



Update Process for Standards Development Organizations and Operating Rule Authoring Entities

Developed by the Subcommittee on Standards with Input from SDOs and ORAEs

June 2017

		Key Themes and Barriers									
1		SDO and Operating Rule entities are learning from experiences and modifying processes based on experiences within and beyond their organizations Advancements									
2		Advancements achieved in standardization and information exchange warrant a fresh look at how we support interoperability objectives (a.k.a. Admin Simp and Clinical Exchange)									
3		Length of time between HIPAA adopted transaction standards substantially increases the volume and complexities of changes to be implemented									
4		Multiple comment periods create disservice to effective standards development (SDO public comment period followed by a federal rulemaking comment period)									
5		Financial models to support standards development often dependent on volunteer workforce									
6		Resource intensive development work mostly supported by volunteers with limited time availability and corporate support result in ongoing challenges to support maintenance of standards, implementation specifications and external code lists									
7		Lack of obligation for everyone to play under current definition of Covered Entity erodes efficiency and effectiveness of Administrative Simplification									
8		Current framework does not promote industry participation in testing and/or piloting emerging standards									
9		Industry awaits federal rulemaking trigger due to limited resources and business model priorities									
10		Lack of industry awareness of DSMO role and process; Change requests going directly to applicable entity									
11		NACHA's closed network design with frameworks for development and enforcement aid efficiency of implementation and compliance									
12		Interoperability objectives influenced by international standards work (e.g. ISO, HL7)									

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13		Historical approach of upgrading X12 and NCPDP standards at same time needs further review to fully identify opportunities and challenges to decoupling
14		Regulatory - adoption of new versions of the standard(s)
15		Industry participation, Industry acceptance and SME's
16		(Most Significant): Financial - CAQH CORE assumes the word "financial" refers to people, time, money and business case for all involved parties, which includes executive sponsorship. This is needed for all segments and stakeholder types. Similar assumptions were made for the other terms NCVHS uses in its multiple-choice approach.
17		Industry participation/Gaining stakeholder involvement; requires collaboration among competitors and involvement of a wide range of levels
18		Ongoing state versus federal solutions
19		Technical, Funding, Human resources/subject matter expertise to support the work, Industry acceptance (established respect, trust, implementation); Industry participation, Committed executive leadership
20		#1 barrier to adoption of the healthcare EFT standard by providers is charging of a percentage based fee by some vendors to deliver the standard to the provider (according to 2016 Aite research)

