Department of Health and Human Services
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
September 9-10, 2021
MEETING SUMMARY – Held Virtually

Note: *The transcript and slides for this meeting are posted on the meeting page of the NCVHS website at:* https://ncvhs.hhs.gov/meetings/full-committee-meeting-8/

Due to the COVID-19 pandemic, the National Committee on Vital and Health Statistics was convened virtually via Zoom on September 9 and 10, 2021. The meeting was open to the public. Present:

Committee Members
Nick Coussoule, Chair
Tammy Feenstra Banks, MBA, FACMPE
Denise Chrysler, JD
James Cimino, MD
Jamie Ferguson
Melissa M. Goldstein, JD
Richard Landen, MPH, MBA
Denise Love, BSN, MBA
Vickie Mays, PhD, MSPH
Jacki Monson, JD
Margaret Skurka, MS, RHIA, CCS, FAHIMA
Debra Strickland, MS
Valerie Watzlaf, PhD, MPH, RHIA, FAHIMA
Wu Xu, PhD

Executive Staff
Sharon Arnold, PhD, ASPE, Executive Staff Director
Rebecca Hines, MHS, NCHS, Executive Secretary/DFO

Lead Staff
Lorraine Doo, MPH, CMS
Rachel Seeger, MA, MPA, OCR
Maya Bernstein, ASPE

NCVHS staff
Marietta Squire, NCHS
Geneva Cashaw, NCHS

Guest Presenters
Jim Craver, MAA, NCHS
Lisa Mirel, MS, NCHS
Steve Posnack, MS, MHS, ONC

In addition, 69 members of the public and other federal staff remotely attended the meeting on day 1, and 51 attended on day 2. A list of public attendees and their affiliations is appended to this meeting summary.

ACTIONS

1. The Committee unanimously approved the 2021 NCVHS Report to Congress on Implementation of the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, covering calendar years 2019 and 2020.
2. The Committee unanimously approved a letter to the Secretary on Updated Recommendations for Immediate Action on ICD-11.

—DAY ONE—

Opening Remarks—Ms. Hines, Mr. Coussoule

Ms. Hines welcomed all participants and expressed hope that it will be possible to meet in person in 2022. The meeting schedule is being developed. Chairman Coussoule thanked members and staff for their work in preparing for this meeting, and reviewed the agenda. He then welcomed Dr. Arnold for the first briefing of the day.

ASPE Update—Sharon Arnold, PhD

Dr. Arnold said that while most of the HHS workforce continues to telework, plans are under way for a return to workplace when indicated by science. HHS is supporting the Biden Administration's Executive Orders, including those to advance racial equity, restore trust in government through evidence-based policymaking, tackle the climate crisis, and support the COVID-19 response. HHS has established a new Office of Climate Change and Health Equity. Dr. Arnold enumerated some of the specific American Rescue Plan funding targets that HHS has mobilized. Among other activities, the Department recently marked the 25th anniversary of HIPAA; is helping place large numbers of refugees; and declared public health emergencies for Louisiana and Mississippi and waivers for states affected by flooding.

Within ASPE, work continues on the HHS strategic plan and on implementing the Evidence Act. ASPE has released several reports and briefs on COVID-19 and it is conducting research on vaccine hesitancy and related topics.

- **Discussion**

Asked about the focus of the new Office of Climate Change and Health Equity, Dr. Arnold said it will primarily coordinate and develop policy. Members also asked how HHS is approaching the data component of Evidence-Based Policymaking work, especially with respect to underrepresented populations; and they pointed to opportunities for NCVHS to assist in these areas. Dr. Arnold noted that she will discuss with the Committee on day two of this meeting about an area in which she hopes NCVHS will engage.

NCHS Update—James Craver and Lisa Mirel

Data Modernization Initiative—James Craver, MAA (**slides**)

Mr. Craver is the Acting Deputy Director for Management and Operations at NCHS. The goal of CDC's Data Modernization Initiative (DMI) is to shape a new paradigm for sharing and using data across the entire public health ecosystem. The guiding vision is to move from siloed, brittle systems to an interconnected and response-ready system at every level of public health. This will overcome problems with siloed information, outdated skills, outdated technologies, point-to-point (rather than spoke-and-hub) data transmission, and disconnects between public health and health care data systems. Early-warning surveillance will be enhanced through automated reporting of emergency room visits, electronic health records (EHRs), lab results, and death data, reducing the burden on states to report notifiable diseases.

