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August 18, 2010

National Committee on Vital and Health Statistics
Subcommittee on Standards
c/o Lorraine T. Doo, MSWA, MPH
Committee Lead Staff and Senior Advisor
Centers for Medicare and Medicaid Services
Office of E-Health Standard and Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Comments on July 20-21 Hearing on Operating Rules for HIPAA Transactions

Ladies and Gentlemen of the Subcommittee:

The purpose of this letter is to comment on the contents and comments made during the Subcommittee hearings of July 20 and July 21, 2010, and the legislation that served as the basis for this hearing. AHIMA's desire is for the Subcommittee to consider the comments in this letter as recommendations to be presented to the Secretary of Health and Human Services.

The American Health Information Management Association (AHIMA) is a nonprofit professional association whose membership is made up of over 59,000 professionals involved in the management of health information. Among the many functions health information management (HIM) professionals engage in is the identification of data from the health record that is used in the HIPAA transactions and assurance of its integrity. With this interest, AHIMA was engaged in transaction standards development organizations' initiatives to develop the Accredited Standards Committee X12 transaction standards used by most health professionals as well as various terminology and classifications organizations including the ICD-9-CM Coordination and Maintenance Committee and the CPT® Editorial Advisory Board that set the standard and guidelines for the diagnostic and procedural classification codes used in the HIPAA transactions. AHIMA's goal in working among these standards groups is to ensure accurate and correct identification of the services or procedures provided and the diagnoses involved in the individual's care – the information in the transaction must accurately reflect the information in the source health record.

AHIMA's recommendations can be summarized as follows:

- **To align with the requirements from Congress under Section 1104 of Public Law 111-148, AHIMA proposes that NCVHS recommend only one organization be selected as the “nonprofit entity” to be established for all transaction guides. We further urge the NCVHS and the Secretary to appoint the CAQH/CORE to this position.**

- **HHS and the NCVHS should undertake an initiative to provide the processes and regulations necessary to achieve an on-going and regular update of HIPAA standards including Secretarial approval as called for under HIPAA and PPACA.**
- **NCVHS should acknowledge the gap between operating rules and the “current” standards and work with the “nonprofit entity” to develop uniform operating rules that achieve closure of this gap as well as updated HIPAA transaction standards (versions) as needed.**
- ***In choosing a single “nonprofit entity” to develop the operating rules for all of the HIPAA transactions, the entity should be permitted to engage additional entities, as needed, for a particular standard.***
- ***The NCVHS and its designated “nonprofit entity” should include in its determination of operating rules acknowledgement and compliance with the requirements healthcare entities must apply to shared clinical data for various population health purposes.***
- ***The NCVHS and the Secretary should also require the designated “nonprofit entity” to consider business rules for the common use of additional transactions standards that support the HIPAA designated transactions use.***
- ***At this point in time, AHIMA recommends that the Subcommittee not require ANSI accreditation of the designated “nonprofit entity.”***

An explanation of AHIMA’s comments follows:

HIPAA has not supported Administrative Simplification

Since the law was passed in 1996, the HIPAA process has not supported uniformity and data integrity. While transaction standards and implementation guides have been adopted the manner in which the standards have been used has varied considerably, not only failing to achieve administrative simplification but also negatively impacting data integrity. For example, in testimony to the Subcommittee’s predecessor in 2007 WEDI reported that it had identified over 1200 guides for the use of the X12 – 837 claims transaction. Our members’ reports echo that statement and the guides come from a variety of health plans including Medicare and Medicaid.

If the guides were merely to provide information related to identifiers – where to send the claim and so forth – there would be no problem, but many of these guides require modification of clinical coding standards and other rules that have been established. This is not the intent of standards use within the healthcare industry, or any industry. HIPAA established the NCVHS as the body to determine how the standards should be used and we are pleased that we are finally getting to such a state some 13 years later.

Public Law 111-148

In the interest of transparency, AHIMA was one of several organizations that pushed for legislation to address HIPAA operating guidelines and processes in the Patient Protection and Accountable Care Act (PPACA or P.L. 111-148). This effort culminated a six year campaign to streamline the HIPAA process so the industry never again had to face the kinds of decisions to upgrade HIPAA transaction standards and classification standards as we have seen over the last decade.

