

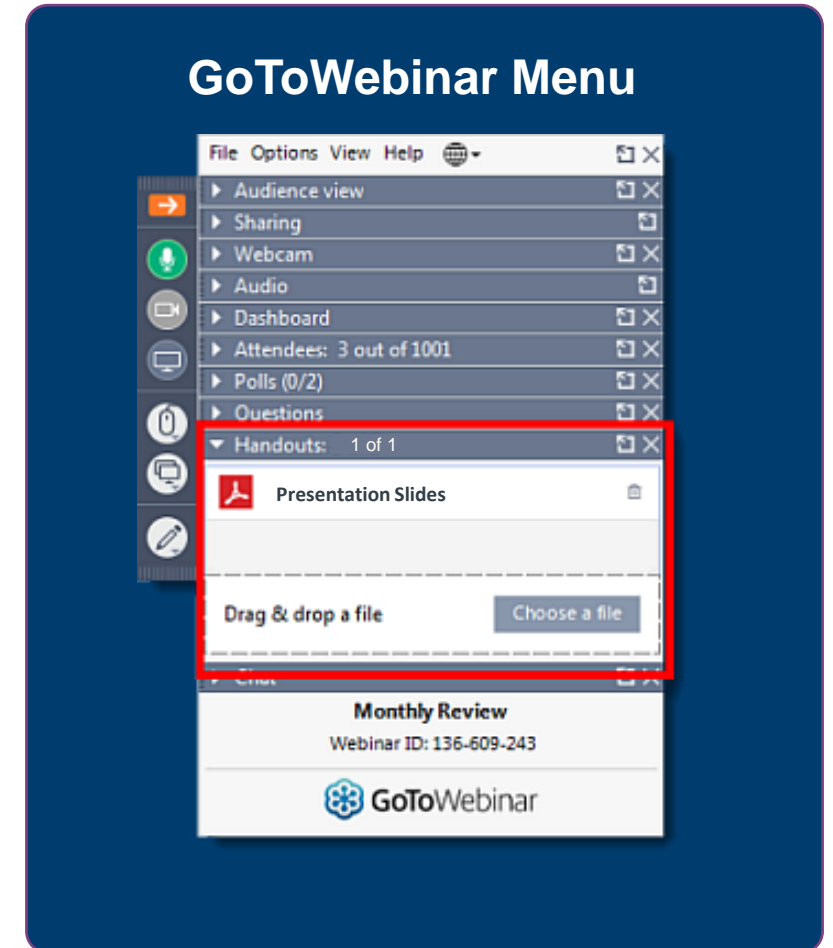


The Basics of HIPAA Standards and Operating Rule Adoption

Michael Cimmino and Beth Karpiak, National Standards Group
Erin Weber, CORE
July 27, 2023

Webinar Logistics

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September 27-29, 2023, *Westin Georgetown, Washington, D.C.* [Register Here!](#)



Agenda

- CORE Operating Rule Update
- CMS National Standards Group: HIPAA Standard Transactions
- Questions

Today's Speakers



Michael Cimmino
Director
National Standards Group

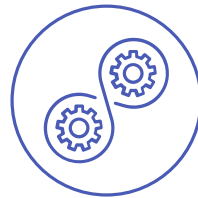


Beth Karpiak
Policy Advisor
National Standards Group

Committee on Operating Rules for Information Exchange



Federally Designated by the Department of Health and Human Services (HHS) as the National Operating Rule Authoring Entity for all HIPAA mandated administrative transactions.

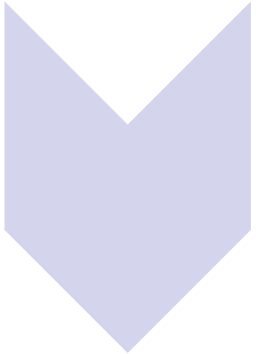


Develop business rules to help industry effectively and efficiently use electronic standards while remaining technology- and standard-agnostic.



Multi-stakeholder Board Members include health plans, providers, vendors, and government entities. Advisors to the Board include SDOs.