Within NCHS, the DMI is expressed through projects to improve data sourcing, production, and access. Mr. Craver outlined several projects in each area, with a focus on the efforts to improve the National Vital Statistics System (NVSS). Projects on sourcing and production include continuing to improve the quality and timeliness of national mortality data and incorporating EHR data into the public health picture through a cloud-based system. In addition to efforts to acquire non-sampled EHR data, there is a project to develop model-based estimates to fill in data gaps for small area analysis, and on underrepresented demographic groups. To increase data visibility and accessibility, a new data query system is being developed, along with efforts to standardize NCHS metadata and develop APIs. A virtual data enclave is also being created. There is significant new funding to support these efforts.

The future envisioned through these and other efforts is a state in which hotspot analyses can happen quickly, with more granular level data, at the county level or smaller area levels, for tracking disease and its impacts, enabling better forecasting and response.

Data Linkage Activities—Lisa Mirel, MS (**slides**)

Ms. Mirel is Chief of the NCHS Data Linkage Methodology and Analysis Branch. She said the Data Linkage Program is designed to help answer key policy questions, for example on the effectiveness of health and housing policies in reducing lead exposure. She noted the potential analytical power to be gained from linking data from NCHS health surveys (National Health Interview Survey, National Health and Nutrition Examination Survey, and National Health Care Surveys) with data from Medicare, Medicaid, Housing and Urban Development, the Social Security Administration, and the National Death Index. Such linkages would yield new insights by leveraging data on health behaviors, health conditions, socioeconomic status, and health care access and utilization in combination with data from the other sources.

Ms. Mirel stressed that NCHS takes privacy and security seriously, and only uses data from "linkage-eligible" survey participants—those who have provided consent and necessary personally identifiable information for linkage. A change to only ask for the last four digits of the Social Security Number dramatically increased participation rates, which are now at around 90 percent.

The data linkage program coordinates geocoding of its survey data, including geocoding death certificate data. The data available at the geocoded level can provide information, for example, on air pollution exposure and heart disease mortality. In all, more than 1,000 publications have used NCHS linked data files; they are listed in a bibliography on the NCHS website. NCHS is working to create resources that support evidence-building.

Most linked data files are restricted use files, accessible through NCHS or Federal Statistical Research Data Centers; and there are a few public use files such as the linked mortality file. The DMI initiative and virtual data enclave may lead to improvements in access to such data. In the future, the data linkage program will incorporate machine learning algorithms to improve accuracy and efficiency. A current pilot is creating methods for using synthetic data to increase access to public-use linked data files while reducing disclosure risk.

- **Discussion**

Members had questions and comments for the NCHS presenters about involving the states in these efforts; doing an inventory of state data assets; and involving associations such as NAHDO. They asked what priority is attached to enhancing race and ethnicity data; the prospects for modernizing the National Violent Death Reporting System; how the NCHS linkage project relates to the larger linkage goals of the Evidence Act; and what changes to the consent protocols are anticipated.

Briefing on the July Subcommittee on Privacy, Confidentiality and Security (PCS) Hearing (slides) —Jacki Monson and Melissa Goldstein, Co-chairs

The Subcommittee held a virtual Hearing on Security in Healthcare on July 14. Ms. Monson characterized the hearing as productive and robust, and said the Subcommittee now seeks the Committee's feedback on the findings and next steps. There were four panels:

- Panel 1: Addressing Healthcare Security Challenges (practitioner perspective)
- Panel 2: State, Tribal and Other Perspectives on Healthcare Security
- Panel 3: Emerging Security Threats and Preparedness across the Healthcare Industry
- Panel 4: Federal Perspectives on Security Infrastructure and Enterprise-wide Risk Management in Healthcare

The slides for this presentation provide more details on the themes and top priorities identified by each panel. The hearing agenda and speaker slides are posted on the NCVHS website, linked to the July 14, 2021 meeting page.

Panel 1 themes included the need for more sharing and coordination of best practices for cybersecurity; for greater awareness of HR 7898; for sharing threat information; and for a playbook on how to respond to cybersecurity threats. All panels were asked for their top priorities. Panel 1 priorities included a playbook; greater accountability for vendors on security updates; more support within the Operations division; more dedicated FTEs to coordinate among government agencies; implementation of the public law; and more coordination and help when incidents happen.

Panel 2 themes included governance, critical infrastructure, workforce development, the need for response planning, and the challenges of legacy systems. Priorities included giving public health a seat at the table in the Cyber Safety Review Board, and help with legacy systems.

Panel 3 themes included the need to adopt best practices, money as a motivator for criminals, privilege misuse, and new opportunities for outreach to health care organizations. Priorities included the need to scale security solutions to size.

Panel 4 themes included the need to be proactive with education, use a comprehensive approach, and focus on small and medium organizations' security needs. Priorities included more education and enforcement, and greater clarity about how to assess risks.

Ms. Monson also noted a number of relevant actions by government since the hearing (refer to slides for details).

She then outlined a four-phase project proposed by the Subcommittee, aimed at sending recommendations to the Secretary in the third quarter of 2022 and producing a report and possible toolkit for industry around the same time. She and Ms. Goldstein asked their NCVHS colleagues for questions and comments.

