

September 6, 2011

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0032-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-0032-IFC; *Administrative Simplification: Adoption of Operating Rules for Eligibility for a Health Plan and Health Care Claim Status Transactions* (RIN 0938-AQ12)

Dear Administrator Berwick:

The CAQH Committee on Operating Rules for Information Exchange (CAQH CORE) greatly appreciates the opportunity to submit comments to the Department of Health and Human Services (HHS) regarding the Interim Final Rule with Comment: “Administrative Simplification: Adoption of Operating Rules for Eligibility for a Health Plan and Health Care Claim Status Transactions” (CMS-0032-IFC) (IFC). CAQH CORE applauds the Secretary and the Centers for Medicare and Medicaid Services (CMS) for promulgating this important rulemaking, which, as stated in the IFC, is projected to “save an estimated \$12 billion for physicians, other health providers, and health insurance companies by reducing transaction costs in the form of fewer phone calls between physicians and health plans, lower postage and paperwork costs, fewer denied claims for physicians, and a greater ability to automate health care administrative processes.”¹ Further, under the IFC, patients will “benefit from more accurate information about their out-of-pocket costs at the time of service” and are expected to experience “expanded access to care as clinicians will have more time to spend treating patients by spending less time calling health plans.”²

The IFC, which implements part of Section 1104 of the Patient Protection and Affordable Care Act (ACA),³ achieves important forward progress in the area of health care administrative simplification, as it adopts operating rules for two of the electronic health care transactions required under HIPAA: (1) eligibility for a health plan and (2) health care claim status. We are pleased that the IFC largely adopts the operating rules developed by CAQH CORE for purposes of achieving greater uniformity in the implementation of these two HIPAA transaction standards. CAQH CORE is extremely proud of the work by the industry in developing these rules on a voluntary basis over the past several years, and we applaud CMS for recognizing the value of these efforts by requiring, through the IFC and pursuant to ACA Section 1104, that HIPAA covered entities must, by January 1, 2013, comply with most aspects of the CAQH CORE Phase I and Phase II operating rules for non-retail pharmacy eligibility and claim status transactions (updated for the Version 5010 HIPAA standards).

While we wholeheartedly endorse this landmark step by CMS, we urge several important modifications to the IFC and consideration of several changes and clarifications. *In each case we have included our rationale.* For your convenience, below is a summary of our recommendations:

¹ HHS, Press Release, *Affordable Care Act Cuts Health Care Red Tape, Saves \$12 Billion* (June 30, 2011), available at <http://www.hhs.gov/news/press/2011pres/06/20110630a.html> (last visited Aug. 30, 2011).

² *Id.*

³ References to ACA refer to the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010), and the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152 (2010).

- I. CAQH CORE commends CMS for recognizing and defining the valuable role of operating rules in achieving administrative simplification.
- II. CMS should include acknowledgements within the ACA-adopted operating rules.
- III. CMS should formally name CAQH CORE as the operating rules authoring entity.
- IV. CMS should clarify the relationship of the adopted operating rules to retail pharmacy and business associates.
- V. CAQH CORE urges CMS to continue to recognize voluntary certification for health plans, vendors/clearinghouses, and large providers, as exemplified by the CAQH CORE program.
- VI. As currently and appropriately articulated in the IFC, CMS should maintain the CAQH CORE Companion Guide Template as the single template.
- VII. Clarification on voluntary efforts is warranted.
- VIII. If CMS issues any modifications to, or clarifications of, the IFC, CAQH CORE encourages the Agency to issue any such modifications or clarifications promptly and, in any event, by no later than January 1, 2012.
- IX. Address technical corrections and clarifications with CAQH CORE.

I. CAQH CORE commends CMS for recognizing and defining the valuable role of operating rules in achieving administrative simplification. (Reference IFC Sections I and II.A)

We enthusiastically support the IFC’s adoption of the CAQH CORE Phase I and II operating rules for the eligibility and health care claim status for non-retail pharmacy transactions,⁴ as well as CMS recognition that these operating rules “further enhance the HIPAA transactions by better facilitating communication between trading partners, including providers, filling gaps in the associated standards, and fulfilling the requirements, purposes, and principles set out in the statute [Social Security Act § 1173, as amended by the ACA].”⁵ The IFC appropriately defines the scope and role of operating rules and their distinct, yet very complementary, role in relation to the adopted HIPAA standards.⁶ As CMS states in the IFC, operating rules, while not without limitations, are crucial to the goals of administrative simplification in that they “augment the standards” in several key ways, including that they:

- Contain additional requirements that help implement the standard for a transaction in a more consistent manner across health plans;
- Address ambiguities or conditional requirements in the standard and clarify when to use or not use certain data elements or code values; and
- Specify how trading partners, including providers, should communicate with each other and exchange patient information, with the goal of eliminating connectivity inconsistencies.⁷

⁴ For a listing of the specific CORE operating rules adopted under the IFC for eligibility for a health plan and health care claim status transactions, see 76 Fed. Reg. 40496 (adding a new § 162.1203 and a new § 162.1403 to 45 C.F.R. Part 162).

