Addressed to:
Aaron Miri, Co-Chair, Health Information Technology Advisory Committee
Denise Webb, Co-Chair, Health Information Technology Advisory Committee

CC: Mike Berry, Designated Federal Officer, Office of the National Coordinator for Health Information Technology

Dear Aaron and Denise,

The American Medical Association (AMA) greatly appreciated the opportunity to comment and present during a recent Health Information Technology Advisory Committee's (HITAC) Interoperability Standards Priorities Task Force (ISPTF) meeting. As you know, the AMA is very committed to helping our nation improve health care interoperability and promote health care innovation, as well as maximize Electronic Health Record (EHR) data for pragmatic research. The collaboratively maintained AMA Current Procedural Terminology (CPT®) Code Set plays an important role in providing uniformity in connection with health care data as it relates to certain professional services. Such uniformity is critical to achieving the administrative simplification requirements originally included in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that 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 the interoperability of health care information.

In the spirit of participating collaboratively in the ISPTF's process of crafting meaningful and actionable recommendations to the National Coordinator for Health IT, the AMA offers the immediate set of comments herein related to draft Recommendation 03 of the ISPTF. Attached please find a redlined version of the most recent July 14 draft of Recommendation 03 (Attachment A). The redlined edits are the AMA's comments. The purpose of these edits is to achieve clarity and transparency as to the precise recommendation that the ISPTF is attempting to make.

For example, if the ISPTF intends to include a reference to the 2019 NCVHS Vocabulary Recommendations, then we recommend that the language of Recommendation 03 should clearly state which document is being referred to. Specifically, we recommend that the language of Recommendation 03 should include both the exact date of the 2019 NCVHS Vocabulary Recommendations, which we believe was February 13, 2019, and confirmation that the referenced recommendations are the ones that have already been presented to the Secretary.

We also recommend that the HITAC should revise the language of Recommendation 03 to make it clear that the references to "free or low cost" licenses following the references to OMB Circular A-119 and the 2019 NCVHS Vocabulary Recommendations are merely examples of ways in which terminology standards might be developed in accordance with the referenced documents. These examples are not, in and of themselves, additional terms to this new ISPTF recommendation. Furthermore, within these examples, we added the phrase "reasonable royalty terms" because this phrase is used in OMB Circular A-119 (on "Voluntary Consensus Standards"). If ISPTF is going to highlight the "free or low cost" language from the February 13, 2019 NCVHS Vocabulary Recommendations document, then the ISPTF also should highlight the corresponding language from the OMB Circular A-119.

The current language of Recommendation 03 makes two references to "this policy" in the final sentence. We believe it is important to more specifically describe to which "policy" the code sets are expected to conform, as it is unclear to the reader which "policy" is being referenced herein. We also suggest that the last sentence of Recommendation 03 should be qualified with language allowing for an "attempt to comply" with whatever policy is being referenced. This is important because not all standards bodies will be subject to certain requirements, not all standards bodies will be able to meet certain requirements even though the standards body is a required source of terminology, and certain terms may be aspirational or not otherwise required by law or regulation.

Finally, we wanted to note that it may not be possible for terminology curators to be in compliance with both OMB Circular A-119 and the February 13, 2019 NCVHS Vocabulary Recommendations. The current draft of Recommendation 03 says that terminology standards should be developed in accordance with OMB Circular A-119 "and" the NCVHS Vocabulary Recommendations. During the June 9, 2021 ISPTF meeting, when asked the question whether NCVHS saw its prior recommendation work as supplementing OMB Circular A-119, replacing it, or being in contradiction of it in some way, Rich Landen (of NCVHS) replied that he could not give the ISPTF a definitive answer to this question. We are not aware of whether the ISPTF has conducted such an analysis itself. Prior to finalizing the language of Recommendation 03 with reference to the NCVHS Vocabulary Recommendations, the HITAC should direct the ISPTF to undergo a legal analysis to determine whether the NCVHS Vocabulary Recommendations are consistent with OMB Circular A-119, which is based upon a federal law (the "National Technology Transfer and Advancement Act of 1995"), and which cannot be eliminated or replaced by a Federal Advisory Task Force.

We thank you for this opportunity to comment, and we would welcome the opportunity to discuss our comments with you in greater detail. Please feel free to contact Matt Reid (Matt.Reid@ama-assn.org) with any questions or to arrange a time for further discussion.

Attachment A – AMA Recommended Edits and Highlighted Language for Cover Letter Comments

The AMA recommends that if the following edits are accepted, any corresponding changes to the detailed subparts of Recommendation 3 should align with these revisions:

DRAFT

Recommendation 03 - In order to improve interoperability and innovation as well as maximize the deployed EHR base for pragmatic research, we **recommend** that ONC work with other Federal stakeholders and terminology curators to move the nation towards evidence-based terminology standards that are developed in accordance with OMB Circular A-119[1] (on Voluntary Consensus Standards) and with the February 13, 2019 NCVHS Vocabulary Recommendations[2] issued to the Secretary;, such as have having licenses that allow for free or low cost use or reasonable royalty terms by providers, researchers, developers, patients and other stakeholders; and are designed to address multiple needs (clinical care, research, public health, administrative needs). In areas where code sets that do not conform to this policy are currently required by Federal actors, we **recommend** that ONC work with key Federal stakeholders and terminology curators to attempt to comply align national terminology with this policy.

[1] https://www.whitehouse.gov/wp-content/uploads/2020/07/revised_circular_a119_as_of_1_22.pdf

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