- **Discussion**

Members' suggestions included the following points:

- Focus less on penalizing and more on education and capacity-building.
- Besides prevention, help improve the health care industry's ability to respond to events quickly, to minimize their impact.
- Think through how to increase skills and training to expand the cybersecurity workforce.
- There are parallels with standards implementation with respect to the challenges for smaller organizations. Also, incentives would help, and making it as simple for implementers as possible.
- Non-PCS members with interest/expertise in this topic are encouraged to join in this project.

NCVHS 2021 Report to Congress—Mr. Coussoule

Mr. Coussoule presented the latest iteration of the 2021 report to Congress on HIPAA implementation for review, modification as needed, and approval. The report addresses calendar years 2019 and 2020 and also briefly summarizes NCVHS planned activities going forward. He noted that NCVHS has a statutory obligation to provide this report to Congress on a regular basis, and he thanked everyone who worked on the report.

He then walked through the document section-by-section and invited feedback from members. Members suggested a number of minor modifications; they identified no substantive issues. The Committee then voted unanimously to approve the report, authorizing staff to make any needed copy-editing corrections in the final preparation. After submission to Congress, the final report will be posted on the NCVHS website.

Subcommittee on Standards: Recommendations for Immediate Action on ICD-11 (slides) —Margaret Skurka and Valerie Watzlaf

Ms. Skurka explained that the U.S. will adopt the 11th edition of the International Classification of Diseases (ICD-11) for mortality, and it also "should and will" adopt it for morbidity. Pursuant to its charge, in 2019 NCVHS recommended HHS actions on ICD-11 related to research and communications; however, HHS did not initiate action on those recommendations, presumably because of the pandemic. Now the Subcommittee has developed a new letter and recommendations to the Secretary, which she and Dr. Watzlaf presented for review and approval. She stressed the urgency of Departmental action without further delay to enable the U.S. to make informed decisions regarding ICD-11 adoption.

The new NCVHS recommendations are informed by research by NIH/NLM researchers who presented to the Committee in March 2021. In brief, the Committee recommends: 1) that HHS conduct research to evaluate the impact of different approaches to transition and implementation; and 2) that HHS conduct outreach and communicate regularly to the U.S. health care industry about the ICD transition.

Ms. Skurka explained that adoption of ICD-11 will begin (in some countries) in January 2022. There are three dimensions to adoption: for mortality, for morbidity, and for payment. The U.S. took 25 years to implement ICD-10-CM for morbidity after WHO endorsed it for adoption, and implementation deadline delays were very costly and wasteful for the health care system. She outlined some of the merits and potential benefits of ICD-11, notably that it is entirely electronic and its design is based on a logic model that would negate the need for future versions, i.e., an ICD-12.

Dr. Watzlaf then described the rationales and enabling actions specified in the draft NCVHS letter for each recommendation. This includes actions and research questions for recommendation 1 (research), key messages for recommendation 2 (communication), and considerations for recommendation 3 (access). See the slides for details. She stressed that the Subcommittee believes that taking a proactive approach to ICD-11 in these three areas is essential. After thanking the ICD-11 subgroup and NCVHS staff, she asked for feedback from the Committee.

- **Discussion**

After affirming the significance of this work, members suggested various ways to strengthen the key messages in the letter and proposed other topics that might be added or further emphasized. The group discussed alternative wording in a few sections. Members urged that the letter be kept at a manageable length and that it highlight the key message that research should begin immediately. After a wide-ranging discussion, the Subcommittee agreed to bring back a revised version of the letter for review on day two of this meeting.

Follow-up to PCS Hearing on Data Collection and Use during a Public Health Emergency (slides) —Melissa Goldstein and Jacki Monson, Co-chairs

Ms. Goldstein provided context given that the PCS Subcommittee held this hearing on September 14, 2020, under former Chair Frank Pasquale, but was unable to follow up at that time because of the pandemic. The broad question addressed by the hearing was what tools might be used for public health surveillance in a public health emergency (PHE), and their privacy implications. The objectives of the hearing were to understand current policies and practices for data collection and use with respect to the privacy and security of identifiable COVID data; to identify best practices; to consider needed technical assistance, building on prior NCVHS work; and to consider developing recommendations. A summary of the September 2020 hearing is posted on the NCVHS website.

The major themes of the hearing were the need for a data collection and use framework; the need to address health disparities and improve health equity; several technology and ethics goals; the difficulty caused by the patchwork of laws; the possible need for a broader definition of “covered entity” under HIPAA; and limitations of using de-identification as the backbone of using administrative data. (See slides for details in each area.)