Operating Rule Path to Federal Mandate: NCVHS



CORE Proposal to NCVHS

	Proposed Operating Rules	NCVHS Rulemaking Recommendation
Updated	<ul style="list-style-type: none"> CAQH CORE Eligibility and Benefits (270/271) Infrastructure Rule CAQH CORE Claim Status (276/277) Infrastructure Rule CAQH CORE Payment and Remittance (835) Infrastructure Rule 	<ul style="list-style-type: none"> Recommended HHS conduct rulemaking to federally adopt
Updated	<ul style="list-style-type: none"> CAQH CORE Connectivity Rule vC4.0.0 	<ul style="list-style-type: none"> Recommended HHS conduct rulemaking to federally adopt
Updated	<ul style="list-style-type: none"> CAQH CORE Eligibility and Benefits (270/271) Data Content Rule 	<ul style="list-style-type: none"> Recommended HHS conduct rulemaking to federally adopt
New	<ul style="list-style-type: none"> CAQH CORE Eligibility and Benefits (270/271) Single Patient Attribution Data Content Rule 	<ul style="list-style-type: none"> Recommended HHS conduct rulemaking to federally adopt
New	<ul style="list-style-type: none"> CAQH CORE Attachments Health Care Claims Infrastructure Rule CAQH CORE Attachments Health Care Claims Data Content Rule CAQH CORE Attachments Prior Authorization Infrastructure Rule CAQH CORE Attachments Prior Authorization Data Content Rule 	<ul style="list-style-type: none"> Do not conduct rulemaking to adopt
	CORE Certification Requirement Language	<ul style="list-style-type: none"> Do not conduct rulemaking to adopt (consistent with past recommendations).



CMS National Standards Group: HIPAA Standard Transactions

July 27, 2023

Michael Cimmino, Director
Beth Karpiak, Policy Advisor



Agenda

- What is HIPAA Administrative Simplification?
- How HIPAA Standards apply to Health Care Interoperability
- How Standards are Adopted under HIPAA
- How Operating Rules are Adopted under HIPAA
- Modifications and Exceptions to HIPAA Transaction Standards/Operating Rules
- Industry Consideration to Support HIPAA Adoption
- Questions?



Learning Objectives

- Identify the legal requirements for adopting transaction standards and operating rules under HIPAA
- Distinguish requirements for adoption under HIPAA from the standards and operating rule development processes
- Outline the requirements for testing under HIPAA



What is Administrative Simplification?

Vision

It's the idea that the health care industry can reduce burden and lower costs by standardizing how business is done.

HIPAA

Administrative Simplification requirements are part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

CMS Office of Burden Reduction and Health Informatics

The National Standards Group (NSG) within the Office of Burden Reduction & Health Informatics (OBRHI), administers HIPAA Administrative Simplification requirements related to the format and content of electronic, administrative health care transactions, such as claims and payment.

The responsibility for administering HIPAA Administrative Simplification provisions related to privacy and security has been delegated to the Office for Civil Rights (OCR).



Administrative Healthcare Transactions

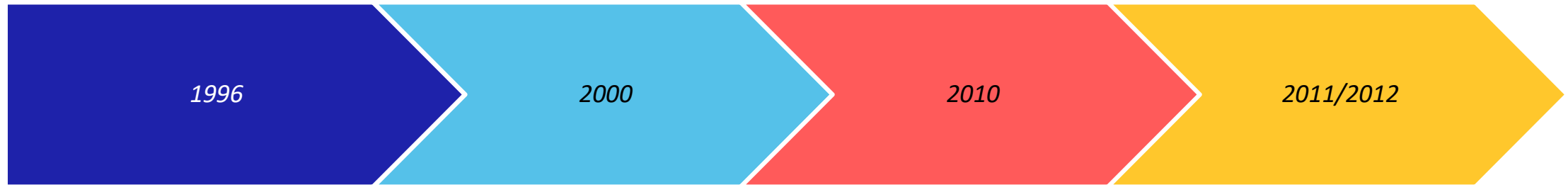


42 U.S.C. § 1320d-2(a)

- Health Care Claims or Equivalent Encounter Information
- Health Claims Attachments
- Enrollment and Disenrollment in a Health Plan
- Eligibility for a Health Plan
- Health Care Payment and Remittance Advice
- First Report of Injury
- Health Claims Status
- Referral Certification and Authorization
- Electronic Funds Transfers
- Other financial and administrative transactions determined appropriate by the Secretary of the Department of Health and Human Services (the Secretary)



HIPAA Standard Transactions Timeline



Health Insurance Portability and Accountability Act (HIPAA)

Rule adopting initial standards and code sets

Patient Protection and Affordable Care Act (ACA)

Rule adopting initial operating rules for HIPAA standard transactions

These slides contain summaries of statutory provisions and federal regulations. For the full text of requirements in context see Social Security Act, Title XI, Part C and 45 CFR Parts 160 and 162.

