Department of Health and Human Services
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
November 13-14, 2019
Wilbur Cohen Building, Washington, DC

MEETING SUMMARY

Note: *For details on this meeting, please refer to the transcript and slides posted at ncvhs.hhs.gov. See "Related Items" associated with the meeting agenda.*

The National Committee on Vital and Health Statistics was convened on November 13-14, 2019, in the Wilbur Cohen Building in Washington, DC. The meeting was open to the public. Present:

Committee Members
William W. Stead, MD, Chair
Nicholas Coussoule
Llewellyn Cornelius, PhD
Alexandra Goss
Richard Landen, MPH, MBA
Denise Love, BSN, MBA
Jacki Monson, JD (by phone)
Frank Pasquale, JD (by phone)
Bob Phillips, MD, MSPH
Debra Strickland, MS
Absent:
Vickie Mays, PhD, MSPH
Roland Thorpe, Jr., PhD

Lead Staff and Liaisons
Sharon Arnold, PhD, ASPE, Exec. Staff Director
Rebecca Hines, MHS, NCHS, Exec. Secretary
Kate Brett, PhD, NCHS
Lorraine Doo, MPH, CMS
Rachel Seeger, JD, OCR

NCVHS Staff
Marietta Squire, NCHS
Geanelle Herring, CMS

Others (not including presenters)
Chris Freedman, Karna
Warren Strauss, Karna
Loren Choi, BCBS
Paula Mosley-Dupee, CMS
Margaret Weiker, NCPDP
Andrew Fitzpatrick, X12
Amy Blum, NCHS
Daniel Kalwa, CMS
Jean Narcisi, ADA
James Ferguson, Kaiser
Charles Stellar, WEDI
Kelly Schultz, AHIP
Gail Kocher, BCBSA
Robert Tennant, MGMA
Christine Gerhardt, CMS
Kate Knapp, VHA
Leslie Prellwitz, AMA
Renee Gindi, NCHS
Margo Schwab, OMB
Quinn Hirsch, OMB
Thomas Mason, ONC
Marissa Gordon-Nguyen, OCR

In addition to those present in person or by phone (listed above), 211 people on day 1 of the meeting, and 124 people on day 2 connected into the meeting broadcast.

ACTIONS

1. The Committee approved a letter and recommendations to the Secretary on the upcoming transition to ICD-11, including a recommended research agenda and communication plan. The Committee delegated to the Executive Subcommittee responsibility for approving the final clean version.

2. The Committee accepted a letter with recommendations for HHS actions to improve the adoption of HIPAA standards, with suggestions for minor modifications. It delegated to the Executive Subcommittee responsibility for approving the final clean version.

The final versions of the letters and attachments are posted on the NCVHS website.

—DAY ONE—

Welcome and Agenda Review—Dr. Stead

After welcoming those present, Dr. Stead acknowledged the "steadfast leadership" of the Committee's privacy work by recently-retired member Linda Kloss, and he thanked member Bob Phillips, whose term ends with this meeting, for his leadership in the areas of population health and data access. He then reviewed the agenda and outlined the priorities for the meeting.

ASPE Update—Sharon Arnold, Executive Staff Director

Dr. Arnold added her thanks to Dr. Phillips and to Roland Thorpe, who is also leaving the Committee. She announced that the Secretary has approved four new members; and Mr. Coussoule, Mr. Landen, Ms. Monson, and Ms. Strickland have been renewed for second four-year terms. She invited suggestions of additional members with appropriate expertise, to bring the total number of members to 18. She reported that in addition to pursuing the Secretary's longstanding priorities, including value-based purchasing and dealing with the opioid crisis, the Department is very focused on implementing the Evidence Act, working with OMB to develop guidance and assessing its data resources for implementing the Act. As of the meeting, there isn't a final 2020 budget.

ICD-11 Follow-up and Action—Mr. Landen and Dr. Stead [slides]

Before presenting proposed research questions, a communication plan, and a draft letter to the Secretary related to the transition to ICD-11, Mr. Landen reviewed the NCVHS developmental process leading to this final stage. Dr. Stead pointed out that it has been a two-year journey. Once these documents, which frame a proposed approach for the Department, are approved by the Committee, the Committee will pause any further work related to the transition to ICD-11 until research and other proposed steps take place.

