CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule

Version PA.2.0

May 2020

Revision History for CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule

Version	Revision	Description	Date
4.0.0	Major	• Phase IV CAQH CORE Prior Authorization (278) Infrastructure Rule balloted and approved via CAQH CORE Voting Process.	September 2015

4.1.0	Major	• Substantive updates include:
		  ○ Time requirement for health plan to request additional information/documentation
		  ○ Time requirement for final determination (approval/denial)
		  ○ Optional time requirement for a 5010X217 278 close out
		• Additional non-substantive adjustments for clarity.
			January 2020

PA.2.0	Minor	• Non-substantive adjustments to support re-organization of operating rules into rule sets organized by business transaction (e.g., Eligibility & Benefits, Claim Status, etc.) rather than phase (e.g., Phase I, II, etc.) as approved by the CAQH CORE Board in 2019. • Operating rule naming, versioning and numbering methodologies updated to align with business transaction-based rule sets.	May 2020

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1. Background Summary

The CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule addresses the health care services request for review and response transactions to allow the industry to leverage its investment in the CAQH CORE Claims Status (276/277), Eligibility & Benefits (270/271) and Payment & Remittance (835) Infrastructure Operating Rules and apply them to conducting the X12/005010X217 Health Care Services Review – Request for Review and Response (278) transactions (hereafter referenced as "5010X217 278 Request and Response" and referred to as prior authorization in general) as well as the X12/005010X231 Implementation Acknowledgment for Health Care Insurance (999) and all associated errata hereafter referred to as "5010X231 999".

The 5010X217 278 Request and Response supports these key business events[1]:

- Admission certification review request and associated response
- Referral review request and associated response
- Health care services certification review request and associated response
- Extend certification review request and associated response
- Certification appeal review request and associated response
- Reservation of medical services request and associated response
- Cancellations of service reservations request and associated response

Benefits to the industry from applying the CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule include:

- Increased consistency and automation across entities
- Increased electronic prior authorizations and a commensurate decrease in phone inquiries
- Reduced administrative costs
- More efficient processes
- Improved customer service to patients/subscribers
- Reduced staff time for phone inquiries
- Enhanced revenue cycle management
- Improved cash flow

The inclusion of this CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule for the 5010X217 278 Request and Response continues to facilitate the industry's momentum to increase access to the HIPAA-mandated administrative transactions, and will encourage all HIPAA-covered entities, business associates, intermediaries, and vendors to build on and extend the infrastructure they have established for other business transactions.

1.1. Affordable Care Act Mandates

This CAQH CORE Rule is part of a set of rules that addresses requirements in Section 1104 of the Affordable Care Act (ACA). Section 1104 contains an industry mandate for the use of operating rules to support implementation of the HIPAA standards. Using successful, yet voluntary, national industry efforts as a guide, Section 1104 defines operating rules as "the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications." As such, operating rules build upon existing healthcare transaction standards. The ACA outlines three sets of healthcare industry operating rules to be approved by the Department of Health and Human Services (HHS) and then implemented by the industry.

The third set of ACA-mandated operating rules address the health care claims or equivalent encounter information transactions, enrollment and disenrollment in a health plan, health plan premium payments, claims attachments, and referral certification and authorization.[2] The ACA requires HHS to adopt a set of

[1] X12/005010X217 Health Care Services Review – Request for Review and Response (278) Technical Report Type 3 Implementation Guide, Section 1.4.1.

[2] The first set of operating rules under ACA Section 1104 applies to eligibility and claim status transactions; these operating rules were effective 01/01/13. The second set of operating rules applies to EFT and ERA; these operating rules were effective 01/01/14.

operating rules for these five transactions by July 2014. [3] In a letter dated 09/12/12 to the Chairperson of the National Committee on Vital and Health Statistics (NCVHS),[4] the Secretary of HHS designated CAQH CORE as the operating rule authoring entity for the remaining five HIPAA-mandated electronic transactions.

Section 1104 of the ACA also adds the health claims attachment transaction to the list of electronic healthcare transactions for which the HHS Secretary must adopt a standard under HIPAA. The ACA requires the health claims attachment transaction standard to be adopted by 01/01/14, in a manner ensuring that it is effective by 01/01/16.[5]

NOTE: HHS has not adopted a standard for health claims attachments or indicated what standard(s) it might consider for the transaction, and an effective date for these operating rules is not included in the ACA.

2. Issue to Be Addressed and Business Requirement Justification

When the HIPAA transactions were first mandated for use in October 2000[6], many HIPAA-covered health plan systems were not capable of processing the ASC X12N v4010 278 Request and Response transactions in Real Time. Usually, only Batch transactions were accepted. If Real Time transactions were accepted, the responses would not be returned in Real Time.