HIPAA Standard Transaction



**Implementation Guides
(Standard)**
Set the data content and
format requirements for the
electronic exchange of
information.

Unique Identifiers
Mandate how entities are
identified within a standard
transaction as directed by
an implementation guide.

*HIPAA
Standard
Transaction*

Code Sets
Mandate which code sets
must be used to encode
data elements, such as
tables of terms, medical
concepts, medical
diagnostic codes, or
medical procedure codes
as directed by an
implementation guide.

Operating Rules
Set the business rules and
guidelines for electronic
exchange of information
that are not defined by an
implementation
specification.

General Requirements



Mandating Standard Transactions Between Covered Entities



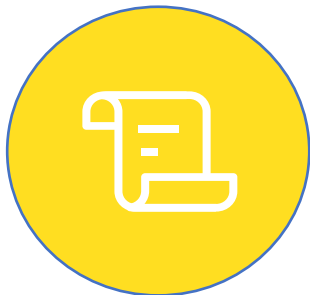
When a covered entity conducts a transaction for which a standard has been adopted with another covered entity using electronic media, the covered entity must conduct the transaction as a standard transaction.

45 CFR § 162.923(a)



A health plan must conduct a transaction as a standard transaction when requested to do so.

45 CFR § 162.925(a)(1)



A covered entity can't enter into a trading partner agreement that would change the definition, data condition, or use of a data element or segment in an adopted standard or operating rule.

45 CFR § 162.915

This slide is not inclusive of all requirements. See *45 CFR Part 162*.