To review, the World Health Organization approved ICD-11 in May 2019. There is a U.S. Coordinating Committee. Mortality adoption is not discretionary, but the morbidity aspect is a matter of national rulemaking, on which NCVHS is directed to advise the Secretary. NCVHS initially looked at the transition to ICD-11 in the context of its work on health terminologies and vocabularies. After completing an environmental scan and holding a 2018 expert roundtable that identified gaps and areas of overlap and recommending a number of actions, the Committee developed recommendations regarding a pathway to ICD-11 that incorporates a simplified regulatory process. It sent a letter to the Secretary in February 2019 (also part of the 13th Report to Congress) and then convened an expert roundtable in August 2019. A

detailed summary of that roundtable is posted on the NCVHS website.[1] A major takeaway was that ICD-11 is a major advance over ICD-10.

The Subcommittee on Standards then presented for review a letter to the Secretary based on the foregoing body of work. The letter advises HHS to take a proactive approach toward the transition from ICD-10 to ICD-11. The letter recommends a research agenda to develop key use cases to demonstrate the suitability of ICD-11 in the U.S. and to address the opportunity costs of alternative timelines for the transition and other questions. It also proposes a communications plan that would establish "a trusted source of truth for the industry" to help mitigate inconsistent messaging and misinformation.

Members first discussed the proposed research agenda, which will be attached to the letter to the Secretary. The letter identifies seven key questions that should be addressed in the next 12-18 months, for the following purposes: 1) to develop U.S.-specific use cases to guide evaluation of ICD-11 for mortality and morbidity in preparation for implementation; 2) to evaluate content, consistency and stability of ICD-11; 3) to inform HHS decisions about the process and timeline for implementing ICD-11 for mortality in the U.S.; and 4) to inform HHS decisions regarding adoption and implementation of ICD-11 for morbidity in the U.S. NCVHS members offered various comments and suggestions on the research agenda and questions. (See the transcript for the details, and the website for the final letter and attachments.)

Next, members were asked to review the recommended communication plan for ICD-11, which covers the general approach, key messages, and key audiences. The letter recommends that HHS provide timely leadership on strategic outreach and communications to the U.S. health care industry regarding the transition to ICD-11. No changes were suggested. Members then reviewed the letter, which conveys the Committee's major recommendations in the aforementioned areas. The Committee then **passed a motion** to approve this body of work, with minor changes discussed in the meeting to be made subsequently and vetted and finalized by the Executive Subcommittee.

Ms. Goss acknowledged the support of NLM, the VA, and NCHS leadership in this project, along with that of Dr. Stead. She also acknowledged the recent death of Mike Lincoln, who had served as a subject matter expert on this project, expressing the Committee's sense of loss and its gratitude for his support of the full Committee and Standards Subcommittee.

X12 Update and Enhanced Implementation Guide Processes —Cathy Sheppard, Executive Director [slides]

X12 is an ANSI-accredited, consensus-based, multi-stakeholder nonprofit charged with the development, implementation, and ongoing use of electronic data interchange standards. It is more than 40 years old, and collaborates with more than 20 entities. X12 standards are "the workhorse of business-to-business exchanges." Much has changed in health care and technology in the 20 years since X12 transactions were mandated. Ms. Sheppard briefly described several of the current X12 health care initiatives, including those with DaVinci, NCPDP, and CAQH CORE, in addition to its non-health care initiatives.

Broadly speaking, X12 is working hard to listen and respond to feedback from stakeholders and to make things easier, and it wants to get more public feedback earlier in the process. Improvements include GLASS, its online viewer; simplified implementation guide naming (in response to an NCVHS recommendation); creation of an example library; centralizing its maintenance requests at one site; a simplified maintenance process with a new step for solicitation of public input; and a technical report

[1] https://ncvhs.hhs.gov/meetings/subcommittee-on-standards-icd-11-evaluation-expert-roundtable-meeting/

library. All X12 work products are based on a layer of metadata that it intends to make more visible in the future. A new Web resource, Bridge, will show the metadata. In conclusion, Ms. Sheppard stressed that as X12 moves forward, it will remain true to its organizational strengths and not lose focus on its implementation base and their needs. At the same time, it intends to move new ideas forward "at a much more rapid clip" than in the past.

Discussion

In discussion with Ms. Sheppard, NCVHS members explored questions about the changes she outlined and how the transition would work. Ms. Goss told members to "stay tuned" for something to come forward through the DSMO process for consideration as an upgrade to 5010. Other questions concerned how X12 planned to reach out to underrepresented audiences, and the plans for testing. Ms. Goss told Ms. Sheppard that NCVHS has "some very pointed thoughts about the need for testing," to be presented in the next session.

