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1. Phase V CAQH CORE Operating Rule Set: Background

1.1. CAQH CORE Overview

CAQH CORE is an industry-wide facilitator committed to the creation and adoption of healthcare operating rules that support standards, accelerate interoperability and align administrative and clinical activities among providers, health plans and patients. Guided by over 130 participating organizations – including providers, health plans, government entities, vendors, associations and standards development organizations – CAQH CORE Operating Rules drive a trusted, simple and sustainable healthcare information exchange that evolves and aligns with market needs.\(^1\) To date, this cross-industry commitment has resulted in four phases of operating rules addressing many pain points of healthcare business transactions, including: eligibility and benefits verification, claims and claims status, claim payment and remittance, health plan premium payment, enrollment and disenrollment and prior authorization.

1.2. Industry Interest in Prior Authorization Operating Rules

Prior authorization is currently a time-consuming and costly process, and a critical area of industry interest as all parties stand to benefit from greater efficiency. A recent American Medical Association study revealed that a majority of surveyed providers report increased burden associated with prior authorization over the past five years. On average, these physician practices complete 31 prior authorizations per physician per week resulting in 36 percent of practices hiring staff to work exclusively on prior authorizations.\(^2\) By developing consensus statements, attending conferences and working through associations and work groups, industry stakeholders are actively developing improvements to reduce administrative burden, improve continuity of care and enhance overall patient experience and outcomes. CAQH CORE works extensively alongside these complementary efforts to develop pathways to automate parts of the prior authorization process with CAQH CORE Operating Rules.

CAQH CORE addressed some components of the prior authorization process in its Phase IV Operating Rules. The Phase IV CAQH CORE 452 Health Care Services Review – Request for Review and Response (278) Infrastructure Rule applies to the X12/005010X217 Health Care Services Review – Request for Review and Response (278)\(^3\) transactions (hereafter referred to as “5010X217 278 Request and Response”). The CAQH CORE Phase IV rule established foundational requirements that build consistency with other operating rules for HIPAA transactions, including receipt acknowledgement, common connectivity methods (i.e., a “safe harbor”), required response times, minimum system availability and a common companion guide format.

The proven CAQH CORE model for working with industry consists of continuous feedback channels to research and develop rules, measure adoption, enhance existing rules and create new rules. Industry feedback, as well as federal recommendations, demonstrate significant interest in additional operating rules to further streamline the prior authorization process. The National Committee on Vital and Health Statistics (NCVHS), a public advisory committee to the Secretary of the Department of Health and Human Services (HHS), recommended additional research to understand barriers to improving the prior authorization process and additional operating rules to address these barriers.\(^4\) Specifically, NCVHS recommended that, given the relatively low adoption of the 5010X217 278 Request and Response, requirements be considered to further enhance its “usefulness and effectiveness” and that research be

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1. In 2012, CAQH CORE was designated by the Secretary of the Department of Health and Human Services (HHS) as the author for federally mandated operating rules under Section 1104 of the Patient Protection and Affordable Care Act (ACA). See Appendix Section 5.1 for more information.
3. The X12 Technical Report Type 3 that details the full requirements for this transaction along with the license for its use is available at [http://store.x12.org/store/](http://store.x12.org/store/). Note: Permission to use X12 copyrighted materials within this document has been granted.
4. Letter to the Secretary - Recommendations for the Proposed Phase IV Operating Rules, National Committee on Vital and Health Statistics.
conducted to identify “why portals and other HIPAA-compliant alternative technology data exchange means are more effective and provide all the necessary and useful information, compared to the adopted transaction standard.”\textsuperscript{5} NCVHS also recommended that operating rules contain data content requirements to further explain “pended” statuses and “encourage payers and providers to standardize across all systems to ensure consistency in transmitting and receiving information…including payer portals.”\textsuperscript{6,7}

CAQH CORE participant and industry-wide surveys have shown growing industry commitment to the development of the data content operating rules for the 5010X217 278 Request and Response. In 2012 and 2013, surveys prioritized infrastructure requirements as a foundational step for the Phase IV transactions. Results also revealed that, relative to the other transactions surveyed\textsuperscript{8}, interest in data content requirements was highest for prior authorization. In 2017, CAQH CORE participating organizations ranked prior authorization operating rule opportunities, including those related to data content, workflow, format, transport and utilities.\textsuperscript{9} Data content and workflow received the highest percentage of support and the highest priority rankings. With continued industry interest and commitment to driving greater efficiency regarding prior authorization, CAQH CORE will continue to engage the industry on additional operating rules related to prior authorization in the near future.