After reviewing the key takeaways from the hearing, Ms. Goldstein engaged fellow NCVHS members in a discussion of salient topics and next steps. She noted the challenge that the pandemic itself has evolved in the last year, as have the tools for addressing it and governmental priorities. One possible focus of a letter/report is what has been learned during that period that will help the nation be better prepared for the next PHE. Other possible topics include the implications of the Evidence Act, analysis of federal program and policy waivers, and how to strengthen immunization information systems. Possible next steps for the Subcommittee on Privacy, Confidentiality and Security include:

- A transmittal letter to the Secretary with the hearing summary and possible suggestions or recommendations;
- Additional hearings; and
- Study of related topics such as community outreach on data collection, use and sharing, and community consent.

- **Discussion**

Members suggested that the transmittal letter to the Secretary convey the hearing summary and other relevant documents could provide a high-level summary of the work. It should explain to the new HHS Secretary why the Committee is doing this work now, how it is relevant, and what it anticipates going forward. They suggested thinking of the letter as informing the Secretary about the landscape, rather than offering recommendations.

As future actions, they suggested finding out what else is going on in the ecosystem before deciding on a focus for future work in this area and identifying other groups with which NCVHS might work on these issues. There was broad interest in updating the NCVHS toolkit (“playbook”) on data stewardship with information on how to manage data assets in a PHE. This should be linked to the Evidence Act, and could address the notion of community consent.

The Committee agreed to return to this discussion on day two.

Public Comment

Katherine Isbell, Education Services Manager, LexiCode

Ms. Isbell thanked Ms. Skurka for her many years of service with regard to ICD-11, and said she is “very excited” about ICD-11. Among other things, it aligns well with other classifications, and training will be much simpler than it was for ICD-10. She does not believe a clinical modification will be needed. She encouraged and affirmed NCVHS in its work in this area.

Robert Gellman, Privacy Consultant

Mr. Gellman called the Committee’s attention to a report that he and Pam Dixon of the World Privacy Forum authored on the HIPAA waivers HHS adopted because of the pandemic. He suggested that NCVHS look at the report and the authors’ recommendations (posted on worldprivacyforum.org).

Wrap Up and Adjourn—Mr. Coussoule

Mr. Coussoule commended the Committee on a productive day, noted the two items that are carried over to day two, and highlighted other forthcoming agenda items. He then adjourned the meeting.

—DAY TWO—

Rebecca Hines welcomed members and the public back and took roll call. Nick Coussoule reviewed agenda topics for the day ahead.

Subcommittee on Standards Update—Mr. Landen, Co-chair

Mr. Landen began with background on the Subcommittee, its charge, and its recent activities. Its major project at present and ahead is called "Convergence 2.0," or officially, "Standardization of Information for Burden Reduction and Post-Pandemic America." (A recent listening session on that topic will be summarized later in the meeting.) The Subcommittee also works with ONC and its Health IT Advisory Committee (HITAC), notably on the Intersection of Clinical and Administrative Data (ICAD) Task Force and report and the follow-up to that joint work. It also works on ICD-11 and on updates to HIPAA transactions, code sets, and operating rules.

The timeline for the Convergence 2.0 project is anticipated to run two years and will build on previous Subcommittee work, especially the Predictability Roadmap. As an advisory body, NCVHS provides guides and frameworks for possible implementation by operating entities.

Mr. Landen then introduced and welcomed Steve Posnack, the Deputy National Coordinator at HHS Office of the National Coordinator for Health Information Technology (ONC).

Conversation with Steve Posnack, MS, MHS, ONC (slides)

After expressing his longstanding appreciation for NCVHS and its work, Mr. Posnack gave an overview of ONC, describing how its mission and work are evolving along with the health IT landscape. Since it was created in 2004, a series of statutes have increased its authority and responsibility in areas such as reducing burden; and it has significantly modified its certification program. The three areas of focus are standards, certification, and exchange, working with and for federal and state entities and the public. Its dual objectives are to advance the development of IT capabilities and to establish expectations for data sharing. It approaches this work from both technology and policy perspectives, with the ratio between the two perspectives varying over time.

In addition to its Health IT Certification Program, ONC conducts a range of workshops. ONC's standards certification and exchange activities are carried out with standards development organizations, and it works directly with semantics-oriented organizations and with industry in general to share best practices. He cited patient matching as an example of the latter. ONC also administers the Interoperability Standards Advisory, which is updated regularly, as well as the U.S. Core Data for Interoperability (USCDI) platform. A major goal is to give industry greater predictability for regulatory decisions and to be more transparent.

In the standards area, he highlighted several programmatic and issue domains, some in response to Executive Orders. The recent public health data infrastructure and modernization effort is an example; other areas include quality and safety-related activities and work on equity and social determinants of health, patient matching, and privacy and security. Other foci include patient access and interoperability.

