CMS/WEDI/CAQH CORE Webinar Part 2: CMS Compliance Reviews
Follow-Up Responses from the CMS Division of National Standards

7.18.19

In the second webinar of a two-part summer collaboration between the Centers for Medicare and Medicaid Services (CMS), WEDI and CAQH CORE, the CMS Division of National Standards provided an overview of the Compliance Review Program to ensure conformity among covered entities with HIPAA Administrative Simplification rules for electronic health care transactions. The follow-up responses from the first webinar can be found here.

CMS has submitted the following responses to outstanding questions received from webinar attendees:

1. **How are the types of organizations categorized for compliance review?**

Organizations are categorized by covered entity type: Provider, Health Plan and Clearinghouse (as well as business associates).

2. **If an entity is not a medical provider, are they relieved from covered entity or business associate requirements?**

The regulation is applicable to a health care provider who transmits any health information in electronic form in connection with a covered transaction. A health care provider means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)) or a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business. Therefore, there may be entities that are not medical providers, but are still covered entities. To determine if your organization is a covered entity, please visit: https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/AreYouaCoveredEntity.html.

3. **Are organizations that provide non-medical services and items subject to any requirements under Medicare in terms of privacy and compliance?**

All covered entities must comply with Privacy and Administrative Simplification requirements under HIPAA (https://www.hhs.gov/**ocr**). The requirements apply to all health care providers who conduct electronic transactions, not just providers who accept Medicare or Medicaid. Please visit the Administrative Simplification Overview website at: https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/index.html.

4. **What constitutes a real-time transaction?**

Specifications for real-time transactions are defined in the CAQH CORE operating rules. Please visit https://www.caqh.org for further information.

5. **If an entity is selected for a compliance review, will it include an audit on implementation changes or modifications that are within the timeframe allotted to make changes?**

At this time, the compliance review does not include an evaluation of when a covered entity implemented the requirements or became compliant. The compliance review does include, however, a

review of the required transactions as of a specific date. Any violations that are detected during a time when there is an overlap period between the implementation of changes and the final compliance date will be given mitigating consideration.

6. **Why does CMS not follow some of the operating rules for the COBA process? While they transmit 837 compliant files, they do not accept 999 or 277CA standard transactions to communicate rejections.**

The 999 and 277CA are transaction acknowledgements that have not been adopted by HIPAA, but may be used voluntarily.

7. **If a health plan is providing 835s to one type of provider (pediatrician) but not to a dentist, how is compliance viewed in that scenario? Does the dentist have to complain?**

Yes, the provider must file a complaint for investigation of an alleged violation. If a provider is requesting an 835, the health plan is required to comply. Filing a complaint provides the enforcement team the opportunity to investigate and require corrective action, if needed.

8. **Do the Compliance Review Program and the Complaint Reporting Process for HIPAA non-compliance intersect? Is the ASETT tool used for both?**

The ASETT tool is used for both complaint review and resolution and compliance reviews, however complaint processing and compliance reviews are in separate modules that do not intersect. Please visit https://asett.cms.gov for more information.

9. **Is there a detailed list of the items that were determined to be non- compliant?**

At this time there is no list of items determined to be non-compliant, but we intend to compile reports and share types of violations to display non-compliant trends.

10. **Will both inbound and outbound transactions be included in the compliance review**?

Compliance reviews are conducted on the outbound transactions the selected covered entity transmits or sends to another entity. It does not include inbound transactions received by the selected covered entity.

11. **How is a compliance review initiated? Can any covered entity file a complaint that another is not in compliance? How?**

Anyone can file a complaint against a covered entity. Complaints can be filed using the tools located at https://asett.cms.gov. Compliance reviews are separate initiatives from complaints. Covered entities are selected randomly for those reviews.

12. **Can you be more specific in terms of the transaction violations? Which transactions and what were the problems?**

It is early in our compliance review and assessment process. We will post compliance review statistical information when it becomes available: https://go.cms.gov/adminsimp.

13. **We are hearing from numerous physician practices that they are being charged unreasonable fees for conducting standard transactions by their health plans. This appears to be prohibited under HIPAA and under past CMS guidance. Are fees an area of enforcement, and are there plans to issue definitive guidance on the fee issue?**

CMS is actively investigating the fee-charging issue. We will release information as soon as it becomes available.

14. **As a provider, we have a payor that the only way they will pay our claims is via a Virtual Credit Card (which we do not want) or EFT at what I feel is an exorbitant fee. They want to charge us $1.50 per transaction, increasing 25c per year. They refuse to offer a check option. Are they really allowed to do this? We provided the services in good faith that we would be paid for our services. How can they be charging us these fees?**

We suggest that a complaint be filed so that the enforcement team may fully investigate. Please visit https://asett.cms.gov.

15. **Are the files sent as production files or test files? If production, do they need to be de-identified?**

Production files are required for compliance review. Your files do not need to be de-identified, the system is regularly assessed for security compliance.