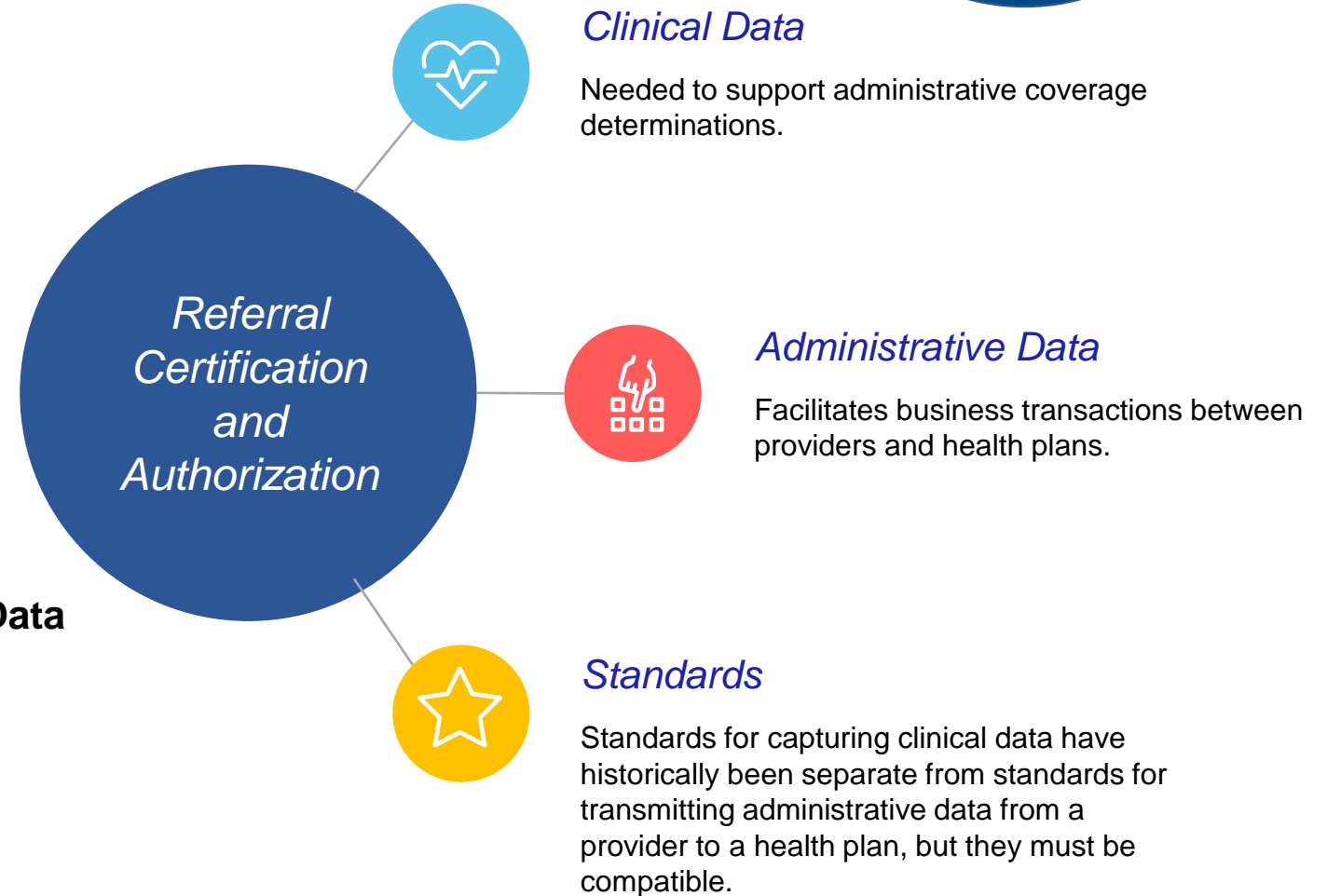
HIPAA & Interoperability

How do HIPAA standards impact and align with general principles of healthcare interoperability?





Interoperability & HIPAA Example



Integration of Administrative and Clinical Data

Interoperability and HIPAA - Identifying ways that clinical data can be used, more seamlessly and efficiently, to support administrative transactions.

How are Standards Adopted under HIPAA?



1

Standards Development

With a few exceptions, any standard adopted under HIPAA must be developed by a standard setting organization. *42 U.S.C. § 13202-1(c)*.

2

National Committee on Vital and Health Statistics (NCVHS)

The Secretary must rely on the recommendations of NCVHS. *42 U.S.C § 1320d-1(f)*.

3

Regulation Development

Rulemaking is required to adopt new or updated standards and operating rules.



Standards Development Process

45 CFR § 162.910(c)

The Secretary considers a recommendation for a proposed standard only if the recommendation is developed through a process that provides for the following:

- Open public access
- Coordination with Designated Standards Maintenance Organizations (DSMOs)
- An appeals process if a requestor or DSMO is dissatisfied with the decision on the request
- An expedited process to address content needs identified within the industry
- Submission of the recommendation to the NCVHS



NCVHS Role and Recommendation Process - Standards

- Federal Advisory Committee (FACA) and the statutory public advisory body to the Secretary on health information policy <https://ncvhs.hhs.gov/>
- **ROLE:** When adopting standards and modifications to standards, the Secretary must rely on the recommendations of NCVHS *42 U.S.C § 1320d-1(f)*
- The Subcommittee on Standards conducts hearings with industry as a forum to obtain relevant information about current issues and to solicit innovative ideas that can be used in their recommendations

Regulation Development for Adoption of Standards



Proposed Rule

Provides notice of proposed adoption of a standard and an opportunity for the public to comment.



Final Rule

Responds to comments received on the proposed rule, finalizes any changes, and sets compliance dates. Standards are incorporated by reference in the Federal Register.



Compliance Dates

Covered entities must comply with an initial standard no later than 24 months after the date it is adopted. Small health plans have 36 months to comply. *42 U.S.C. § 1320d-4(b)*.

How are Operating Rules Adopted under HIPAA?



1

Rule Development

Operating rules must be developed by a qualified nonprofit entity. *42 U.S.C. § 1320d-2(g)(2)*.

2

National Committee on Vital and Health Statistics (NCVHS)

from NCVHS. *42 U.S.C. § 1320d-2(g)(4)(A)*. The Secretary shall adopt operating rules following consideration of a recommendation

3

Regulation Development

Rulemaking is required to adopt new or updated operating rules.

