



**BlueCross BlueShield
Association**

An Association of Independent
Blue Cross and Blue Shield Plans

COMMENTS
to the
NATIONAL COMMITTEE ON VITAL AND
HEALTH STATISTICS
SUBCOMMITTEE ON STANDARDS
for the
NCVHS PREDICTABILITY ROADMAP
HEARING

The Blue Cross Blue Shield Association (BCBSA) is a national federation of 36 independent, community-based and locally operated Blue Cross and Blue Shield companies (“Plans”) that collectively provide healthcare coverage for one in three Americans. BCBS Plans have offered quality healthcare coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid.

On behalf of BCBSA and the Plans, we would like to thank you for the opportunity to respond to the Subcommittee on Standards’ questions and provide our perspective on the NCVHS Draft Predictability Roadmap. These comments are reflective of feedback from all Blue Plans.

We continue to strongly support the goals of HIPAA Administrative Simplification to promote efficiency and reduce the costs of administrative transactions. Our comments are in the numerical order of the draft recommendations, calls to action and measurements without any grouping for the targeted implementation timeframes identified within the NCVHS document.

NCVHS Draft Recommendation 1:

HHS should increase transparency of their complaint driven enforcement program by publicizing (de-identified) information on a regular basis. HHS should use all appropriate means available to share (de-identified) information about complaints to educate industry.

BCBSA Recommendation 1:

BCBSA supports increasing the enforcement process transparency. We recommend, however, that it be paired with more instructional guidance on best practices and avoidance of situations that have given rise to complaints. There is value for the industry in having a more transparent enforcement process in that covered entities can learn from the challenges and barriers faced by others. We caution that any release of compliance enforcement results must be conducted in a practical and de-identified manner which does not detract or diminish the business standing or reputation of any involved entity. We support the goal of transparency for the purpose of education and achieving compliance. The sharing of best practices across all stakeholders, allowing covered entities to learn from one another, is likely to improve stakeholder communication and collaboration.

More detailed information around complaints specific to the standard or operating rule, volume of complaints and resolutions can then be used to create industry education and guidance to assist other covered entities.

If an enhanced and transparent enforcement process is not reconciled with the call in NCVHS’ Recommendation 12, for enabling the use of voluntary standards and an exceptions process, there is the possibility of unintended consequences to those testing alternatives in that there may be the perception of noncompliance, which may result in unneeded enforcement activities.

NCVHS Draft Recommendation 2:

HHS should comply with the statutory requirements for handling complaints against non-compliant covered entities and process enforcement actions against those entities and their business associates. Information should be publicized about the status of complaints to the extent permitted by the law.

BCBSA Recommendation 2:

BCBSA agrees with, and also supports, steps to ensure that covered entities and business associates (BA) are in compliance with the terms of BA agreements to the extent that failure to do so results in violations of laws and regulations. The value to the industry and the potential improvements to the process are the same as identified above related to Recommendation 1.

NCVHS Draft Recommendation 3:

HHS should disband the Designated Standards Maintenance Organization (DSMO) and work with its current members for an organized transition.

BCBSA Recommendation 3:

BCBSA is concerned with the potential disruption that could be caused by the NCVHS recommendation. Disbanding the current DSMO entails regulatory change, which could be a lengthy undertaking, without a guarantee that the replacement process would be any more efficient or representative of industry needs. More clarification is needed as to what a new entity would bring to the process that the current DSMO does not meet. Replacing one entity with another without any gain in efficiency or purpose will not provide value or create improvements in the process. Therefore, BCBSA recommends that any disbanding of the DSMO only occur through an active, coordinated transition to a new process or new entity, ensuring there are no gaps in the identification, development or implementation of new or updated standards.

NCVHS Draft Recommendation 4:

HHS should enable the creation of an entity tasked with oversight and governance (stewardship) of the standards development processes, including the evaluation of new HIPAA standards and operating rules. HHS should provide financial and/or operational support to the new entity to ensure its ability to conduct effective intra-industry collaboration, outreach, evaluation, cost benefit analysis and reporting. Oversight criteria would take into account ANSI Essential Requirements for any ANSI accredited organization; these would also provide consistency to governance of all standards and operating rule entities.