Predictability Roadmap—Ms. Goss [slides]

Ms. Goss reviewed the process whereby the Subcommittee on Standards concluded that the development, adoption and implementation of the standards are not keeping pace with health care business needs and industry innovations, despite the fact that administrative simplification achieved under HIPAA and the Affordable Care Act (ACA) has provided many benefits and improved the state of electronic information exchange between health care organizations. Barriers or challenges exist at each stage of the process. Starting in 2006, standards organizations have urged that the modification and adoption processes for standards be expedited, and NCVHS has sent letters expressing and addressing the industry's concerns about barriers. The Committee's reports to Congress on HIPAA implementation during this period also have addressed these concerns. The fundamental problem is that covered entities do not know when standards will be available or mandated for use. The barriers were elevated as part of NCVHS's Review Committee work in 2015 and 2016, after which NCVHS conducted an appreciative inquiry session in 2017 and a follow-up hearing in December 2018 for input on a set of 23 draft recommendations. Based on feedback, these were refined into five recommendations that were submitted in a letter to the Secretary in February 2019. NCVHS received feedback from the Division of National Standards on each of the five recommendations.

A subsequent visioning session was held in July 2019 for input on the following problem statement: "Barriers exist for the industry to adopt and implement updated versions of standards, implementation guides, or operating rules on a predictable, reliable, and timely basis, sufficient to meet the evolving business needs of industry, trading partners, and their business associates." The session yielded a consistent set of themes, the overarching message of which was summarized as "Do something, and do something now." Mr. Landen noted that while there is a solid base of value underlying the HIPAA standards, there are also many obstacles and challenges, and "HIPAA needs to evolve."

Ms. Goss then reviewed the findings from the July visioning session, which led to the letter before the Committee for review: 1) Rulemaking is a prerequisite to industry's use of updated national standards. 2) The adoption of updated HIPAA standards must come more frequently, more predictably and more reliably, in smaller, more easily assimilated sets. 3) End users of the standards, especially small clinician offices or their representatives, and public health agencies, do not have the economies of scale to participate directly in the current SDO/ORAE processes for standards development.

Based on these findings, the letter offers three action-oriented recommendations. Ms. Goss concluded that the Subcommittee will work on a longer-term vision over the next year, taking into consideration industry input, proposed and final rules released from HHS (CMS and ONC), and standards convergence efforts with ONC and HITAC.

Discussion

Dr. Stead stressed the importance of understanding how the recommendations work together in terms of what the letter is trying to accomplish. Members were supportive of the intent and content of the letter, although Ms. Love suggested conveying more of a sense of urgency. The Committee **passed a motion** to accept the letter, with suggestions for minor modifications, delegating to the Executive Subcommittee responsibility for reviewing and approving the final version.

Prior Authorization: Introduction — Ms. Goss [slides]

Prior authorization is an administrative process that requires a health care provider (physicians, pharmacists, medical groups, and hospitals) to request approval from a health plan to provide a medical service, prescription medication, or supply to a patient. There are existing and proposed standards for how the information is exchanged electronically. (See the slides and transcript for details.) The HIPAA standard, "the 278," has low utilization rates compared to phone, fax, mail, and portals. The information flow is not getting the information where it is needed to advance patient care and safety. Dr. Stead noted the process is highly fragmented and variable. Ms. Goss shared a compilation of past testimony on prior authorization, noting the impact on patient well-being and safety and the challenges related to pharmacy.

The 21st Century Cures Act directs ONC and its Health Information Technology Advisory Committee (HITAC) to consult with NCVHS as it develops policy, such as on the convergence of administrative and financial and clinical standards, and on prior authorization in that context. At the March 2019 HITAC meeting, the two FACAs discussed a collaborative project scope on prior authorization. The discussion with ONC then continued at the June NCVHS meeting. An early priority is to get an update from industry, where a number of relevant activities are taking place at a rapid pace, so that the FACAs can stay out of the way and help remove barriers.

