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October 11, 2021

National Committee on Vital and Health Statistics
Subcommittee on Standards
Full Committee Members
3311 Toledo Road
Hyattsville, MD 20782-2002

Re: Public Comment on Healthcare Standards Development, Adoption and Implementation and the Convergence 2.0 Project

Dear Full Committee Members:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to offer further comments to the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards (Subcommittee) on the Convergence 2.0 Project, as informed by the August 25, 2021, Listening Session[1] and the September 10, 2021, presentation of the Subcommittee[2] to the Full Committee. These comments expand upon previous comments submitted by the AMA in response to the Request for Public Comment on Healthcare Standards Development, Adoption and Implementation and can be found in the Appendices below.

I.   <u>Summary of Comments</u>

We offer our comments from the perspective of the largest association that represents the physician's voice in patient care. We believe that all actions must be grounded in what is best for the patient and their care team. Technology, data, and policy decisions ultimately trickle down to the patient level and therefore should not be made in a vacuum. The AMA also has the perspective of a federally designated maintainer of a universally adopted medical data code set under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification Program. Through that lens, the AMA offers the following comments and recommendations:

- Protect the integrity of NCVHS recommendations by following the process and scope of work enumerated in NCVHS' authorizing statute, charter, and the Charge of the Subcommittee on Standards.
- For all recommendations, clarify whether or not those recommendations reflect the views of NCVHS alone. Identify for the Secretary which stakeholders support any recommendation, as well as which ones do not and why.

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[1] National Committee on Vital and Health Statistics Standards Subcommittee Listening Session. Listening Session on Healthcare Standards Development, Adoption and Implementation. August 25, 2021. Available at: https://ncvhs.hhs.gov/meetings/standards-subcommittee-listening-session/.
[2] National Committee on Vital and Health Statistics Full Committee Meeting. Available at: https://ncvhs.hhs.gov/meetings/full-committee-meeting-8/.

- Clarify to what degree Convergence 2.0 is a continuation of the Predictability Roadmap or whether NCVHS has learned more about the Administrative Simplification Program since then.
- For any recommendations proposing changes to existing provisions or regulations, be specific about both the provisions/regulations to be modified and the exact change being suggested.
- In the interest of thorough deliberation, provide the opportunity for public notice and comment for any recommendations to adopt mandatory national standards.
- To help the Secretary meet the statutory requirement that new standards being considered for adoption have been proven to "reduce the administrative costs of providing and paying for health care," ensure that any recommendations to change administrative simplification transaction standards and operating rule regulations are supported with data in the public record.
- Use the following reasonable definition for "semantic harmonization:" "*Ensuring that data from multiple sources that may be represented differently but have the same meaning can be translated and understood when used or exchanged.*"
- Develop a semantic harmonization framework that re-uses what is available instead of designing novel vocabularies.
- Respect and abide by the unified message heard from a wide variety of stakeholders at the Listening Session—namely, "**do not try to fix what is not broken**"—and include that message in any recommendations to the Secretary.
- Continue to build on the foundations that are universally trusted and well-integrated within health care and rely on terminology standards that are fit for their purpose of use.

We appreciate the opportunity to provide comment and feedback on each stage of Convergence 2.0 as NCVHS collects new information and stakeholder input. The AMA will comment on the Subcommittee's eventual recommendations to the Full Committee, in addition to any recommendations that the Full Committee makes to the Secretary of HHS under the Phase I "Assess Standards Landscape," as identified in the Convergence 2.0 Project Scope.

II. Role and Authority of Full Committee and Subcommittee Under Convergence 2.0

All efforts by NCVHS' Full Committee to develop a semantic harmonization framework and the Convergence 2.0 effort should be tied back to the Project Scope and the NCVHS mission. NCVHS' Charter reflects the following Administrative Simplification tasks that Congress authorized NCVHS to perform through 42 USC § 242k(k):

- Advise the Secretary in complying with the Administrative Simplification statute.
- Advise the Secretary on the status of the implementation of the Administrative Simplification statute, including submitting a public report to Congress on the status of implementation of the Administrative Simplification statute.
- Study adoption of uniform data standards for patient medical record information and the electronic exchange of such information.
- Report to the Secretary, no later than August 2000, recommendations and legislative proposals for adoption of uniform data standards for patient medical record information and the electronic exchange of such information standards and electronic exchange.

The Subcommittee's Charge directs it to assist NCVHS' work on health data standards and implementation of the Administrative Simplification statute. The Charge states that to accomplish this, the Subcommittee will:

- Identify opportunities and issues in health data standards for Full Committee attention;
- Make recommendations to the Full Committee related to: Electronic transactions, Health terminologies and vocabularies, Clinical documentation, Security measures, Identifiers for employers, health plans, health care providers and patients, and Operating Rules; and
- Make recommendations to the Full Committee on strategies to promote a continuing process of developing, coordinating, adopting, implementing and maintaining standards. These strategies may include public information and educational efforts as well as research and development efforts.

As a part of its work for NCVHS, the Subcommittee is to consult with, among others, the health care industry, standards development organizations, health information technology companies, and consumer groups. We trust that the Subcommittee will consider the input of all facets of the health care industry, especially physicians and clinicians who engage directly with patients at the point of care. Further, we remind NCVHS and the Subcommittee to be specific when referring to "industry" comments or feedback. Which specific sectors or organizations hold a position, and which ones do not? The term "industry" should be avoided unless a position is truly the unified view of all stakeholders that have engaged on these topics over the years.

While NCVHS is only obligated to provide its own recommendations and advice to the Secretary, **we urge the NCVHS and the Subcommittee to be transparent and explain any differing views from or among health care stakeholders regarding its recommendations—particularly recommendations differing from those submitted through verbal and written public comment and testimony**. For example, we appreciate that at the September 10, 2021, presentation to the NCVHS Full Committee regarding preliminary results from the Listening Session, James Cimino, one of the Panel moderators, said: "Nobody asked NCVHS to do more than to support the status quo . . . I'm not sure that we all agree that that's true but that's what we heard from the Listening Session." To transparently identify the difference between stakeholder input and the opinions of NCVHS is fair to the Secretary, the public, stakeholders, and NCVHS members themselves.

III.   Clarifying Scope and Direction of Convergence 2.0

As the Subcommittee prepares recommendations to the Full Committee, and as the Full Committee prepares possible recommendations to the Secretary, it will be helpful to tie that content, and what was heard in the Subcommittee Listening Session and Full Committee meeting, back to the subject areas of the Convergence 2.0 Project Scope. At times during the September 10, 2021, Full Committee meeting, members of the Subcommittee seemed daunted by the volume of issues potentially in play following the Listening Session. It may be helpful and more realistic to narrow the scope of Convergence 2.0 to ensure adequate time to focus on fundamental, high-priority issues. Listening Session presenters suggested NCVHS start with the "low-hanging fruit;" the AMA could not agree more.

a.   "Regulatory Framework" - Adequacy of HIPAA Statute or Regulations?

We heard in the September 10, 2021 presentation to NCVHS that under Convergence 2.0, the Subcommittee will "refine" NCVHS' earlier recommendations on the HIPAA regulatory framework. **We urge the Subcommittee to clarify in its Project Scope document how its work regarding the HIPAA statute and regulations is different from previous recommendations that the Full Committee made to the Secretary.**

Specifically, in its December 10, 2019, *Additional recommendations for HHS actions to improve the adoption of standards under [HIPAA]*, the Full Committee recommended that the Secretary of HHS "Facilitate a nimbler approach to standards development to better support federal policy objectives, industry business requirements and emerging technologies." The Convergence 2.0 Project Scope states that "for other functions like prior authorization and health care attachments, [the HIPAA statute] has yet to offer industry sufficient efficiencies to adopt at scale."

The Subcommittee should clarify if the Project Scope is making a conclusion that is the same as or different from that of the Full Committee in 2019. We believe the Project Scope means that the *Secretary of HHS* has not proposed transaction standards for prior authorization and health care attachments, which are needed by industry. Or that, in general, the Secretary is not proposing and adopting new transaction standards and operating rules at a pace that meets industry needs. If the Subcommittee intends to say that the problem lies with the HIPAA Administrative Simplification statute itself, the Subcommittee should identify specific provisions of the law that the Subcommittee believes are problematic and explain why.

In preparing its report and any ultimate recommendations for the Secretary and Congress, NCVHS and the Subcommittee should bear in mind that the Secretary's power consists of administering laws through regulations and that Congress' power consists of enacting new laws. The Subcommittee's recommendations will be more readily understood and evaluated and potentially acted upon if they are presented in relation to specific current statutory and regulatory provisions.

If NCVHS and the Subcommittee believe that "the need to modernize the standards adoption framework" means that Congress should amend the HIPAA administrative simplification statute so that mandated national transaction standards or operating rules can be adopted by federal advisory committees or standards development organizations (SDOs) without any public notice and comment rulemaking process, then NCVHS and the Subcommittee should be clear on that. **However, the AMA is strongly opposed to any approach that would sidestep the public notice and comment rulemaking process.** The public, including physicians, should be provided an opportunity to comment on policies that directly impact the provision of care to patients.

For the purposes of thorough deliberation, the Subcommittee should also acknowledge what would be lost in foregoing such public rulemaking. The purpose of the federal notice and comment rulemaking process is not necessarily to be fast or efficient, but rather to be fair. Stakeholders are frequently frustrated by the slow pace of the regulatory process. Nevertheless, the process is beneficial in that it ensures that any proposed new federal requirements: (1) are developed with the input of federal experts on the policy, scientific, economic, budgetary, and legal aspects; (2) are broadly disseminated to the public with a thorough preamble discussion of those aspects, such as a formal economic impact analysis; (3) provide public stakeholders at least 60 days to evaluate and comment; (4) clearly identify the staff and officials who developed the proposals; and (5) respond to comments and concerns from the public, explaining why proposals are amended or not.

        b. *Standards Adoption and Implementation*

We recommend that the Standards Subcommittee consider what it heard during the Listening Session—"not to attempt to fix what is not broken"—with respect to modernizing the standards adoption framework.

The Convergence 2.0 Project Scope document suggests that over the past 25 years, significant progress was made as a result of the transaction and code set standards adopted and implemented under the Administrative Simplification Program. While CMS was making progress with respect to administrative and financial data exchanges, clinical data exchange also began to expand under the Office of the National Coordinator's (ONC's) electronic health records (EHR) certification program. Now that both types of data (administrative/financial and clinical) are generally digital, these data should be able to be used, exchanged, and integrated to support processes like prior authorization or to measure quality and outcomes for value-based care payments.