Even with the transition to v5010 in 2011, manual reviews still occur depending upon the complexity of the authorization and given many authorizations require supporting documentation. Although Batch processing of the ASC X12N v5010 278 Request facilitates the processing of certifications, referrals, admissions, and authorizations, etc., there is still a heavy reliance on manual processes within the HIPAA- covered health plan systems to generate a response. This manual process hinders broader adoption of the ASC X12N v5010 278 Request and Response transactions as the same information can be obtained more readily via phone or fax options already commonly used. While HIPAA-covered health plans have made much progress in accepting and responding to Real Time ASC X12N v5010 278 Requests and streamlining their manual processes, adoption of the HIPAA-mandated ASC X12N v5010 278 Request and Response still proves to be a challenge for many entities.

In addition to Batch only and manual processing of the ASC X12N v5010 278 Request and Response transactions, lack of product support for the ASC X12N v5010 278 Request and Response transactions also poses a challenge to greater industry adoption. Many vendors do not support this transaction within their practice management and patient accounting systems offerings. As such, providers are required to use the ASC X12N v5010 278 Request and Response submission tools that each HIPAA-covered health plan offers, often a web tool to submit the request. The development of vendor products for the submission and receipt of the ASC X12N v5010 278 Request and Response transactions is far behind the other HIPAA-mandated transactions and has hindered adoption of the ASC X12N v5010 278 Request and Response transactions across the industry.

By promoting consistent connectivity methods between HIPAA-covered providers and HIPAA-covered health plans, manual processes for requesting and receiving prior authorization can be reduced and electronic transaction usage increased. Defining acceptable acknowledgement response times, appropriate Batch and Real Time acknowledgements, system availability, and requiring entities that publish a Companion Guide do so in a common standard format to ensure that trading partners are informed of the nuances required for successful transaction processing will allow the industry to more easily adopt the ASC X12N v5010 278 Request and Response transactions.

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[3] This date is statutory language and statutory language can be changed only by Congress.
[4] 09/12/12 HHS Letter from the Secretary to the Chairperson of NCVHS.
[5] These dates are statutory language and statutory language can be changed only by Congress.
[6] The first set of HIPAA-mandated transaction standards were adopted in the August 2000 HSS Final Rule, Health Insurance Reform: Standards for Electronic Transactions, with an effective date of October 16, 2000. This Final Rule adopted the ASC X12N 278 Health Care Services Review - Request for Review and Response as the standard for the referral certification and authorization transaction.

The CAQH CORE Eligibility & Benefits (270/271) Infrastructure Rule is designed to bring consistency and to improve the timely flow of the eligibility transactions. These infrastructure requirements include:

- Real Time exchange of eligibility transactions within 20 seconds or less
- The consistent use of the 5010X231 999[7] for both Real Time and Batch exchanges
- 86% system availability of a HIPAA-covered health plan's eligibility processing system components over a calendar week
- Use of the public internet for connectivity
- Use of a best practices Companion Guide template for format and flow of Companion Guides for entities that issue them

The CAQH CORE Claim Status (276/277) and the CAQH CORE Payment & Remittance (835) Infrastructure Rules were applied to the exchange of the HIPAA-mandated X12/005010X212 Health Care Claim Status Request and Response (276/277) transactions and the HIPAA-mandated X12/005010X221A1 Health Care Claim Payment/Advice (835) transaction. These infrastructure rules included more robust, prescriptive, and comprehensive connectivity requirements.

During the development of the CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule, CAQH CORE used discussion, research, and straw poll results to determine which infrastructure requirements should be applied to the exchange of the 5010X217 278 Request and Response transactions. Listed below is an overview of the infrastructure requirements incorporated into this rule in §4.

Infrastructure Requirements for the 5010X217 278 Request and Response Transactions	
CAQH CORE Infrastructure Requirement Description	**Apply to CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule for the 5010X217 278 Request and Response**
Processing Mode*	Y
Connectivity	Y
System Availability	Y
Real Time Processing Mode Response Time	Y
Batch Processing Mode Response Time	Y
Real Time Acknowledgements	Y
Batch Acknowledgements	Y
Companion Guide	Y
***Note:** The CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule explicitly clarifies processing mode requirements. In previous rule sets this requirement was not as explicit as needed resulting in questions from implementers. The CAQH CORE Connectivity Rule vC3.1.0 specifies the processing mode(s) that must be supported for each applicable transaction.	

This CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule defines the specific requirements that HIPAA-covered health plans or their agents[8] and HIPAA-covered providers or their agents must satisfy. As with all CAQH CORE Operating Rules, these requirements are intended as a

[7] The use of the ASC X12 TA1 Interchange Acknowledgement is not specifically addressed by the CAQH CORE Operating Rules. The A1 errata to Appendix C.1 of the ASC X12 999 provides industry guidance for the use of the TA1.

[8] One who agrees and is authorized to act on behalf of another, a principal, to legally bind an individual in particular business transactions with third parties pursuant to an agency relationship. Source: West's Encyclopedia of American Law, edition 2. Copyright 2008 The Gale Group, Inc. All rights reserved.

base or minimum set of requirements, and it is expected that many entities will go beyond these requirements as they work towards the goal of administrative interoperability. This CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule requires that HIPAA-covered health plans or their agents make appropriate use of the standard acknowledgements, support the CAQH CORE Connectivity requirements, and use the CAQH CORE v5010 Master Companion Guide Template when publishing their 5010X217 278 Companion Guide.

By applying these CAQH CORE infrastructure requirements to the conduct of the 5010X217 278 Request and Response transactions, this CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule helps provide the information that is necessary to electronically process a prior authorization request and thus reduce the current cost of today's manual transaction processes.

It is understood that applying the CAQH CORE infrastructure requirements to the exchange of the 5010X217 278 Request and Response transactions does not address the industry's transaction data content needs but rather establishes an electronic "highway".

2.1. Update to the CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule

Approved by CAQH CORE Participating Organizations and published in 2015, the response time requirement established in the initial version of the CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule represented a first step to setting national expectations for the completion of a prior authorization request and response exchange. Since then, industry commitment towards improving prior authorization response times only strengthened. A 2018 poll of CAQH CORE Participating Organizations indicated 73% participants supported pursuing development of additional response time requirements to build upon the CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule.

In response, CAQH CORE performed an extensive analysis of national and state-level prior authorization response time requirements and conducted interviews with a diverse mix of industry experts to understand the feasibility and impact of updating the existing response time requirement which, prior to this update, only specified a maximum timeframe for a health plan or its agent to return an initial 5010X217 278 Response – an approval, denial or pend.

From May 2019 through November 2019, the CAQH CORE Participating Organizations representing a diverse mix of provider, health plan, vendor and government representation convened to consider updates to the existing response time requirement. Participating Organizations completed impact assessments, straw polls, ballots, and participated in discussions to agree upon key response time enhancements. Ultimately, three key enhancements to the CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule were approved via the CAQH CORE Voting Process that enable timelier sending and receiving of batch and real time prior authorizations that are not urgent or emergent:

- Time requirement for health plan to request additional information/documentation
- Time requirement for final determination (approval/denial)
- Optional time requirement for a 5010X217 278 close out

As with all CAQH CORE Operating Rules, the response time requirements included in this update are a floor and not a ceiling, and health plans are encouraged to respond to prior authorization requests as quickly as possible to support patient care.

3. Scope

3.1. What the Rule Applies To

This CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule applies to the:

- X12/005010X217 Health Care Services Review – Request for Review and Response (278) Technical Report Type 3 and associated errata

  And

- X12/005010X231 Implementation Acknowledgement for Health Care Insurance (999) Technical Report Type 3 and associated errata.

3.2. When the Rule Applies

This CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule applies when any HIPAA-covered entity or its agent uses, conducts, or processes the 5010X217 278 Request and Response transactions.

3.3. What the Rule Does Not Require

This rule does not require any entity or its agent to:

- Conduct, use, or process the 5010X217 278 Request and Response transactions if it currently does not do so or is not required by Federal or state regulation to do so.

3.4. Outside the Scope of This Rule

- This rule does not address any data content requirements of the 5010X217 278 Request and Response transactions. This CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule applicable to health care services review requests and responses is related to improving access to the transaction and **not to** addressing content requirements.
- Retail pharmacy benefit electronic prior authorizations are out of scope for this rule, i.e., pharmacist-and/or prescriber initiated prior authorization for drugs/biologics and other treatments covered under a pharmacy benefit.[9]
- Section 4.4 *Health Care Services Review – Request and Response Real Time Processing Mode Response Time Requirements* and Section 4.5 *Health Care Services Review – Request and Response Batch Processing Mode Response Time Requirements* do not apply to:
    1. Emergent[10] review request and associated responses.
    2. Urgent review request and associated responses.
    3. Review request and associated responses conducted retrospectively (i.e. neither prospectively[11] nor concurrently[12]).
    4. Review request and associated responses undergoing the Appeals Review Process (internal or external).

3.5. Maintenance of This Rule

Should implementation of this rule be required via Federal regulation, any substantive updates to the rule (i.e., change to rule requirements) will be made in alignment with Federal processes for updating versions of the operating rules.