Operating Rule Development Process



Consensus-Based

Must include Multi-stakeholder and consensus-based process for development of operating rules, including representation by or participation from health plans, health care providers, vendors, relevant Federal agencies, and other standard development organizations. *42 U.S.C. § 1320d-2(g)(2)(B)*



Open and Transparent

Must follow a public set of guiding principles that ensure the operating rules and process are open and transparent and supports nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory practices. *42 U.S.C. § 1320d-2(g)(2)(C)*



Public Review and Updates

Must allow for public review and updates of the operating rules. *42 U.S.C. § 1320d-2(g)(2)(e)*.

NCVHS Role and Recommendation Process – Operating Rules



42 USC § 1320d-2(g)(3)

NCVHS shall:

- Advise the Secretary as to whether a nonprofit entity meets the requirements to be an operating rule authoring entity
- Review operating rules developed and recommended by such nonprofit entity
- Determine whether such operating rules represent a consensus view of the health care stakeholders and are consistent with and do not conflict with other existing standards
- Evaluate whether such operating rules are consistent with electronic standards adopted for health information technology
- Submit to the Secretary a recommendation as to whether the Secretary should adopt such operating rules

Changes to Adopted Standards and Operating Rules



1

Code Set Maintenance

Each code set is valid within the dates specified by the organization responsible for maintaining that code set. *45 CFR § 162.1000.*

The compliance dates are specified by the code set maintaining organization responsible for maintenance changes to that code set.

2

Errata and Standards Maintenance

Maintenance includes non-substantive changes and error correction. Public comment and notification is required as part of the normal, ANSI-accredited standards development process, but regulatory action is not required for maintenance.

3

Modification/Updates

Substantive changes to an already adopted implementation specification requiring a new version or edition of a standard or operating rule must be adopted through regulatory action.

Modifications to Adopted Standards



42 U.S.C § 1320d-3(b)(2) and 42 U.S.C. § 1320d-4(b)(2)

- The Secretary may not adopt any modification to a standard adopted under HIPAA during the 12-month period beginning on the date the standard is initially adopted, unless the Secretary determines that the modification is necessary in order to permit compliance with the standard
- Covered entities must comply with a modified standard at such time as the Secretary determines appropriate, taking into account the time needed to comply due to the nature and extent of the modification
 - The time determined appropriate under the preceding sentence may not be earlier than the last day of the 180-day period beginning on the date such modification is adopted. The Secretary may extend the time for compliance for small health plans, if the Secretary determines that such extension is appropriate

Modifications to Adopted Operating Rules



42 U.S.C. § 1320d-2(i)

- Any recommendations to amend adopted operating rules that have been approved by NCVHS and reported to the Secretary shall be adopted by the Secretary through promulgation of an interim final rule not later than 90 days after receipt of the committee's report
- The effective date of any amendment to existing operating rules that is adopted through an interim final rule published under this paragraph shall be 25 months following the close of such public comment period

The Exceptions Process



45 CFR § 162.940

- If a covered entity believes there is a need to modify an adopted standard they may request an exception from the Secretary to test a proposed modification
- The purpose is to test whether the modification improves the efficiency and effectiveness of the health care system by leading to cost reductions or improvements in benefits from electronic transactions
- Additional guidance on the topic may be found in the [Go-To-Guidance Letters](#) section of our website



The Exceptions Process



Request

The requestor must provide a detailed explanation of how the proposed modification would be a significant improvement to the current standard. *45 CFR § 162.940(a).*



Test

The Requester must describe how the organization intends to test the standard, including the number and types of health plans and providers expected to be involved in the test, geographical area, and beginning and ending dates of the test. The Secretary may grant an initial exception for up to 3 years. *45 CFR § 162.940(a)(3).*



Report and Extension

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. *45 CFR 162.940(d).*

The Secretary may grant an extension to the period granted for the exception. *45 CFR § 169.920(e).*

