wedi ™ *Partnering for Electronic Delivery of Information in Healthcare*

Statement To

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS

SUBCOMMITTEE ON STANDARDS

REGARDING: MAINTENANCE OF STANDARDS AND OPERATING RULES

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Members of the Subcommittee, I am Jim Daley, Chair-elect of the Workgroup for Electronic Data Interchange (WEDI) and Director, IS Risk & Compliance at BlueCross BlueShield of South Carolina. I would like to thank you for the opportunity to present testimony today on behalf of WEDI concerning the matter of standards and operating rules maintenance.

WEDI represents a broad industry perspective of providers, clearinghouses, payers, vendors and other public and private organizations that partner together to collaborate on industry issues. WEDI is named as an advisor to HHS under the HIPAA regulation and we take an objective approach to resolving issues.

BACKGROUND

WEDI has previously provided testimony on this topic in July 2010 and April 2011. Some of the following testimony has been drawn from those statements in order to respond to the specific questions posed to this panel. In response to these specific questions WEDI offers the following perspectives.

1. What is the value of the current maintenance process for standards? What are the pitfalls?
   - Openness: The value of the current process lies in its policy of open participation. Any organization or individual with interest has the ability to participate in development of the standards. There are processes in place to accept requests for standards changes and processes to review these requests for prioritization and applicability. However, participation is limited to those who have the time and funding necessary to participate. This can limit participation by smaller organizations and individual physicians. Public comment periods are relatively short and many impacted parties may not even be aware of upcoming proposed changes. For those who haven't participated in the standard development, it is difficult to analyze proposed changes and fully assess the impact to their organization. It also leaves little time to note any potential gaps in the new version. Enhanced external communication during development of standards may be helpful in this regard.
   - Timing: The development and adoption of a new version of a standard can take several years. While this is valuable to assure the new version meets the needs of the industry and does not create unintended difficulties, it also limits the ability to quickly respond to new industry needs. The timing of development, publication and adoption is not in synchronization. For example, the ASC X12 4010 version was implemented in 2003, the 4050 version was published but not adopted, the 5010 version will be implemented in January 2012, but the 6020 public comment period will commence before 5010 is in production. This leads to two concerns. First, some versions may never be adopted; therefore time spent participating in development and assessing impacts of these may not be well spent for organizations with limited resources. Second, a subsequent version may be finalized before fully understanding issues or limitations associated with the previous version.
   - Adoption: Timeframes for publication and adoption of new versions of standards are unpredictable. Some standards versions may not be adopted. Others may be adopted, but at varying intervals. The requirement in the ACA to review standards every two years may help in this regard, but it does not guarantee that a newer version would be adopted at that time. Therefore, organizations are less able to predict

workloads and plan for allocation of resources. It is not evident when new industry needs would be supported by an adopted version.

- Testing: New versions of standards are often untested before adoption. Therefore, gaps or unintended issues are not identified until after a regulation has been issued mandating adoption and often not until after implementation.

2. What would industry say about the effectiveness of the current process?
   - Participation: Due to factors described above, public participation is not equal. This leads to standards that reflect the needs of larger organizations and can lead to standards that may not adequately consider the needs of individual physicians or small provider offices.
   - Communication: Up to this point, communication between some standards development organizations and operating rules entities has been limited. There is need for increased ongoing communication such that standards and operating rules are developed in harmony.
   - Multiple implementations: The current implementation of the ASC X12 5010 version has led to multiple implementation efforts. The first was the requirement to implement 5010 as specified in the Technical Report Type 3 (implementation guide). The next will be the requirement to implement changes needed to comply with operating rules for eligibility and claim status transactions. This will be followed by additional implementations for operating rules for other transactions. These multiple implementations each consume resources for development and testing and can lead to throw-away efforts as some work may have to be redone to accommodate the differences the operating rules necessitate versus those implemented for the base version of the standard. It is understood that the current state of the standards processes did not allow for concurrent adoption, but for future standards versions better alignment would allow organizations to work toward a single target set of implementation requirements.
   - References: Implementation requirements are in multiple locations and sometimes each location contains additional references. For example, the ASC X12 standard itself is supplemented by the implementation specifications contained in the TR3. Although, TR2 operating rule information is being developed, it may not be part of any adopted requirement. The TR3 contains front matter that is pertinent to transaction usage and contains external code set references that become part of the standard. The CAQH CORE operating rules contain references to prior versions of the rulesas well as to other associated rules that are part of the operating rule. Therefore, it requires significant understanding and research to fully gather the complete implementation requirements.