Prior Authorization: NCVHS and ONC/HITAC Collaboration
—Don Rucker, National Coordinator for Health IT

Dr. Rucker observed that the root problem is the current inability to couple financial and clinical information. The 21st Century Cures Act requires ONC to report on provider burden, one aspect of which stems from "the goofiness of documentation" and the "quandary of quality measures." NCVHS, ONC, the national standards groups, and others need to figure out how to get a bolus of clinical data with a bolus of algorithmic data, all heretofore parts of asynchronous transactions, in an automated fashion into the workflow at the point of care. The end goal is a seamless, end-to-end connection that gets clinical data into real-time workflow. The purpose of the forthcoming panel, he said, is to start thinking about next steps.

Expert Panel on Prior Authorization

- **Heather McComas, Pharm D., American Medical Association (AMA) [slides]**

Dr. McComas, who directs the AMA's Administrative Simplification Initiatives, said that both physicians and their patients feel the burdens related to prior authorization every day. (Refer to slides for details.)

A December 2018 AMA survey of 1000 practicing physicians found strong evidence of delays in medically necessary care, sometimes leading to serious adverse events for their patients. The problem is getting worse over time. The AMA has launched a grassroots campaign, FixPriorAuth, to detail the impact. The AMA and a coalition of organizations released prior authorization and utilization management reform principles in January 2017, and in January 2018 with other entities it released a consensus statement recommending 21 principles of reform in five broad categories. However, progress has been very slow. One cause of the slowness is that despite nearly universal adoption of the electronic claim, the transaction is largely administrative and does not carry useful clinical data. What is needed, as has been widely known for years, is a standard way to communicate supporting clinical data. But despite interesting activity in this area, no one is sure "how to get from A to B."

Dr. McComas outlined the level of effort needed, including an extensive report; pilots; formal study; a decision; and a path forward with timelines. She concluded by pointing out that while automation is part of the solution, it is not a full answer.

- **Kate Berry, America's Health Insurance Plans (AHIP)**

Ms. Berry shared preliminary highlights from a recent AHIP survey of all health insurers, along with an update on a prior authorization demonstration project and information on a forthcoming project using claims analysis to identify outlier practices and bring them into standard practice. The work has been organized around the consensus statement referenced by Dr. McComas, to which AHIP was a party.

The survey of health insurers covers topics including the insurers' basis for prior authorization requirements, the types of procedures and drugs subject to prior authorization, their initiatives to streamline the process, and the major challenges they face. (See the transcript for details of the preliminary survey findings.)

The AHIP prior authorization automation demonstration project is looking at functionality in the prescription medication space and the medical services space (i.e., two use cases). The goal is to use scalable, standard-based approaches that are payer-agnostic and can be integrated into physician workflow. Seven health plans, both national and regional, have agreed to participate. RTI will be the independent evaluator. The project will launch in 2020 and run for about six months, with a report by the end of 2020.

Next year, AHIP will work with a Johns Hopkins team on a project using claims analysis to identify outlier practices and figure out how to bring them into standard practice.

- **April Todd, CAQH CORE [slides]**

Ms. Todd leads CAQH CORE, which is designated by HHS as the author of national operating rules for HIPAA-covered administrative transactions. It is a non-profit, multi-stakeholder organization that serves as a facilitator of business rules to help with the adoption of standards and interoperability. The

organization's surveys have found that today, 51% of prior authorizations are submitted and responded to manually (phone, fax, email); 36% are partially electronic (portal, interactive voice response system); and 12% are electronic (5010X217 278 Prior Authorization Request and Response). Even if some parts of prior authorization are electronic, other parts are manual. CAQH CORE has developed connectivity rules that CAQH has recommended for adoption; she predicted they would help advance efforts around prior authorization.

CAQH CORE surveys have identified the barriers to prior authorization. Ms. Todd outlined the organization's initiatives to address top barriers in five areas: 1) enhancing data content, 2) establishing national timeframes, 3) providing for consistent connectivity modes for data exchange, 4) enabling consistent electronic exchange of additional clinical information, and 5) evaluating across pilots for impact and further gap identification. (See the slides for details, including a roadmap for the work.)

CAQH CORE sent out a survey in Fall 2019 related to the exchange mechanisms used for medical documentation, as well as to information on attachments volume for each clinical service line. The preliminary findings show the clinical service lines needing the greatest volume of documentation. The organization has a number of pilots intended to help industry understand the path of prior authorization and the opportunities for more streamlined information exchange.