The input from the CMS National Standards Group representative at the Listening Session was very valuable to remind all standards and interoperability stakeholders to orient recommendations around a return on investment in both providing and paying for health care. CMS added another important reminder that, under the Administrative Simplification statute, new standards must reduce the administrative costs of providing and paying for health care. Specifically, section 1172(b) of the Social Security Act says: "Any standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care." These comments underscore and echo points that the AMA has made multiple times on the need for any new or updated administrative simplification standards to be oriented to meet the business needs of the health care industry and have proven value across stakeholder groups.

This is why, for the Secretary of HHS to be in a position to adopt recommendations to change administrative simplification transaction standards and operating rule regulations, any NCVHS recommendations should be supported with data in the public record. We remind the Subcommittee that return on investment is not solely about money but also time, opportunity cost, and consensus, to avoid inertia and workarounds. At the same time, work to achieve interoperability must not result in disruptions in the health care ecosystem that would negatively impact the quality and cost of patient care. We further emphasize that the health care ecosystem is diverse, comprised of small, solo, and rural medical practices along with large health systems. Yet, physicians will bear the brunt of systems and workflow changes. **All NCVHS recommendations should therefore be considered with low- and under-resourced physician organizations in mind.**

c. Harmonization of Clinical, Public Health, and Other Standards

During the Subcommittee's August 25 Listening Session, there was a robust discussion during Panel 3 on how to define "semantic harmonization." We recommended that a reasonable definition for semantic harmonization is "*ensuring that data from multiple sources that may be represented differently but have the same meaning can be translated and understood when used or exchanged.*"

In the AMA's presentation during Panel 3, we also shared that data capture, harmonization, and knowledge communication occurs when leveraging consensus and evidence-based standards. Meaningful interoperability requires terminologies that support health care workflows—starting with the patient encounter and culminating with payment for the services delivered. Fortunately, there is near-universal adoption of code sets that are trusted by and well-integrated within the health care system. We stressed that a semantic harmonization framework should re-use these code sets instead of designing novel vocabularies. Furthermore, in NCHVS' effort to promote semantic harmonization, **NCVHS must closely**

evaluate and refrain from actions that would lead to a massive disruption in the current claim submission and adjudication process; this would threaten the existence of independent physician practices, particularly those of small size.

The foundational Administrative Simplification Medical Data Code Sets (CPT-4, HCPCS and ICD) were among the first standards that were adopted under the Administrative Simplification Program, as well as adopted by ONC as part of the Interoperability Standards Advisory. Under the Administrative Simplification regulations, the Secretary also designated "code set maintaining organizations" that are responsible for updating and enhancing their respective code sets.[3] The Code Set maintenance process is similar to the Standards Version Advancement Process that is part of ONC's Health Information Technology Certification Program and interoperability standards framework. These are examples of efforts in harmonization, both with respect to semantics and the regulatory frameworks.

We urge the Subcommittee and NCVHS to continue to build on the foundations that are universally trusted and well-integrated within health care and rely on terminology standards that are fit for their purpose of use. This is exactly what NCVHS did on October 16, 2000, when it advised the Secretary on the original implementation of the Administrative Simplification Program and told the Secretary to adopt Level I and II HCPCS code sets because they "are nationally listed and maintained." We believe that NCVHS' advice to the Secretary was sound then, and that its rationale and reasoning are still relevant today.

d. Address Critical Unmet Business Needs for Physicians and Their Patients

At the Subcommittee's August 25 Listening Session, the AMA provided several specific recommendations that are necessary and near-term opportunities HHS can take to aid the practice environment for physicians and improve care for the patients they treat.

- The process of prior authorization as it currently stands is overused and inefficient. This onerous process also imposes unnecessary care delays on patients, interfering with treatment and even adversely impacting clinical outcomes. These patient harms can be quite significant: almost one-third (30 percent) of physicians responding to an AMA survey reported that prior authorization has led to a serious adverse event (e.g., hospitalization, permanent disability, or even death) for a patient in their care.[4] Physicians complete an average of 40 prior authorizations, per physician, per week—eating up roughly two business days (16.0 hours) of physician and practice staff time. Prior authorization automation and clinical data exchange between providers and payers must be improved. **NCVHS should recommend transaction standards to support data exchange between providers and payers of all types for medical services and prescription drug prior authorizations.**
- Real-time, patient-specific prescription benefit information in EHRs supports informed decision-making, prevents treatment abandonment, and reduces administrative burdens. While CMS regulations require that Part D plans support real-time prescription benefit (RTPB) tools, CMS set a very low bar, requiring these plans to support only one or more RTPB tools that integrates with one or more EHR system. This puts physicians at a disadvantage and would require unnecessary customization or costly configuration if a physician uses a different EHR than the one selected by

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[3] 45 CFR § 162.1002

[4] 2020 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/2021-04/prior-authorization-survey.pdf.
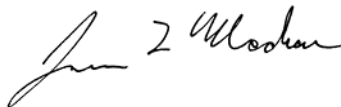
a Part D plan. **NCVHS should recommend adoption of a transaction standard for RTPB technology that integrates with all EHR systems and provides accurate information for all drug plans and patients.**

- More study is needed to evaluate how transaction standards or operating rules can support good faith estimates (GFEs)/advanced explanation of benefits (AEOBs) exchange, as required by the No Surprises Act, for organizations of all sizes and resource limitations. This should include an analysis of existing physician practice and health plan claim submission and adjudication workflows to determine the most efficient, uniform solution for creating GFEs and AEOBs. Additionally, **NCVHS should study, evaluate, and recommend a single transaction standard and/or operating rule that delivers AEOBs to providers and patients to support informed conversations about care costs.**

- The lack of standardized payer rules and requirements hobbles our national efforts to improve the clinical utility of data and adds unnecessary friction and confusion to reporting and data completion requirements imposed on physicians. Third-party billing complexities must be addressed in any practical approach to improve the business needs for physicians and improve care for the patients they treat. **NCVHS should recommend standardizing rules of data submissions to reduce the burden on physicians and streamlining compliance with disparate payer billing rules and requirements.**

IV.   <u>Conclusion</u>

Once again, the AMA appreciates the Subcommittee's efforts to improve our health care system through adoption of electronic standards that will improve efficiency and reduce administrative costs. In addition to considering our Summary of Comments in Section I, we urge the Subcommittee to continue to seek input from individuals representing the business and operational units of various stakeholder groups. This is critical to ensure policy recommendations meet the needs of those that directly participate in the care of patients. The AMA stands ready to assist the Subcommittee and the NCVHS Full Committee in representing the physician's voice in patient care. If you have any further questions or need additional information, please contact Matt Reid, Senior Health IT Consultant, at <u>matt.reid@ama-assn.org</u> or (202) 789-7419.

Sincerely,

James L. Madara, MD

Attachment

APPENDIX A1

July 30, 2021

Richard W. Landen, MPH, MBA
Co-Chair
National Committee on Vital and Health
Statistics
Subcommittee on Standards
3311 Toledo Road
Hyattsville, MD 20782-2002

Denise E. Love, BSN, MBA
Co-Chair
National Committee on Vital and Health
Statistics
Subcommittee on Standards
3311 Toledo Road
Hyattsville, MD 20782-2002

Dear Co-Chairs Landen and Love:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to respond to the *Request for Public Comment on Healthcare Standards Development, Adoption and Implementation* (the Notice) issued by the Subcommittee on Standards (the Subcommittee) of the National Committee on Vital and Health Statistics (NCVHS).[5] While the AMA provides remarks below in response to the four general questions posed in the Notice, the AMA also appreciates the opportunity to speak at the August 25, 2021 Listening Session on Healthcare Standards Development, Adoption and Implementation (the Listening Session) and looks forward to providing more detail for the Subcommittee's consideration at that time. The AMA intends to submit a more comprehensive set of comments following the Listening Session after the rich dialogue it is expecting from the variety of speakers.

As you know, the AMA is very committed to promoting interoperability and encouraging health care innovation and supports efforts to enhance the exchange of clinical and administrative data. The health care community relies on high-quality data that can literally make the difference in life-or-death situations. To that end, the entire health care system, including physicians, requires data standards that are credible and comprehensive and that adopt code sets developed using a rigorous and evidence-based process fit for the purposes for which they are meant to be used. The scope of data sharing within the health care system has expanded to encompass several clinical and administrative needs. Interoperability—the seamless exchange of electronic health-related data—enables clinicians to coordinate care among institutions and act based on current and comprehensive information.

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[5] This Request for Public Comment is also published in the Federal Register at 86 FR 33318, "National Committee on Vital Health Statistics: Notice of Meeting and Request for Public Comment" (June 24, 2021).

Interoperability also enables individual access to and ownership of one's health data and is critical to safe, responsible, and transparent public health reporting and monitoring. Further, interoperability is a key component in the Learning Health System[6] and—when data are properly coded in consensus-based standards—makes the promise of the Quadruple Aim achievable.[7]

As we understand it, in this RFI, the Subcommittee seeks to understand the extent to which current and emerging standards for exchanging electronic health-related data under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and other applicable federal legislation and regulatory processes are meeting the business needs of the health care system. The AMA supports NCVHS' role and responsibility in providing recommendations to the Secretary of the U.S. Department of Health and Human Services (the Secretary). While the AMA commends the Subcommittee for issuing the RFI and holding the Listening Session, and recognizes the importance of the issues raised, **the AMA urges the Subcommittee to ensure that its work aligns with the requirements and processes outlined in Title XI of the Social Security Act, the Administrative Simplification provisions of HIPAA, to include: adoption of standards that will reduce the costs of providing and delivering health care; consultation with designated organizations in standards development and advancement; and ensuring protections against the wrongful disclosure of individually identifiable health information.**

The AMA urges that, in the Subcommittee's eventual report of recommendations to the NCVHS, the following fundamental points be included. These fundamental points are listed here and are addressed in more detail in our responses to specific questions below:

- **The Subcommittee should recommend that any changes in federal standards as to which code sets should be selected within a government-adopted standard should be implemented incrementally to minimize the disruption to the flow of information among physicians, providers, health insurance organizations, and government agencies of varying sizes and capabilities. The unique needs of patients and the way that physicians fulfill those needs must not be endangered from rapid, significant changes.**

- **The Subcommittee should recognize and reconfirm the foundational role that the efficient and low-cost Current Procedure Terminology (CPT®) code set provides, having been selected to be included within various government-adopted standards.**

- **The Subcommittee should recognize and reconfirm that the entire health care system, including physicians, requires health-related data standards that are credible, comprehensive, and developed using a collaborative, rigorous, evidence-based process. As the definition of "health care" broadens and drives the need for additional codes, the CPT® Editorial Panel must play a key role in creating or facilitating the creation of these additional codes to address these emerging needs, including social determinants of health (SDoH) and public health. Coordination with existing foundational vocabulary sets, such as with the CPT® code set, is key to having the least amount of disruption and burden when adding such codes to the health care system.**

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[6] The Agency for Healthcare Research and Quality defines a Learning Health System as a health system in which internal data and experience are systematically integrated with external evidence, and that knowledge is put into practice. As a result, patients get higher quality, safer, more efficient care, and health care delivery organizations become better places to work.