2. Phase V CAQH CORE Operating Rule Set: Issues to Be Addressed and Business Requirement Justification

2.1. Problem Space

Prior authorization began as a means to manage the utilization of healthcare resources: people, time and dollars. It requires providers to request approval from a health plan before a specific procedure, laboratory test, service, device, supply or medication is provided to the patient. Referrals require a provider to obtain approval from a health plan before a patient can be referred to another provider (e.g., specialist).

Each step of the prior authorization process is labor-intensive and generates time-consuming and costly administrative burden for provider organizations as well as health plans and can delay patient care. These inefficiencies can largely be attributed to a lack of uniformity in prior authorization processes across and within health plans. Lack of uniformity perpetuates a need for manual intervention (i.e., phone, fax, human involvement) to proceed to the next step. While electronic methods (5010X217 278 Request and Response, web portal, etc.) reduce manual intervention in certain parts of the prior authorization process, the end-to-end workflow still requires manual intervention in almost all components of the process, from gathering and submitting provider information to adjudication of the request by the health plan. Further, the prior authorization process is siloed; it is separate from the patient eligibility and claims processes. These siloes can impact the delivery of patient care, provider reimbursement and can result in...

\textsuperscript{5} Letter to the Secretary - Findings from Administrative Simplification Hearing, National Committee on Vital and Health Statistics.

\textsuperscript{6} Letter to the Secretary - Recommendations for the Proposed Phase IV Operating Rules, National Committee on Vital and Health Statistics.

\textsuperscript{7} Review Committee Findings and Recommendations on Adopted Standards and Operating Rules, National Committee on Vital and Health Statistics.

\textsuperscript{8} X12/005010X222 Health Care Claim (837) Professional, X12/005010X223 Health Care Claim (837) Institutional, and X12/005010X224 Health Care Claim (837) Dental; X12/005010X220 Benefit and Enrollment Maintenance (834); X12/005010X218 Payroll Deducted and Other Group Premium Payment for Insurance Products (820); Claim Attachments.

\textsuperscript{9} Descriptions of categories: Data Content: Includes opportunities for the data content of electronic transactions; Work Flows: Addresses business processes for prior authorization and/or eligibility; Formats: Describes the type of document format in which prior authorization data is collected and delivered to the health plans by providers; Transport: Addresses the method by which prior authorization data is delivered to the health plans by providers; Utilities: Includes industry-wide solutions such as a prior authorization-specific clearinghouse.
unintended patient out-of-pocket expenses. Approval for a requested prior authorization does not guarantee that the claim subsequently submitted will be approved for reimbursement.

CAQH CORE conducted extensive research to understand the barriers to automation of the prior authorization and referral process. Research revealed that each part of the process varies in its maturity level, falling along a spectrum of automation, from manual to automated. It also revealed that while referrals are still often done manually, they are not nearly as burdensome as obtaining a prior authorization. The research engaged over 100 entities via participation in surveys, interviews and site visits. An industry Advisory Group led by CAQH CORE, with provider, health plan, vendor and government representation, guided the research and analysis of results, as well as subsequent prioritization of opportunities to address the identified issues.

2.1.1. Barriers to Automation of the Prior Authorization Process

The prior authorization process begins when a provider determines that a patient needs a medical service, special medical equipment or medications\(^\text{10}\) and related supplies. To understand if a prior authorization is required for provision of that service, provider staff often manually review lists of services requiring prior authorization. These lists differ by and within health plans. There is also a lack of uniformity in data field requirements for the requests themselves, which leads provider staff to seek clarification by phone. Provider-facing web portals also offer access to the lists of services requiring prior authorization. While these lists may be more frequently updated than lists available via other look-up methods, outdated information is still an issue, given how frequently the requirements can change. Once a provider confirms that a prior authorization request is required, portals may also allow the provider to look up the requirements for that specific request and submit the request from a single web-based application. The functionality of portal-based lists varies in sophistication. Some health plans use a more manual PDF look-up process, while others employ a search capability to find the prior authorization requirements by procedure code.