- **Mary Greene, MD, CMS**

Dr. Green is a Senior Advisor in the CMS Office of the Administrator and leads Patients Over Paperwork, a CMS burden-reduction initiative. The initiative has found that prior authorization is a leading source of clinician burnout. Solving the problem is a top priority for the CMS Administrator, who charged her staff with looking into a process for doing so. Dr. Green organized her presentation around three key messages: first, that enabling CMS beneficiaries to get needed medical services in a timely manner is the primary reason for fixing prior authorization; second, that some but not all of the associated problems are amenable to technical solutions; and third, that CMS wears multiple hats as it works to make prior authorization "exceptional."

CMS is now analyzing the findings from a recent investigation that yielded 2300 datapoints and put 96 issues on the table. Dr. Green cited some of the issues that require more than a technical solution, and noted that different people cite different problems when asking CMS to standardize specific aspects of prior authorization. Finally, she outlined the hats CMS wears and juggles in dealing with this: managing national standards, being a payer, and innovating and fostering innovation.

- **Jay Eisenstock, WEDI [slides]**

Mr. Eisenstock is the board chair of WEDI, the Workgroup for Electronic Data Interchange. He presented the findings of a recent small survey on prior authorization, to which 127 providers (most of them practicing physicians), payers, and vendors responded. The high-level findings are listed below; see the slides for the details, nuances (e.g., differences between providers and payers), and highlights.

  - Prior authorization has increased in the past year.
  - Web portals are the leading method for determining prior authorization requirements.
  - Ability is mixed for determining if prior authorization is required without initiating a request.
  - A small percentage of prior authorizations is delegated to utilization management organizations.
  - It is difficult to determine which method to use to submit a prior authorization request.

- Method used to initiate prior authorization request: payer portals and phone are the leading methods.
- Findings were mixed on the response to the initial prior authorization request.
- Data on final determination from a previously pended response: See slide.
- Support of the X12 278 request and response: Vendors and payers showed a high level of support, while providers were unsure how to answer the question.
- Barriers X12 278 request for review and response: See slide.
- 66 percent of providers have EHR support for the use of clinical attachments, and 55 percent of vendors' organizations support exportation or receipt of clinical attachments. The lack of a standard continues to be a barrier in the use of the 278 and other means of automation.

- **Pam Dixon, World Privacy Forum**

Ms. Dixon is founder and Executive Director of the World Privacy Forum, and her remarks provide context on prior authorization from the perspective of a privacy expert. After establishing some context for her remarks, she outlined a set of key risks and eight proposed solutions. As context, she noted, first, the shift from an era of the internet as a general-purpose technology to an era of prediction, employing artificial intelligence (AI); and second, the meaningful changes in privacy law over the past 25 years, including the recent advent of Europe's general data protection regulation.

She enumerated the following risks in terms of their health consequences (see the transcript for details):

- The impetus to remove the burden at all costs
- The reduction of data minimization (roughly akin to minimum necessary) as a goal
- The "infinite mirror problem" in an era of prediction, with resulting data interoperability problems
- Pathologies in the use of AI
- The problem of "social traps," caused by a lack of trust among stakeholders

She then offered these proposed solutions:

- Expanded oversight of third-party data uses and analysis in the AI and scoring sectors
- A reckoning between research and HIPAA's T/P/O (treatment, payment, and health care operations) provisions — a question she urged the Committee to grapple with
- Adding governance for the role of AI in health care decision-making
- Real-time governance
- New transparency mechanisms
- Bringing all stakeholders into the standards process
- Development of risk-scoring rules
- Voluntary consensus agreements and standards

In conclusion, Ms. Dixon articulated three desired outcomes for this endeavor: evidence-based use of data and technology, evidence-based decisions about the amount of data needed, and the engagement of patients in the process and their never being surprised by a data use.

In a brief discussion period with the panelists, NCVHS members had comments and questions about identifying high performers ("gold-carding"), the role of state laws and regulations, user education about

278s, mechanisms for feedback to vendors, and the ways in which 'data minimization' and 'minimum necessary' are and are not synonymous, among other topics. Dr. Stead commented on the growing complexity of the information needed to authorize specialty drugs, and others expressed agreement that this area would account for growing burden on providers and needs more attention.

From the audience, Bob Gellman, a privacy consultant and previous NCVHS member, observed that data minimization is a much broader concept than minimum necessary, as the latter applies under HIPAA to only some disclosures while the former term applies at all points of the process.