⁵ 76 Fed. Reg. 40464 (July 8, 2011); *see also id.* at 40459, 40460, 40461, 40464, 40469 (stating the important role of operating rules to “fill gaps” in the standards).

⁶ *Id.* at 40460 (“Standards and operating rules overlap in their functions to increase uniformity, but differ in their purposes. While standards are mainly concerned with the content transmitted in a transaction, operating rules provide for the method of how the information should be transmitted, as well as the elimination of certain situationality in the use of data content contained in the standards.”).

⁷ *Id.* at 40460–40461.

We also enthusiastically support the broad scope of operating rules adopted by CMS. A broad scope is necessary to honor Congressional intent. Without such a scope, the variability in companion guides will not be remedied and will continue to frustrate adoption of electronic data interchange in the health care industry. Furthermore, the savings CMS projected in the IFC would not be achieved with a narrow scope.

Additionally, we are pleased to see that, consistent with the statute, the IFC notes that operating rules must be consistent and not in conflict with either the existing HIPAA-adopted standards or adopted Health Information Technology standards.⁸ We applaud CMS for adopting, for the purposes of this IFC, a definition of conflict under which an operating rule would impose a conflict with an existing HIPAA standard only if the operating rule requirement “would make it impossible for a party to comply with both the associated HIPAA standard and the operating rule.”⁹ As noted by CMS, “[t]his interpretation is consistent with fundamental principles and precedents regarding when a conflict exists. If a party is able to satisfy both the requirements of the standard and the requirements of the operating rule, there is no conflict and the operating rule is consistent with the standard.”¹⁰ We agree with the Agency’s interpretation and also appreciate the inclusion of Table 2 entitled “Could an Operating Rule Conflict with a Standard?” as it is a very useful tool included in the IFC to communicate to the industry the relationship between standards and operating rules.

II. CMS should include acknowledgements within the ACA-adopted operating rules.¹¹ (Reference IFC Section II.D.1.a)

There are strong legal and policy justifications supporting the Secretary’s adoption at this time of the CAQH CORE Phase I and Phase II operating rules for acknowledgements.

A. The plain text of the ACA requires the adoption of acknowledgements.

First and foremost, the plain text of the ACA requires the adoption of acknowledgements. Operating rules are defined in the statute and the IFC as “the necessary business rules and guidelines” that are “needed to facilitate better communication between trading partners, including providers, to fill gaps in the standards, and to fulfill the purposes and principles set out in sections 1173(a)(4)(A)(i) through (iv) and (B) of the [Social Security] Act.”¹² These statutory purposes and principles include an express requirement that the “standards and associated operating rules adopted by the Secretary *shall . . . provide for timely acknowledgment*, response, and status reporting that supports a transparent claims and denial management process (including adjudication and appeals).”¹³

Not including the CAQH CORE Phase I and II operating rule requirements for acknowledgements undermines the statute by producing results that run directly counter to the goals of administrative simplification, and to the statutorily specified purposes and principles that the Secretary is required to advance through the adoption of standards and associated operating rules under HIPAA.

⁸ *Id.* at 40461–40462; *see also* Social Security Act § 1173(g)(3)(C) & (D), added by ACA § 1104(b)(2)(C).

⁹ *Id.* at 40462.

¹⁰ *Id.*

¹¹ CAQH CORE Phase I 150: Eligibility and Benefit Batch Acknowledgement Rule version 1.1.0; CAQH CORE Phase I 151: Eligibility and Benefit Real Time Acknowledgement Rule version 1.1.0; and the real-time and batch Acknowledgements requirements contained in the CAQH CORE Phase II 250: Claim Status Rule, version 2.1.0.)

¹² 76 Fed. Reg. 40461 (July 8, 2011).

¹³ SSA § 1173(a)(4)(A)(iii), added by ACA § 1104(b)(2)(B) (emphasis added).