3. What are your suggestions for how the maintenance process should work for operating rules?
   - Definition: First and foremost there is need for clear definition of what is a standard versus what is an operating rule. This is important for two

reasons – first to avoid duplication of effort or potential conflicting information, and second to provide clear direction of where requests for changes or clarification should be directed. Furthermore, it must be clear that the operating rule cannot address data content or the rules around content usage.

- Alignment: To the extent possible, operating rules should be developed in conjunction with standards and should be harmonized such that the rule supplements the standard as opposed to attempting to 'fix' shortcomings in the standard. Such alignment would facilitate organizations working toward a single set of implementation requirements at a common compliance deadline.
- Emergency changes: Despite the checks and balances that exist in the current processes, there may still be need for corrections or adjustments that were not identified prior to implementation. It does not seem efficient to wait potentially for several years for such items to be rectified. Establishing an expedited modification and adoption process for such 'emergency' changes would be beneficial.
- Public participation: It is essential to assure public participation in the process continues. If the process becomes too closed, the resulting products would most likely not meet the full set of industry needs and would increase the likelihood of emergency fixes being needed. It is also essential that the process clearly distinguish between what might be mandated versus voluntary additional certification aspects. Blending basic operating rules with voluntary capabilities would create confusion in the industry.

4. What is not working in the current system?
- Conflicts: Despite best efforts, sometimes there are conflicts between the standards, their implementation specifications and operating rules. To address these situations a dispute resolution process is needed. This process might be part of a request for clarification, but may need a disinterested party to assist in the resolution.
- Duplication: Since organizations must now reference documentation for two organizations to understand what is required for a given implementation, the implementation process is more complicated, especially when the documentation is published and adopted in significantly different timeframes. With ASC X12 creating operating rules via TR2 documentation, there is potential for additional confusion, duplication, or conflicts.
- Public participation: Despite the ability of the public to participate, there is the practical matter of the time and expenses needed to participate. It would be helpful for interim summary-level communications during the development process that the public could more easily understand with minimal effort to assess whether upcoming changes will meet their needs and how these changes might impact their organization. This information should be made available without need to travel to organizational

meetings or participate in ongoing workgroup activities. Of course if an organization had significant concerns about a particular change, then they could focus their participation at that time.

5. How can we streamline the change request process for industry stakeholders (standards and operating rules)
   - Definition: As stated above there is need for a clear definition of what comprises a standard versus an operating rule. This will help avoid duplication of effort, will help implementers understand where to find certain information and where to send requests for changes or for interpretation. Stakeholders need a clear common understanding of each in order to reduce the potential for differing interpretations among trading partners.
   - Dispute resolution: In the event a conflict or perceived conflict occurs a request for interpretation and a dispute resolution process is needed that encompasses both the standard and the operating rule. Although some of these elements exist, they are primarily in silos within one organization or the other.
   - Coordination: The concept of operating rules must be defined in the context of a broader framework that includes standards, business operating rules, and potential certification requirements. These aspects must be developed in harmonization and to a certain degree in synchronization. Introduction of any new processes cannot lengthen the adoption and implementation timeline. The goal of this coordination should be to minimize additional costs for industry stakeholders both in participation and implementation.
   - Emergency changes: As mentioned above, it seems that despite best efforts there will always be need for a means to modify requirements during or after implementation to accommodate oversights, unintended consequences or new industry needs. This necessitates need for an expedited change process separate from the customary development and adoption process. This emergency process however must work in conjunction with other existing processes.
   - Communication: There must be a clear and easy way for public participation in the development process both to receive public input and to assure broad effective communication. The requirement to pay to participate or to receive implementation documentation inhibits public participation and must be addressed with the understanding that standards organizations need certain revenues in order to continue their operations.

CONCLUSION

WEDI supports the need to enhance the process for development and adoption of standards and associated operating rules and will continue to provide industry

support to help achieve compliance in the most expeditious and efficient manner possible. We want to emphasize the need for all entities to work together, in close collaboration, to avoid conflicts and ensure successful implementations and more industry consistency. The range of standards that will be needed to manage administrative health data exchange has grown beyond those in just the DSMO (e.g. NACHA, IHE.) Operating rules can assist with how the industry can fully benefit from the evolving versions of this range of standards. Moving forward the industry should carefully consider how best to ensure that the iterative process between operating rules and standards provides the most ROI and industry structures speak to the evolving landscape. WEDI in its advisory role offers our support to NCVHS and HHS in helping to achieve these goals and stands ready to assist as needed. WEDI is also ready to collaborate with the standards and operating rule entities to provide the education and outreach arm to the industry.

Members of the Subcommittee, thank you for the opportunity to testify. This concludes our statement.