The retrieval of information required to accompany a prior authorization request is also mostly manual. Demonstrating medical necessity for a service requires access to systems that house clinical data. Due to the relative lack of integration between clinical and administrative systems, providers often rely on non-electronic methods of data retrieval, including phone and fax. Some providers may have a solution in place that provides integration between systems and allows for time savings from reduction in manual keystrokes.

Prior authorization request submission options range from manual (phone, fax, email) to electronic (5010X217 278 Request and Response, web portal and interactive voice response). According to the 2018 CAQH Index, 51 percent of prior authorization requests are submitted manually, 36 percent are submitted via web portal or interactive voice response and 12 percent are submitted via the 5010X217 278 Request.\(^\text{11}\) While manual options, such as the phone, may seem more burdensome, providers report that this method frequently results in the most clarity regarding requirements, status and next steps. In addition, both health plans and providers indicate that competing electronic options do not yet offer enough benefit.

Provider-facing web portals are one of the most common methods for prior authorization submission—they offer more automation than phone—and many portal-based requests are mapped to the 5010X217 278 Request and Response for processing. However, the lack of data field uniformity and consistency consumes a significant amount of provider staff time. For each health plan with which the provider contracts, provider staff must log into a different portal, to key information into the system manually. As a result, providers need to employ and train personnel in the specifics of each web portal, resulting in considerable time to enter the data for one patient.

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\(^{10}\) Pharmacy benefit electronic prior authorization is out-of-scope for this rule set, i.e., pharmacist- or prescriber-initiated prior authorizations for drugs/biologics/other treatments covered under a pharmacy benefit are not a function of the web portals addressed in this rule as drug authorizations covered under the pharmacy benefit are the function of the National Council for Prescription Drug Programs (NCPDP).

\(^{11}\) 2018 CAQH Index, CAQH.
The standard transaction 5010X217 278 Request and Response is the federally mandated standard for prior authorization under HIPAA; however, it is not a viable option if the provider does not have the system to support it. This is common given that vendor solutions do not always support the 5010X217 278 Request and Response transaction, partially due to low adoption and business needs that occur outside of the 5010X217 278 Request and Response (e.g., provision of additional documentation or attachments that do not yet have a federally mandated standard). When vendors do offer the 5010X217 278 Request and Response, the transaction is typically offered only in a premium configuration that providers may not choose to purchase due to cost and relative lack of benefit given the low user base. In general, even when providers are ready to submit a prior authorization request, the availability of a system to receive the request is not always consistent, and it is difficult to determine such availability. Finally, once a provider submits the request, there may be no indication that the submission was successfully received.

Once the health plan receives a prior authorization request, most are routed through a manual internal review rather than an automated adjudication process. This especially pertains to requests that require additional medical documentation. Some health plans are able to automate the adjudication process when no additional documentation is needed. Health plans are regularly limited by a lack of robust electronic communication channels and are unable to update the provider in a timely fashion, to communicate errors, to indicate the need for additional information and to identify next steps. Providers routinely call the health plan to determine the status of the request, as well as any next steps to get the request approved. Missing or incomplete information, including proof of medical necessity, is one of the most common reasons for a health plan to pend a request. Providers are not always able to include this information on the request itself, either because it is not known or they need to transmit it separately from the prior authorization request. Missing or incomplete information, as well as code errors, lengthen the time to final adjudication and further delay patient care. Ultimately, when the health plan has collected the information it needs to render a decision, the health plan delivers the decision back to the provider. This decision is usually communicated to the provider via a decision notice letter, a returned provider review letter, a web portal notification or over the phone, which is often the quickest method for individual providers to retrieve the final determination response from health plans.

Many points along the prior authorization process fall to manual steps for both providers and health plans, often due to lack of application systems and software developed to enable automation. As stated above, providers drop to manual or partially manual processes from the initiation of the request to the final status of the prior authorization – using phone, fax and web portal tools. Health plans are equally challenged with supporting the entire process through a fully developed auto-adjudication system or platform. This is often due to the complexity of the prior authorization process, as well as the various systems and databases that need to be accessed along with many competing priorities.

According to the 2018 CAQH Index\textsuperscript{12}, full adoption of the standard prior authorization transaction (5010X217 278 Request and Response) by health plans and providers could result in a savings of $7.28 per transaction, for the portions of the prior authorization process included in the 5010X217 278 Request and Response. However, the proportion of prior authorization transactions using the standard remains much lower, relative to the other standard transactions, and progress to reduce the use of costly, time-consuming manual transactions has waned.\textsuperscript{13} There is significant opportunity to strengthen existing electronic tools for prior authorization and move toward a more automated process.