BCBSA Recommendation 4:

BCBSA would support HHS enabling a stewardship entity for the proposed purposes of exercising leadership to encourage effective intra-industry collaboration, outreach, evaluation, cost-benefit analysis and reporting. We recommend further consideration of whether such an entity needs or could effectively apply the authority to exercise governance activities over SDOs, given the ANSI-accredited consensus-based nature of standards identification and development.

The potential improvement in enabling a new entity is the alignment of the processes for standards and operating rules adoption. Currently the processes are not aligned, which creates an imbalance in the process as well as confusion across the industry.

NCVHS Draft Recommendation 5:

HHS should conduct appropriate rulemaking activities to give authority to a new governing body (replacing the DSMO) to review and approve maintenance and modifications to adopted (or proposed) standards.

BCBSA Recommendation 5:

BCBSA supports the enabling of a stewardship entity to improve the efficiency of the standards development process, including maintenance and modifications to adopted and proposed standards. We recommend further consideration of whether such an entity needs or could effectively apply the authority to exercise governance activities over SDOs, given the ANSI-accredited consensus-based nature of standards identification and development.

The same potential noted in our response to Recommendation 4 applies here as well. The alignment of the adoption processes for standards and operating rules enables greater collaboration, especially with respect to implementation timelines.

NCVHS Draft Recommendation 6:

SDOs and ORAE should publish incremental updates to their standards and operating rules to make them available for recommendation to NCVHS on a schedule that is not greater than 2 years. Publication of a new or updated standard is intended to mean the cycle of preparation that meets ANSI requirements (if applicable) for maintaining or modifying a standard or operating rule, including the consensus process, necessary governance compliance and readiness for submission to NCVHS.

NCVHS should align its calendar to the SDO/ORAE updates to review and deliver its recommendations to HHS within 6 months.

HHS should adopt the NCVHS recommendations on a regular schedule.

BCBSA Recommendation 6:

BCBSA is supportive of a normalization of the publication and adoption cycles for updated standards and operating rules into a predictable schedule. While BCBSA supports a predictable cycle for adopting updated standards and operating rules, such revisions need to be based upon business need, not just change predicated on the need for content to fill an established cycle for issuing updates.

Even routine updates to systems and processes utilize budget and other resources, which when updates are being made absent business need or gain, detract from using those resources for other initiatives entities need or wish to make.

NCVHS Draft Recommendation 7:

HHS should regularly publish and make available guidance regarding the appropriate and correct use of the standards and operating rules.

BCBSA Recommendation 7:

BCBSA agrees and supports this recommendation. Overall there is value to all stakeholders when the expectations are clearly defined. Improving the information available in a consistent and timely fashion provides an improvement to implementers seeking greater information and clarification on their implementation plans.

We would note, however, that there is a distinction between regulatory implementation requirements and consistency with the operational parameters of the standards as developed by the Standards Development Organizations (SDOs) and of the operating rules as developed by the Operating Rule Authoring Entities (ORAEs) . Because of this distinction between regulatory implementation issues and operational issues, we encourage HHS to work with the subject matter expert SDOs and ORAEs in developing such guidance.

We also recommend that this guidance be expanded to include the development of an FAQ or document-topic intake process so that guidance can be provided both timely and targeted for industry-identified issues.

NCVHS Draft Recommendation 8:

HHS should publish regulations within one (1) year of a recommendation being received and accepted by the Secretary for a new or updated standard or operating rule (in accordance with what is permitted in §1174 of the Act).

BCBSA Recommendation 8:

BCBSA agrees that new or updated standards and operating rules should be adopted within one year of a recommendation, if not immediately after receipt of the recommendation from NCVHS, considering HHS' direct involvement in that recommendation development process. Early adoption, with a reasonable period for implementation before the published effective date, would signal the industry to initiate implementation preparations in earnest. We recognize the need for some flexibility for either shorter or longer timeframes, due to other strategic and regulatory activities across the industry.