Follow-up Discussion, NCVHS and ONC—Ms. Goss, Dr. Rucker

Ms. Goss indicated the purpose of this session is to consider strategies and next steps for NCVHS and ONC in view of the preceding input on prior authorization from key stakeholders. Dr. Rucker noted the opportunity for WEDI and CAQH to think about a way to graft onto X12 processes some of the richer clinical information that will be available over time through FHIR (Fast Healthcare Interoperability Resources). He pointed out that interoperability, in which the Secretary and CMS Administrator have a strong interest, requires progress in areas such as that. He asked NCVHS members what stood out for them.

Ms. Love pointed to the interesting things going on with HIEs and state data agencies.

Ms. Goss noted that the work on attachments is not advancing, and NCVHS needs to figure out, in the broader context established in the previous session, how to make data exchange between payers and providers more effective. Dr. Stead agreed with this emphasis and suggested starting by looking for consensus in the industry about whether the work on an attachment standard should go forward, versus an alternative path. He proposed asking the payer community to look at USCDI to determine if prior authorization decisions could be handled in that way, and also exploring possible pilots with X12 and WEDI. These suggestions stimulated further discussion among NCVHS members and Dr. Rucker, who offered ONC's participation in such an effort, in conjunction with DaVinci.

The Subcommittee on Standards will hold a follow-up call soon to consider a work plan in this area.

The Committee then recessed until the following day.

—DAY TWO—

Dr. Stead welcomed Mr. Noonan and acknowledged OCR's guidance for the Committee's privacy work and particularly the support of Rachel Seeger as lead staff of the Subcommittee on Privacy, Confidentiality and Security.

HHS Office of Civil Rights (OCR) Briefing and Update—Tim Noonan, Deputy Director [slides]

Mr. Noonan, who echoed Dr. Stead's praise of Ms. Seeger, briefed the Committee on OCR's activities in the policy realm and those related to enforcement and audits. (See his slides for details.) He introduced Marissa Gordon-Nguyen, OCR's Head of Policy, and offered a more detailed briefing from her at another time.

OCR received more than 1300 comments in response to a December 2018 request for information on modifying the HIPAA rules to improve coordinated care. The resulting proposals will be issued in a notice

of proposed rulemaking. The proposed modifications relate to encouraging timely information-sharing for treatment and care coordination, addressing the opioid crisis and serious mental illness, and changing the current signature requirement on the Notice of Privacy Practices.

OCR issued a Notification of Enforcement Discretion early in 2019, and in April issued FAQs regarding health apps and the right of access. Right of access, he said, is a continuing thread in OCR's work as well as an enforcement priority. He commented on health apps with respect to privacy and HIPAA, noting the links to NCVHS's Beyond HIPAA work. OCR is concerned about protecting consumer data when it moves, and how it can make sure that consumers understand the risks. The FAQs were its first step, and it will work with ONC to develop more products. Its work on surprise billing, following an executive order from the President to look into it, began with listening sessions with various stakeholders, and it is still gathering information. OCR hopes to put something out in 2020 for feedback.

OCR's resolve to continue to enforce HIPAA and seek compliance from covered entities remains unchanged. Serena Mosley-Day is its head of HIPAA enforcement. Mr. Noonan shared data on complaints, corrective action plans, and penalties, as well as trends over time and types and locations of breaches. (See slides.) Investigations take place all over the U.S. and look at both small and large covered entities. Common issues related to right of access include lack of timeliness, unreasonable fees, and identity validation burdens.

OCR has done two phases of audit. The purposes of the audits, as mandated by HITECH legislation, are to identify best practices, uncover risks and vulnerabilities not identified through other enforcement tools, and encourage consistent attention to compliance. The audits found issues with risk analysis, risk management, and right of access, but general compliance with the Notice of Privacy Practices and timely breach notification.

In the discussion period, Mr. Noonan stressed that new security risk assessment tools and guidance are a tool, not a guarantor of compliance. Members engaged him about OCR's major concerns about surprise billing, its experience regarding health apps, the major concerns with right of access, and how to deal with people who claim to be "stewards of health data."

Redesign of *Health, United States* Data Program—Renee Gindi, Ph.D., NCHS [slides]

Dr. Gindi is Chief of the NCHS Population Health Reporting and Dissemination Branch. *Health, U.S.* is the congressionally-mandated annual report on the nation's health, submitted by NCHS to Congress and the President since 1975. NCVHS has historically advised on the report, and she was present to seek the Committee's guidance on its redesign.