3.6. How the Rule Relates to Other CAQH CORE Rule Sets

The CAQH CORE Eligibility & Benefits (270/271) Infrastructure Rule focused on improving Real Time electronic eligibility and benefits verification as eligibility is the first transaction in the claims process. The CAQH CORE Eligibility & Benefits (270/271) Data Content Rule focused on extending the value of electronic eligibility by adding additional data content requirements that deliver more robust patient financial liability information, including remaining deductibles, and adding more service type codes that must be supported. Building on this, CAQH CORE also determined that a rule set should be created to address infrastructure rules around the claim status transaction to allow providers to check electronically, in Real Time, the status of a claim, without manual intervention, or to confirm receipt of claims, and thus created the CAQH CORE Claim Status (276/277) Infrastructure Rule. The Payment & Remittance (835)

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[9] NCPDP is the Standards Setting Organization responsible for standards for retail pharmacy.
[10] The ACA prohibits requirements for prior authorization to access emergency services under section 29 CFR 2590.715-2719A, patient protections. In line with federal law, a growing number of state laws set additional limits around prior authorizations for emergency and urgent care.
[11] In the context of this CAQH CORE rule "prospective review" is defined as a utilization review conducted before an admission or a course of treatment including any required preauthorization or precertification, including extensions of outpatient treatment.
[12] In the context of this CAQH CORE rule "concurrent review" is defined as a utilization review conducted during a patient's hospital stay or course of inpatient treatment.

Infrastructure Rule includes rules around the health care claim payment/advice transaction to allow the industry to leverage its investment in the eligibility and benefits and claim status transactions.

This CAQH CORE Prior Authorization & Referrals (278) Infrastructure Rule leverages the previously mentioned CAQH CORE Infrastructure Rule requirements by specifying the use of the 5010X231 999 and the CAQH CORE infrastructure requirements when conducting the 5010X217 278 Request and Response transactions.

This rule supports the CAQH CORE Guiding Principles that CAQH CORE Operating Rules will not be based on the least common denominator but rather will encourage feasible progress, and that CAQH CORE Operating Rules are a floor and not a ceiling, i.e., entities can go beyond the CAQH CORE Prior Authorization & Referrals (278) Rule Set.

3.7. Assumptions

A goal of this rule is to adhere to the principles of electronic data interchange (EDI) in assuring that transactions sent are accurately received and to facilitate correction of errors for electronically submitted prior authorization requests.

The following assumptions apply to this rule:

- A successful communication connection has been established.
- This rule is a component of the larger set of CAQH CORE Operating Rules; as such, all the CAQH CORE Guiding Principles apply to this rule and all other rules.
- This rule is not a comprehensive companion document addressing any content requirements of the 5010X217 278 Request and Response transactions or the 5010X231 999.
- Compliance with all CAQH CORE Operating Rules is a minimum requirement; any HIPAA-covered entity is free to offer more than what is required in the rule.

3.8. Abbreviations and Definitions Used in This Rule

Batch (Batch Mode, Batch Processing Mode): Batch Mode is when the initial (first) communications session is established and maintained open and active only for the time required to transfer a Batch file of one or more transactions. A separate (second) communications session is later established and maintained open and active for the time required to acknowledge that the initial file was successfully received and/or to retrieve transaction responses.

Batch Mode/Batch Processing Mode is also considered to be an asynchronous processing mode, whereby the associated messages are chronologically and procedurally decoupled. In a request-response interaction, the client agent can process the response at some indeterminate point in the future when its existence is discovered. Mechanisms to implement this capability may include: polling, notification by receipt of another message, receipt of related responses (as when the request receiver "pushes" the corresponding responses back to the requestor), etc.

Batch Mode/Batch Processing Mode is from the perspective of both the request initiator and the request responder. If a Batch (asynchronous) request is sent via intermediaries, then such intermediaries may, or may not, use Batch Processing Mode to further process the request.

Business Day: A business day consists of the 24 hours commencing with 12:00 am (Midnight or 0000 hours) of each designated day through 11:59 pm (2359 hours) of that same designated day. The actual calendar day(s) constituting business days are defined by and at the discretion of each HIPAA-covered health plan or its agent.

Processing Mode: Refers to when the payload of the connectivity message envelope is processed by the receiving system, i.e., in Real Time or in Batch mode.

Real Time (Real Time Mode, Real Time Processing Mode): Real Time Mode is when an entity is required to send a transaction and receive a related response within a single communications session, which is established and maintained open and active until the required response is received by the entity initiating that session. Communication is complete when the session is closed.

Real Time Mode/Real Time Processing Mode is also considered to be a synchronous processing mode.