While industry stakeholders can always consider voluntary adoption, absent the mandate, the exceptions process is required for updates to adopted standards or operating rules. There is also generally a cost to covered entities who use vendors when changes outside of the federal mandate are being requested. These turn into custom implementations which may not in the end be important enough to move toward without the weight of a mandate. This forward movement of regulations must be balanced against Recommendations 6 and 10 in that the call for timely adoption should still be driven by a business need for the new or updated standards and operating rules.

NCVHS Draft Recommendation 9:

HHS should ensure that the operating division responsible for education, enforcement and the regulatory processes is appropriately resourced within the Department.

BCBSA Recommendation 9:

BCBSA agrees that adequate resources need to be given to the operating division(s) accountable for education, enforcement and regulatory processes for the Administrative Simplification provisions. This is essential to achieving all of the recommendations that specifically identify activities for HHS to undertake.

NCVHS Draft Recommendation 10:

HHS should adopt incremental updates to standards and operating rules. In accordance with Sec 1174 of the Act, the adoption of modifications is permitted annually, if a recommendation is made by NCVHS, and if updates are available.

BCBSA Recommendation 10:

BCBSA agrees that HHS should adopt incremental updates to standards and operating rules on an annual basis as provided for in statute, to the extent that the updates are based on business needs and are compliant with the versioning requirements of the standards development process. Updates should not, in effect, represent a new and different set of requirements that would initiate a massive system overhaul for affected stakeholders.

In addition, predictability should mean not just the establishment of a regular cycle of the adoption of updates, but the recognition and inclusion of information on other information technology and electronic data interchange system implementations in federal, state or private sector programs that would be necessary and consume entity resources during the proposed cycle of HIPAA Administrative Transaction updates, modifications, versioning changes and the application of Operating Rules.

The incremental updates ultimately need to improve processes without putting stakeholders in the situation of implementing multiple versions or versions, of standards and operating rules, simply to meet a mandate. When these standards are rarely if ever applied in business operations moving forward, the result is there is not administrative simplification coupled with use of resources with little to no benefit. This is further explained under the next recommendation,

NCVHS Draft Recommendation 11:

HHS should publish rulemaking to enable the adoption of a floor (baseline) of standards and operating rules. This rulemaking should also consider other opportunities that advance predictability and support innovation.

BCBSA Recommendation 11:

BCBSA agrees with the general goal of publishing baseline standards, but any such baselining regulation should confirm the standards underpinning the current and functioning administrative standards-based systems. In addition, adopting a “baseline” approach to standards sets up the potential for the proliferation of voluntary and innovative “standards” that may be non-interoperable and corrosive to the

goals of HIPAA Administrative Simplification. Stakeholders may end up in the position of implementing multiple “versions” of a baseline standard as a result. This outcome must be avoided.

BCBSA recommends further definition around the concept of “baseline/floor” in this instance. If this concept is such that there is a baseline version and the other opportunities equate to different standards or methodologies, we support that definition. If however, the definition is such that the baseline e.g. if version 1 and the other opportunities equate to allowing version 1a and version 2, this creates significant concerns that stakeholders will find themselves having to implement multiple versions, in this example 1, 1a and 2, in order to conduct business with three different trading partners. This approach would not be efficient for the industry nor would it provide any administrative simplification.

NCVHS Draft Recommendation 12:

HHS should enable voluntary use of new or updated standards prior to their adoption through the rule making process. Testing new standards to enable their voluntary use may be explored by testing alternatives under §162.940 Exceptions from standards to permit testing of proposed modifications. The purpose of this recommendation is to enable innovation.

BCBSA Recommendation 12:

BCBSA agrees and supports pilot testing of new voluntary and innovative standards, but again cautions that wholesale encouragement of voluntary and innovative standards may undermine the goals of interoperability, transparency of data use and enforcement of data transaction standards implementation in support of data exchange and consumer access and use.

NCVHS Draft Call to Action A:

Health plans and vendors should identify and incorporate best practices for mitigating barriers to the effective use of the transactions, determining which issues are the most critical and prioritizing use cases.