[7] The Quadruple Aim enhances the patient experience of care and outcomes, improves population health, reduces overall costs for the health care system while increasing value, and supports the professional satisfaction of physicians and the health care team.

The AMA provides the following comments in response to the four questions the Notice presents and looks forward to further expounding upon our remarks during and after the Listening Session.

1. ***How can data sharing be improved between patients, providers, payers, [the] public health system, and other actors in health care? What are the barriers to these improvements?***

Improving data sharing begins with recognizing the important role that the CPT® code set currently plays in our health care system. The CPT® code set is the most widely accepted nomenclature for the reporting of physician and other qualified health care professional procedures and services under government and private health insurance programs. Code sets such as the International Classification of Diseases (ICD) and CPT® are the backbone of interoperable health information.[8] These code sets ensure consistency of meaning as data are exchanged and used for a broad range of essential purposes. These code sets are the content foundation for clinical and administrative transactions and for use by electronic health records (EHRs) and health information systems. Uniformity is critical to achieving both the administrative simplification requirements of HIPAA, which are aimed at reducing the administrative costs of providing and paying for health care, as well as current efforts to achieve the nation's goals related to health care information interoperability. Further improvements to data sharing should build upon this efficient, low cost, and effective foundation.

Through the Editorial Panel, the AMA has curated and maintained the physician-developed CPT® code set for 55 years. The CPT® Editorial Panel—an expert, volunteer group of physicians and other qualified health care professionals—devotes hundreds of hours of their time to the maintenance of the CPT® code set. The CPT® Editorial Panel uses a public, transparent, consensus-driven development process open to all interested parties, which results in a trusted, evidence-based standard. The CPT® code set serves the needs of a data-driven health system, allowing physicians, patients, researchers, medical groups, allied health care professionals, health systems, hospitals, medical coders, accreditation organizations, payers, and health information technology (Health IT) professionals to easily exchange data on the medical services and procedures provided to patients. The CPT® code set is updated annually on a predictable schedule to meet the health care industry's needs in a timely manner.

Additionally, as the curator of the CPT® code set, the AMA, along with the CPT® Editorial Panel, are proud to highlight that, as the definition of health care has expanded to include other aspects of health— such as SDoH and in rapid response to the emerging pandemic—the AMA has already played a key role in the development of new codes, and has been working with other industry stakeholders to create and promote these new, needed codes.

SDoH

The AMA has facilitated collaboration with other stakeholders to begin creating codes for SDoH. CPT® codes have been developed to describe services that address identified SDoH concerns, problems, or diagnoses. These SDoH concepts are integral to medical services and procedures used by clinicians. SDoH CPT® codes have also been recognized by the Office of the National Coordinator for Health Information Technology (ONC) and included in the United States Core Data for Interoperability (USCDI) version 2. The AMA is also a founding member of the Gravity Project, which is responsible for developing SDoH standards included in the USCDI

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[8] See, https://ncvhs.hhs.gov/wp-content/uploads/2019/03/Recommendation-Letter-Criteria-and-Guidelines-for-Health-T-V-Standards.pdf.

v2. The AMA's years of experience maintaining complex code sets has served as a critical resource to the Gravity Project, a multi-stakeholder group that seeks to create and maintain a consensus-building community focused on expanding available SDoH core data for interoperability and accelerating standards-based information exchange by using Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®). Since the Gravity Project's inception, the AMA has played a major role in the Project's governing bodies, and was critical in the development, standardization, and testing of the HL7® FHIR® SDoH implementation guide.

Addressing COVID-19 Pandemic Needs

The current COVID-19 pandemic has also highlighted that the rapid need for trusted coding in public health remains paramount. Delays in the development of new codes could have derailed vaccination efforts. However, due to the CPT® code set's flexibility, agility, and foundational presence throughout the health care system, new CPT® codes were created to effectively meet the industry's ever-changing public health needs. During the public health emergency, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) approached the CPT® Editorial Panel with ideas for COVID-19 vaccine and vaccine administration codes to support the agencies' tracking requirements. Responding to the federal government's needs, the CPT® Editorial Panel met multiple times to review, approve, and rapidly make available new COVID-19 vaccine codes. The AMA also quickly developed, produced, and distributed various educational resources to assist the nation's health care professionals in understanding and implementing the new codes. The AMA was and is proud to support this national imperative and has embraced its role as a rapid responder in the midst of this international crisis.

The COVID-19 public health emergency exposed several faults in the nation's health care system. Inconsistent guidance, inept or legacy technology, and a lack of rapid response to public health needs made clear that improvements are needed. Fortunately, vaccine administration has fared better. While more must be done to address inequities, access, and vaccination hesitancy, progress cannot happen without tracking vaccine distribution and administration. In other words, one cannot improve what one cannot measure. Similarly, long-term research on COVID-19 variant/vaccination efficacy, breakthrough infections, and "long-haul" COVID-19 survivor recovery will require the close monitoring of vaccine administration.

In furtherance of the Subcommittee's recommendations to NCVHS to build off of the foundation established by the CPT® code set, the AMA has identified barriers and gaps upon which the Subcommittee may wish to recommend improved data sharing. These are summarized as follows and are illustrated in more detail in the **Appendix**.

Barriers/Gaps	Overview of the AMA's Recommendation
Physicians lack access to usable health information	The Subcommittee should recognize and reconfirm the foundational role of the CPT® code set to address high-impact use cases with known needs and identified gaps.
Meeting patients where they are and addressing consumer needs	Patients should be empowered through accessible and consumable data. Resources like the CPT® Consumer-Friendly Descriptors meet clinical, administrative, and consumer needs by empowering

	patients to take ownership of their care through straightforward, consumable descriptions of health care procedures and claims data.
The complexity and clinical utility considerations of data and third-party billing	Standardizing the rules of data submissions that use the CPT® code set would reduce the burden on hundreds of thousands of physicians contracted with multiple health plans by streamlining compliance with different billing rules and requirements. Wide-spread adoption of the CPT® Guidelines and Conventions (Guidelines)—which are readily available and freely included with a CPT® license—provides an opportunity for substantial burden relief by promoting the use of a single transparent set of data submission rules for multiple payers.
	More broadly, the Subcommittee should challenge assumptions that physicians and other medical providers can simply "purchase more management services" to manage complex health care operations. Scarce physician resources should not be used to solve for payer-generated complexities. The AMA also recommends the federal government conduct a national effort to analyze inconsistencies in prior authorization (PA) data requirements and criteria across the payer community and review the clinical validity of payers' PA guidelines. Federal regulatory levers should be considered to ensure such guidelines and data requirements are made publicly available for review.
Excessive physician burden due to the churn in health IT adoption	The adoption of reusable clinical and administrative concepts—leveraging the appropriate terminologies—promotes consistent data representation across the entirety of the health care system, reduces burden, and improves efficiency.

2. *Are there any new standards or use cases available or under development that should be considered by NCVHS for recommendation to Health and Human Services (HHS) for adoption to support interoperability, burden reduction and administrative simplification? Some examples might include new information sharing in health care, such as data or semantics for SDoH, public health case reporting, or All Payer Claims Databases. Please do not limit responses to these examples.*

With its knowledge and experience as the curator of the CPT® code set, the AMA and the CPT® Editorial Panel have sought out opportunities to bring other stakeholders to the table to collaborate and continue advancing the CPT® code set forward as health care advances. For example, the CPT® Editorial Panel has made significant progress in establishing CPT® codes for digital medicine services. In addition, the AMA has been instrumental in informing the analysis of digital health reimbursement through the Digital Medicine Payment Advisory, a collaborative initiative of a diverse cross-section of nationally recognized experts convened by the AMA.

As the Subcommittee considers new use cases, the AMA encourages the Subcommittee to identify ways to strengthen existing foundational code sets, terminologies, vocabularies, and value sets used in the health care system—including for public health, social services, clinical, and administrative functions. The AMA supports NCVHS' desire to improve interoperability, reduce burden, and promote

administrative simplification. Care coordination requires standardized data and individuals' ownership of their health care information. Likewise, efforts to promote health equity, public health, price transparency, burden reduction, and data privacy are essential.

The AMA stresses, however, that any changes in the selection of code sets within federal standards must evolve at a practical and incremental pace. Large and sophisticated academic medical centers are uniquely different environments than small, solo, and rural medical practices and federally funded health centers (e.g., FQHCs, Title X clinics, etc.). Administrative and workflow disruptions have an outsized impact on these less-resourced health care facilities. Also, while technical expertise is important, that should not supplant the real-world knowledge and experience that clinical, operational, and administrative personnel bring to the table. Efforts should allow for all stakeholders to participate in the process, and with its knowledge and experience as the curator of the CPT® code set, the AMA, and its Editorial Panel, have unique expertise in bringing other stakeholders to the table to collaborate and continue advancing the CPT® code set as health care advances. Capturing input from frontline professionals who understand the data and workflow needs required by administrative and clinical processes is critical. Lastly, standards maturity, impact to the health care system, transition costs, workforce capacity, and industry consensus/readiness for implementing new/emergent standards should be factored into the Subcommittee's recommendations.

The AMA has detailed several examples of priority use cases, including those that build off of the CPT® code set, which the AMA encourages the Subcommittee to include in its recommendation to NCVHS. These are listed below and described in more detail in the Appendix.