Criteria	CAQH CORE	HL7	NACHA	NCPDP	X12	HHS	DSMO
Type of Organization	Authoring Entity for Operating Rules (ORAE)	Standards Development Organization (SDO)	Standards Development Organization (SDO) and Operating Rule Authoring Entity	Standards Development Organization (SDO)	Standards Development Organization (SDO)	Regulatory Body	Collaborating body operating under a self renewing MOU.
Accreditation Type (ANSI, ISO, etc.)	N/A	ANSI	ISO	ANSI	ANSI	N/A	
Product (s)	CAQH CORE has three types of products: the CAQH CORE Operating Rules, CAQH CORE Education & Implementation Tools and voluntary CORE Certification. CAQH CORE has published four phases of CAQH CORE Operating Rules; Phases I-III are federally mandated under the Patient Protection and Affordable Care Act of 2010 (ACA), except for rule requirements for use of Acknowledgements. Phase IV implementation is voluntary. CAQH CORE Education/Implementation and Certification products are offered for all four phases of CAQH CORE Operating Rules.	Clinical Messaging and Document standards such as CDA and FHIR. Standards adopted by HITECH / Meaningful Use related regulations.	Financial Standards, operating rules, and enforcement procedures for ACH payments and the ACH Network	Pharmacy transactions such as claims, eligibility, and e-prescribing and 25 other standards. Standards also adopted by HITECH/MU, and Medicare Modernization Act	Non-pharmacy administrative transactions such as claims, eligibility, referrals, remittance advice, prior authorization, claim status and health care attachments	Publishing regulations to adopt mandatory standards to increase the use of electronic standards and operating rules.	Recommendation to advance next version of HIPAA adopted standards.
Member of DSMO?	No	Yes	No	Yes	Yes	Yes	N/A
Paid Staff work on Products?	Yes	Yes	Yes (?)	Yes	No	Yes	No
Governance	CAQH CORE Board has 13 Voting Members (5 Providers, 5 Health Plans, and 3 "Others", i.e., Vendor, Clearinghouse, Bank, etc.) and 5 Non-Voting Advisors (i.e., SDOs and Others). CAQH CORE rule development is governed by a multi-level process that requires approval by Subgroups, Work Groups and the Full CAQH CORE Voting Membership.	HL7 is a 501 c(6) organization. The HL7 Board of Directors is responsible for the strategic direction of the organization and has fiduciary responsibility for adopting sound, ethical and legal governance and financial management policies that ensure the organization's sustainability while advancing its mission. Technical Governance is provided by the HL7 Technical Steering Committee.	NACHA is a 501 (c)(3) organization with a Board and Advisory Group. The Advisory Group serves in a formal capacity, with a cross-section of non-financial institution entities including fintechs, processors and end users of the ACH Network to communicate directly with the NACHA Board of Directors on ACH payment priorities, needs and capabilities from the perspective of end-user clients and technology firms that enable ACH payments.	Board of Trustees has supervision, control and general charge of the business of the Council. It establishes and modifies the Council's policies and executes the purposes of the Council, has discretion for the disbursement of funds, establishes the strategic direction, appoints the standardization committee, and has final authority on all industry standard development procedures. It is comprised of providers, payers and vendors.	The X12 Board defines the overall direction and strategy of the organization, maintains a policy based governance system, oversees corporate policy and procedure compliance, protects the organization's assets, and supervises, controls, and directs the organizational affairs of X12.	HHS is the Federal Agency with responsibility for administering the health care regulations under the White House. It has 16 operating divisions, including the Centers for Medicare and Medicaid (CMS). The Administrator of CMS is responsible for implementing and enforcing the regulations related to HIPAA and ACA.	Comprised of SDOs, Code Content Committees and HHS. Created through regulation. Chairpersonship is rotating.
Workgroup structure	CAQH CORE uses an open multi-stakeholder process to draft its operating rules and any entity is welcome to join this process. The CAQH CORE rules development process occurs at four levels: Level 1: CAQH CORE Subgroups Level 2: CAQH CORE Work Groups Level 3: Full CAQH CORE Voting Membership Level 4: CAQH CORE Board NOTE: • Only implementing entities vote at the Full CAQH CORE Voting Membership level. • The CAQH Board/CAQH does not have veto or voting power over the CAQH CORE Operating Rules. • Only CAQH CORE Participating Organizations contribute to the CAQH CORE rules development process and can directly vote on development of the CAQH CORE Operating Rules.	Members and non-members can participate in HL7's work groups, which develop the standards. All HL7 members are entitled to vote on all standards. Per ANSI rules, non-members pay for the privilege of voting. Must be HL7 member to vote. Work groups reconcile all comment received for the standards they create through a consensus process outlined in HL7's Governance and Operations Manual and HL7's Essential Requirements.	NACHA has standing work groups for development of ACH Operating Rules. Participation in the Rules Work Group is open to direct members of NACHA or their representatives and ACH Operators	NCPDP members may participate and vote with no additional fees. Non-members may participate. Members and non-members engaged in workgroups inform development and vetting of standards and operating rules. All comments must be reconciled.	Members and non-members engaged in workgroup development and vetting of standard and technical reports. Must reconcile all comments. Must be member of X12 to vote.	N/A	N/A