BCBSA Recommendation A:

BCBSA supports industry collaboration to identify best practices for the most effective use of standards. The value is found, however, when all stakeholders are part of this process. Limiting this to only health plans and vendors leaves out providers, who are integral to the overall process of health information exchange. This collaboration is also best served to occur jointly and not in siloes. Business and technical

resources from all stakeholders need to engage together, not just when barriers are identified, but during future development as well, to ensure business needs are addressed in the most efficient technical manner.

NCVHS Draft Call to Action B:

The Workgroup for Electronic Data Interchange (WEDI), through its work group structure, should continue to identify issues and solutions. WEDI should publish white papers advising on agreed upon policy implications and best practices related to use of HIPAA standards and operating rules.

BCBSA Recommendation B:

BCBSA supports this continued role for WEDI, whom, as a multi-stakeholder collaborative organization, brings value to the overall process through its ability to gain broader input into best practice development. WEDI provides a “safe space” for trading partners to engage and dialogue about best practices outside of a one-on-one trading partner contractual or other formal relationship.

NCVHS Draft Call to Action C:

HHS and the SDOs should identify and fund a best of class third party compliance certification/validation tool recognized and approved by each standards development organization to assist in both defining and assessing compliance. HHS should develop and test criteria for certification, and build a program to enable multiple 3rd parties to qualify to conduct the validation testing by demonstrating their business value. To implement this recommendation, HHS should look at successful precedents such as how the ONC certification criteria was developed for Promoting Interoperability and the eRx requirements which were a joint effort between HHS, NIST and the SDO.

BCBSA Recommendation C:

BCBSA recommends further work be done related to this call to action. There are already certification and validation tools available within the industry. All criteria related to the correct use of standards and operating rules need defined by the entity that developed the standards and operating rules. Any effort undertaken by HHS must include all impacted stakeholders, i.e. covered entities, as primary participants. Efforts to develop criteria for a validation tool must include all impacted stakeholders, i.e., covered entities who have primary compliance responsibility under HIPAA as well as business operations impacts. Other entities not directly regulated by HIPAA with supporting and system development roles, must ensure that

their work contracted by covered entities is compliant and capable and therefore also play a role in the criteria development process.

NCVHS Draft Call to Action D:

HHS should fund a cost benefit analysis of HIPAA standards and operating rules to demonstrate their Return on Investment. HHS may consider collaborating with or supporting any existing industry initiatives pertaining to such cost benefit studies to increase data contribution by covered entities and trading partners.

BCBSA Recommendation D:

BCBSA supports cost-benefit analysis (CBI) but recommends that HHS utilize any existing activities within the industry. We also note that CBI should be more inherent in the process as standards development is organic and iterative, occurring primarily when there is a demonstrated business need, and self-correcting as operational issues under a current standard are encountered and addressed. Undertaking more formal CBI activities during development as opposed to post-publication during the rulemaking portion of processes would be an improvement over current processes.

NCVHS Draft Call to Action E:

SDOs should consider collaboration with the private sector to plan and develop outreach campaigns, with the intent to increase the diversity of participants in standards development workgroups.

BCBSA Recommendation E:

BCBSA agrees that more diversity in the SDOs' participants should be encouraged and additional outreach conducted to those under-participating stakeholder groups. We also recommend that consideration be given to public sector support to enable participation by those who would struggle to participate. Any increase in participation, especially by stakeholder groups currently participating the least, improves the standards and operating rules as a result of enabling broader input during development, which ensures more comprehensive business needs are addressed.

Additionally, the goals of the outreach should include encouraging greater participation in the public comment process as an adjunct and alternative to direct participation in the development process, in the absence of resources and financial support for that participation. Plans report holding sessions with

providers when new transactions are being implemented. Any ability to have these discussions more ongoing, enables more feedback into future development as well as current implementations.

NCVHS Draft Call to Action F:

Leadership from the public and private sector should commit to membership in Standards Development Organizations, assign appropriate subject matter experts to participate in the development and update process, and facilitate improvements to operations as needed. This may enhance diversity of representation in the SDOs so that content changes meet a cross section of stakeholder needs.

BCBSA Recommendation F:

BCBSA agrees with encouraging a higher level of diversity in stakeholder participation in the SDO processes, at the highest levels of stakeholder leadership and subject matter expertise. Having this message come from HHS lends value in that it is likely to have the message be heard by the leadership levels within organizations that are making budget and resource decisions. Greater participation ultimately improves the development processes in that more business needs and rationale are available during development as opposed to items not being identified until public review periods are occurring.