- B. *Full return on investment (ROI) cannot be accomplished without inclusion of acknowledgements; the industry relies on acknowledgements to facilitate electronic health transactions.*

Important policy reasons related to cost savings and other goals of administrative simplification support the position that the CAQH CORE Phase I and II acknowledgements rules can, and should, be included at this time in the adopted operating rules for eligibility and claim status transactions. The IFC omission of acknowledgments from the operating rules adopted under Section 1104 of the ACA for eligibility and claim status transactions, contrary to the original National Committee on Vital and Health Statistics' (NCVHS) recommendation in September 2010 to adopt all of the CAQH CORE Phase I and II rules, is significant as the return on investment (ROI) for the use of operating rules drops considerably unless acknowledgements are integrated into daily administrative data exchange. As recognized by the IFC, a study reviewing the experiences and ROI of early adopters of the CAQH CORE Phase I operating rules is available online at <http://www.caqh.org/COREIBMstudy.php>. Both providers and health plans view acknowledgements as essential to improve the end-to-end processing of transactions and to avoid the electronic "black hole" that can arise in their absence. Treating acknowledgements as a separate transaction and delaying their inclusion in operating rules leaves ambiguity in the exchange process and severely undermines the value of the operating rules while diminishing the ROI for all stakeholders, including the government.

Since CAQH CORE was established in 2005, acknowledgements have been a critical aspect of the CAQH CORE Phase I and II operating rules. As CMS itself recognizes in the IFC, "we have received anecdotal reports of wide-spread industry use of acknowledgements on a voluntary basis, and we understand that provisions for acknowledgements are contained in many health plans companion guides."¹⁴ Industry participants – including providers as well as health plans – view acknowledgements as *essential* to improve the end-to-end processing of transactions. Because of the industry's reliance on this information, the CORE participants have consistently included acknowledgements as a critical part of the CAQH CORE operating rules. Acknowledgements address a vital and basic, almost fundamental, business need – knowing with certainty whether a transaction is accepted or not. Because of the significant and widely recognized value of acknowledgements to the eligibility and claim status transactions, CAQH CORE very strongly recommends that the use of acknowledgements be retained as a requirement for the adopted operating rules for these transactions.

- C. *Operating rules are not limited to addressing only existing standards mandated under HIPAA.*

Congress did not limit the scope of operating rules under Section 1104 of the ACA to address only existing HIPAA-mandated standards. Rather, ACA Section 1104 amends HIPAA to permit the development of operating rules that meet common business needs for functions that HIPAA does not address – and it expressly requires the Secretary to adopt standards and operating rules that "provide for timely acknowledgement, response, and status reporting."¹⁵

Development of operating rules, including those for acknowledgements, is important because the industry relies on many non-HIPAA standards to support the daily exchange of the ten transactions required under HIPAA. For example, standards commonly utilized by trading partners include transmission standards such as Simple Object Access Protocol (SOAP), which have been included in the

¹⁴ 76 Fed. Reg. 40467 (July 8, 2011).

¹⁵ SSA § 1173(a)(4)(A)(iii), added by ACA § 1104(b)(2)(B).

Nationwide Health Information Network designed by the Office of the National Coordinator for Health Information Technology (ONC).

As outlined in Table 2 of the IFC, the critical criterion for an operating rule is that it supports – and is not in conflict with – an existing standard mandated under HIPAA. There is no conflict between the CAQH CORE operating rules related to acknowledgments with an existing HIPAA standard, and standards that are not mandated by HIPAA.¹⁶ Operating rules that include acknowledgements fit squarely within the statutory definition of operating rules because they support and fill gaps in the *existing* 270/271 eligibility standard and the 276/277 claim status standard. Operating rules that incorporate acknowledgements enable even greater and more rapid adoption of HIPAA transactions. This is precisely consistent with the goals of administrative simplification and well within the statutory definition of operating rules.

D. CMS need not, and should not, wait to adopt acknowledgements as a HIPAA transaction before adopting operating rules that incorporate acknowledgements.

There is no legal requirement, statutory or otherwise, providing that a standard transaction must be mandated under HIPAA before an adopted set of operating rules may address the same matter. For example, nothing in HIPAA or the ACA states or indicates that an acknowledgements standard would have to be mandated under HIPAA before a set of operating rules for eligibility transactions may include requirements for acknowledgements. As such, the fact that CMS may intend to formally adopt acknowledgements as a HIPAA-adopted standard in the future does not prohibit the Agency from mandating the use of acknowledgements *now* in operating rules for existing HIPAA standards.

