is expected that a successful test conducted through the exception authority and resulting in comprehensive and compelling data would facilitate the movement of a modification through the DSMO, NCVHS and rulemaking processes.

Additional Information

For additional information, contact any of the following National Standards Group personnel:

Dan Kalwa, Senior Policy Advisor, at 410-786-1352 or Daniel.Kalwa@cms.hhs.gov ;

Geanelle Herring, Technical Advisor, at 410-786-4466 or Geanelle.Herring@cms.hhs.gov;

Gladys Wheeler, Technical Advisor, at 410-786-0273 or Gladys.Wheeler@cms.hhs.gov.

If you have questions about this guidance, send inquiries to AdministrativeSimplificationException@cms.hhs.gov with the subject line: HIPAA Transaction Exception Question. Questions on other topics related to the adopted standards or operating rules, may be sent to this same e-mail address. For more information about Administrative Simplification requirements, visit the [CMS website](#). For the latest news about Administrative Simplification, [sign up for Email Updates](#).

Sincerely,

Christine Gerhardt
Director
National Standards Group

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Appendix:

Principles for Comparison of the Proposed Standard to the Adopted Standard

The request for an exception must include a comparison of the proposed standard to the adopted standard. The comprehensive comparison will address each of the following ten questions in a document not to exceed ten pages in length. The questions below are answered most effectively by including discussion, and where appropriate, artifacts or data to support the response (Appendices may be included to supplement the information in a response, and appendices will not be considered towards the ten-page limit). The discussion must address each of the following, not only as they relate to the proposed standard, but as the proposed standard compares to the existing adopted standard with respect to each of these elements.

- (i) How does the proposed standard 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) How does the proposed standard meet the needs of the health data standards user community, particularly health care providers, health plans, and health care clearinghouses?
- (iii) Will the proposed standard be uniform and consistent with the other adopted standards and, as appropriate, with other private and public sector health data standards?
- (iv) Does the proposed standard have low additional development and implementation costs relative to the benefits of using the standard?
- (v) Will the proposed standard be supported by an ANSI-accredited SSO or other private or public organization that would maintain the standard over time?
- (vi) Does the proposed standard have timely development, testing, implementation, and updating procedures to achieve administrative simplification benefits faster?
- (vii) Will the proposed standard be technologically independent of the computer platforms and transmission protocols used in electronic health transactions, unless they are explicitly part of the standard?
- (viii) Is the proposed standard precise, unambiguous, and as simple as possible?
- (ix) Will the proposed standard result in minimum data collection and paperwork burdens on users?
- (x) Does the proposed standard incorporate flexibility to adapt more easily to changes in the health care infrastructure (such as new services, organizations, and provider types) and information technology?