We note the following statements in P.L. 111-148 (with some emphasis added):

- §1104. Administrative Simplification
 - “(b) Operating Rules for Health Information Transactions (1) Definition of Operating Rules – Section 1171 of the Social Security Act (42 U.S.C. 1320d) is amended by adding at the end of the following:
 - (9) Operating Rules – The term ‘operating rules’ means the necessary **business rules and guidelines for the electronic exchange of information** that are not defined by a standard or its implementation specifications as adopted for purposes of this part”.
 - (g) Operating Rules. –
 - “(1) In General – The Secretary shall adopt a single set of operating rules for each transaction referred to under subsection (a)(1) with the **goal of creating as much uniformity in the implementation [use?] of the electronic standards as possible**. Such operating rules shall be consensus-based and reflect the necessary business rules affecting health plans and health care providers [consumers?] and the manner in which they operate pursuant to standards issued under Health Insurance Portability and Accountability Act of 1996.”
 - (2) Operating Rules Development – In adopting operating rules under this section, **the Secretary shall consider recommendations for operating rules develop by a qualified nonprofit entity** that meets the following requirements:
 - “(A) The entity focuses its mission on administrative simplification.”
 - “(B) The entity demonstrates a multi-stakeholder and consensus-based process for development of operating rules, including representation by or participation from health plans, health care providers, vendors, relevant Federal agencies, and other standard development organizations.”
 - “(C) The entity has a public set of guiding principles that ensure the operating rules and process are open and transparent, and supports nondiscrimination and conflict of interest, policies that demonstrate a commitment to open, fair, and nondiscriminatory practices.”
 - “(D) The entity builds on the transaction standards issued under Health Insurance Portability and Accountability Act of 1996.”
 - “(E) The entity allows for public review and updates of the operating rules.”

We also want to point out that in §1104 (g) (3) Review and Recommendations it notes that the NCVHS must:

- “(A) Advise the Secretary as to whether **a nonprofit entity** meets the requirements under paragraph (2);”
- “(B) Review the operating rules developed and recommended by such nonprofit entity;”

A single entity must be chosen to author the Administrative Simplification Operating Rules

One of our purposes for repeating the legislative language above is to illustrate our belief and interpretation that Congress meant for one “nonprofit entity” to serve as the author of all the operating rules. Our belief comes from, first our involvement with the Congressional staff that put this language together for the legislation and, second from our interaction with other industries that set the guidelines in their respective industries.

Standards do not stand alone. Standards are used in combinations, and information or data exchanges are carried through various transaction standards including transaction standards that are not considered HIPAA standards. In fact, as was pointed out in the hearing, there are a number of standards being used in healthcare beyond the HIPAA transaction standards, which make the HIPAA transaction standards work. How these standards are used in combination with the HIPAA transaction standards must be considered in this guide process that NCVHS is constructing. In addition, and as an example, the link between claim status and the claim transactions show how the standards and the functions are interactive and require a continuous view to maintain continuity and uniformity.

Having potentially a different “nonprofit entity” for each HIPAA transaction or function will create significant duplicative costs as well as import a lack of conformity and uniformity in the operating guides. *AHIMA proposes that NCVHS recommend only one organization be selected as the “nonprofit entity” as required under Section 1104 of Public Law 111-148.*

Operating Rules v Guides v Implementation Guide

The difference between operating rules or a single guideline versus the implementation guides was clarified in the testimony. AHIMA agrees the difference must be clear as both have a purpose. It must be recognized; however, the lack of clarity, to date, comes from the HIPAA processes that have been established over the last 14 years, and the intent of PL 111-148 was to achieve clarity. In the process of setting billing rules it is often found that the standards need to be modified. Were the HIPAA designated transaction standards easy to update the SDOs would make the necessary changes or upgrades (suggested by the industry) in a regular cycle and the problem could be resolved. In the case of healthcare; however, no changes could be made to the standards because of the HIPAA rule.

Unfortunately, this static situation called for a variety of “modifications” that took place not only in the example of the CORE project, but in the case of the many of the hundreds of provider guides required by health plans.

It is important to note that PL 111-148 provides for the more timely upgrading of the HIPAA designated transaction standards **and AHIMA recommends that HHS and the NCVHS undertake an initiative to provide the processes and regulations necessary to achieve the on-going and regular updating of the HIPAA standards which includes Secretarial approval.** The healthcare industry will already be behind on its versioning of the HIPAA standards when the 5010 version comes into compliance on January 1, 2012. The closer the version can become

between HIPAA and the SDO and the closer the national uniform operations guide can become to the current standards the better off the industry will be.