16. **Is there a checklist available for entities to follow or action items an entity performs to check to make sure they are compliant? How often should that entity be checking for their own compliance?**

An entity is free to test their transaction files using our X-Engine testing tool. We are in the process of compiling a checklist. There is information currently available on our website, but not a detailed checklist. Please visit https://asett.cms.gov to register to use this tool and view additional details about ASETT.

17. **What are the requirements for the pre-compliance review? Will CMS request a population of transactions from which CMS will conduct the "pre-compliance review"?**

The pre-compliance review consists of obtaining and verifying appropriate contacts to communicate with during the compliance review and voluntary training for an entity to use the compliance review system for uploading documents. Testing occurs after your artifacts (transaction files) are submitted.

18. **What do you mean by artifacts?**

Artifacts include the transaction files for testing and an entity's attestation that they are compliant with all of the operating rules. Artifacts also may include companion guides and any other documents that the enforcement team considers relevant for the review.

19. **Are these transactions limited to HIPAA 5010 transactions, or do they apply to other transactions as well, such as 837 post-adjudicated encounters or claims attachment transactions or acknowledgements like 277CA?**

Compliance review transactions are limited to the HIPAA-covered transactions (X12N 5010 transactions and NCPDP D.0).

20. **My clearinghouse, which does not work with all insurance plans, still relies on outside emails and/or the insurance company websites to receive ERA/835 forms (not Medicare/ Medicaid). Is this potentially a compliance issue in the part of the health plans?**

This may be a compliance issue; we suggest that you file a complaint so the enforcement team may fully investigate. Please visit https://asett.cms.gov to file a complaint.

21. **Are reviews based only on a filed complaint against the covered entity or randomly selected (without a complaint filed against them)?**

Compliance review entities are selected randomly and are unrelated to entities that complaints are filed against; if an entity that is a candidate for compliance review is involved in an active complaint, they are deferred from compliance review selection until the complaint is resolved.

22. **How much notice does an entity get if they are chosen for a real audit?**

When an entity is notified that they have been selected for a compliance review, they have seven business days to respond to our triage request; this first contact is to establish a contact for communications during the compliance review.

23. **During the presentation it was mentioned that a covered entity must use a transaction even though no one wants it. I thought the operating rules state that covered entities do not have to use the transaction but must be able to do the transaction if someone requests it. Could you clarify?**

A health plan must be able to conduct the HIPAA-covered transactions when requested to do so.

24. **Will all inbound enrollment transactions for a health plan need to be in an 834 format, since many of the enrollment formats used by health plans are in proprietary format?**

The adopted standard for enrollment and disenrollment in a health plan is the 5010 834 transaction. If the sending entity meets the definition of a covered entity, the adopted standard must be used.

25. Many health plans/TPAs send outbound remittance advice in custom format; the clearinghouse maps it to an 835 format. Based on the compliance review, will the outbound remittance from health plan now need to be in an 835 format?

The outbound transaction in this scenario will not need to change since the health plan contracts with a clearinghouse to convert their outbound remittances into a compliant format on its behalf.

26. Are payers (insurance companies) being audited?

Any payers that meet the definition of a health plan (please review definitions under 45 CFR 162.103) are subject to compliance reviews.

27. What is meant by random selection – how are they randomizing the covered entities? (Names in a hat?)

We are using an in-house random selection tool (found on the Office the Inspector General's (OIG) website) on different covered entity databases.

28. What organizations were involved in the Optimization Pilot Program?

We have posted statistical information on the Optimization Pilot but did not post the names of the entities. Please visit https://go.cms.gov/adminsimp for the results.

29. For the statement on slide 8 - "Covered entities who do not achieve may be subjected to escalated enforcement actions." - what types of things are done for these escalated enforcement actions?

For escalated enforcement action, we currently use corrective action, but have authority to assess money penalties.

30. Do you consider a claim submission system that can't send all DX codes on a single transaction for a member service out of compliance for the transaction?

The TR3 Report specifies the number of diagnosis codes permitted. Does the submitter wish to send additional diagnosis codes, or does the submitter have system limitations on the number of diagnosis codes it can send? Is this a professional, institutional or dental claim? Please email an example to HIPAACompliance@cms.hhs.gov for a more in-depth response.

31. What is the timeline from notification through closure notice?

The elapsed time for a compliance review may vary depending on the number of transactions reviewed and any violations that are detected. The compliance review will not be closed until any corrective action is complete, tested, and verified.

32. **As a follow-up, once you have been selected for review, how quickly are you eligible for re-selection?**

Your organization is not eligible for re-selection until one year after completion of the previous review.

33. **Are you considering publishing the names of covered entities found to be noncompliant, as does the Office for Civil Rights when it issues civil monetary penalties?**

At this time, we are not planning to post the names of compliance review subjects and our findings.

34. **What percentage of entities do you plan to select for auditing?**

We do not have a set percentage at this time. We have started slowly during our first year of the program but intend to increase the number of compliance reviews as the program matures.

35. **How many entities have been contacted since April? How many have been reviewed?**

We currently are doing compliance reviews on nine entities (five health plans and four clearinghouses). Each entity is in a different phase of the assessment process. We also are conducting a compliance review pilot on three volunteer provider entities.