\subsection*{2.2. CAQH CORE Process in Addressing the Problem Space}

Once the barriers to automation were clearly defined, CAQH CORE developed a list of opportunity areas for potential industry resolution that would address pain points and increase industry adoption of electronic prior authorization. These opportunity areas were cultivated via a thorough review and analysis of the X12/005010X217 Health Care Services Review – Request for Review and Response (278) Technical Report Type 3, public comment and testimonies submitted to NCVHS, industry forum discussions and initiatives, CAQH CORE industry surveys and Phase IV CAQH CORE Subgroup

\textsuperscript{12} Ibid.

\textsuperscript{13} CAQH CORE Board Prior Authorization Response Letter, CAQH.
discussions. During this stage, CAQH CORE identified over 20 unique opportunity areas for improving the prior authorization process.

A CAQH CORE Prior Authorization Advisory Group with a diverse mix of provider, health plan, vendor and government representation used agreed-upon evaluation criteria (e.g. benefits across stakeholder types, effective approach, etc.) to prioritize which opportunity areas should be addressed via operating rules. Opportunity areas that were discussed but ultimately did not rise to the top for development in this rule set (but could be addressed in the future) pertain to a list of services for which prior authorization is required/not required (including not required for emergency services14), as well as a timeframe for sending a final determination. Opportunities that rose to the top related to data content, standardizing the prior authorization request and response for all formats (e.g. web portals), workflows and attachments (additional documentation). The Advisory Group sent these to the Subgroup for further specification.

The Advisory Group charged a CAQH CORE Prior Authorization Subgroup with creating operating rules for data content requirements for the 5010X217 278 transaction and the standardization of prior authorization requests and responses. Given pending federal regulations regarding standards for attachments (additional documentation), operating rules for attachments were put on hold. CAQH CORE has since launched a separate initiative related to attachments (additional documentation), and operating rules may be expected in a subsequent phase of rule writing. Furthermore, given the current varied and proprietary nature of workflows, the Advisory Group advised that more assessment and research were needed. As a result, the opportunity area will be considered for future CAQH CORE operating rules.

To develop operating rules for the chosen opportunity areas, the CAQH CORE Prior Authorization Subgroup responded to a series of surveys and participated in discussions to further identify potential requirements within these opportunities. Subgroup participants were asked to identify the most common reasons for prior authorization denials and pended responses. From there, potential rule options were drafted. Subgroup participants then completed straw polls to indicate their support for each rule option and build out rule requirements.

2.3. Focus of the Phase V CAQH CORE Prior Authorization Web Portal Rule

The following rule options addressing data content of the electronic prior authorization transaction or web portals received the highest support from the CAQH CORE Prior Authorization Subgroup:

- Consistent patient identification and verification on prior authorization requests.
- Additional guidance on situational use of AAA Error Codes and corresponding action codes.
- Receipt and processing of diagnosis/procedure/revenue codes for specified categories of services on the Request to enable adjudication.
- Use of LOINC and PWK01 Attachment Report Type Codes to communicate what additional clinical documentation is needed from the provider to move a pended prior authorization request forward.
- Use of HCSDRCs to provide the most comprehensive information back to the provider.
- Application of standard X12 data field labels to web portals to reduce variation and ease submission burden.
- Confirmation of receipt of prior authorization or referral request (submitted via web portal) to reduce manual follow-up for providers.
- System availability requirements for a health plan to receive a prior authorization or referral request, to enable predictability for providers when using a web portal.

The Phase V CAQH CORE Prior Authorization Web Portal Rule15 builds a bridge toward overall consistency for referral and prior authorization requests and responses by addressing fundamental uniformity for data field labels, ensuring confirmation of the receipt of a request and providing for system

14 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.
15 This rule does not require any HIPAA-covered entity and its agent to use a web portal if it currently does not do so or is not required by federal or state regulation to do so.
availability. The rule – which applies to referrals as well as prior authorizations for procedures, laboratory testing, medical services, devices, supplies or medications within the medical benefit – reduces administrative burden and encourages pathways to automation by:

- Requiring use of the 5010X217 278 Request and Response TR3 implementation names for the web portal data field labels for prior authorizations and referrals, which supports the HIPAA-mandated standard transaction.
- Adhering to the requirements outlined in the Phase V CAQH CORE Prior Authorization (278) Request / Response Data Content Rule when the portal operator maps the collected data from the web portal to the 5010X217 278 Request and Response transaction.
- Reducing variation in data element names to ease submission burden and encourage technology solutions to minimize the need for providers to submit information to multiple web portals.