Real Time Mode/Real Time Processing Mode is from the perspective of both the request initiator and the request responder.

Safe Harbor: A "Safe Harbor" is generally defined as a statutory or regulatory provision that provides protection from a penalty or liability.[13]

In many IT-related initiatives, a safe harbor describes a set of standards/guidelines that allow for an "adequate" level of assurance when business partners are transacting business electronically.

The CAQH CORE Connectivity Safe Harbor requires the implementation of the CAQH CORE Connectivity Rule so that application vendors, HIPAA-covered providers, HIPAA-covered health plans or their respective agents can be assured the CAQH CORE Connectivity Rule will be supported by any trading partner. All entities must demonstrate the ability to implement connectivity as described in CAQH CORE Connectivity Rule vC3.1.0.

4. Rule Requirements

4.1. Health Care Services Review – Request and Response Processing Mode Requirements

A HIPAA-covered health plan or its agent must implement the server requirements for either Real Time Processing Mode **OR** Batch Processing Mode for the 5010X217 278 Request and Response transactions as specified in the CAQH CORE Connectivity Rule vC3.1.0. Optionally, a HIPAA-covered health plan or its agent may elect to implement both Real Time and Batch Processing Modes.

The CAQH CORE Connectivity Rule vC3.1.0 Real Time Processing Mode requirements are applicable when Real Time Processing Mode is offered for these transactions. The CAQH CORE Connectivity Rule vC3.1.0 Batch Processing Mode requirements are applicable when Batch Processing Mode is offered for these transactions.

A HIPAA-covered health plan or its agent conducting the 5010X217 278 Request and Response transactions is required to conform to the processing mode requirements specified in this section regardless of any other connectivity modes and methods used between trading partners.

4.2. Health Care Services Review – Request and Response Connectivity Requirements

A HIPAA-covered entity or its agent must be able to support the CAQH CORE Connectivity Rule vC3.1.0.

This connectivity rule addresses usage patterns for Real Time and Batch Processing Modes, the exchange of security identifiers, and communications-level errors and acknowledgements. It does not attempt to define the specific content of the message payload exchanges beyond declaring the formats that must be used between entities and that security information must be sent outside of the message envelope payload.

All HIPAA-covered entities must demonstrate the ability to implement connectivity as described in the CAQH CORE Connectivity Rule vC3.1.0. The CAQH CORE Connectivity Rule vC3.1.0 is designed to provide a "Safe Harbor" that application vendors, HIPAA-covered providers and HIPAA-covered health plans (or other information sources) can be assured will be supported by any trading partner. Supported means that the entity is capable and ready at the time of the request by a trading partner to exchange data using the CAQH CORE Connectivity Rule vC3.1.0. These requirements are not intended to require trading partners to remove existing connections that do not match the rule, nor are they intended to require that all trading partners must use this method for all new connections. CAQH CORE expects that in some technical circumstances, trading partners may agree to use different communication mechanism(s) and/or security requirements than those described by these requirements.

4.3. Health Care Services Review – Request and Response System Availability

Many healthcare providers have a need to request prior authorizations outside of the typical business day and business hours. Additionally, many institutional providers are now allocating staff resources to

[13] Merriam-Webster's Dictionary of Law. Merriam-Webster, Inc., 28 May, 2007. <Dictionary.com http://dictionary.reference.com/browse/safeharbor>

performing administrative and financial back-office activities on weekends and evenings. As a result, providers have a business need to be able to conduct prior authorization transactions at any time.

On the other hand, HIPAA-covered health plans have a business need to periodically take their prior authorization processing and other systems offline in order to perform required system maintenance. This typically results in some systems not being available for timely processing of 5010X217 278 Request and Response and 5010X231 999 transactions on certain nights and weekends. This rule requirement addresses these conflicting needs.

4.3.1. System Availability Requirements

System availability must be no less than 86 percent per calendar week for both Real Time and Batch Processing Modes. System is defined as all necessary components required to process a 5010X217 278 Request and Response and a 5010X231 999 transaction. Calendar week is defined as 12:01 a.m. Sunday to 12:00 a.m. the following Sunday. This will allow for a HIPAA-covered health plan or its agent to schedule system updates to take place within a maximum of 24 hours per calendar week for regularly scheduled downtime.

4.3.2. Reporting Requirements

4.3.2.1. Scheduled Downtime

A HIPAA-covered health plan or its agent must publish its regularly scheduled system downtime in an appropriate manner (e.g., on websites or in Companion Guides) such that the HIPAA-covered health plan's trading partners can determine the health plan's system availability so that staffing levels can be effectively managed.