ONC's Advisory Committee, the Health Information Technology Advisory Committee (HITAC), has had several task forces, including the one for the Intersection of Clinical and Administrative Data (ICAD) project in which NCVHS collaborated. Mr. Posnack said ONC is going through the ICAD Task Force's recommendations, working with other federal agencies to implement some of them; and it is looking for future synergies between the two "sister" advisory bodies. He noted that this will be an iterative process.

ONC also does a lot of policy alignment and regulatory work, especially around CMS rules, and it collaborates with software development and innovation communities. It is also working to "refresh" the Federal Health IT Strategic Plan (2020-25).

Mr. Posnack then turned to opportunities to collaborate with NCVHS. Setting the stage for conversation with members, he offered thoughts about four areas of interest to ONC that are in the NCVHS purview: data (quality, vital and health statistics statistics); convergence areas (encompassing human services and equity); automation and burden reduction (with related governance and data use issues); and metrics and benchmarks for progress.

- **Discussion**

Asked if ONC had reviewed industry commenters' suggestions about patient matching, Mr. Posnack noted that ONC received a congressional request to produce a report and recommendations on patient identity and patient matching, which is underway. Last year, ONC issued an RFI and held public workshops to gather input. There are increased calls for having a unique identifier for patients – but split opinions whether or not one should be mandated at a federal government level or that it should generally be supported through a national infrastructure. Overall, stakeholders are indicating that a patient identifier would be helpful – with mixed opinions whether to design and implement it as voluntary or mandatory.

He noted the relatively recent shift of the Medicare beneficiary ID from the Social Security Number to a unique identifier. It is not clear how often the Medicare beneficiary ID right now is used to support patient matching for Medicare beneficiaries. He noted this question would lend itself to investigation – how are health care organizations making use, or not, of the availability of these identifiers?

Asked about the high-level administration goals and objectives that might inform NCVHS' work, Mr. Posnack said the key question is, "Is the e-health health care experience easier?" This applies to patient/caregiver, clinical, and care coordination perspectives. Further, everyone in the nation must derive similar benefits, getting at the equity goal. There are intermediate and incremental metrics and stages toward these goals.

Asked for his thoughts on improving data and EHRs for better patient care and decision support, he framed it as "pinpointing the information people need at a particular time, immediately," and added that "a lot of work" still lies ahead to meet that need.

He agreed with Ms. Love that there are still many "data ecosystems," not just one. She expressed concern about preserving data flows while modernizing, given the disparate demands and functions of these data ecosystems; he said the question is how to go vertically through the layers. This change will happen incrementally, starting with the points of the system that are ready to change first and building momentum from there. Ms. Love urged that modernization be done "carefully" and proposed that the two advisory groups work together on a roadmap for this process.

With Dr. Mays, Mr. Posnack discussed issues around equity and public trust, and the possibility of a metric around bias specific to certain populations in the context of machine learning. He noted the growing recognition of these issues and increasing dialogue with industry stakeholders about them, and invited further discussion with NCVHS in this area. Dr. Mays suggested that the government might impose requirements on grant recipients in this area.

Mr. Landen pointed to the growing sentiment in industry that “one size fits all” regulation no longer works. Mr. Posnack said he is hearing that, too, and support for multiple standards/versions has increased. He added that it is worthwhile to consider who would need to run multi-version support.

Finally, responding to a query from Ms. Banks, he reflected on the impacts of HIPAA and related regulations on the new interoperability framework, and on how “interoperability convergence” should be approached in view of limited resources. He stressed that ONC and OCR work to make the regulations work for industry, and they are open to feedback.

Summary of Subcommittee on Standards Listening Session for Convergence 2.0 Project (slides) —Ms. Love, Co-chair, and Members

In this early phase of the Convergence 2.0 project, the Subcommittee is assessing the current health data standards landscape. For this purpose, the Subcommittee held a listening session on August 25 and issued a request for comments. To date, it has received more than 30 detailed comment letters (more than 200 pages). The Subcommittee asked the panelists and commenters to address four topics: how data sharing of all kinds can be improved; whether any new standards or use cases should be recommended to HHS for adoption; best practices in other industries with respect to standards; and priorities for the next 5 to 10 years.

After noting some of the 18 themes that emerged from the written comments, which are still under review, Ms. Love asked the moderators of each panel to report on the major takeaways from their panels. See the Subcommittee’s slides for further content.

Panel 1: National Standards Coordination—Mr. Ferguson
This panel focused on coordination of standards across entire sectors of the economy and on successful processes for standards adoption and implementation in health care and non-health care sectors. In addition to hearing about successful examples inside and outside the HIPAA context, the session highlighted that standards coordination requires dedicated resources and that collaborations have to start with clear objectives and measures of success. There was extensive discussion of how standards frameworks can adapt to changing technology and manage transitions, something that may require a different legislative framework.