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Voting Process	<p>Formal voting, with required quorums and approval percentages, occurs at Levels 2, 3, and 4 of the CAQH CORE rule development process (see cell 7B). At all the levels, approval occurs via:</p> <p>Level 1 (CAQH CORE Subgroups): Informal surveys and strawpolls; all comments are reviewed and adjudicated in a transparent, documented process to reach consensus.</p> <p>Level 2 (CAQH CORE Work Groups): Online ballot; comments are collected and summarized and adjudicated.</p> <p>Level 3 (Full CAQH CORE Voting Membership): Online ballot; results publicly shared.</p> <p>Level 4 (CAQH CORE Board): Voting Board Member email to Managing Director; results publicly shared.</p> <p>For more information, see https://www.caqh.org/core/voting-process.</p>	HL7 balloting process approves or return standards to applicable workgroup.	Request for changes to the operating rules are submitted to the Rules and Operations committee for review and if approved assigned to a standing rules work group. The rules work group reviews the request and depending on the complexity of the change request will develop either a request for information or request for comment that is sent out to members and posted on the NACHA website, comments on the RFI's and RFC's can be submitted by any interested party. Once the RFI's or RFC comments are received they are reviewed by the rules work group and if the proposal is supported the work group will send a recommendation to the Rules and Operations Committee to put the proposal out for ballot. A ballot is issued to NACHA direct members only.	Work groups develop standards/revisions on regular schedule each year. Electronic ballots are issued twice a year. Changes advance to a ballot for consensus group vote.	Base standard data maintenance reviewed/adopted through ballot process. Work groups create technical reports tied to a version of the base standard. Series of votes through workgroups and trimester meets, followed by higher level work groups.	N/A - notice of proposed rule making solicits industry feedback.	Discussions of change requests lead to vote.
Cost of Standards/OR	Free to entire industry	HL7's standard are licensed free of charge to members and non-members like.	Membership required to access the standard; cost for non-members (need to verify with NACHA)	Membership required to access the standard or implementation guides/ technical reports; cost for non-members	Anyone can license X12 work products	NA	N/A
Development and Maintenance	<p>For all new rules, CAQH CORE Operating Rules development begins with thorough research, an exhaustive environmental scan and a sound business case. This initial analysis is then utilized by either a CAQH CORE Advisory Group, as appropriate, or a larger CAQH CORE Subgroup as appropriate, to begin to identify a set of rule opportunities for which to pursue rule development.</p> <p>CAQH CORE Advisory Groups are comprised of a targeted group of SME CAQH CORE Participants. The role of Advisory Groups is to conduct preliminary prioritization of draft rule opportunity areas for Subgroup consideration. With or without the support of a CAQH CORE Advisory Group, CAQH CORE Subgroups are responsible for reaching consensus on the high priority opportunity areas to be addressed by a phase of new CAQH CORE Operating Rules and developing the draft rule language requirements.</p> <p>After extensive Subgroup vetting, research, strawpolls, surveys and consensus agreement, the draft rules are referred up to the respective CAQH CORE Work Group for review, discussion and, if appropriate, approval.</p> <p>Once approved via Work Group ballot, draft rules move forward to the Full CAQH CORE Voting Membership and then to the CAQH CORE Board for final review and approval. At this stage, the CAQH CORE integrated model is not focused on developing rules on standards or requirements for which there is no available, public experience for setting national expectations.</p>	Work groups determine need for new or updates to existing standards. The scope and timeline for development of new standards or updates is proposed as a new project, which requires approval by the Work Group, Steering Division and Technical Steering Committee. Once approved as a project, new or updated material is developed Draft ballot is created and released for ballot. Members and non-members who join the ballot pool may vote.	Proposed rule changes can be submitted by anyone. Rules work groups review and develop business cases for proposals but also works with outside consultants to conduct research on more complex rules proposals.	Business need presented in Data Element Request Forms (DERFs) or New Project Requests. Workgroups maintain and update standards via the NCPDP Data Element Request Form (DERF). Any person or group may submit a DERF. Maintenance of a standard is accomplished through the NCPDP DERF process also. DERFs are reviewed and adjudicated 4 times a year. Once the DERF is approved at the work group level, a ballot is prepared according to the semi-annual ballot schedule after February and August Work Group meetings.	Workgroups maintain and update standards. Base standard is updated every two years. Implementation specifications are updated through workgroups comprised of volunteers. Four levels of review take place to approve updated Imp Specs (TR3s)	Various federal processes influence internal/closed processes with periods defined for industry engagement and formal commenting processes.	N/A
Maintenance	<p>Prior to the ACA mandate for federal healthcare operating rules, CAQH CORE began as a voluntary effort to build consensus among industry stakeholders on a set of operating rules that facilitate administrative interoperability between providers and health plans. As a voluntary effort, CAQH CORE has always supported a process for maintenance of the operating rules using a transparent approach that addressed both Substantive and Non-substantive updates. The mandated CAQH CORE Operating Rules support this process as well as the ability for CAQH CORE to conduct routine, periodic maintenance of specific federally adopted operating rule requirements, based on ongoing use, need and lessons learned. Note, periodic maintenance does not change underlying rule requirements but does upgrade content requirements. This type of maintenance – which is focused on a specific rule requirement - requires a formal, transparent process of obtaining multi-stakeholder input.</p> <p>More detail on the CAQH CORE maintenance process is available here: https://www.caqh.org/core/change-process-and-maintenance</p>	Maintenance is handled by the work group that developed the standard.	Maintenance of the operating rules and standards are handled through the NACHA rule making process.		The development and maintenance of the X12 work products is conducted by the volunteer members with assistance from X12 support staff.		
					X12 approves the publication of a new Release of the X12 Standard each calendar year.		
					Implementation Guides are continuously maintained and updated based upon Change Requests received. There are four levels of review that take place to approve updated Implementation Guides to assure technical accuracy and business needs are met. This includes broad public review and commenting by members and non-members of X12		