4.3.2.2. Non-Routine Downtime

For non-routine downtime (e.g., system upgrade), a HIPAA-covered health plan or its agent must publish the schedule of non-routine downtime at least one week in advance.

4.3.2.3. Unscheduled Downtime

For unscheduled/emergency downtime (e.g., system crash), a HIPAA-covered health plan or its agent are required to provide information within one hour of realizing downtime will be needed.

4.3.2.4. No Response Required

No response is required during scheduled, non-routine, or unscheduled downtime(s).

4.3.2.5. Holiday Schedule

Each HIPAA-covered health plan or its agent will establish its own holiday schedule and publish it in accordance with the rule requirements above.

4.4. Health Care Services Review – Request and Response Batch Processing Mode Response Time Requirements[14]

Each HIPAA-covered entity or its agent must support the *maximum* response time requirements to ensure that at least 90 percent of all required responses are returned within the specified maximum response times as measured within a calendar month.

Each HIPAA-covered entity or its agent must capture, log, audit, match, and report the date (YYYYMMDD), time (HHMMSS) and control numbers from its own internal systems and the corresponding data received from its trading partners.

[14] The CAQH CORE Prior Authorization & Referrals (278) Infrastructure requires that a HIPAA-covered health plan or its agent must implement the server requirements for either Real Time Processing Mode OR Batch Processing Mode for the 5010X217 278 Request and Response transactions as specified in the CAQH CORE Connectivity Rule vC3.1.0. Optionally, a HIPAA-covered health plan or its agent may elect to implement both Real Time and Batch Processing Modes.

Each HIPAA-covered entity or its agent must support the response time requirements in this section and other CAQH CORE Operating Rules regardless of the connectivity mode and methods used between trading partners.

4.4.1. 5010X217 278 Initial Response Time Requirement (Batch Mode)

Maximum response time for availability of 5010X217 278 Responses when processing 5010X217 278 Requests submitted in Batch Processing Mode by a provider or on a provider's behalf by a clearinghouse/switch must be no later than the second business day following submission.

4.4.2. 5010X231 999 Batch Processing Mode Response Time Requirement

A 5010X231 999 must be available to the submitter within one hour of receipt of the Batch:

- To the requester in the case of a Batch of 5010X217 278 Requests

And

- To the HIPAA-covered health plan or its agent in the case of a Batch of 5010X217 278 Responses.

4.4.3. Time Requirement for Requesting Additional Information/Documentation (Batch Mode)

When a health plan or its agent pends a 5010X217 278 Request due to a need for additional information/documentation from the provider or its agent, a health plan or its agent must make available a 5010X217 278 Response specifying what additional information/documentation is needed to reach a final determination within two business days following submission of the 5010X217 278 Request.

4.4.4. Time Requirement for Final Determination (Batch Mode)

Once a health plan or its agent receives a complete prior authorization request with all information and documentation necessary, including any peer to peer medical reviews conducted prior to a final determination[15], the health plan or its agent must return either a solicited or unsolicited 5010X217 278 Response containing an approval or denial within two business days following receipt of the completed prior authorization request.

4.5. Health Care Services Review – Request and Response Real Time Processing Mode Response Time Requirements

Each HIPAA-covered entity or its agent must support the *maximum* response time requirements to ensure that at least 90 percent of all required responses are returned within the specified maximum response times as measured within a calendar month.

Each HIPAA-covered entity or its agent must capture, log, audit, match, and report the date (YYYYMMDD), time (HHMMSS) and control numbers from its own internal systems and the corresponding data received from its trading partners.

Each HIPAA-covered entity or its agent must support these response time requirements in this section and other CAQH CORE Operating Rules regardless of the connectivity mode and methods used between trading partners.

4.5.1. Time Requirement for a 5010X217 278 Initial Response (Real Time Mode)

Maximum response time for the receipt of a 5010X217 278 Response from the time of submission of a 5010X217 278 Request must be 20 seconds when processing in Real Time Processing Mode. A 5010X231 999 response errors must be returned within 20 seconds.

The recommended maximum response time between each participant in the transaction routing path is 4 seconds or less per hop as long as the 20-second total roundtrip *maximum* requirement is met.

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[15] Peer to peer medical reviews conducted after a final determination are a part of the appeals process, which is out of scope for this rule, per Section 3.4 *Outside the Scope of this Rule*.