Panel 2: Information Exchange Beyond HIPAA, Today and Beyond—Ms. Banks
One takeaway from this session concerned the need for greater coordination and collaboration among the SDOs to drive interoperability, as well as coordination between existing and emerging standards and between SDOs, HHS, and industry stakeholders. This includes the need for ongoing measurement of benefits and outcomes. The session also discussed gaps in current X12 standards; and it reconfirmed the need to test standards before adoption, and for HHS to support pilot standards. The extended pace of the current standard adoption process was questioned. Another theme was the methodology and challenges of collecting monetary and non-monetary return on investment. Ms. Banks referred members and others to the Convergence 2.0 project’s scoping document, posted on the NCVHS website.

Panel 3: Semantic Harmonization—Dr. Cimino

The idea of semantic harmonization is that the parties exchanging information have a common understanding of the meaning of the information being exchanged so it can be used in a functional way. The ecosystem is "closing in on the data models" that will enable that. The consensus in the panel was that current efforts underway may be sufficient to eventually achieve semantic interoperability; there is no need for any radically new approach; manually-curated terminology is the way to go; and NCVHS doesn't need to do anything other than encourage continued support of efforts already happening.

Panel 4: Social Risk Data—Ms. Love and Ms. Chrysler

This panel highlighted insights about the exchange of public health, vital statistics, and social service data as part of a national standard strategy, encompassing administrative and vital records data that originate in payer and provider systems. Session participants agreed on the need for a national coordinated system that includes workforce training, enforcement, validation, imputation, disaggregation frameworks, and purposeful uses. Both social and structural determinants of social risk data are needed to address social risk versus social need. Collection and use of social service data will require interagency and cross-sector coordination; and industry (providers and payers) are also key partners. Sustainable funding for the states for modernization will be essential. Concerns about the variations in access and collection laws across the states point to the need for federal leadership action, and there was support on the panel for a best practices framework to promote and enable consistency for interoperability. The discussion also highlighted the privacy, confidentiality and security issues with social risk factor data that are exacerbated by variations among states, which govern much of the public health arena.

The Subcommittee will continue to review and process the inputs received as it works toward a long-term vision for the health and wellness data ecosystem. Mr. Landen noted that the critical input received from data ecosystem experts is greatly enhanced by the expertise of participating NCVHS members. After acknowledging the key roles of NCVHS staff members Lorraine Doo and Rebecca Hines in the listening session, he invited Committee discussion.

- **Discussion**

Members offered these suggestions:

- Bring CDC into the discussions, as well as human services agencies.
- Look at existing federal activities in these areas and identify potential leverage points.
- Consider using machine learning to help process the rich inputs received.
- The Standards and PCS subcommittees should work together on the issues around varying laws among states and a potential federal role in resolving them. Timing is critical because of the recent new funding to states for updates.
- Participants in the ecosystem who wish to submit comments should make an effort to be clear, so their voices are heard.
- Some testimony suggests confusion about the fact that OMB directives on how race and ethnicity data are reported do not prohibit the collection of more detailed data, as can be seen in the California example; this points to the need for further education on the subject.

Mr. Landen said the Subcommittee will work on this project during the year ahead, with tentative plans to produce a report and possible recommendations. A project timeline is forthcoming.

Public Comment

1. Heather McComas, American Medical Association *(in her words, slightly abridged for conciseness)*

The listening session was a much-needed opportunity to hear stakeholder perspectives on what is and is not working correctly in the current interoperability and standards health care landscape. A clear message emerged from the listening session: The time is now to address unmet business needs in our industry. The AMA could not agree more.

There was overwhelming consensus in the listening session and written comments that the Subcommittee should follow several fundamental principles as it considers solutions to standards and interoperability challenges to support the delivery of high-quality efficient care. First, we must avoid disrupting systems and processes that are currently working in the health care system. Similarly, foundational terminologies and code sets will continue to play a major role in supporting patient care, meeting business needs, and health information interoperability. Any changes in transaction standards and operating rules must be rigorously tested and show a return on investment before being recommended for adoption. ROI is not solely about money, but also time, opportunity costs, and improving the quality and efficiency of patient care. Electronic transactions may not be efficient for the end users, and we really need to figure them out before we recommend them for adoption. Importantly, small and under-resourced physician practices must also realize an ROI.

As we heard during the listening session from the CMS Division of National Standards, any recommendations for changes in transaction standards and operating rule regulations must be supported with data in the public record, illustrating successful testing and return on investment. And, finally, to ensure the success of any recommendations, it is critical to include and carefully consider feedback from the right stakeholder throughout the process. It is really important to get the clinician perspective in all these decisions.