Moreover, the Administrative Procedures Act (APA) does not pose an impediment or require a different result. Acknowledgements may be adopted by the Secretary as operating rules and then as a standard, assuming APA requirements are met with respect to each. The Secretary has the authority to adopt acknowledgements for eligibility and claim status now as HIPAA mandated operating rules, on the basis that acknowledgements are currently missing from HIPAA mandated standards and are needed now to promote administrative simplification. Pursuant to the language added through the ACA, APA requirements are satisfied where the operating rule adopted by the Secretary is adopted through an interim final rule.¹⁷ If and when a HIPAA mandated standard is adopted requiring the use of a particular

¹⁶ Currently, HHS has not adopted a HIPAA standard for acknowledgements. See https://questions.cms.hhs.gov/app/answers/detail/a_id/10159/kw/acknowledgements (last visited Aug. 31, 2011). (cont'd) Even if acknowledgements were interpreted as a HIPAA-mandated standard, which it is not per CMS, there would be no conflict because covered entities could comply with both CAQH CORE rules incorporating acknowledgements and the guide for these standards.

¹⁷ ACA added a new subsection (g) to section 1173 of the Social Security Act, regarding the adoption of operating rules. Within that section is a requirement for “Expedited Rulemaking”—which states: “The Secretary shall promulgate an interim final rule by applying any standard or operating rule recommended by the National Committee on Vital and Health Statistics pursuant to paragraph (3). The Secretary shall accept and consider public comments on any interim final rule published under this subparagraph for 60 days after the date of such publication.” SSA § 1173(g)(4)(C), added by ACA § 1104(b)(2)(C). Although there is a preference for full notice and comment under the APA, adoption through an interim final rule is appropriate where, as here, Congress has expressly required an interim final rulemaking process in the statute delegating authority to the agency. See Jeffrey S. Lubbers, *A Guide to Federal Agency Rulemaking*, at 14, 4th ed. (American Bar Association 2006). Typically, interim final rules require a comment period following issuance of the interim final rule, after which a final rule may but need not make modifications to the interim final rule. See, e.g., “The Reg Map” at <http://www.reginfo.gov/public/reginfo/Regmap/regmap.pdf> (last visited Aug. 31, 2011).

acknowledgement, the operating rules would be revised to delete this element of the rules. This is because fundamentally, operating rules do not repeat what is in the standard or conflict with it.¹⁸

Some have suggested that the rationale behind the CMS decision to not mandate acknowledgements in the IFC is a concern that the Agency may not adopt operating rules related to a transaction before adopting a standard format for the transaction under HIPAA. First, we believe this view incorrectly states the issue. The issue is *not* whether CMS may adopt mandatory operating rules for a transaction before a HIPAA standard is adopted for the transaction, since operating rules are not being proposed for any acknowledgement transaction. Rather, they have been used in existing operating rules and were recommended to support the 270/271 eligibility and the 276/277 claim status transactions. Thus, the issue is whether CMS may adopt a standardized method for communicating receipt of a HIPAA-mandated standard transaction as part of a set of operating rules adopted to facilitate that HIPAA-mandated standard transaction. We believe that the clear answer to that question is that, yes, CMS may adopt a standardized method for communicating receipt (i.e., an acknowledgement) as a mandated operating rule for the purpose of facilitating the same existing HIPAA standard for eligibility and the existing HIPAA standard for claim status.

Second, if CMS believes that non-HIPAA standards must be adopted under HIPAA in order to meet the requirements of either HIPAA and/or the ACA, CMS should clarify its rationale, so that the industry may understand the Agency's reasoning and comment on it before final regulations are put into place. If there is no time limitation when acknowledgements are implemented under the ACA and HIPAA, and CMS chooses to officially designate acknowledgments as HIPAA standards, then CMS should outline to both the public and private sectors the rationale for the lost ROI while this delay is taking place.

In light of all of the above, we urge that CMS revise the IFC to keep intact the full set of CAQH CORE Phase I and II Operating Rules, including acknowledgements. These components of the rules are fully consistent with the statutory definition and scope of operating rules under the ACA Section 1104.

¹⁸ While not directly the subject of this comment letter, we question whether it makes sense for HHS to adopt a standard under HIPAA for acknowledgements. The HIPAA statute authorizes the Secretary to adopt standards for "financial and administrative transactions", which under current law include the following:

- (A) Health claims or equivalent encounter information.
- (B) Health claims attachments.
- (C) Enrollment and disenrollment in a health plan.
- (D) Eligibility for a health plan.
- (E) Health care payment and remittance advice.
- (F) Health plan premium payments.
- (G) First report of injury.
- (H) Health claim status.
- (I) Referral certification and authorization.
- (J) Electronic funds transfers.