This change in processes and catching up on versions will take time and the industry will have the advantage of at least having one national uniform operations guide for the standards which can convey a single use of the standards versus variable guides in the hundreds we have today. While using the operating guide in place of a standards modification to address a current problem is not appropriate, in the current environment the industry is better served to have a single guide to handle the issue than hundreds. ***AHIMA recommends that NCVHS acknowledge the gap between operating rules and the “current” standards and collaborate with the “nonprofit entity” to develop any uniform operating rules that work to close this gap.***

Health Plan Guide Certification

It was suggested by some that perhaps we could have a certification of the individual health plan guides that exist today. ***AHIMA believes that such certification of individual health plan guides would take an inordinate amount of time – especially as any guide needs to be updated on a regular basis – and would also be expensive to the industry.*** The NCVHS and the Subcommittee are better suited for approval of one guide for each of the standards than maintaining multiple guides for each. Health plans will need to post information that is needed to exchange health information via the HIPAA transactions, but such information should not conflict with any of the standards in the transaction or with the operating rules. The Subcommittee should determine whether such health plan information is better kept in a single national directory [which would imply some oversight of the directory (previously called a health plan guide)] or allow this information to be one-on-one between health plans and healthcare providers.

Developers/Authors of the HIPAA Operating Rules

There was some discussion in the hearing about the fact that there are multiple organizations that could be included in the development of operating rules. In fact we heard from both CAQH and NCPDP that they had worked with each other and with others to develop such rules in the past. ***AHIMA recommends that a single “nonprofit entity” be chosen to develop the operating rules for all of the HIPAA transactions and that this entity be permitted to include other similar entities as needed for a particular standard.*** Clearly cases in point would be NACHA and NCPDP for a certain number of the standards. It must also be understood that the operating rules body would, as the legislation requires, include the affected SDOs.

Other Issues

Three other items were raised that we would like to address. First is the interplay between administrative and clinic data in healthcare. As anticipated we are seeing the interface between clinical and administrative data being addressed quite frequently. CMS has already announced that it will be accepting all of the ICD-9-CM codes a provider has for an encounter/admission once the 5010 changeover occurs (1/1/2012). The CMS EHR Incentive Program “Meaningful Use” proposed rule also included clinical data and administrative transactions. While not in the final rule, OESS has certainly indicated that these transactions will be covered in Stage 2 of

Meaningful Use. We understand that the introduction of SNOMED-CT® in Stage 2 will impact an organization's classification diagnostic coding, and it is clear from the requirements that providers also must make data available for secondary uses for public health, syndromic surveillance, and other uses, which will touch on the classification codes also used in our HIPAA transactions. ***AHIMA recommends that the NCVHS and its designated "nonprofit entity" include in its determination of operating rules acknowledgement and compliance with the requirements healthcare entities must apply to shared clinical data for various population health purposes.***

Operating rules cannot impact the integrity of the classification codes in the HIPAA transactions, nor can the classification codes used for one function or report differ for another function or report whether or not they are related to the same type of use (e.g., reimbursement/claims). AHIMA has on other occasions, pointed out its concern that the health plan guide in many cases causes healthcare providers to modify codes or structure groups of such codes for the reimbursement purposes of the health plan without recognizing that this same health plan may be using these codes to populate a personal health record product offered to individuals. Data integrity has always been a requirement of the NCVHS and we hope it will continue to provide oversight of this concern.

- As noted above there is a second issue that has to deal with necessary transactions that were not identified in the original HIPAA legislation or by the Secretary as provided in the HIPAA Act. These transactions are used to allow the receiver and sender to acknowledge the sending or receipt of a transmission or other such information. Since the process surrounding the use of the HIPAA transactions relies on these standards as well, ***AHIMA recommends that the NCVHS and the Secretary also require the designated "nonprofit entity" to consider business rules for the common use of additional transactions standards that support the HIPAA designated transactions .***