Examples of Use Cases	Overview of the AMA's Recommendation
Consumer Empowerment/ Consumer Shopping	The AMA and the CPT® Editorial Panel continue to demonstrate successful coordination in the development, adoption, implementation, and conformity of procedure coding, with the CPT® code set meeting the needs of both business and consumers. Recent industry initiatives seeking to address patients' critical need for accurate information about the anticipated costs of their health care and aiming to promote transparency in pricing for "shoppable services" are supported by the trusted, unambiguous procedure definitions that the CPT® code set provides.
Prior Authorization (PA) Automation	The AMA believes the current manual PA process should be a priority use case for new standards adoption due to the significant burdens it currently imposes on both patients and physician practices. The overall PA volume reduction; improved transparency of PA requirements, criteria, and decision rationale; and protections for continuity of patient care must be part of any meaningful effort to reform PA programs. Any electronic PA technology involving health plans' access to EHR data must include appropriate guardrails so that the privacy and security of patients' health information is not sacrificed in the name of efficiency.
Medical Service PA	The AMA urges the Subcommittee to address the critical need for electronic standards to support medical services PA and clinical data exchange between physician practices and health plans. Any recommendations for such standards should: 1) apply to all health plans; 2) have undergone sufficient real-world testing in practices of all sizes to ensure viability and the ability to handle errors and situations beyond the "happy path" demonstrated in Connectathons and other closed testing systems; 3) show sufficient return on investment (ROI) across stakeholder groups;

	and 4) ensure that payer access to patient EHR clinical data is limited only to information needed to support a particular PA.
Prescription Drug PA	The AMA urges the Subcommittee to recommend the adoption of the National Council for Prescription Drug Programs (NCPDP) ePA standard for all types of prescription drug plans to eliminate industry confusion and ensure that patients covered by any plan type benefit from the reduced processing time offered by the ePA standard. The AMA requests that the Subcommittee recommend that support of the NCPDP ePA standard be incorporated into the ONC EHR certification program.
Real-Time Pharmacy Benefit (RTPB) Standard	To meaningfully improve physicians' ability to prescribe clinically appropriate medications that patients can access and afford, the industry needs an electronic standard that provides information on coverage, patient financial responsibility, utilization management requirements, and alternative therapies across all patients, plans, and EHRs. To facilitate informed conversations between physicians and patients regarding drug selection, the AMA urges the Subcommittee to recommend adoption of a standard RTPB technology that integrates with all EHRs and provides accurate information for all drug plans and patients.
All Payer Claims Databases (APCDs)	The AMA has long supported the development of APCDs, recognizing the value of aggregated, independent claims data in many state and national health initiatives. The AMA emphasizes the important role the CPT® code set plays in making these databases of health information a valuable resource for cost, outcome, and utilization analyses. The CPT® code set is key in the analysis of APCD data. CPT® codes directly identify the services or procedures a patient undergoes. These codes facilitate establishing, implementing, revising, or monitoring the care plan; coordinating the care of other professionals and agencies; and educating the patient or caregiver about the patient's condition, care plan, and prognosis.
Advanced Explanation of Benefits (AEOB)	Given the fast-approaching implementation deadline, the AMA urges NCVHS to prioritize this issue and engage in a thorough study of how existing or emerging electronic transactions could be leveraged to meet the AEOBs requirement, as well as recommend a standard solution for the industry. The AMA recommends the Subcommittee evaluate the underlying physician practice and health plan workflows needed to prepare "good faith estimates" and AEOBs, as the similarities between the AEOB use case and the current claims submission and adjudication processes suggest that the most appropriate electronic standards for this new functionality would mirror those currently used in claim and remittance advice transactions.
Clinical Data Registries	The CPT® code set plays a key role in clinical data registries, as CPT® codes directly identify the services provided to the patient. CPT® Category II codes are supplemental tracking codes that can be used for performance measurement and support registry reporting.
Augmented Intelligence (AI)	Through its partnerships and collaborations, the AMA has quickly gained capacity to help set priorities for health care AI; integrate the perspective of practicing physicians into the design, validation, and implementation of high-quality, clinically valuable health care AI; and promote greater understanding of the promise and limitations of AI across the health care community. The CPT® Editorial Panel has responded to the need for algorithmic and machine-driven services with several additions to the CPT® codes set.

International Use Cases	In support of multi-regional pooled research, the CPT® code set is used internationally by several countries for a variety of use cases. Altogether, the CPT® code set is licensed in over 40 countries globally to support interoperability, research, quality improvement, and efficient care.
Considerations Applicable Across All Use Cases	The AMA encourages that the Subcommittee recommend consideration of the following issues for applicability across all use cases: operational issues, technical issues, workforce implications, establishing patient authentication and authorization to support consent, privacy and security, trust and representation, and equity.

Success of these use cases will require semantic interoperability across multiple stakeholders. Ensuring that all stakeholders "move together" will create certainty and consistency for physicians and payers, while avoiding needless disruption and harm to patients. The federal government also must have a clear and comprehensive understanding of the impact of its policy changes and related implications. For instance, should the Subcommittee ultimately recommend the development of standards adoption toolkits and resources to assist under-resourced or new digital health entrants in the health care system, then the Subcommittee also should recommend increased coordination of shared value sets for administrative transactions, clinical care, and quality assessments while promoting broader stakeholder engagement in voluntary consensus activities.

3. *How have other industries effectively implemented, tested, and certified standards for data and their exchange that could be considered for health care?*

The AMA notes that the Subcommittee has dedicated the first panel of the Listening Session to this question. However, the current list of invited speakers comes from the health care industry or government. While the health care industry has its own unique footprint in the United States because of its vibrancy and diversity of providers and payers, **perhaps the Subcommittee may wish to seek out panel participants from other industries who can comment on industry standards for data sharing**. This might enable the Subcommittee to better explore whether other industries have effectively implemented and tested standards for data. For example, panels might include stakeholders from the American Society of Heating, Refrigerating & Air Conditioning Engineers; the American Society of Mechanical Engineers; ASTM International; and the Underwriters Laboratories, Inc.

Additionally, the AMA highlights that current federal law and policy regarding standard-setting promotes the use of marketplace-developed, proprietary consensus code sets—including those protected by copyright and available at a reasonable fee—and seeks to minimize any use of government unique standards.[9] While the AMA holds the intellectual property rights to the CPT® code set, the AMA has made the CPT® code set available royalty-free to the federal government, through long-standing public-private cooperation, for the benefit of the public. This is instead of charging the reasonable licensing fee the AMA typically charges third parties who are seeking to commercialize the AMA's copyrighted CPT® code set in their various products. This collaboration has allowed for widespread use of the CPT® code set to increase efficient operation of the health care system, while enabling the federal government to avoid the substantial administrative and financial burdens associated with creating, maintaining, and updating a code set. Such code sets can be most effectively authored and kept current by private entities that are most knowledgeable about their respective fields. Federal law also has long protected the

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[9] Pub. L. 104-113, The "National Technology Transfer and Advancement Act of 1995" and A-119 (revised), "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities."

copyrights in privately created works that are used by the federal government and whose use is incorporated by the government.

4. ***What short term, mid-term and long-term opportunities or solutions do you believe should be priorities for HHS?***

The open-ended nature of this question illustrates HHS' very broad responsibilities as a federal agency. The AMA urges the Subcommittee to focus its attention, instead, on NCVHS' statutory responsibility to assist the Secretary in implementing the Administrative Simplification provisions of HIPAA. In doing so, the Subcommittee should recognize and reconfirm the foundational role that the efficient and low-cost CPT® code set provides having been selected to be included within various government-adopted standards. The AMA has invested a significant amount of time and resources over many years in creating and maintaining the CPT® Code Set. The AMA encourages the Subcommittee to recognize the value that the CPT® Code Set provides in increasing accuracy and efficiency. The CPT® Code Set is a critical working component within the data-sharing health care system, as a universally adopted and relied-upon code set developed through consensus and informed by practicing physicians. Indeed, in the preamble to the 2000 Final Regulations implementing the HIPAA administrative simplification standards, HHS noted "The comments we received regarding code sets were overwhelmingly in favor of the selection of currently used code sets as the initial standards."[10]

In its recommendations to the Secretary, the Subcommittee should recognize the strong foundation that currently exists through the CPT® Code Set and should prioritize its recommendations to focus on identifying and implementing incremental changes to areas and processes in the data-sharing continuum that may require further innovation and attention to facilitate and improve the exchange of clinical data under HIPAA. The AMA also urges the Subcommittee to prioritize employing a moderate, realistic path that fully considers the overwhelming success of many electronic transactions and existing code sets used today, the significant risks to patient safety and our entire health care system posed by a complete overhaul in administrative and clinical standards, and the finite resources available across stakeholder groups that will limit their ability to operationalize the massive system changes.

Regarding further opportunities for successful adoption and implementation of any standards, the AMA urges the Subcommittee to consider the following, as further detailed in the Appendix:

| Short Term Priorities | The AMA recommends HHS study end-to-end data exchange workflows from the health care professional, health plan, and vendor prospective and identify "detours" where processes drop into manual workflows due to limitations in current electronic standards

It is imperative that NCVHS address the lack of clarity in PA electronic standards—both for medical services and for prescription drugs—in the very near term. Other immediate priorities should be adopting standards that will support improved price transparency, as outlined in the above sections discussing RTPB and AEOBs. |
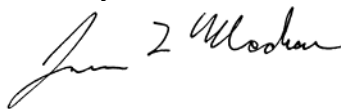| Mid Term and Long | **The AMA urges consideration of certain criteria before recommending any standards or code sets for adoption. Specifically, the AMA recommends:** |

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[10] Health Insurance Reform: Standards for Electronic Transactions Final Rules (65 Fed. Reg. 50313, August 17, 2000).

Term Priorities	• Evaluation of several key criteria, such as through real-world piloting in physician practices, medical groups, and hospitals of all sizes, to ensure that the benefits of new technology will offset what will likely be significant implementation costs • A thorough analysis of the ROI across all stakeholders, of all sizes, before recommending a new electronic standard or code set for adoption • Careful consideration of the privacy and security implications of bidirectional provider-to-payer exchange of patient clinical data and establish the appropriate guardrails so that health plan access to EHR data is limited to what is needed to complete a particular business function • Acknowledgment that abandonment of standards and code sets that are working extremely well in our current health care ecosystem would lead to a massive disruption in the current claim submission and adjudication process and threaten the existence of physician practices, particularly those of small size

Conclusion

The AMA appreciates the Subcommittee's efforts to improve our health care system through adoption of electronic standards that will improve efficiency and reduce administrative costs. In formulating its recommendations and plans to NCVHS, we urge the Subcommittee to continue to seek input from individuals representing the business and operational units of various stakeholder groups. This will ensure a full understanding of workflow complexities, potential for disruptions, and the ability of a proposed recommendation or plan to work in a real-world, full-scale production environment. The AMA stands ready to assist the Subcommittee and NCVHS in providing the perspective of practicing physicians that have created and maintained an efficient, low-cost, and consensus-based code set for many years. If you have any further questions or need additional information, please contact Matt Reid, Senior Health IT Consultant, at matt.reid@ama-assn.org.