In keeping with the Social Security Act § 1173(a)(1)–(2) as amended by the ACA § 1104(b)(2) (adding electronic funds transfers) all of the above transactions are financial or administrative in nature. Acknowledgements, on the other hand, simply communicate that a transaction has been received. In this way, acknowledgements seem in some ways qualitatively different than the transactions currently mandated under HIPAA. Specifically, acknowledgements do not appear to constitute a "financial" or "administrative" transaction but, rather, are a communication that *facilitates* a financial or administrative transaction.

III. CMS should formally name CAQH CORE as the operating rule authoring entity.
(Reference IFC Section II.C)

The IFC should be amended to formally name CAQH CORE as the operating rule authoring entity for the 270/271 eligibility and claim status transactions. Further, we recommend that CAQH CORE be named as the single operating rule authoring entity for all HIPAA-mandated transactions. In that capacity, CAQH CORE will further its collaboration with operating rule authoring entities in other industries, including NACHA for banking, as well as the relevant standard setting bodies. Having CAQH CORE as the primary, formally named operating rule authoring entity for the full suite of HIPAA transactions will prevent market confusion; eliminate burden to providers, health plans and other stakeholders in negotiating among multiple entities and their separate processes; prevent duplication of efforts and associated costs; and maximize efficiencies.

Operating rules offer the greatest value when they build upon each other, thus providing the industry with direction on where to expend its efforts towards that goal. In order to achieve the goals of administrative simplification as reflected in the ACA, the industry needs predictability, as well as a single focal point for developing iterative, consensus-based improvements to ensure that ROI is fully achieved. A single operating rule authoring entity enables a phased-in approach to rule development that consistently focuses and builds on existing operating rules, promotes national operating rules, and facilitates sharing of best practices. In addition to providing the optimal approach for maximizing efficiencies, this approach is also fully feasible to implement in practice. For example, during the development of the operating rules for Electronic Funds Transfer (EFT) and Electronic Remittance Advice (ERA) operating rules, CAQH CORE has solidly demonstrated the ability to collaborate successfully with other groups, such as NACHA.

IV. CMS should clarify the relationship of the adopted operating rules to retail pharmacy and business associates. (Reference IFC Sections II.C and II.D)

The IFC repeatedly speaks to the scope of the adopted operating rules as those pertaining to “non-retail pharmacy.” We urge clarification from CMS on this point, because retail pharmacy uses ASC X12 HIPAA-adopted transactions and standards in some instances. For example, retail pharmacy is using the ASC X12 270/271 for durable medical equipment (DME), and the e-prescribing process begins with the 270 to determine drug benefit eligibility and coverage. These interdependencies have also been recognized when writing CORE operating rules for other transactions; for example, the draft CAQH CORE Uniform Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes (835) Rule was created to address crossover issues with the use of the ASC X12 835 standard by pharmacy. Put another way, the Final Rule should clarify that the Secretary’s adopted operating rules for ASC X12 HIPAA-adopted transactions and standards apply to retail pharmacy in those cases where retail pharmacies engage in such transactions, with the exception that if retail pharmacy does not have a gap in its application of these standards or has market implemented, pre-existing business rules, then application to or coordination with retail pharmacy is not needed. In this exception instance, CMS may decide that operating rules do not apply to retail pharmacy. We encourage CMS to consider addressing the scope of operating rules as applied to retail pharmacy in the final rule.

We also urge CMS to clarify in the final rule the applicability of the adopted operating rules to business associates. Specifically, CMS should clarify that business associates that engage in HIPAA standard transactions on behalf of covered entities, such as clearinghouses, must comply with the HIPAA-

mandated standard format and operating rules.¹⁹ Our understanding is that the adopted operating rules would apply to all HIPAA covered entities and their business associates because of the way in which the ACA amends the HIPAA statute. We believe this point needs clarification due to the considerable confusion that exists regarding business associates' obligations in general, and, in particular, how these obligations would intersect with the adopted operating rules.

V. CAQH CORE urges CMS to continue to recognize voluntary certification for health plans, vendors/clearinghouses, and large providers, as exemplified by the CAQH CORE program.
(Reference IFC Section II.D.1.b)

NCVHS has recommended in two instances that CAQH CORE draft operating rules meeting the statutory definition of operating rules, which CAQH CORE has accomplished. Per the CORE process, the CAQH CORE rules do include language related to CAQH CORE certification, which the IFC reiterates is voluntary. Our understanding is that HIPAA covered entities, and business associates engaging in HIPAA standard transactions on behalf of covered entities, must comply with the CMS adopted operating rules under the ACA, whether or not they are certified by CAQH CORE or any other entity.