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Timelines	<p>Development of New Operating Rules: The process for new CAQH CORE rule development described in cell B12 can take between 6-18 months depending on the complexity and business issues addressed.</p> <p>Maintenance of Existing Operating Rules: CAQH CORE has an established timeline for conducting periodic, routine maintenance for operating rules that include specific maintenance requirements in the rule language; currently four CAQH CORE Operating Rules include some rule-required maintenance language. For example, the CORE Code Combinations required by the CAQH CORE 360 Rule are updated three times per year to align with updates to the published CARC and RARC lists, which are maintained by CARC and RARC code authors external to CAQH CORE. Once a year, the code combinations are also updated to incorporate adjustments to address new and evolving business needs. This "Market-based" update occurs concurrent with one of the "Compliance-based" updates, resulting in a single updated publication of the code combinations. Expected deadlines and collaboration are key to this maintenance process.</p>	Standards are developed and updated as needed. Documents are typically published 6-18 months following the ballot, depending upon the number of ballot participants, the comments received, and the identification of a specification as a standard for trial use (STU) or a normative standard.	Standards are updated as needed, and could take up to 9 months; it depends on the changes that are being made.	Standards are balloted twice a year. If there are no substantive categorized ballot comments, a standard can be produced every 6 months. If a recirculation ballot is required (a comment was categorized as substantive), the standard would be produced every 9 months. The exception to this is the NCPDP External Code List (ECL) which can be updated 4 times a year and does not require a ballot.	X12 approves the publication of a new Release of the X12 Standard each calendar year. Implementation Guides are continuously maintained and updated based upon Change Requests received.	Variable and difficult to forecast	Triggered by change request submission.
Triggers	<p>A range of criteria drive CAQH CORE Operating Rules, including:</p> <ul style="list-style-type: none"> • Business changes impacting one segment of industry • Professionally executed research • Technological advances or discoveries • Federal or state law or regulation requires a change • Number of change requests submitted by industry <p>CAQH CORE responds to all of these drivers, and may prioritize or address all or some more than others depending on the circumstances.</p>	Stakeholder submits business need not meet by current standard, messaging or document transaction.	Managing network efficiency and payment system risk; business changes; change requests from stakeholders that revise standard or operating rules. NACHA rarely has regulatory change requirements but those are implemented when they are received.	Change requests submitted by Stakeholders. Business changes impacting one or more segments of industry. Reason: needs not meet by current standard/implementation guide or external code list.	Stakeholder submits business need not meet by current standard, technical report or external code list.	Industry need, congressional mandate, federal objectives or recommendations of advisory committees.	Change request submission, by SDO or industry stakeholder.
Piloting	Given its guiding principles, CAQH CORE does not promote the national adoption of untested methods, standards or processes. CAQH CORE Operating Rules support well recognized standards and best practices that have been tested in the market. All CAQH CORE rule development takes into consideration existing best practices such as state-based efforts, comparative pilot results (with qualitative and/or quantitative results), and the experience of existing implementations. CAQH CORE offers a voluntary certification process that highlights adopters of the CAQH CORE Operating Rules. The CORE Certification process requires entities to conduct simulated testing that is specific to stakeholder type; test site is alpha and beta tested by each stakeholder type before going live. For areas without recognized best practices or standards, CORE uses its research process, reference tools such as the CAQH Index, and education tools to have the industry/CORE participants examine untested/minimally used standards and thus strength of business case.	Most normative standards will be piloted during a Standard for Trial Use period that may last anywhere from 12 months to several years. Occasionally there may be a government need to ballot and publish a normative standard without a trial use period.	Pilot programs can be conducted on some new applications and uses of existing standards.	Not required.	Not required. Voluntary pilots have been conducted of some of the transactions, such as attachments.	N/A	N/A