Sincerely,

James L. Madara, MD

<u>**APPENDIX A2**</u>

The following points provide further information and examples for the Subcommittee's consideration their recommendations to the Secretary.

<u>**Supplemental Information for Question 1**</u>

In furtherance of its encouragement for HHS to build off the foundation set by the CPT® code set, the AMA has identified and illustrated below barriers and gaps to data sharing between patients, providers, payers, the public health system, and other actors in health care that the AMA encourages HHS to address.

(1) Physicians lack access to usable health information

The AMA recommends that NCVHS leverage the foundational language of the CPT® code to address high-impact use cases with known needs and identified gaps. Sharing patient health information continues to be a challenge for physicians, who still often lack access to usable health information. There is a gap between certified capabilities of EHR systems and actual interoperability in the field, especially among smaller practices and among patients. Achieving the goals of data sharing requires addressing uniformity and consistency in information access, exchange, and use. Yet, data sharing is too big of an ocean to boil at once. As such, the AMA urges the Subcommittee to consider a sensible and realistic approach to improving data exchange.

Further, the AMA recommends that any recommendations to improve data sharing should be practical and scalable across the health care system. An examination of care coordination would best enable HHS to identify, prioritize, and address barriers to data sharing. Care coordination is the movement of patient information from one setting of care (e.g., hospital, ambulatory physician practice, home health, long-term care, rehabilitation facility) to another, as well as from providers to payers. Care coordination not only requires that disparate health IT systems function at syntactic (information structure) and semantic (information meaning) levels, but also—to be most effective—requires all participants to agree upon certain rules and policies. Common agreements are needed in several areas for each participant-type within the health care ecosystem regarding transaction types, purposes (acceptable uses), transport standards, format standards, vocabulary standards, patient access, security levels, patient matching, and consequences for violating the rules. Data governance, trust, business, and administrative processes must also be established and supported to facilitate care coordination.

(2) Meeting patients where they are and addressing consumer needs

Empowering patients effectively requires clearing two key hurdles: patients' data must be both *accessible* and *consumable*. As patients play a central role in their own care, the lack of an informed patient compromises care coordination. Yet, physicians often hear that patients desire information and knowledge—rather than raw data—to take charge of their own care.

Resources like the CPT® code set's Consumer-Friendly Descriptors meet clinical, administrative, *and* consumer needs by empowering patients to take ownership of their care through straightforward, consumable descriptions of health care procedures and claims data. Claims data are a combination of administrative data (e.g., patient demographic information, dates of service, provider name and address, and health plan information) with coded health data (e.g., diagnosis code and procedure code). While physician and qualified health care professional-developed CPT® codes play a critical role in supporting

clinical and administrative communications using detailed clinical elements of a procedure, CPT®
Consumer Friendly Descriptors extend the use of the CPT® code set by translating the medical
terminology required by physicians and payers into terms that patients and their caregivers will better
understand. Information-blocking regulations further pave the way for improved patient access. Examples
of CPT® Consumer Friendly Descriptors include:

CPT® Code	Long Descriptor	Consumer Friendly Descriptor
77067	Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed	Screening mammogram
47562	Laparoscopy, surgical; cholecystectomy	Removal of gallbladder using an endoscope
59410	Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care	Vaginal delivery with post-delivery care

(3) The complexity and clinical utility considerations of data and third-party billing

The AMA strongly urges the Subcommittee to consider actions the federal government can take to
incentivize the adoption of consistent coding guidelines and rules across payers so code sets can better
support traditional fee-for-service, value-based care, and quality measures. The AMA appreciates that the
Subcommittee seeks information to help assess the "state of readiness for certain administrative and
clinical standards to be considered for adoption or use as standards under HIPAA, for interoperability,
and other subjects beyond HIPAA transactions." The AMA wishes to emphasize that requirements to
comply with third-party billing often add significant administrative burden to physicians, clinical staff,
and their medical practices. For example, regulatory and payer demands for point-of-care information
have increasingly shifted documentation requirements. Payers' third-party billing systems are complex,
expensive, and inefficient with billing rules varying by payer. Physicians who contract with multiple
payers encounter an array of disjointed rules—often without justification or evidence of improved patient
outcomes or quality.

Standardizing the rules of data submissions that use the CPT® code set would reduce the burden on
hundreds of thousands of physicians contracted with multiple health plans by streamlining compliance
with different billing rules and requirements. The wide-spread adoption of the CPT® Guidelines and
Conventions (Guidelines)—which are readily available and freely included with a CPT® license—
provides an opportunity for substantial burden relief by promoting the use of a single transparent set of
rules for multiple payers. The AMA wishes to emphasize its belief that the Guidelines are critical to the
correct use of the CPT® code set. Payers, however, have not consistently adopted the Guidelines and
have instead created their own instructions for CPT® code reporting. In addition to the costs payers incur
by developing and maintaining their own codes, the resulting variation imposes a burden on the entire
health care system that requires extra effort and special attention to payer-specific rules and adds
unnecessary time and resources to the billing process. For example, physicians must monitor and track
rules from different payers and must alter the coding of their claims dependent on the specific payer.
Failure to follow the payer-specific rules results in the denial and claim rework of even "clean claims,"
which burdens the entire health care system. Further, third-party variation hinders the coordination of

patient benefits in instances when a secondary payer does not recognize a primary payer's rules, which may also result in additional rounds of denials and claim rework. Third-party variation also inhibits the transfer of procedure data, disrupting aggregation and analysis for utilization, payment, and other purposes.

More broadly, the AMA recommends NCVHS conduct a study of end-to-end data exchange workflows from the health care professional, health plan, and vendor prospective. Such a study should identify disorganized or inconsistent segments of the health care revenue cycle. Significant physician time and resources are wasted on administering health care operations. Stricter adherence to existing or new policies standardizing health care PA operations could reduce the costly reliance on health care technology companies, e.g., analytics and solution providers, who financially thrive due to its complexity. Assumptions that physicians and other medical providers can simply "purchase more management services" should be challenged. More should be done to make PA tools and resources more accessible, available, and better support physicians' needs for health care operations. This is increasingly true to ensure the stability of our nation's independent medical practices. This could be accomplished through a mixture of federal policy interventions, normalizing payer requirements, fewer custom and more "off-the-shelf" health IT solutions that align with standard payer processes, moving to bi-directional information exchange, and promptly making data available to health care facilities.

As an example, NCVHS should make recommendations to ONC and CMS to standardize health care analytics/operational functionality and payers' administrative practices—embedding them in EHR certification and CMS' administration of Medicare Advantage plans. The intent is to shift costs away from physicians and other providers and promote uniformity in payer operations. Likewise, the AMA would encourage ONC and CMS to incent the private payer industry to align with these requirements. Furthermore, the AMA recommends the federal government conduct a national effort to analyze inconsistencies in PA data requirements and criteria across the payer community and review the clinical validity of payers' PA guidelines. There is concern that payer PA guidelines prioritize revenue ahead of patient health, wellness, or quality of life. Federal regulatory levers should be considered to ensure such guidelines and data requirements are made publicly available for review.

The AMA also urges NCVHS to take stock in systems that are working extremely well in the health care ecosystem. There are revenue cycle functions that are exclusively administrative and have been functioning well for decades. While improvements can be made, such as adopting an attachments standard, these processes do not require new linkages to clinical exchanges or transitioning code sets. As we state throughout this letter, any such unnecessary changes in mandated standards and code sets would jeopardize well-functioning current processes and waste limited resources that would be better directed towards high-priority areas that could reduce administrative burdens.

(4) Excessive physician burden due to the churn in health IT adoption

The adoption of reusable clinical and administrative concepts—leveraging the appropriate terminologies—promotes consistent data representation across the entirety of the health care system, reduces burden, and improves efficiency. The dual challenges of consistent data representation and information access compromises the ability of payers and physicians to create efficient care delivery solutions and care coordination models. Health IT continues to cause frustration, burden, and burnout among physicians, while medical information mismanagement by health IT systems leads to waste, data fragmentation and inconsistency. Difficulty using EHRs stems from both poor usability and the challenges with accessing, exchanging, and using data. Yet, impediments to data sharing are often a result of bad front-end system design rather than back-end data coding.

Real-world testing is necessary to develop a detailed analysis of a code set's costs and benefits, and understanding the economic impact of a new or revised standard is critical. As curator of the CPT® code set, the AMA has been working with other stakeholders, such as the Health Level 7 (HL7), to promote more seamless data-sharing operations. Solutions built on Fast Healthcare Interoperability Resources (FHIR)-based Application Programing Interfaces (APIs) use common data models and value sets to correct for these issues. FHIR profiles, developed to address known gaps and weak points in the health care system, incorporate coding terminologies used by millions of clinicians and medical professionals. HL7 efforts like Da Vinci and the Gravity Project, for instance, address gaps in payer/provider information exchange and improve SDoH data management. Further, efforts like Da Vinci leverage procedure coding to unleash critical data between payers and physicians required for value-based care workflows.

Supplemental Information for Question 2

The AMA has detailed several examples of priority use cases for which the AMA encourages the Subcommittee to consider new standards, including those that build off of the CPT® code set, in its recommendation to the Secretary.

(1) Consumer Empowerment/Consumer Shopping

The AMA and the CPT® Editorial Panel continue to demonstrate successful coordination in the development, adoption, implementation, and conformity of procedure coding, with the CPT® code set meeting the needs of both business and consumers. Health insurers and payers use the same codes for all medical services and procedures, ensuring uniformity and reducing waste. CPT® codes also serve as the foundation for health plans' claims adjudication systems. The effective use of existing standards provides an important path to consumer empowerment. This consistency—combined with the power of Consumer-Friendly Descriptors—enables consumers to clearly understand which services are described and allows an "apples-to-apples" comparison across health care organizations and the entire health care ecosystem.

