NCVHS Predictability Road Map Comments

2019 – 2020 Improved education, outreach and enforcement* will promote efficient planning and use of the adopted HIPAA standards and operating rules.	2020-2021 Policy levers will successfully support industry process improvement changes.	2021 – 2024 Regulatory levers will enable timely adoption, testing and implementation of updated or new standards and operating rules
Recommendations		
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. ***LabCorp Input:*** The publication of complaints along with the final resolution could bring about more accountability for the industry. Differences in interpretation of the transactions happen all the time. Visibility into challenges identified through the complaint process could help industry stakeholders begin to police themselves by making areas of misinterpretation as well as invalid processes visible. Once areas of misinterpretation and invalid processes are documented, the resolution may be utilized as a best practice for the industry. If the industry does not agree with the resolution, the complaint process provides a way to identify gaps in the transactions that need to be corrected.	3. HHS should disband the Designated Standards Maintenance Organization (DSMO) and work with its current members for an organized transition. ***LabCorp Input:*** There is a need to re-imagine the DSMO. If the DSMO is disbanded, more than likely the same people would participate in the new organization. There is a small number of people and organizations that have learned to navigate the process to update the standards and it may be an unrealistic expectation that a new entity would engage additional resources. Please consider enhancing the current organization.	6. SDOs and ORAE should publish updates to their standards and operating rules and 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. ***LabCorp Input:*** LabCorp agrees that the cycle for change should be quicker. Quicker development cycles help move the industry into a constant improvement cycle. To help prevent unintended road blocks with a quicker adoption cycle, the administrative simplification transactions should allow for backward and forward compatibility.

A major challenge that will be associated with a quicker adoption cycle will be how to test new versions of the standards with trading partners. As a provider, differences in interpretation of the transactions are identified as quickly as possible in order to protect our revenue. Once differences between our organization and our trading partner are documented, trading partner specific edits are made to the electronic data interchange programs to ensure data is interpreted correctly. These trading partner specific edits are identified through the testing process.

Would certification be required in place of testing? Certification, as the concept is applied today for other programs, just ensures the information in each field is in the correct format and does not validate that the data in the field contains actionable information. If certification is used in place of testing, please consider adding trading partner attestations as a requirement.

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.

*enforcement includes complaints, audits and compliance reviews as defined in statutory language

LabCorp Input:

LabCorp agrees that HHS should comply with the statutory requirements for handling complaints against non-compliant covered entities. Additionally, the complaint process should be clearly defined, publicized and followed. When a complaint is filed, HHS should consult with the appropriate standard setting organization to investigate the challenges identified in the complaint and a summary of the problem, based on research completed with the standard setting organization, should be published. If possible, dates associated with milestones should be documented to allow the industry to monitor the progress and status of each complaint. Milestone dates should include the date the complaint was filed; the date the investigation began; the date a corrective action plan was initiated; the length of the corrective action plan; and the date when changes made due to the corrective action plan were validated and in production. If a corrective action plan is not completed during the prescriptive timeframe, it would be helpful for the industry to know if the dates were modified, why the corrective action plan was not completed, and what next steps are associated with the original complaint. If fines are levied, the amount should be reported as well.

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

LabCorp Input:

Guidance is nice to have, but without holding the industry to the regulation, guidance is not meaningful.

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).

LabCorp Input:

WEDI already provides the type of guidance in this recommendation. Is the intent to formalize the process? If so, the relationship between WEDI and HHS should be enhanced to allow for better collaboration toward facilitating the use and adoption of the administrative simplification transactions. Both WEDI and HHS should utilize the standard setting organizations to help identify areas where guidance is needed and develop best practices for HHS to publish.

LabCorp agrees that HHS should publish proposed regulations once the Secretary receives and accepts a recommendation. By the time the Secretary receives a recommendation, the industry has weighed in on the use of the revised standard or operating rule and has agreed there is a business need to adopt the new tool. If the Secretary receives any recommendations and chooses not to act, it is disheartening that the lack of response from HHS becomes a barrier to adoption. If the goal is to adopt revised transactions and operating rules quicker, the entire process must be open and transparent.

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.

LabCorp Input:

The adoption of a floor (baseline) of standards and operating rules could be very difficult for the healthcare industry to support. Today, the administrative simplification transactions are standards. This means that regardless of the trading partner, the same information is sent or received. The adoption of a baseline implies that different information may be sent or received based on the needs of different trading partners.

For example, Payer A may want the baseline data from its providers. In this case Payer A will represent Medicare. Payer B may request providers to send enriched data. The enriched data may consist of adding data elements L, M and N to the baseline program. Then the provider could have Payer C who also requires enriched data. However, Payer C would like data

elements L, X, Y, and Z. So, in this example the provider has to support three (3) provider specific programs. Not only does the provider have to support three (3) different programs, but they also have to try to untangle Medicare crossover claims. In this example, Payer A is Medicare and Medicare only receives the baseline data. When Medicare crosses claims over to Payer B and Payer C who require enriched data, we need to think through how Payer B and Payer C would process the Medicare crossover transactions without the enriched data.

In order to support the concept of having a baseline and to help prevent unintended road blocks, the administrative simplification transactions would need to be backward and forward compatible to allow for at least some of the data from a future version to be processed.