Considering these consensus principles, the AMA urges the Subcommittee to prioritize the following critical unmet business needs for patients and physicians. NCVHS should:

- Recommend transaction standards to support data exchange between providers and payers of all types for medical services and prescription drug prior authorizations;
- Recommend adoption of the transaction standards for real-time prescription benefit technology that integrates with all electronic health record systems and provides accurate information for all drug plans and patients;
- Study, evaluate, and recommend a transaction standard and/or operating rule that addresses the good faith estimate and advance explanation of benefits requirements of the No Surprises Act; and
- Recommend standardizing rules of data submissions to reduce the burden on physicians and streamlining compliance with disparate payer billing rules and requirements.

The AMA greatly appreciates the opportunity to provide verbal comment and intends to follow up with a more detailed comment letter to the Full Committee. It commends NCVHS for undertaking this ambitious and critically needed work and stands ready to further assist in this effort.

2. Stanley Nachimson *(written comment)*

In the development and implementation of new standards, it is critical to include time after standards adoption for vendors and others to develop and test software, the distribution of new software, and the education and training process for end users. This infrastructure update has to be considered when publishing regulations for standards use. We tend to forget the time that this may take. In fact, the ACA required a 27-month implementation for new HIPAA standards.

CMS did recognize this in their FAQs about the new standards under the No Surprises Act, promising no enforcement until after standards are developed and infrastructure is operating. Any timeframes for standards changes (including security and privacy) must build this in.

Subcommittee on Privacy, Confidentiality and Security Discussion Continued from Day One (slides) — Ms. Goldstein

Picking up on the previous day's discussion, Ms. Goldstein put forward a list of potential topics that had coalesced specific to the September 2020 hearing on data collection in a PHE. They include the idea of vaccine status passports and exploring possible standards and guidelines for that type of information sharing; questions about the lifecycle and long-term maintenance and use of public health data collected in an emergency; waivers of various sorts; and standards for what data should be shared. She invited further discussion of these ideas.

Much of the ensuing discussion focused on the idea of a possible project and product on data stewardship in a public health emergency. As a case study, Ms. Love suggested looking at the lessons learned from the 2002 Olympics regarding guidelines that can be put in place ahead of an emergency; Ms. Goldstein called this "data crisis standards of care." As other good case examples, Ms. Watzlaf pointed to the Chicago testimony on lead exposure and the testimony from the Maine Department of Health.

Mr. Landen suggested that a letter to the Secretary call out what has changed since the hearing, list national priorities to pursue, and identify the priorities NCVHS/PCS plans to pursue.

Dr. Mays focused on the need to build a bridge of public trust, which will require a communication plan and an effort to ensure that all the right people are brought to the table to think through the principles. She noted that some players, such as FEMA and Homeland Security, inevitably have dominant roles during an emergency. She also suggested keeping separate a resource on data stewardship in an emergency and a general data stewardship resource.

Health Equity Update and Committee Discussion—Dr. Arnold

Dr. Arnold summarized the varied activities under way in the Department around the collection of data to support health equity. Several recent executive orders have heightened the efforts in this area. There is growing awareness of the data gaps and lack of routine data collection on sexual orientation and gender identity, and interest in achieving consensus on how to consistently assess social determinants of health.

ASPE believes NCVHS could be helpful in this area. Dr. Arnold asked the Committee to develop analysis and recommendations around the collection of sexual orientation and gender identity (SOGI) and social determinants of health (SDOH) data, encompassing survey, administrative, and clinical data. The

Department is interested in the most important data points that should be systematically collected, best practices for this data collection, and recommendations on privacy considerations.

She invited discussion and questions from members and an indication of whether there is interest and how the project might be staged in terms of short-term and longer-term stages and objectives. She noted that, although this is a multi-year set of questions requiring a long-term agenda, the Department would like initial recommendations in six to eight months. She also asked for recommendations on the most important priority variables—common data elements that are necessary across all settings and cases, and how to make them usable and transferrable.

- **Discussion**

Members expressed interest and excitement about this requested work. It was suggested that research be added as a data collection "bucket." All agreed that it will be important for NCVHS to identify and convene stakeholders and experts with relevant experience in different sectors, including academic medical centers.

It was noted that patients and consumers are a significant and possibly direct source of this information. Another topic raised was what sensitive data will need to be stored safely behind a firewall. An early issue will be identifying the best practices in different sectors.

Mr. Coussoule thanked Dr. Arnold for this request, and agreed that NCVHS is well suited for it. After getting a show of hands of members interested in working on this project, he said the Executive Subcommittee would think through how to frame and move forward on it.

ICD-11 Letter Discussion Continued from Day One and Action—Ms. Hines

Ms. Hines facilitated a review and discussion of a revised draft of the letter on ICD-11, building on the previous day's suggestions. The letter was further modified in response to additional suggestions and discussion. The Committee then voted unanimously to approve the ICD-11 letter, allowing for non-substantive copy-editing changes by staff before sending it to the Secretary. (The final letter is posted on the NCVHS website.)