A third issue is the rules or processes under which the entity itself will develop the operating rules. The Subcommittee is right to insist on knowing the operating rules of the organization and to suggest modifications that will allow the designated "nonprofit entity" to comply with the PL 111-148 legislation. However, it was suggested that CAQH consider applying for ANSI accreditation. Being deeply involved with the issue of accreditation AHIMA is aware that to go through such an accreditation process would add significant time to CAQH's ability to qualify as the designated "nonprofit entity." Further we believe that CAQH's success with the CORE project along with its testimony in the hearing demonstrates its capacity to function as the legislation requires and abide by the requirements of the Secretary. Concern was also raised concerning CAQH's phase process. While we understand the phase concept CAQH has used, we don't believe it precludes CAQH using a process more in line with the requirements of the legislation. ***At this point in time, AHIMA recommends that the Subcommittee not require ANSI accreditation of the designated "nonprofit entity."***

Designation of a Recommended "Nonprofit Entity" to the Secretary

As the hearing continued it became clear that two organizations were identified as candidates to be the "nonprofit entity" called for in the legislation – NCPDP and CAQH/CORE.

AHIMA appreciates and respects the wonderful work and distinguished service that NCPDP has provided the healthcare industry and its guiding role in the Designated Standards Maintenance Organization (DSMO). We understand that in a subsector of the industry – pharmacy – both standards and guides can be written and agreed to because the number of major parties involved in these decisions is low. We fully expect that the NCPDP guides most likely will be further adopted as national guides once the process under discussion is complete.

AHIMA does not believe, however, that NCPDP has the ability to take on the entire healthcare industry and its diverse set of players as the operations rule body. In fact it appeared in the hearing that this role was being thrust on the NCPDP by the DSMO members who may be concerned about DSMO's future status once the operating rule process is adopted. If the NCPDP were to take up this new role it would have to make significant changes to its structure and bylaws to entertain membership from the industry.

AHIMA supports the petition by CAQH/Core to become the designated “nonprofit entity” for all of the operating rules for the HIPAA related transaction standard as defined in Section 1104 of PL 111-148, and we call on the Subcommittee and the NCVHS to make such a recommendation to the Secretary. AHIMA is not a member of CAQH or the CORE project (or the NCPDP for that matter), but we have worked with CAQH on issues related to administrative simplification and have found their approach and process to be most acceptable. AHIMA has endorsed CORE. We believe CAQH's petition to become the designated entity with the accompanying changes in their organization points to their stipulated desire to establish administrative simplification.

As pointed out in the hearing, CAQH originated under health plans. Health plans are the customer for administrative health information in our industry, and it is appropriate that they have some say in how such information is to be defined for HIPAA transactions. The difference at this point in time is achieving uniformity of the operating guides which does not exist at present. At the same time CAQH has rightly engaged healthcare providers, and SDOs, and others to achieve industry consensus. Isn't this what we are all trying to achieve including PL 111-148?

AHIMA welcomes the opportunity to comment on the current requirement under consideration by the Subcommittee and the comments made in the July hearings. One of HIM profession's long term goals has been the uniform definition, integrity and use of healthcare data and information. We supported the HIPAA legislation and its attempt to achieve such uniformity and we support the revisions PPACA has brought forth to bring us closer to these goals. AHIMA also appreciates the endless hours and work that have gone into the ASC X12N and NCPDP to develop the standards and the implementation guides for the HIPAA transactions. We hope to see the day when the work of these bodies will support the industry's use of current transactions and not lag behind in versions.

It is time that we take the necessary steps toward our administrative simplification goals and adopt uniform operating guides used in our healthcare transactions and functions. AHIMA urges the NCVHS to recommend for appointment one “nonprofit entity” to facilitate the development

of these operating guides for approval by NCVHS and the Secretary, and we urge the NCVHS and the Secretary to appoint the CAQH to this position.

AHIMA looks forward to participating in the development of these operating guides as needed and in an accelerated fashion to meet the demands being made of the industry. In the meantime, if there are any questions regarding the recommendations and statements made in the letter, please feel free to contact me at the number or address above or at dan.rode@ahima.org, or in my absence Allison Viola, MBA, RHIA, AHIMA's director for federal relations at the same contact or at allison.viola@ahima.org.

We thank you for your time and consideration of these comments and recommendations.

Sincerely,

A handwritten signature in blue ink that reads "Dan Rode". The signature is written in a cursive style with a large initial "D" and a long, sweeping underline.

Dan Rode, MBA, CHPS, FHFMA
Vice President, Policy and Government Relations

cc. Allison Viola, AHIMA