The Exceptions Process – 10 Principles



45 CFR § 162.940

- 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
- Meet the needs of the health data standards user community, particularly health care providers, health plans, and health care clearinghouses
- Be uniform and consistent with the other standards adopted under this part and, as appropriate, with other private and public sector health data standards
- Have low additional development and implementation costs relative to the benefits of using the standard
- Be supported by an ANSI-accredited SSO or other private or public organization that would maintain the standard over time
- Have timely development, testing, implementation, and updating procedures to achieve administrative simplification benefits faster
- Be technologically independent of the computer platforms and transmission protocols used in electronic health transactions, unless they are explicitly part of the standard
- Be precise, unambiguous, and as simple as possible
- Result in minimum data collection and paperwork burdens on users
- Incorporate flexibility to adapt more easily to changes in the health care infrastructure (such as new services, organizations, and provider types) and information technology



Industry Considerations to Support HIPAA Adoption

- Consider mapping out where clinical processes and administrative processes overlap – Do the standards being developed align with HIPAA Standard Transaction definitions?
- Keep HIPAA processes in mind as you consider interoperability moving forward
 - These processes take time, don't wait until a standard has been implemented elsewhere to request an exception and test for use with a HIPAA Standard Transaction



Questions?

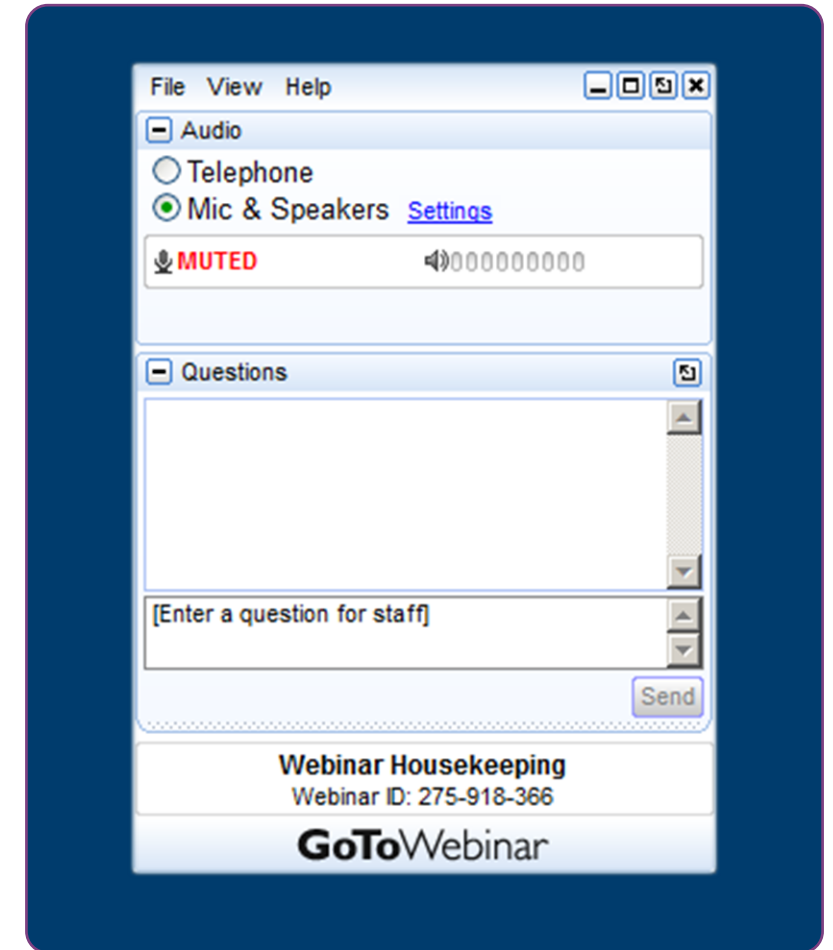
You may submit questions to Administrative
Simplification@cms.hhs.gov



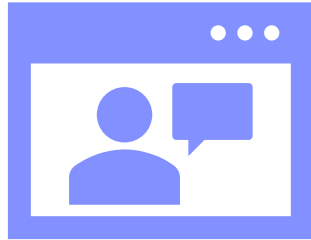
Thank You!



Reminder: Ask our speakers your questions by typing in the “Questions” pane on the lower right hand corner of your screen.



Call to Action



Join our upcoming webinar on **August 15, 2:00pm ET** to learn more about the operating rules recommended by NCVHS to HHS.

[Register Here!](#)



Become a CORE Participant:

E-mail CORE@CAQH.ORG