3. Web Portal Rule: Requirements Scope

3.1. What the Rule Applies To

This Phase V CAQH CORE Prior Authorization Web Portal Rule applies to any web portal used by a provider to submit a prior authorization request for any healthcare service or referral, either directly or via a business associate\textsuperscript{16} to a health plan and its agent, hereafter referred to as a “web portal operator.”\textsuperscript{17}

3.2. When the Rule Applies

This rule applies when any entity and its agent make available a web portal to a provider to submit a prior authorization request for any healthcare service or referral and corresponding response.

3.3. What the Rule Does Not Require

This rule does not require any entity and its agent to conduct, use or process a prior authorization request or referral and corresponding response via a web portal if it currently does not do so.

3.4. Applicable Loops, Segments and Data Elements for Web Form Data Field Labels

This rule addresses the use of 5010X217 278 Request and Response transactions IMPLEMENTATION NAME for each corresponding Loop, segment and data element field where an IMPLEMENTATION NAME exists or the use of the ALIAS if it is available and identified as such in the 5010X217 278.

3.5. Outside the Scope of This Rule

Pharmacy benefit electronic prior authorization web portals are out-of-scope for the rule, i.e., pharmacist-or prescriber-initiated prior authorizations for drugs/biologics/other treatments covered under a pharmacy benefit are not a function of the web portals addressed in this rule, as drug authorizations covered under the pharmacy benefit are the function of the National Council for Prescription Drug Programs (NCPDP).

\textsuperscript{16} Under 45 CFR § 160.103, “business associate” includes: (i) A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires access on a routine basis to such protected health information. (ii) A person that offers a personal health record to one or more individuals on behalf of a covered entity. (iii) A subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.

\textsuperscript{17} A “web portal operator” is defined as any organization that makes available to either providers and their agents, payers and their agents, health plans and their agents, or other organizations a web portal which supports the prior authorization process.
3.6. Maintenance of This Rule

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, or as determined by industry need or CAQH CORE Participants.

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. Fundamentally, electronic data interchange refers to the long-standing concept of an entity receiving information electronically from another entity which is needed to deliver support to one or more business processes.

The following assumptions apply to this rule:

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


Many healthcare providers have a need to request prior authorizations outside of the typical business day and business hours. Additionally, many providers allocate substantial staffing resources to perform 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.

Conversely, web portal operators have a business need to periodically take their prior authorization web portal processing systems offline to perform required system maintenance. System unavailability can lengthen processing time of an electronic prior authorization submission via a web portal, increase processing times and delay patient care.

This rule requirement addresses these conflicting needs.

4.1.1. Web Portal System Availability Requirements

Web Portal system availability must be no less than 86 percent per calendar week. “System” is defined as all necessary components required to process the completion and submission of a prior authorization request.

“Calendar week” is defined as 12:01 a.m. Sunday to 12:00 a.m. the following Sunday. This will allow for web portal operator to schedule system updates to take place within a maximum of 24 hours per calendar week for regularly scheduled downtime.

4.1.2. Web Portal System Availability Reporting Requirements

Reporting of downtime and other schedule notifications may occur via website or companion guide, or via another method identified by the web portal operator and communicated to the provider. When a web portal system is down, the web portal operator should provide an alternative mode of submission, if applicable.
4.1.2.1. Scheduled Downtime
A web portal operator must publish its regularly scheduled system downtime in an appropriate manner such that the provider can determine the web portal system availability, so that staffing levels can be effectively managed.

4.1.2.2. Non-Routine Downtime
For non-routine downtime (e.g., system upgrade), a web portal operator must publish the schedule of non-routine downtime at least one week in advance.

4.1.2.3. Unscheduled Downtime
For unscheduled/emergency downtime (e.g., system crash), a web portal is required to provide information within one hour of realizing downtime will be needed.

4.1.2.4. Holiday Schedule
A web portal operator will establish its own holiday schedule and publish it in accordance with the requirements specified in the above sections.