Although the purpose of this IFC is not to mandate CAQH CORE certification, it is also the case that the purpose of the ACA is not to limit voluntary efforts that are improving industry ROI. We strongly urge that CMS reiterate in the IFR that CAQH CORE certification is voluntary, and state that CMS, as soon as practical, will issue a statement on how compliance with the CMS adopted operating rules can be demonstrated.

Similar to operating rules, we note that standards contain elements that are not required, such as significant front matter and optional data elements. We encourage that CMS not be overly prescriptive, especially regarding items that are not within the scope of the IFC. CORE is a voluntary industry effort that is supporting administrative simplification and ROI in an open and transparent manner. As a non-profit effort, CORE has limited resources that are focused on maintaining an integrated model which has support from its voluntary participants.

Based on the ACA requirements and industry needs, we urge CMS to issue regulatory guidance on this topic, and to leverage the CAQH CORE experience, as appropriate. Voluntary CAQH CORE Certification for Phase I and II has demonstrated proven benefits for a wide variety of stakeholders. Monitoring of CAQH CORE certification processes has confirmed that the maximum ROI is achieved when all entities in the chain of data exchange follow the rules and have online access to easily assessable testing to verify their compliance. We urge CMS not to reduce the impact of the progress of voluntary efforts, but rather clarify in the IFC how Federal compliance will work. In the meantime, it will be important to retain the language on voluntary CAQH CORE certification procedures as part of the adopted rules, integrated in the language of the final regulations, rather than removing such language as some stakeholders have suggested. A "non-integrated" approach to rule-writing and certification is not advisable, as it divorces rule implementation from rule compliance. CMS should ensure that the CAQH CORE certification language remains part of the adopted rules, with a confirmed understanding that CORE certification procedures are voluntary. Entities must comply with the adopted rules, and the CAQH CORE certification language provides useful and relevant guidance that can assist entities with meeting their obligations under the adopted rules. Moving forward the government can continue to work

¹⁹ Under 45 C.F.R. § 162.923(c), covered entities are permitted to use business associates to conduct a HIPAA standard transaction, but they must require the business associate to comply with the HIPAA transaction and code set regulations. In this way, covered entities may not contract out of HIPAA standard transaction requirements.

on determining the formal procedures that ultimately will be mandatory for purposes of health plan certification as contemplated in Section 1104.

Moving beyond the scope of the IFC, certification and testing are two separate activities. In our view based on the CAQH CORE experience, if a testing approach is taken by CMS in the future, such testing should be administered through authorized testing entities. Additionally, testing for compliance by these authorized testing entities should occur independently from the process of assessing testing results to determine whether the entity has met all certification requirements and certifying the entity as compliant.

VI. As currently and appropriately articulated in the IFC, CMS should maintain the CAQH CORE Companion Guide Template as the single template. (Reference IFC Section II.D.1.c)

In 2003, CAQH and WEDI collaboratively developed a standard outline and flow template for companion guides. This template was widely distributed throughout the industry and adopted by many health plans for their ASC X12 v4010 implementation; plans have used it for their ASC v5010 implementation as well. It should be remembered that:

- The CORE Companion Guide was the only consensus-based companion guide available for review and consideration at the time of the creation of the CORE Phase I and Phase II operating rules, which occurred from 2005-2009.
- The CORE Companion Guide was the only consensus-based, CORE-approved, complete, and published companion guide that was available for review and consideration at the time when the CORE participants did a review of its rule at the request of NCVHS, when the Committee recommended the adoption of the CAQH CORE Phase I and Phase II rules for eligibility and claims status and potential enhancements, pursuant to a NCVHS letter issued in September 2010 to the HHS Secretary.