Recent industry initiatives seeking to address patients' critical need for accurate information about the anticipated costs of their health care and aiming to promote transparency in pricing for "shoppable services" are supported by trusted, unambiguous procedure definitions the CPT® code set provides. The AMA supports adoption of new standards that build off of the CPT® code set to improve and facilitate informed conversations between physicians and their patients about treatment costs while minimizing burden on the health care system.

(2) PA Automation

The current manual prior authorization (PA) process should be a priority use case for new standards adoption due to the significant burdens it currently imposes on both patients and physician practices. In a December 2020 AMA survey, 94 percent of physicians reported that PA can delay access to medically necessary treatment, with an alarming 30 percent stating that PA has led to a serious adverse event (e.g., hospitalization, life-threatening event, or death) for a patient in their care. Practices reported completing an average of 40 PAs per physician per week, with this weekly PA workload for a *single physician* consuming two business days of physician and staff time. Notably, these PA practice burdens reflect physicians' experiences between 11/23/20 and 12/14/20, when COVID-19 cases were surging in the United States.

As stated in the 2018 Consensus Statement on Improving the Prior Authorization Process released by national health care professional organizations and health plan trade associations, any meaningful effort to reform PA programs must include an overall PA volume reduction; improved transparency of PA requirements, criteria, and decision rationale; and protections for continuity of patient care. While automation using standard electronic transactions has the potential to reduce the patient harms and practice hassles associated with PA, technology must not be viewed as the single "silver bullet" solution to address the complex challenges PA poses to our health care systems. Additionally, any electronic PA technology involving health plans' access to EHR data must include appropriate guardrails so that the privacy and security of patients' health information is not sacrificed in the name of efficiency.

(2a) Medical Service PA

The AMA urges the Subcommittee to address the critical need for electronic standards to support medical services PA and clinical data exchange between physician practices and health plans. Any recommendations for such standards should: 1) apply to all health plans; 2) have undergone sufficient real-world testing in practices of all sizes to ensure viability and the ability to handle errors and situations beyond the "happy path" demonstrated in Connectathons and other closed testing systems; 3) show sufficient return on investment across stakeholder groups; and 4) ensure that payer access to patient EHR clinical data is limited only to information needed to support a particular PA.

It is widely acknowledged that implementation of the HIPAA-mandated X12 278 for medical services PA is subpar: the 2020 CAQH Index reports industry adoption of the X12 278 at a meager 21 percent. In comparison, 96 percent of claims are submitted using the X12 837, making it the "star" of the electronic transactions. In robust discussions over the past few years—including at NCVHS hearings—industry stakeholders have explored the reasons for this limited use of the X12 278. Health plans, vendors, and health care professionals agree that the major contributing factor is the lack of a standard to exchange the supporting clinical documentation needed to approve the overwhelming majority of medical service PAs. Despite multiple NCVHS letters to the Secretary recommending adoption of an electronic attachment standard (the most recent from July 2016, with the recommendation reiterated in a November 2020 letter regarding operating rules), an electronic attachment standard has not been named and required. The lack of an attachments standard has been a rate-limiting factor in PA automation, as is perhaps best captured by a quote from a large EHR vendor in the June 2014 NCVHS Subcommittee on Standards Meeting transcript: ". . . the uncertainty in the area has a paralyzing effect . . . There's a huge disincentive for me to allocate resources for my team to any specific changes."

In the absence of regulatory direction on attachments, newer technologies to exchange clinical documentation between health care professionals and health plans, such as FHIR, have been explored to advance electronic PA for medical services. In alignment with a December 2020 NPRM[11] issued by CMS that proposed adoption of three HL7 Da Vinci FHIR Implementation Guides (IGs) to support PA automation, the AMA strongly supports efforts that simplify PA requirements and embed payer documentation needs within physicians' EHR workflow, **which the specifications of these FHIR IGs should promote**. However, as detailed in the AMA's comments on the NPRM, we have concerns about the maturity of the IGs and the lack of real-world testing in physician practices of all sizes. Moreover, the

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[11] A final rule was released in January but has since been withdrawn.

provisions of the NPRM applied to a narrow set of health plans (i.e., Medicaid, CHIP, and federally facilitated exchange health plans). This sets an alarming precedent, as the benefits of HIPAA administrative simplification will only be realized if <u>all health plans</u> are required to use the same electronic standards.

(2b) Prescription Drug PA

Unlike medical services PA, the industry has developed and implemented a standard for prescription drug electronic PA—the National Council for Prescription Drug Programs (NCPDP) SCRIPT electronic PA (ePA) standard. The AMA supports adoption of the NCPDP ePA standard due to the multiple efficiencies it offers to physician practices, including a uniform electronic PA process across all prescription drug plans, integration of the PA process within the EHR/e-prescribing system, and conditional logic that skips questions that do not apply to a particular patient. The AMA offers a three-part educational video series on prescription drug ePA to support physician practices in using this technology.

We urge the Subcommittee to recommend the adoption of the NCPDP ePA standard for all types of prescription drug plans to eliminate industry confusion and ensure that patients covered by any plan type benefit from the reduced processing time offered by the ePA standard. In December 2020, CMS issued a final rule mandating use of the NCPDP ePA standard in Part D plans, with compliance enforcement effective January 1, 2022. However, the rule notes that its provisions do not apply to non-Part D plans, for which the X12 278 remains the HIPAA-mandated standard. As with the previously mentioned CMS PA NPRM, this sets a disturbing precedent in which rulemaking carves out standards mandates for only certain plan types. Again, the efficiencies gained through standards transactions can only be achieved if mandates apply to <u>all plans</u>.

Along with expanding the NCPDP ePA mandate to all plan types, it is critical that all physicians be aware of this new technology and have access to it in their EHRs. As mentioned above, the AMA offers resources and an ongoing educational campaign to ensure that practices are aware of ePA and can request this functionality from their EHR vendors. Unfortunately, under one-quarter (24 percent) of physician respondents in the 2020 AMA PA survey reported that their EHR system offers ePA for prescription drugs. As such, the AMA requests that Subcommittee recommend that support of the NCPDP ePA standard be incorporated into the ONC EHR certification program.

(3) Real-Time Pharmacy Benefit (RTPB) Standard

To meaningfully improve physicians' ability to prescribe clinically appropriate medications that patients can access and afford, the industry needs an electronic standard that provides information on coverage, patient financial responsibility, utilization management requirements, and alternative therapies across all patients, plans, and EHRs. The current lack of transparency regarding prescription drug benefits and costs at the point of prescribing poses enormous challenges to both physicians and patients. Physicians select the most clinically appropriate prescription drug for a particular patient and send the electronic prescription to the patient's pharmacy of choice, usually with no idea: (1) if the patient's plan will cover the drug; (2) if there are utilization management requirements (i.e., PA or step therapy); (3) the scope of the patient's out-of-pocket cost; or (4) any preferred formulary alternatives. Unfortunately, this sets the stage for treatment abandonment: patients arrive at the pharmacy to pick up a prescription only to be stymied by unmet PA requirements or the sticker shock of high out-of-pocket costs. These pharmacy counter surprises harm patients, with 74 percent of surveyed physicians reporting that PA can lead to treatment abandonment—with devastating effects on clinical outcomes. For example, Benjamin Galper,

MD, MPH, details in a [FixPriorAuth video clip](#) how his patient suffered a second heart attack after being unable to obtain the medication needed to keep a stent open due to an unknown PA requirement. Beyond these patient harms, the lack of transparency surrounding drug coverage and costs at the point of care lead to enormous administrative burdens and workflow disruptions for both physician practices and pharmacies.

To facilitate informed conversations between physicians and patients regarding drug selection, the AMA urges the Subcommittee to recommend adoption of a standard RTPB technology that integrates with all EHRs and provides accurate information for all drug plans and patients. Effective January 1, 2021, CMS requires Part D plans to support at least one prescriber real-time drug benefit tool that integrates with at least one EHR system. While the AMA appreciates CMS' underlying intention, this requirement does little to improve transparency of drug coverage and pricing at the point of prescribing: only Part D plans are subject to the requirement, and physicians' access to this information completely depends upon the integration of their EHR with a particular plan's RTPB tool. For physicians to routinely use RTPB EHR technology, they must be able to access drug coverage and pricing information for *every patient* in their panel; physicians' frustration with the current proprietary tools that only provide information for a limited number of plans discourages adoption. Of note, NCPDP has developed an RTPB standard that should support uniform provision of these critical data across all patients, plans, and EHRs.

(4) All Payer Claims Databases

The AMA has long supported the development of All Payer Claims Databases (APCD), recognizing the value of aggregated, independent claims data in many state and national health initiatives. We believe APCDs have the potential to advance not only price transparency as it pertains to benefits consumers purchase, but also to assist policymakers in understanding price variation, trends in costs, and gaps in service. Additionally, as value-based contracting continues to grow and payers and physicians explore alternative payment models, physicians and other health care providers, as well as payers, can benefit from APCD data to evaluate the feasibility and impact contract arrangements. Additionally, state stakeholders may use the data to better assess changes in spending, utilization, and quality that result from certain payment models. The AMA sees much promise in the availability of independent health care data to help move the needle on alternative payment models and value-based care. APCD data can also be excellent tools for studying utilization trends, health care disparities, the impact of chronic conditions, and more broadly, population health. Furthermore, APCDs can serve to evaluate, address, and improve health outcomes among historically marginalized and marginalized populations. The AMA advocates for improved price transparency in health care, an issue of great importance to the Biden Administration.

The AMA emphasizes the important role the CPT® code set plays in making these databases of health information a valuable resource for cost, outcome, and utilization analyses. APCDs are state-based, which may make the scope, intended uses, and goals of APCDs—such as for utilization analysis, costs, quality of care, or other aspects of care delivery—unclear to physicians. This variation further highlights that the CPT® code set is key in the analysis of APCD data. CPT® codes directly identify the services or procedures a patient undergoes. These codes facilitate establishing, implementing, revising, or monitoring the care plan; coordinating the care of other professionals and agencies; and educating the patient or caregiver about the patient's condition, care plan, and prognosis. The CPT® also meets the needs of a bundled coding structure for chronic conditions with care management services. The physician or other health care professional provides or oversees the management and/or coordination of services, as needed, for all medical conditions, psychosocial needs, and activities of daily living. In addition, CPT® has maintained Category II Performance Measurement codes designed to support alternative payment models.