The four major subject areas of the report are health status and determinants, health care utilization, health care resources, and health care expenditures and payers. Dr. Gindi outlined the different products and tools available to casual, sophisticated, and in-depth users, and she showed examples of each one. In addition to a printed book (fewer copies of which are now being printed), other products include Spotlight Infographics, FastStats, and Datafinder. (See slides for details.) She also called attention to the Appendix, which has useful materials for in-depth users.

As it engages in redesigning *Health, U.S.*, NCHS is addressing challenges in three areas: understanding audience needs, reaching the target audience, and ensuring easy-to-find information. It is also trying to adapt more quickly to changes in technology and subject matter importance. The stated goal or vision of the redesign is that "*Health, U.S.* will have an enhanced position as an authoritative source of analysis that

describes the health of the nation and how it is changing over time." The primary activity to date has been gathering data and inputs to help make the best decisions. They plan to wrap up the input by January 2020 and move into the content synthesis phase. Dr. Gindi said she hopes to return to a future NCVHS meeting to get feedback on the synthesized content and the utility of the new product.

Discussion

Discussion with NCVHS members centered on the utility of the redesigned *Health, U.S.* with respect to small area data for assessing community health. Dr. Phillips described the Measurement Framework for Community Health and Well-being, originally developed by NCVHS and now being stewarded by the Institute for Healthcare Improvement's (IHI) 100 Million Healthier Lives as "Well-being in the Nation (WIN)." He suggested looking for ways to align the *Health, U.S.* measures with this Framework, so the annual report could become a source for people wanting to produce those measures. Dr. Gindi expressed interest in this idea. Noting that action around national health is increasingly local and depends on granular data, Dr. Stead suggested establishing even loose links to related sources from IHI, the Kaiser Family Foundation, and the Robert Wood Johnson Foundation. The idea, which the group further explored, was to make *Health, U.S.* a gateway to other resources that would enable a deeper dive. Members had further suggestions of related resources.

Committee Member Updates

NCVHS members reported on their recent presentations on behalf of NCVHS.

- Mr. Landen spoke in August to the National Plan Automation Group, primarily on the Predictability Roadmap and ICD-11.

- Dr. Phillips updated the Committee on the status of the aforementioned Wellbeing in the Nation (WIN) activities, derived from NCVHS work. Among other things, the WIN network is being pulled into a formal partnership with Healthy People 2030; and Dr. Phillips, Dr. Cohen, and the WIN leadership produced a paper on the measures and the process that Millbank Quarterly invited the authors to submit.

- Dr. Stead and former member Linda Kloss presented the Beyond HIPAA approach at a recent NIST/OCR conference.

- Mr. Coussoule spoke on the Beyond HIPAA path and report to the AHIP Health IT and Interoperability Workgroup in September.

Updates from the Federal Data Strategy—Margo Schwab, Ph.D., OMB

As background for Dr. Schwab's briefing and her conversation with the Committee, Dr. Phillips commented on the juxtaposition between the growing interest in small area measurement of wellbeing and health, as seen in the activities and measurement Framework described above, on the one hand, and the simultaneous loss of key federal data tools on which communities rely to assess local health, on the other. He added that NCVHS has tracked the evolution of the Evidence-Based Policymaking Act of 2018 and the Federal Data Strategy. It submitted formal comments on the draft Federal Data Strategy in June 2019, particularly regarding the need for community-level data and analytic products. OMB has a key leadership role for the Federal Data Strategy. He welcomed Dr. Schwab, a Science Advisory and Policy Analyst in the OMB Office of Information and Regulatory Affairs.

Dr. Schwab thanked the Committee for its comments on the Data Strategy, which she agreed fits well with the Evidence-Based Policy Act. She introduced Quinn Hirsch, a member of the OMB team working on the Data Strategy who works with data from CDC, HRSA, NIH, and CMS; she noted that Ms. Hirsch could be a good collaborator for NCVHS on future projects in this area. The team is working on an updated action plan based on three phases of feedback received; the action plan should be out by the end of the year. OMB is thinking about how to get all the participating agencies to buy into the idea of a Federal Data Strategy, with consistent roles and responsibilities in data management across agencies, given the different cultures within agencies.

Moving into discussion with NCVHS members, Dr. Schwab recommended prioritizing key areas of missing data—notably for small-area analysis—and then identifying which specific agency/department to talk to about it. Accordingly, her purpose in this session was to talk with NCVHS about the kinds of data needed—breaking it into "bite-sized chunks"—and to advise them on how to move forward on getting the data.