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	<p>Government-driven: All HIPAA-covered entities are required to comply with the ACA-mandated CAQH CORE Operating Rules (Phases I, II, and III, excluding Acknowledgments requirements) as these operating rules are part of the HIPAA Administrative Simplification transaction requirements. The Secretary of HHS is responsible for managing HIPAA transaction enforcement through the complaint driven process.</p> <p>CAQH CORE-driven: Separate from and independent of any HHS compliance processes, CAQH CORE has a transparent certification program that includes testing as well as enforcement via a compliant process. CAQH CORE offers voluntary CORE Certification to health plans, providers, clearinghouses, and software/services vendors. Per the CORE Certification Enforcement Policy, any healthcare provider that is exchanging transactions with a CORE-certified health plan OR that is an end-user of a CORE-certified vendor or clearinghouse product/service may lodge a complaint against a voluntarily CORE-certified entity or product/service if the provider believes the CORE-certified entity or product/service is non-conformant with the CAQH CORE Operating Rules and/or Policies. CORE Certification policies and requirements are voted on by the CAQH CORE Participants.</p> <p>For more information on the: CORE Certification Program, see: https://www.caqh.org/core/core-certification-process For the CORE Certification Enforcement Policy, see: https://www.caqh.org/faq-page/539</p>	N/A until standards are adopted by federal regulation or named within legislation.	While HHS responsible for managing HIPAA enforcement through complaint driven process. NACHA enforces the rules & guidelines for the ACH Network and developed a enforcement process which went through the rulemaking process and was voted upon by the members. An entity can submit a violation. If the violation is not corrected a violator will receive a fine based on the violation.	HHS responsible for managing HIPAA enforcement through complaint driven process. In addition, NCPDP members have established a process that identifies the steps that should be followed when there is a suspected misapplication of an NCPDP standard(s). More information on this process can be obtained at http://www.ncdp.org/Resources/Hipa-a-Compliance.aspx	X12's "Compliance in X12" guideline establishes the technical and semantic requirements for compliance with the X12 work products.	HHS has an enforcement program in place that is complaint driven. It is evaluating an audit program.	N/A
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