The baseline concept moves the industry away from the identification of differences in interpretation of the standards and creating trading partner specific edits toward supporting trading partner specific programs and processes. Programs and processes are a heavier lift than just tweaking a standard process. Business flows would have to be modified to include directions to support each payers enriched data requirements. Processes that may not be part of the regular sequence will have to be developed to handle the exception processing. Supporting different programs and processes increases the administrative burden.

If the concept of adopting a baseline standard or operating rule moves forward, please consider requiring trading partners that

want to adopt standards or operating rules beyond the baseline to request a waiver to do something different. The waiver would need to be vetted through the standard setting organization to ensure the intent of the request may be achieved with the proposed plan of action. Also, the requestor of enriched data should be required to provide metrics on a regular basis that demonstrates how the enriched data improved the process.

We also need to think through the concept of certification. Would the certification process focus only on the baseline version of the transactions? If so, a trading partner that requests enriched data may acquire certification; however, testing would need to be done with that trading partner to ensure programs are written correctly and revenue is protected. The use of enriched data beyond the baseline requirements changes the characteristics of the data traded and could corrupt the independent verification of the trading partner's process.

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.

LabCorp Input:

The concerns outlined in Recommendation 11 are also valid for Recommendation 12.

Please consider that the coordination of benefits process that is in place today is already very difficult to manage. The use of new or updated standards could make coordination of benefits impossible. Depending on what the new standards require, trading partners may be forced to run data through two (2) different programs to allow for and validate coordination of benefits between payers.

Many organizations within the healthcare industry are focused on containing expenses. The voluntary adoption of a new or updated standard would require development resources, time, and processes outside of the normal work flow. The expense associated with each of these items could be for nothing if the new standard is not adopted.

Calls 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.

LabCorp Input:

When identifying best practices for mitigating barriers to the effective use of the transactions, the whole healthcare industry should be included in the assessment. The provider community was not included in this Call to Action. It is very difficult to identify barriers when the full life cycle of the process is not represented. Please consider including the full eco-system in this 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.

LabCorp Input:

LabCorp agrees that HHS should work with the SDOs to identify a certification/validation tool. However, it should be the SDO that

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.

LabCorp Input:

The CAQH CORE Index is a great beginning to collect the cost benefit analysis associated with the adoption of the administrative simplification transactions. However, one challenge with the CAQH CORE Index is the sample size of the data collected. Instead of creating a new process to collect data, please consider enhancing the current process to help encourage participation.

The identification of best practices is best done via a committee. A best practice for one (1) stakeholder may not be a best practice for another stakeholder. Please consider utilizing the full membership base of WEDI to identify issues, gather and evaluate information, and recommend courses of action to enable resolutions for identified barriers.

maintains ownership of the certification/validation process to promote consistency and quality. The healthcare industry already experiences differences in interpretation of the standards; adding an extra level of a third party version to the mix could create unintended consequences.

When looking at successful precedents, please consider the following items:

- If a third party is qualified to perform certification, what does the qualification process look like?
- How often is the third party qualified to perform certification?
- What are the fees associated with certification?
- Do third parties need to be certified prior to using a new version of a mandated standard?
- Is certification based on syntax only, or will trading partners be able to attest to validate that the content is of value?
- How to ensure that trading partners do not apply certification acquired in a prior version to a new version.
- A process needs to be defined on how to report either third party vendors or trading partners that may not be adhering to the intended certification process. For example, a trading partner may be capable of generating the standard but at the time of implementation the trading partner may want to use the standard in a whole new way that does not conform to the standard.

Please also consider the concept of certification. Would the certification process focus only on the baseline version of the transactions? The use of enriched data beyond the baseline

In place of a survey, perhaps an HHS audit done yearly on a sample population could provide the visibility into the use of the different administrative simplification transactions and operating rules.

	requirements changes the characteristics of the data traded and could corrupt the independent verification of the trading partner's process.
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. ***LabCorp Input:*** The investment of time to participate in SDOs is considerable for work that is far in the future and may never be adopted. The organizations that are able to supply volunteers for the SDO work often have dedicated roles within their sponsoring companies which limits participation even further. Participation is further limited by the unique skill set required to participate in a SDO. Volunteers need to understand their business model challenges and divorce themselves from challenges generated by their own internal processes. When organizations do commit to sending volunteers to help with the SDO work, the volunteers find that the SDO work is complex, slow and difficult to manage due to exaggerated processes created in an effort to prove industry collaboration. These convoluted processes make it very difficult to learn to navigate the procedures to update the standards making the volunteers at the table even less effective. It may be an unrealistic expectation to increase diversity of the volunteer pool until SDOs make participation easier.	

What the healthcare industry has seen in the past is that if there is a problem to solve, the industry will band together to solve the problem. Routine maintenance of standards is difficult to support with a volunteer base.

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

LabCorp Input:
The concerns outlined in Call to Action E are also valid for Call to Action F.

Measurement

M3. NCVHS should continue to conduct its stakeholder hearings to assess progress of the Predictability Roadmap.

LabCorp Input:
LabCorp agrees. When NCVHS holds a hearing and makes recommendations, it is important to follow through to maintain trust in the process.