4.5.2. Time Requirement for Requesting Additional Information/Documentation when Known at Time of Request (Real Time Mode)

When a health plan or its agent pends a 5010X217 278 Request due to a need for additional information/documentation from the provider or its agent, and additional information/documentation necessary to complete the 5010X217 278 Request is immediately known by the health plan or its agent, the health plan or its agent must return the pended 5010X217 278 Response specifying what additional information/documentation is needed to reach a final determination within 20 seconds from the time of receipt of the 5010X217 278 Request. [16]

4.5.3. Time Requirement for Requesting Additional Information/Documentation when Unknown at Time of Request (Real Time Mode)

After a health plan or its agent has pended the initial 5010X217 278 Request within 20 seconds from the time of submission due to a need for additional information/documentation, a health plan or its agent must return an unsolicited, 5010X217 278 Response specifying the additional information/documentation needed to reach a final determination within two business days of the initial 5010X217 278 Request.[17]

4.5.4. Time Requirement for Final Determination after an Initial Pended Response (Real Time Mode)

After a health plan or its agent has sent an initial pended 5010X217 278 Response via Real Time Processing Mode, whether within 20 seconds in scenarios when additional information/documentation is immediately known or within two business days when additional information/documentation is not immediately known, a final determination must be sent via an unsolicited 5010X217 278 Response. Once a health plan or its agent receives a complete prior authorization request with all information and documentation necessary, including any peer to peer medical reviews conducted prior to the final determination[18], the health plan or its agent must return the unsolicited 5010X217 278 Response containing an approval or denial within two business days following receipt of the complete prior authorization request.

4.6. Health Care Services Review – Request and Response Request Close Out Requirement

4.6.1. Time Requirement for a 5010X217 278 Response Close Out Due to a Lack of Requested Information/Documentation

A health plan or its agent may choose to close out a 5010X217 278 Request if a provider or its agent does not respond to a request for additional information/documentation from the health plan or its agent after a minimum of 15 business days following the return of a pended 5010X217 278 Response requesting additional information/documentation necessary to adjudicate the pended 5010X217 278 Request.[19]

In the event a health plan or its agent determines to close out a 5010X217 278 Request due to non-receipt of requested additional information/documentation necessary to adjudicate the pended 5010X217

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[16] A health plan or its agent must communicate what additional information/documentation is needed to complete the PA request in real time if the health plan or its agent has a published policy that references the required documentation (e.g. companion guide, provider billing manuals, etc.).

[17] An unsolicited 5010X217 278 Response specifying what additional information/documentation is needed to reach a final determination is only required in cases when the health plan or its agent did not immediately know the information/documentation necessary and return that information with a solicited 5010X217 278 Response within 20 seconds. Therefore, Section 4.5.2 *Time Requirement for Requesting Additional Information/Documentation when Known at Time of Request* and Section 4.5.3 *Time Requirement for Requesting Additional Information/Documentation when Unknown at Time of Request* are mutually exclusive of one another.

[18] Peer to peer medical reviews conducted after a final determination are a part of the appeals process, which is out of scope for this rule, per Section 3.4 Outside the Scope of this Rule.

[19] A health plan or its agent should specify the processes for the close out and resubmission/appeal of a 5010X217 278 Response and any other provider notification in their Companion Guide, provider billing manual, or other organization policy manual to ensure business and technical processes are clearly articulated to its trading partner community.

278 Request, the health plan or its agent must return an unsolicited 5010X217 278 Response communicating the prior authorization has been cancelled to the provider or its agent.

4.7. Health Care Services Review – Request and Response Real Time Acknowledgement Requirements

4.7.1. Use of the 5010X231 999 Implementation Acknowledgements for Real Time Processing Mode

A HIPAA-covered health plan or its agent must return:

- A 5010X231 999 to indicate that a Functional Group(s) or Transaction Set(s) is rejected.

A HIPAA-covered health plan or its agent must not return:

- A 5010X231 999 to indicate that a Functional Group(s) or Transaction Set(s) is accepted or accepted with errors.

Therefore, the submitter of a 5010X217 278 Request in Real Time will receive only one response from the HIPAA-covered health plan or its agent**:** *a 5010X231 999 rejection or a 5010X217 278 Response.*

4.8. Health Care Services Review – Request and Response Batch Acknowledgement Requirements

4.8.1. Use of the 5010X231 999 Implementation Acknowledgements for Batch Processing Mode

These requirements for use of the 5010X231 999 for Batch Processing Mode place parallel responsibilities on both requesters submitting the 5010X217 278 Request (i.e., providers or *their agents) and responders returning the 5010X217 278 Response (i.e.,* HIPAA-covered *health plans* or *their agents) for sending and accepting the 5010X231 999.* The goal of this approach is to adhere to the principles of EDI in assuring that transactions sent are accurately received and to facilitate correction of errors in Functional Groups of 5010X217 278 Requests and Functional Groups of 5010X217 278 Responses.

This rule assumes a successful communication connection has been established.