NCVHS Draft Call to Action G:

Public and private sector stakeholders should collaborate to design a single coordinated governance process. Governance should include detailed and enforceable policies regarding business practices, including policies for identifying and implementing best practices in such an organization.

BCBSA Recommendation G:

BCBSA recommends further clarification be provided regarding this call to action. It is unclear as to what this governance would extend to. The SDOs already fall under the governance process of the American National Standards Institute (ANSI), which we see as sufficient to ensure that the policies and processes used by the SDOs in their standards development.

NCVHS Draft Call to Action H:

HHS should continue to publish a universal dictionary of clinical, administrative and financial standards that are or will be available for use, e.g. the ONC Interoperability Standards Advisory (ISA).

BCBSA Recommendation H:

BCBSA supports a universal dictionary and recommends the ONC Interoperability Standards Advisory (ISA) be that dictionary, as it currently contains the administrative and financial standards. We support the ongoing maintenance of this existing dictionary in lieu of creating a new and separate dictionary for administrative transactions and operating rules.

NCVHS Draft Measurement M1:

HHS should publicly and regularly disseminate results of its enforcement program to promote transparency, opportunities for education, and benchmarking.

BCBSA Recommendation M1:

BCBSA agrees that the results of enforcement actions be shared in a manner that both encourages compliance and assists in the best practice application of the standard. We again caution that the release of compliance enforcement results be conducted in a practical and de-identified manner that does not detract or diminish the business standing or reputation of any involved entity.

Measurement of enforcement activity needs to focus on the change in enforcement actions themselves, i.e. hopefully a reduction in complaints and resultant actions. Measurement should not focus on specific entities, rather the change in the need for enforcement activities across stakeholder groups.

It is critical that any measurement account for changes in enforcement related to the use of voluntary standards and the exceptions process. Voluntary uses and exceptions themselves are not a measure of success for reducing the need for enforcement but do play a role in understanding reasons for such reductions.

NCVHS Draft Measurement M2:

HHS and stakeholders participating in the new governance process should establish metrics for monitoring and performance assessment of the new entity, and oversight/enforcement of SDO and ORAE deliverables and performance.

BCBSA Recommendation M2:

BCBSA supports the development of a stewardship entity and a process to encourage standards development collaboration and predictability. We also agree that the effectiveness of this stewardship

should be measured on an ongoing basis. With regard to grants of authority for oversight and enforcement purposes, BCBSA recommends further consideration of the need for a new governance process and the granting of such authority. As was identified in our comments on Call to Action G, it is unclear as to the extent of this proposed new governance process and therefore it is difficult to fully comment on its applicability.

NCVHS Draft Measurement M3:

NCVHS should continue to conduct its stakeholder hearings to assess progress of the Predictability Roadmap.

BCBSA Recommendation M3:

BCBSA agrees with NCVHS continuing to collect stakeholder feedback through hearings as the Predictability Roadmap moves from concept to reality. Holding hearings will enable the NCVHS to review the Roadmap's progress and make any needed recommendations for revision proactively, effecting any changes identified earlier in the process.

Conclusion

BCBSA supports the work of the NCVHS to address the lack of predictability for the adoption of standards and operating rules under HIPAA. We recommend that this roadmap ensure the limitation of private expenditures being imposed on stakeholders in order to comply with Administrative Simplification regulations. . This roadmap should also balance and account for all federal and state mandates, not just Administrative Simplification provisions, but include ARRA/HITECH mandates as well as other potential regulatory requirements in order to work towards avoiding bottlenecks and overlapping resource commitments for all stakeholders. We appreciate the NCVHS consulting with the industry as this Predictability Roadmap is being developed.

We appreciate the opportunity to supply comments and are happy to answer any questions. Gail Kocher, Director, Commercial Markets will be available as part of the December 12-13, 2018 hearing. Otherwise, please contact Michael DeCarlo, Director, Health IT Policy, Office of Policy and Representation at michael.decarlo@bcbsa.com.