Because of its proven usefulness and the large number of health plans that have already adopted this format for their companion guides, CAQH CORE recommends that CMS retain this companion guide requirement as it is currently and appropriately articulated in the IFC. To do otherwise would be extremely disruptive to the industry and to the progress being made to have *one* common flow and format for companion guides. We ask that the Agency please consider the following items with regard to the CORE Companion Guide Rule:

- The ACA highlights that the purpose of operating rules is to reduce the proliferation of multiple and varied companion guides, and also outlines the qualifications of an entity to write such operating rules.
- Through the CORE Companion Guide Rule the CORE operating rules provide one flow and format for companion guides, while the other CORE rules ensure the varied content currently seen in companion guides is replaced by references to uniform, national operating rules and standards. Importantly, both the national operating rules and standards are publicly available and used by trading partners.
- Content or infrastructure requirements are *not* included in the CORE Companion Guide rule. Rather, the CORE participating organizations use the CORE operating rule process to research, debate and outline such detailed requirements. Then, based on this process, they write specific, national operating rules that are referenced throughout companion guides across the country. By taking this approach the industry is eliminating the variability, while ensuring that the detailed

requirements for national operating rules meet the ACA requirements and bring the industry value – one format and flow, one set of operating rules supporting recognized standards.

- The ACA mandates that the operating rule authoring entity be designated by HHS, and that one set of operating rules, developed by that authoring entity through a consensus-based process, be adopted and mandated under HIPAA for each standard transaction. The CORE Companion Guide was developed using this process, with an emphasis on a review and approval by the CAQH CORE consensus-based operating rule process, where public records are available on such items as quorums and voting.
- If certain entities want to go above and beyond the form and flow formats outlined in the CAQH CORE Companion Guide rule, stakeholders are welcome to do so to the extent that such formats do not conflict with any HIPAA-mandated requirements or other Federal mandate.

CAQH CORE understands that ASC X12 has suggested replacing the CORE Companion Guide rule with a document that ASC X12 has been developing with WEDI; or allowing the use of both the CORE rules and the ASC X12/WEDI document. Having two rules for flow and format is in direct conflict with the ACA Section 1104 goals of uniformity. Moreover, ACA expectations regarding items such as rule scope, impact, content, copyright, transparency, and approval processes have been fully supported by CORE and each of the CORE operating rules proposed in the IFR. Should operating rules achieve the goal to deliver administrative simplification and ROI, such operating rules must stay the course with regard to meeting well-vetted expectations.

In light of these points, we fully support the current IFC requirements and urge CMS to refrain from changing the position of the IFC with regard to companion guide requirements. The IFC reflects a set of approved operating rules, including the Companion Guide Rule. Moving forward, should the industry believe there is sufficient value in changing the current CORE Companion Guide Rule, CAQH CORE will use its open, quorum-based process to review potential updates, as appropriate, and as required by the ACA through the review and update process set forth in the statute. We note, however, that a recent priority survey completed by over 130 organizations – which included the ability to write-in new items – did not indicate that edits to the CORE Companion Guide Rule were a top priority. Instead, the priority was to expand the CORE work on the detailed content and infrastructure operating rules, such as the uniform use of CARCs/RARCs or access to more financial data.

VII. Clarification on voluntary efforts is warranted.

Many CAQH CORE participants and stakeholders believe that CMS should clarify the extent to which States, health plans, or any other entities may diverge from the ACA-mandated operating rules. Our thoughts and recommendations on this issue are as follows. We recommend that voluntary efforts be permitted, understanding that they must not be in conflict with, and must support, any nationally mandated operating rules. Therefore, entities may go above and beyond the adopted operating rules; however, there is no State preemption of the ACA requirements.

The statute provides that operating rules, once adopted by the Secretary, are mandatory. Specifically, subsection 1173(g) of the Social Security Act (SSA), added by the ACA, provides that the Secretary “shall adopt a *single set* of operating rules for each transaction” required under HIPAA, “with the goal of creating *as much uniformity* in the implementation of the electronic standards as possible.”²⁰ As demonstrated by this text, Congress had specific objectives when it passed the ACA Section 1104. Namely, this provision addresses the issue that variability in operating rules among different plans and

²⁰ SSA § 1173(g)(1), added by ACA § 1104(b)(2)(C) (emphasis added).

other entities can be a roadblock to uniform adoption and implementation of the HIPAA standard electronic transactions. Ongoing variation by states or regions could continue such challenges.

Despite this emphasis on uniformity and comprehensiveness, however, the ACA does appear to provide some room for voluntary efforts that go above and beyond the adopted federal rules. Importantly, the statute does not expressly prohibit voluntary efforts to establish operating rules requirements beyond the adopted operating rules mandated under HIPAA. Further reflecting this theme, the terms of the IFC provisions prohibit independent, voluntary efforts to implement separate sets of operating rules. Specifically, the IFC amends the “trading partner agreements” regulation, 45 C.F.R. § 160.915, to specify that trading partners may not modify or vary any standard *or operating rule* adopted by the Secretary.²¹ Under this provision as amended by the IFC, trading partners, which necessarily must include entities such as plans, providers, and the States, “must not” impose requirements that vary or modify a HIPAA-adopted standard *or operating rule*. This effectively prohibits entities from taking different approaches to operating rules if such efforts would “vary or modify” an adopted standard or adopted operating rule. We read this provision to permit voluntary efforts as long as they do not conflict with the ACA-mandated standards or operating rules.