A HIPAA-covered entity or its agent must return a 5010X231 999 for each Functional Group of 5010X217 278 Request or 5010X217 278 Response transactions:

- To indicate that the Functional Group(s) was either accepted, accepted with errors, or rejected

And

- To specify for each included 5010X217 278 Request or 5010X217 278 Response Transaction Set that the transaction set was either accepted, accepted with errors, or rejected.

When a Functional Group of 5010X217 278 Request or a Functional Group of 5010X217 278 Response transactions is either accepted with errors or rejected, the 5010X231 999 must report each error detected to the most specific level of detail supported by the 5010X231 999.

4.9. Health Care Services Review – Request and Response Companion Guide

A HIPAA-covered health plan or its agent have the option of creating a “Companion Guide” that describes the specifics of how it will implement the HIPAA transactions. The Companion Guide is in addition to and supplements the ASC X12 TR3 Implementation Guide adopted for use under HIPAA.

Currently HIPAA-covered health plans or their agents have independently created Companion Guides that vary in format and structure. Such variance can be confusing to trading partners/providers who must review numerous Companion Guides along with the ASC X12 TR3 Implementation Guides. To address this issue, CAQH CORE developed the CAQH CORE v5010 Master Companion Guide Template for health plans or information sources. Using this template, health plans and information sources can ensure that the structure of their Companion Guide is similar to other health plan’s documents, making it easier for providers to find information quickly as they consult each health plan’s document on these important industry EDI transactions.

Developed with input from multiple health plans, system vendors, provider representatives, and health care/HIPAA industry experts, this template organizes information into several simple sections – General Information (Sections 1-9) and Transaction-Specific Information (Section 10) – accompanied by an appendix. Note that the Companion Guide template is presented in the form of an example from the viewpoint of a fictitious Acme Health Plan.

Although CAQH CORE believes that a standard template/common structure is desirable, it recognizes that different HIPAA-covered health plans may have different requirements. The CAQH CORE v5010 Master Companion Guide template gives health plans the flexibility to tailor the document to meet their particular needs.

The requirements specified in this section do not currently apply to retail pharmacy.

4.9.1. Health Care Services Review – Request and Response Companion Guide Requirements

If a HIPAA-covered entity or its agent publishes a Companion Guide covering the 5010X217 278 Request and Response transactions, the Companion Guide must follow the format/flow as defined in the CAQH CORE v5010 Master Companion Guide Template for HIPAA Transactions (CAQH CORE v5010 Master Companion Guide Template available HERE).

NOTE: This rule does not require any HIPAA-covered entity to modify any other existing Companion Guides that cover other HIPAA-mandated transaction implementation guides.

5. Conformance Requirements

Conformance with this CAQH CORE Operating Rule can be demonstrated and certified through successful completion of the Prior Authorization & Referrals CAQH CORE Certification Test Suite with a third party CAQH CORE-authorized Testing Vendor, followed by the entity's successful application for a CORE Certification Seal. A CORE Certification Seal demonstrates that an entity has successfully tested for conformity with all of the CAQH CORE Prior Authorization & Referrals (278) Operating Rules, and the entity or its product has fulfilled all relevant conformance requirements.

Only the Department of Health and Human Services (HHS) can decide whether a particular HIPAA-covered entity's system is **compliant** or **noncompliant** with the HIPAA Administrative Simplification requirements (which include HIPAA-adopted CAQH CORE Operating Rules). HHS may adjudicate on a HIPAA-covered entity's compliance and assess civil money penalties or penalty fees for noncompliance under the following HIPAA Administrative Simplification mandates:

- HIPAA regulations mandate that the Secretary "will impose a civil money penalty upon a covered entity or business associate if the Secretary determines that the covered entity or business associate has violated an administrative simplification provision." (47 CFR 160.402)
- Under the ACA, HIPAA mandates a certification process for HIPAA-covered health plans only, under which HIPAA-covered health plans are required to file a statement with HHS certifying that their data and information systems are in compliance with applicable standards and associated operating rules. (Social Security Act, Title XI, Section 1173(h)) HIPAA also mandates that a HIPAA-covered health plan must "ensure that any entities that provide services pursuant to a contact with such health plan shall comply with any applicable certification and compliance requirements." (Social Security Act, Title XI, Section 1173(h)(3))
- Under the ACA, HIPAA also mandates that HHS is to "conduct periodic audits to ensure that health plans…are in compliance with any standards and operating rules." (Social Security Act, Title XI, Section 1173(h))

6. Appendix

Appendix 1: Reference

- X12/005010X231 Implementation Acknowledgement for Health Care Insurance (999) Technical Report Type 3 and associated errata
- X12/005010X217 Health Care Services Review – Request for Review and Response (278) Technical Report Type 3 Implementation Guide and associated errata