4.2. Web Form Data Field Labels

4.2.1. Web Form Data Request Field Labels
The web portal operator of prior authorization submissions must apply the corresponding Loop, segment, data element name from the 5010X217 278 Request and Response to all web form data fields using the IMPLEMENTATION NAME for each corresponding Loop, segment and data element where an IMPLEMENTATION NAME exists or the use of the ALIAS if it is available and identified as such in the 5010X217 278 when an IMPLEMENTATION NAME does not exist or is considered less common. When an IMPLEMENTATION NAME or ALIAS for a corresponding Loop, segment and data element does not exist the X12 base standard Loop, segment and data element names must be used for the web form data field, when available.\(^\text{18}\)

4.2.2. Web Form Response Data Field Labels
When the web portal operator receives a 5010X217 278 Response transaction in response to a previously submitted prior authorization request it must apply the corresponding Loop, segment, data element name from the 5010X217 278 Response transaction to all web form data fields using the IMPLEMENTATION NAME for each corresponding Loop, segment and data element where an IMPLEMENTATION NAME exists or the use of an ALIAS if it is available and identified as such in the 5010X217 278 when an IMPLEMENTATION NAME does not exist. When an IMPLEMENTATION NAME for a corresponding Loop, segment and data element does not exist the X12 base standard Loop, segment and data element names must be used for the web form data field, when available.\(^\text{19}\)

If a web portal operator maps the data collected from the web form to the X12/005010X217 Health Care Services Review – Request for Review and Response (278) transaction it must comply with the Phase V CAQH CORE Prior Authorization 278 Request/Response Data Content Rule.

\(^{18}\) A web portal operator may present supplemental information regarding the data fields via a “mouse hover” function or some similar functionality.

\(^{19}\) Ibid.
4.4. Confirmation of Receipt of Web Form Submission

When a provider clicks "submit", or similar command button on a web portal form after completing all data fields, the web portal must return a submission receipt indicating to the provider that the completed prior authorization request form was successfully received, as well as information about the “next steps” of the web portal operator. Examples of such information include:

- Notification that the web portal operator requires additional documentation to process the request.
- Option to print and save a PDF.
- View the prior authorization status.
- The status or an update of a previously submitted request.
- Assignment of a transaction or reference control number.
- A detailed timestamp, potentially including date, time and time zone of the submission.

5. Phase V CAQH CORE Operating Rule Set: Appendix

5.1. Operating Rule 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” (ACA, Section 1104). As such, operating rules build upon existing healthcare transaction standards. The ACA outlines three sets of healthcare industry operating rules to be approved by HHS and then implemented by the industry.

The third set of ACA-mandated operating rules address 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. The ACA requires HHS to adopt a set of operating rules for these five transactions. In a letter dated 09/12/12 to the Chairperson of NCVHS, the Secretary of HHS designated CAQH CORE as the operating rule authoring entity for the remaining five HIPAA-mandated electronic transactions.

5.2. HIPAA Compliance Requirements

HHS determines whether the system of a covered entity is compliant or noncompliant with the HIPAA Administrative Simplification requirements (which include HIPAA-mandated CAQH CORE Operating Rules). HHS may adjudicate compliance of a covered entity 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.” (45 CFR 160.402)
- 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))

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20 The first set of operating rules under ACA Section 1104 applies to eligibility and claim status transactions. These operating rules became effective January 1, 2013. The second set of operating rules applies to electronic funds transfer and electronic remittance advice. These operating rules became effective January 1, 2014.
21 HHS Letter from the Secretary to the Chairperson of NCVHS. September 12, 2012.
5.3. **Logical Observation Identifier Names and Codes**

Logical Observation Identifier Names and Codes (LOINC), is the international standard for identifying health measurements, observations and documents. LOINC is a freely available global standard used by a diverse global community including reference labs, healthcare organizations, U.S. federal agencies, insurance companies, software vendors and in vitro diagnostic testing companies. More than 78,300 registered users from 172 countries use LOINC to move data between systems. Regenstrief Institute, Inc., a non-profit 501(c)3 research organization serves as the overall steward and standards development organization (SDO) for LOINC.\(^\text{22}\)

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\(^{22}\) For more information about Logical Observation Identifier Names and Codes (LOINC) and Regenstrief Institute, Inc., visit [https://loinc.org/](https://loinc.org/).