These codes facilitate data collection about the quality of care rendered. Coding for certain services and test results supports nationally established performance measures.

(5) Advanced Explanation of Benefits

In late 2020, Congress passed the No Surprises Act, which requires health plans to provide patients with an advanced explanation of benefits (AEOB) prior to scheduled care or upon patient request prior to scheduling. Health care professionals trigger the need to create the AEOB by sending the health plan a "good faith estimated amount" for scheduled services. These requirements go into effect on January 1, 2022.

Given the fast-approaching implementation deadline, the AMA urges NCVHS to prioritize this issue and engage in a thorough study of how existing or emerging electronic transactions could be leveraged to meet the AEOB requirement and recommend a standard solution for the industry. While the AMA strongly supports patient access to accurate information regarding the costs of their health care, we note that there is currently no electronic standard to support a uniform process for physician practices to submit "good faith estimates" to health plans, nor for health plans to send AEOBs to patients and physicians. While the No Surprise Act does not require health plans to send AEOBs to physicians, we maintain that such information must also be provided to practices to support informed conversations with patients about the costs of scheduled care. The AEOB is critical in cost-of-care discussions, as it reflects the health plan's prediction of how the claim for the scheduled service will be adjudicated. Without this information, physicians and practice staff will be unprepared to have a detailed discussion about treatment costs with patients, which could undermine the patient-physician relationship and erode trust.

The AMA recommends the Subcommittee evaluate the underlying physician practice and health plan workflows needed to prepare "good faith estimates" and AEOBs, as the similarities between the AEOB use case and the current claims submission and adjudication processes suggest that the most appropriate electronic standards for this new functionality would mirror those currently used in claim and remittance advice transactions. This approach would minimize administrative burdens for both practices and health plans, as well as have a realistic chance of meeting the aggressive legislative deadline. As stated above, it is crucial for any electronic standard transaction adopted for this purpose to support delivery of the AEOB to both the *physician* and the *patient*. Leveraging existing claim and remittance advice electronic standards for the AEOB requirement would also support provision of this information to physician practices.

Without a standard electronic transaction, health plans will develop proprietary tools (i.e., portals) to satisfy the AEOB provision of the No Surprises Act. While portals may be efficient solutions for health plans, they are incredibly burdensome for physician practices, as they require maintenance of logins/passwords for many different health plans' systems and re-keying of data from the EHR. Moreover, lack of an electronic standard to support the "good faith estimate" submission and provision of an AEOB will no doubt lead to many different approaches to data content and formats across health plans, which will undoubtedly be highly confusing to both physician practices and patients.

(6) Clinical Data Registries

The CPT® code set plays a key role in clinical data registries as CPT® codes directly identify the services provided to the patient. Consistent procedure identification and data representation are critical to a registry's analytics and quality improvement functions. Although not new, registries play a key role in

broader interoperability needs. A clinical data registry is an interactive database that collects, organizes, and displays health care information. Registries collect and store specific health information for various purposes, often organized by disease or condition. Data collection and use specifics depend on the purpose of the registry. As demonstrated by the examples below, registries may collect data from a single practice or across multiple organizations.

- Clinical registries—also known as patient registries—can be used to analyze clinical practice, disease management, patient outcomes, and quality of care, as well as other patient-related priorities. The focus of these registries is to evaluate patient outcomes over time.
- Product registries are typically used to track implanted medical devices and pharmaceuticals. These registries allow for analysis of various factors including patient outcomes, device or drug performance, and efficacy of the device or drug. These registries can be used to detect device failures or drug side effects and identify patients for recalls.
- Public health registries are usually set up to identify specific information, such as vaccine administration rates or disease case numbers, but do not track patient outcomes.

CPT® Category II codes are supplemental tracking codes that can be used for performance measurement and support registry reporting. The use of the tracking codes for performance measurement decreases the need for record abstraction and chart review, thereby minimizing administrative burdens on physicians and their medical practice. These codes are intended to facilitate data collection about quality of care by coding certain services and/or test results needed for performance measurement and reporting.

(7) Augmented Intelligence (AI)

Patients, physicians, and the U.S. health care system are facing enormous challenges. The combined impact of a rapidly aging population, a relative decline in the working population that reduces revenue essential for safety net programs, and persistent high costs of care will strain the nation's ability to support affordable, accessible, high-quality care. Augmented intelligence (AI) covers a range of methods, techniques, and systems that may help combat these challenges. Common examples of AI systems include natural language processing, computer vision, and machine learning. In health care, as in other sectors, AI solutions may include a combination of these systems and methods. The AMA has adopted the term "augmented intelligence" since it more accurately reflects the purpose of such systems, whether assistive or fully autonomous, because they are intended to coexist with human decision-making.

Ensuring the appropriate implementation of AI in health care requires that all stakeholders forthrightly address challenges in the design, evaluation, implementation, and oversight of AI systems. Software algorithms, coupled with proliferating sources of data (datasets) pertinent to health and medicine, offer the promise of new and more powerful ways to augment human intelligence and expertise in health care. With the engagement of physicians to identify needs and set priorities for design, development, and implementation, health care AI can offer a transformative set of tools to help patients, physicians, and the nation face these looming challenges.

The use of AI and machine learning in health care may be best applied to precision medicine, predictive analytics, and outcomes assessments. AI, for instance, is offering various benefits to medical imaging, including augmenting the capabilities of radiologists to enhance their efficiency and accuracy, as well as reducing costs by improving the appropriateness and cost-effectiveness of medical imaging utilization. AI can streamline health care workflow and improve triage of patients (especially in acute care settings), reduce clinician fatigue, and increase the efficiency and efficacy of training. Moreover, shortages of

medical experts to meet the needs of vulnerable and underserved populations could potentially be relieved, in part, by AI.

Applying AI to improve care is another area of rapid evolution. The University of Pittsburgh Medical Center (UPMC) launched a systemwide effort to reduce hospital readmissions and enhance clinical decision making while a patient is receiving care. UPMC applies machine learning to claims data to predict a patient's risk of readmission before the patient arrives. A second algorithm uses laboratory and clinical metrics extracted from clinical records to update the risk prediction every 15 minutes over the course of the patient's admission. Before discharge, if the risk prediction's two models are in conflict, UPMC uses machine learning to come up with a set of rules that dictate which model takes precedence to inform clinician discharge decisions.

Through its partnerships and collaborations, the AMA has quickly gained capacity to help set priorities for health care AI; integrate the perspective of practicing physicians into the design, validation, and implementation of high-quality, clinically valuable health care AI; and promote greater understanding of the promise and limitations of AI across the health care community. The AMA has also developed comprehensive policy on AI, including AI payment and regulation. Moreover, the AMA created and convened the Digital Medicine Payment Advisory Group (DMPAG), a collaborative initiative of a diverse cross-section of nationally recognized experts, to tackle some of the health care system's biggest challenges in digital medicine.

The CPT® Editorial Panel has responded to the need for algorithmic and machine-driven services with several additions to the CPT® code set. This includes Multi Analyte Algorithmic Analyses (MAAA), which are procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid-based assays (e.g., proteins, polypeptides, lipids, carbohydrates). The CPT® Editorial Panel has also added new AI services to the code set, including a point of care imaging service performed in the primary care setting for the detection of advanced eye disease, such as diabetic retinopathy. A new definitional structure for AI services in the CPT® code set will be considered at the 2021 fall CPT® Editorial Panel meeting. If approved, it will newly define the work of the machines and physicians in an AI service—helping promote a better understanding of how AI can analyze data at distinct levels of autonomy and differentiate between types of AI services.

(8) International Use Cases

In support of multi-regional pooled research, the CPT® code set is used internationally by several countries for a variety of use cases. Altogether, the CPT® code set is licensed in over 40 countries globally to support interoperability, research, quality improvement, and efficient care.

Several years ago, the Department of Health of Abu Dhabi (DOH) and the Dubai Health Authority in the United Arab Emirates selected the CPT® code set as the procedural terminology for their national health insurance programs, claims adjudication systems and/or health information exchanges. Recently, both Emirates adopted a more current version of the CPT® code set to allow their local ecosystem of payers and providers to keep pace with modern medicine and, in the case of DOH, support critical public health initiatives related to the COVID-19 pandemic.

In parallel, the CPT® code set was adopted by the South African Medical Association to describe procedures and services performed by medical practitioners in that country's private sector. Linked to

these procedures and services is the use of the resource-based relative value scale (RBRVS)—the physician payment system used by CMS and most other payers.

In 2019, the CPT® code set was selected by the Health Insurance Organization of the Republic of Cyprus to drive standardization and improve data quality for outpatient services. Data captured and reported by the CPT® code set has helped inform and guide local policy decisions. More specifically, guidelines are being issued to health care providers as a measure to promote better health care quality and correct coding, but also to control costs and define coverage of services.

The CPT® content is also used internationally in the American College of Surgeons National Surgical Quality Improvement Program (NSQIP). NSQIP is a risk-adjusted, outcomes-based program to measure and improve the quality of surgical care. It includes all major cases as determined by the CPT® code set.