Ms. Hines explained that the problem is that there is no home, administratively or legislatively, within HHS with mandated responsibility for sub-county-level data, even as community and public health leaders are saying they need the data. Having already identified the key areas of missing data, as suggested by Dr. Schwab, NCVHS is wondering how to leverage the Federal Data Strategy to increase the availability of the data. Again, Dr. Schwab suggested talking to the individuals within agencies who are familiar with their existing data assets. She also suggested that the Committee propose nominees with varied expertise for the FACA being established under the Evidence Act, and she asked for ideas for filling the new chief statistician position at OMB.

Dr. Phillips described a relevant project of the Robert Graham Center for Family Medicine Policy Studies, which is studying the utility of bringing clinical data from a national registry to help fill gaps in small area Census data in order to understand the health of those communities. Ms. Love described another project using state administrative data that she hopes can be streamlined and become a model. She observed that stronger linkages between such initiatives and NCHS could reduce the reinvention of the wheel in different silos.

2020 Areas of Focus for Subcommittee on Privacy, Confidentiality and Security—Mr. Pasquale, JD [slides]

Mr. Pasquale chairs the Subcommittee on Privacy, Confidentiality and Security (PCS). The Subcommittee is moving on from its work on the Beyond HIPAA initiative, which he briefly outlined. Two of the options for its 2020 area of focus are artificial intelligence (AI) in health care and EHRs and interoperability. Whatever the topic, the Subcommittee envisioned hosting a workshop in late spring and developing a report with recommendations for action by the Full Committee in the 4th quarter of 2020. He noted the fact that the Subcommittee will be gaining two new members.

For the Committee's consideration, he shared his thoughts on a possible NCVHS project on AI in health care, noting some of the key questions and topics involved. For example, such a project might address what the FDA is doing about mobile mental health apps, and/or questions of governance. Areas of interest include the differences between state and federal privacy standards; data-gathering and -sharing standards; and how to handle potentially biased data. The FAT-ML community, which has an annual conference, is a group to keep on the Committee's radar. In conclusion, he stressed that responsible AI development is a critical social aim, and the big focus needs to be on data. Also, both policymakers and

the public need to be educated about inaccurate and inappropriate data. He noted that this AI arena is part of the world of data beyond HIPAA. With that, he asked his colleagues for their feedback.

In the discussion period, Dr. Stead counseled realism about what NCVHS can accomplish. A possible way forward would be to formulate a use case and use it to apply the policy framework and principles outlined in the Beyond HIPAA report. This aligns with the focus of ONC and OCR, and the exercise might generate useful recommendations. Mr. Pasquale expressed strong agreement, adding that many of his ideas might be considered for 2021. He noted two possible ways to scope the project outlined by Dr. Stead, one focused on the consumer and the other encompassing the situations raised by new forms of business associate arrangements.

Ms. Seeger cautioned that the proposed work will not be in sync with rulemaking efforts already under way. She suggested putting together a work product based on the new NCVHS work. However, Ms. Bernstein observed that the rulemaking is unlikely to address the issues being discussed here.

To scope the next step, Dr. Stead asked Mr. Pasquale and the Subcommittee to prepare a brief, high-level scoping document oriented to one or both of the possible endpoints mentioned. Ms. Monson endorsed the general direction.

2020 NCVHS Workplan

Members and staff discussed next steps from the present meeting, and briefly reviewed the NCVHS workplan. There were differing responses to a suggestion by Ms. Bernstein that PCS and the Standards Subcommittee work together on prior authorization in the near term. Dr. Phillips asked how the Committee intends to interact with the Federal Data Strategy, and Dr. Arnold commented that for HHS, the Federal Data Strategy has been superseded by the passage of the Evidence Act, which it is trying to get its arms around; she advised that it is not a good time for the Committee to stake out a specific position.

Public Comments

Margaret Weiker of NCPDP reported that it expects to send a letter to NCVHS by early February 2020.

Cathy Sheppard of X12 urged the Committee not to forget about claims attachments.

Closing Remarks—Dr. Stead

Dr. Stead and others thanked Dr. Phillips for his service, and Ms. Hines thanked lead staff, the NCHS team, the ASPE staff and leadership, and RLA for their support. Dr. Stead then adjourned the meeting.

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

/s/ 03/24/2020

Chair Date