For these reasons, we encourage the Agency to be clear that, if national, regional, or local efforts go above and beyond the mandates to improve upon the goals of the operating rules (e.g., more data, faster response time), it is assumed that adoption of the national mandates has occurred, and that such adoption must be recognized by any other efforts. As the ACA is a federal law, any contrary State requirements would be pre-empted as a matter of law. At the same time, we urge CMS to encourage States to participate in the rule-authoring processes led by CAQH CORE, so that their input regarding “best practices” can be considered at the earliest opportunity. Success with operating rules adopted under HIPAA will require change by all stakeholders, not only now, but also well beyond the ACA deadlines. We therefore encourage the Agency to communicate that States should aim to work with national efforts in order to drive the full ROI and administrative simplification envisioned by the ACA.

VIII. If CMS issues any modifications to, or clarifications of, the IFC, CAQH CORE encourages the Agency to issue any such modifications or clarifications promptly and, in any event, by no later than January 1, 2012. (Reference IFC Section III)

Prompt notification of any modifications or clarifications to the IFC is necessary in order to provide sufficient time prior to the compliance date—January 1, 2013—for the industry to coordinate implementation of the rules as required under the IFC. The IFC notes that, if the Agency receives comments that lead to the revision of the IFC, such changes will be finalized by January 1, 2012, based on the compliance date of January 1, 2013. We urge the Agency, if at all possible, to finalize these regulations *prior to* January 1, 2012, for two key reasons: (1) so that health plans, vendors/clearinghouses, and providers can coordinate implementation of the rules with their HIPAA Version 5010 updates in order to reduce costs; and (2) so that best practices can be shared through

²¹ 76 Fed. Reg. 40495 (July 8, 2011) (emphasis added) (amending 45 C.F.R. § 162.915(a)). As amended by the IFC, the trading partner agreements provision states as follows, with the language added by the IFC shown in italics: A covered entity must not enter into a trading partner agreement that would do any of the following:

- (a) Change the definition, data condition, or use of a data element or segment in a standard, *or operating rule, except where necessary to implement State or Federal law, or to protect against fraud and abuse.*
- (b) Add any data elements or segments to the maximum defined data set.
- (c) Use any code or data elements that are either marked “not used” in the standard's implementation specification or are not in the standard's implementation specification(s).
- (d) Change the meaning or intent of the standard's implementation specification(s).

coordinated industry and stakeholder activities, such as educational sessions. As suggested in this comment letter, we urge the Agency to consider limited modifications to the IFC—specifically, we encourage CMS to modify the IFC to include operating rules requirements for acknowledgements, and to clarify the formal role of CAQH CORE as an operating rule authoring entity.

IX. Address technical corrections and clarifications with CAQH CORE.

A. We encourage CMS to correct the link to the HIPAA Version 5010 update of the CAQH CORE Phase I and II operating rules as it appears in the IFC. Specifically page 40464 of the IFC states: “Both the CAQH CORE Phase I and Phase II operating rules (updated for Version 5010) that we are adopting in this interim final rule with comment period can be found on the CAQH CORE Web site at <http://www.caqh.org/COREVersion5010.php>.” The link should be corrected to instead be: <http://www.caqh.org/COREv5010.php>.

B. CMS should clarify the applicability of batch transactions to the adopted operating rules for eligibility and claim status transactions. Under the ACA, all payers that process batch transactions must follow the ACA-adopted operating rules for real-time and batch processing. Should an entity not offer batch processing, it is not required to begin to offer it; however, real-time processing must be offered.

C. We look forward to working with CMS on a review of any questions they may have on the CAQH CORE Phase I and II rules due to IFC comments. We note that CMS utilizes a similar process in other rulemaking, where authors are asked to address technical questions concerning their respective work products included in federal regulations.

* * *

Thank you for considering our comments. We reaffirm our strong commitment to an active, open process that ensures communication among industry stakeholders, as well as between authoring entities and standards development organizations. We greatly appreciate this opportunity to comment on the IFC, and look forward to continuing to work with the Agency, NCVHS, and other industry stakeholders to advance the vitally important goals of health care administrative simplification.

Sincerely,



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