NCVHS 2021 Workplan Review and Discussion

The Committee briefly reviewed its workplan, adding a line item for the project requested by Dr. Arnold and ASPE. The possibility of reconvening the Subcommittee on Population Health for this purpose was raised. Members also noted the need for resources to carry out the new project.

The next NCVHS meeting is scheduled for January 24-25, the first of three in 2022.

Final Comments and Adjournment—Mr. Coussoule

After thanking NCVHS members, staff, technical partners, and outside participants for their contributions to this productive meeting, Mr. Coussoule adjourned the meeting.

I hereby certify that, to the best of my knowledge, the foregoing summary of minutes is accurate and complete.

/s/	10/20/2021
Nicholas Coussoule Chair, NCVHS	Date

ATTACHED: Public attendee list

Public Attendance

First Name	Last Name	Organization
Jonathan	Adams	CDC OCIO
Irma	Arispe	CDC
Maria	Baron	New Jersey Department of Health
Michelle	Barry	Availity
Alexis	Boaz	
Laura	Caldwell	GDIT
Bill	Campbell	Onehealthport
Chanda	Chhay	Caset Associates
Kristol	Chism	Change Healthcare
Sara	Couture	ASPE
Krycia	Cowling	HHS ASPE
Mike	Denison	Change Healthcare
TUYET	DESJEAN	AMA
Steven	Fink	CDC/DDPHSS/NCHS/DHNES
Stephanie	Fiore	Anthem, Inc.
Rachel	Foerster	Rachel Foerster & Associates Ltd
Kin Wah	Fung	NLM, NIH
Robert	Gellman	Consultant
Christine	Gerhardt	CMS
Renee	Gindi	CDC/NCHS
Alix	Goss	Imprado
Christol	Green	Anthem Inc.
Kenari	Guest	St. Margaret's Daughters Home
Philo	Hall	Epstein Becker & Green, PC
Nancy	Han	CDC/NCHS
Althelia	Harris	CDC/NCHS/OMO
David	Haugen	MN Dept. of Health
Kevin	Heslin	NCHS/CDC
Alston	Hildreth	CDC
Katherine	Isbell	LexiCode
Elizabeth	Jackson	CDC/NCHS
Christine	Jackson	Medtronic
Olga	Joos	CDC Foundation
Jessly	Joy	CDC
Daniel	Kalwa	CMS
Beth	Karpiak	
Richard	Klein	NCHS
Katie	Knapp	Veterans Health Administration
Karen	Knight	CDC
Susan	Langford	BlueCross BlueShield of Tennessee

First Name	Last Name	Organization
Ben	Leonard	POLITICO
Michael	Mabry	RadNet
Karen	Mandelbaum	Epstein Becker Green
Kristina	McCann	CoverMyMeds
Heather	McComas	AMA
Kyle	McDonald	The Berwyn Group
B	McGough	CDC
Lisa J	McKeen	eMedNY/GDIT
Patrick	McLaughlin	National Library of Medicine
Samantha	Meklir	HHS ONC
Stanley	Nachimson	Nachimson Advisors LLC
Brady	Nelson	Wisconsin Hospital Association Information Center
Erin	ORourke	AHIP
Shaundell	Pannell	CDC
Jessica	Porras	CAQH
ROSE	PUDLIN	FAIR HAVEN COMMUNITY HEALTH CLINIC, INC
Molly	Reese	AMA
Matt	Reid	American Medical Association
Erin	Richter	
Tara	Rose	Optum/UHC
Suzy	Roy	SNOMED International
Katie	Russell	CoverMyMeds
Jonnell	Sanciangco	Maximus
Cathy	Sheppard	X12
Gwyn	Smith	VA
Lynn	Snyder	EBG
Ashley	Southerland	American Medical Association
Nancy	Spector	American Medical Association
Merianne	Spencer	NCHS
Mary	Stanfill	UASI
Scott	Stare	CMS OMH
Charles	Stellar	WEDI
Merri-Lee	Stine	Aetna
Tricia	Stuto	GDIT
Walter	Suarez	Kaiser Permanente
Yu	Sun	NCHS
Rashmi	Tandon	HHS CDC
Robert	Tennant	WEDI
Harper Jean	Tobin	interACT: Advocates for Intersex Youth
Rita	Torkzadeh	

First Name	Last Name	Organization
Lisa	Walton	
Erin	Weber	CAQH
Margaret	Weiker	NCPDP
Megan	Wilhelms	MT DPHHS
Chantal	Worzala	
Diana	Wright	Lantana Consulting Group
Rachael	Zuckerman	HHS