(9) Considerations Applicable Across All Use Cases

Issues	Considerations Applicable Across All Use Cases
Operational Issues	New approaches to enhancing interoperability must consider existing workflows and operations to better understand how future roles and technologies will need to evolve. Furthermore, administrative transactions currently flow through a significant existing infrastructure. As policymakers contemplate changes to the existing system, consideration should be given to "what works today" to avoid disruption to the revenue cycle.
Technical Issues	New approaches will require a deeper understanding of the shift in information technology needs, as well as investment and deployment of appropriate systems which could impose a significant cost burden on physicians. Additional challenges may include the timing and scale of deployment. Expectations must be clear as to whether all plans will be required to shift to more automated approaches or whether there will be a mixed model where physicians are expected to send data to different places in different formats.
Workforce Implications	New approaches to data sharing may require a different skill mix, including shifts in needed capabilities, training on new technologies and processes, and the potential for significant workforce re-alignment.
Establish Patient Authentication and Authorization to Support Consent	Standards should be created to enable patients and caregivers to authorize the sharing of their data with a tool of their choice to interface with their corresponding provider and payer systems. This includes the establishment of a standard for third-party authorization that allows patients to access and bi-directionally share their data across the landscape. Consideration must be given to the security implications associated with third-party authentication. Additionally, consideration must be given to the operational impact of bi-directionally sharing data between physician and payer systems at the patient's request, including the need for robust data integrity and data quality practices.
Privacy and Security:	Ensuring the privacy, security, and confidentiality of a patient's health information is an obligation that physicians take seriously. Increased sharing of health information across payers and providers requires careful consideration of privacy issues, including ensuring that only the minimum necessary information is shared and uses of such data beyond the initial specific transaction are limited. With respect

	to security, challenges with authorizing and authenticating data recipients before exchange represents a particular challenge. The lack of a national approach to accurately identify patients further complicates this issue.
Trust and Representation	Trust among individuals, payers, and physicians is key to improving data sharing. Should clinical data be reused for other purposes outside of the initial specific transaction in question (e.g., underwriting, setting premiums, or benefits design), it could have a profound impact on individuals' lives and their overall trust in the health care system. Similarly, such information could be used for other purposes such as contract negotiations between payers and physicians. In both instances, trust may be easily eroded. Participation by all parties is critical to ensure that operational and trust considerations are addressed.
Equity	An equity-centric vision is a nation where all people live in thriving communities where resources work well, systems are equitable and create no harm, and everyone has the power to achieve optimal health—and all physicians are equipped with the consciousness, tools, and resources to confront inequities as well as embed and advance equity within and across all aspects of the health system. As our society becomes more attentive to prioritizing health equity, significant barriers in the form of the digital divide—along with gaps in digital and health literacy—continue to prevent populations from having equitable access to their health data and tools of communication with their physicians. Inadequate funding and staff resources necessary for technology implementation that can enhance connectivity and data sharing while also ensuring privacy and security of data also create barriers to health equity.

Supplemental Information for Question 4

Regarding further opportunities for successful adoption and implementation of any standards, the AMA urges the Subcommittee to consider the following proposals in its recommendation for short-term, mid-term and long-term priorities for HHS.

(1) *Short-Term Priorities*: **The AMA recommends HHS study end-to-end data exchange workflows from the health care professional, health plan, and vendor perspective and identify "detours" where processes drop into manual workflows due to limitations in current electronic standards.**

As outlined above, the medical services PA process is in desperate need of a standard electronic solution to automate what is now an extremely manual, time-consuming process. Moreover, unlike many other revenue cycle functions, PA also directly impacts patients' ability to obtain timely, medically necessary care. Despite intense industry attention over the past few years, we appear no closer to adoption of an electronic standard to exchange clinical data to support medical services PA; meanwhile, patients continue to suffer from care delays and negative clinical outcomes. It is imperative that NCVHS address this lack of clarity in PA electronic standards—both for medical services and for prescription drugs—in the very near term. Other immediate priorities should be adopting standards that will support improved price transparency, as outlined in the above sections discussing RTPB and AEOBs.

(2) *Mid-Term and Long-Term Priorities*: **The AMA urges consideration of certain criteria before recommending any standards or code sets for adoption.**

The AMA recommends evaluation of several key criteria to ensure that the benefits of new technology will offset what will likely be significant implementation costs. As such, any electronic standard under consideration for a federal mandate should first be proven successful in real-world piloting in physician practices, medical groups, and hospitals of all sizes. While Connectathons and similar closed testing systems are an important first step in advancing new technology, they do not accurately reflect real-world workflows in small- to medium-size physician practices with fewer resources, nor do they support the error messaging needed when transactions inevitably fall off the "happy path."

The AMA recommends a thorough analysis of the ROI across all stakeholders, of all sizes, before NCVHS recommends a new electronic standard or new code set for adoption. Again, this assessment must account for the costs of a full-scale implementation and all the underpinning development, not just the minimal work needed to program a single demonstration. For example, in evaluating the costs involved in implementing the Da Vinci FHIR PA-related guides, NCVHS should detail the resources and time involved in digitizing each health plan's proprietary PA criteria, across all medical services, for both payers and EHR vendors. This work would be consistent with NCVHS' statutory responsibility to assist the Secretary in implementing Part C of Title XI of the Social Security Act.

The AMA recommends careful consideration of the privacy and security implications of bidirectional provider-to-payer exchange of patient clinical data and the establishment of the appropriate guardrails so that health plan access to EHR data is limited to what is needed to complete a particular business function. While NCVHS rightfully points out that our health care world has changed in ways that the HIPAA framers could not have predicted or envisioned, the sacred protection of patients' medical information remains as relevant, if not more so, today. Health plans are already partnering with EHR vendors to cull clinical data from patients' medical records for various use cases, and it is unclear what privacy and security guardrails, if any, have been put in place. With unfettered access to EHRs, health plans could misuse patient health information, with the end result being the destruction of patient trust in physicians as curators and protectors of the medical record. With the rapid development of FHIR-based technology, it is crucial that 1) health plan contracts not require EHR access as a condition of a physician's network status and 2) physicians have full line-of-sight into exactly what EHR data health plans will be able to access, and for what purposes. Without such safeguards, any efficiency gains may come at the price of patient privacy and data security.

The AMA urges NCVHS to recommend that HHS take stock of standards and code sets that are working extremely well in our current health care ecosystem. Abandonment of the standard electronic claims process, whether it be the transaction itself or associated code sets, would lead to a massive disruption in the current claim submission and adjudication process and threaten the existence of physician practices, particularly those of small size. As mentioned previously, the overwhelming adoption of the X12 837 electronic claim reflects a clear HIPAA administrative simplification victory. Although we recognize that certain use cases involve co-mingling of administrative and clinical data (such as PA, as referenced above), we maintain that there are revenue cycle functions that are exclusively administrative and therefore do not require a transition to clinical transactions or code sets. As stated throughout this letter, any such unnecessary changes in mandated standards and code sets would jeopardize well-functioning current processes and waste limited resources that would be better directed towards high-priority areas that could reduce administrative burdens.

APPENDIX B

September 9, 2021

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Denise E. Love, BSN, MBA
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Dear Co-Chairs Landen and Love:

Thank you for inviting us to participate in two panels at the Subcommittee's *Listening Session on Healthcare Standards Development, Adoption and Implementation* on August 25, 2021, as a part of the project, *Standardization of Information for Burden Reduction and Post-Pandemic America* ("*Convergence 2.0*"). We appreciate the Subcommittee identifying the American Medical Association (AMA) as an "Anticipated Partner" in *Convergence 2.0*, as the AMA is the largest association that represents the physician's voice in patient care and is designated in federal regulation as the maintainer of a universally adopted medical data code set.

The Subcommittee's June 2021 Request for Public Comment on Healthcare Standards Development, Adoption and Implementation encompassed many issues, some of which were addressed during the Subcommittee's August 25 Listening Session. During the opening of the Listening Session, Mr. Landen described the Subcommittee's goal as identifying what is—and is not—working correctly in the current interoperability and standards landscape in U.S. health care. The Listening Session was equally important for health care stakeholders, like the AMA, to learn from the Subcommittee about the specific scope of *Convergence 2.0* and to hear the perspective of other participants.

As an overall take-away, we heard the following key points from multiple participants in the Listening Session:

- Participants emphasized the overarching theme of **not disrupting systems and processes that are currently working in the health care system, and instead enhancing and expanding (as necessary) existing systems and processes.** For example, recommendations for changes in administrative simplification transaction standards and operating rules must show a return on investment and must be rigorously tested before being considered for adoption by the Secretary of the U.S. Department of Health and Human Services (HHS). Return on investment is not solely about money but also time, opportunity cost, and consensus to avoid inertia and workarounds. Most importantly, a value assessment must address the common overarching goal of improving the quality and efficiency of patient care.

- For the HHS Secretary to be in a position to adopt recommendations to change administrative simplification transaction standards and operating rule regulations, such **recommendations should be supported with data in the public record illustrating successful testing and return on investment.**
- For consensus to be achieved, process matters when implementing a change. The **success of a recommendation depends upon including and carefully considering feedback from the right stakeholders in the process.**
- Semantic harmonization means ensuring multiple sources and representations of data share the same meaning to communicate knowledge.

It was clear from the Listening Session that the stakeholder consensus viewpoints listed above are fundamental principles that the Subcommittee should consider as it conceptualizes solutions to improve efficiency and reduce burden. Moreover, just as important as what was said at the Listening Session is what was **not** said. Participants did not identify nor indicate that terminologies or code sets are impeding semantic harmonization. We agree with the participants that foundational terminologies and code sets will continue to play a major role in supporting patient care, meeting business needs, and health information interoperability.

During the Listening Session, the AMA identified several additional considerations. As stated in our presentations, **the AMA specifically recommends NCVHS address critical unmet business needs for physicians and their patients:**

- Prior authorization automation and clinical data exchange between providers and payers
    - NCVHS should recommend transaction standards to support data exchange between providers and payers of all types for medical services and prescription drug prior authorizations

- Real-time prescription benefit (RTPB) transactions
    - NCVHS should recommend adoption of a transaction standard for RTPB technology that integrates with all electronic health record systems and provides accurate information for all drug plans and patients

- Good faith estimates/advanced explanation of benefits (AEOBs)
    - NCVHS should study, evaluate, and recommend a single transaction standard and/or operating rule that delivers AEOBs to providers and patients to support informed conversations about care costs

- Improve the clinical utility of data while addressing third-party billing complexities
    - NCVHS should recommend standardizing rules of data submissions to reduce the burden on physicians and streamlining compliance with disparate payer billing rules and requirements.

The AMA intends to follow-up with a more detailed comment letter following the Subcommittee's September 10 report to the Full Committee regarding the August 25 Listening Session and the update on *Convergence 2.0*.

In closing, we commend NCVHS for laying out a broad and ambitious range of topics to potentially address under Phase I of *Convergence 2.0*, the purpose of which is to "assess[] the current landscape of standards development and regulatory adoption processes and identifying opportunities for improving

coordination of standards development, adoption, implementation, and conformity across disparate health-related data systems." The AMA will continue to follow and provide constructive input on future actions by the Subcommittee and Full Committee under *Convergence 2.0*. For instance, the AMA will comment on the Subcommittee's eventual recommendations to the Full Committee as well as any recommendations that the Full Committee makes to the Secretary of HHS under the Phase I "Assess Standards Landscape," as identified in the *Convergence 2.0 Project Scope*.

We, and all the resources of the AMA, remain available to provide the Subcommittee and the Full Committee with specific information on any aspects of *Convergence 2.0*. We look forward to continuing to work with NCVHS on this important endeavor.

Sincerely,

Jay Ahlman

Heather McComas