



July 9, 2019

Jesse M. Ehrenfeld, MD, MPH
Chair
AMA Board of Trustees
American Medical Association
AMA Plaza
330 N. Wabash Ave., Suite 39300
Chicago, IL 60611-5885

Dear Dr. Ehrenfeld:

The undersigned members of the Physician Clinical Registry Coalition (the Coalition) appreciate the referral of Report 26-A-19, “Research Handling of De-Identified Patient Information” for further review by the AMA Board of Trustees. The Coalition is a group of medical society-sponsored clinical data registries that collect and analyze clinical outcomes data to identify best practices and improve patient care. We are committed to advocating for policies that encourage and enable the development of clinical data registries and enhance their ability to improve quality of care through the analysis and reporting of clinical outcomes.¹ In addition to the undersigned members of the Coalition, the following groups have expressed their support for this letter: the American Society of Hematology, the American Psychiatric Association, and the AMA Cancer Caucus.

The Coalition shares the AMA’s important goal of safeguarding patient privacy and appreciates the opportunity to continue this discussion with you and other members of the Board. At the recent 2019 Annual Meeting of the AMA House of Delegates, we requested that the AMA work with specialty societies to reconsider this report, and we are reaching out now as active federation members to begin that dialogue.

Report 26 contains valuable information, both about various uses of de-identified clinical data and the differences between individually identifiable health information or protected health information (PHI) and de-identified data. We share the authors’ concerns about patient protections in research, including guarding against the risk of re-identification.

However, as the AMA contemplates updating guidance on confidentiality of patient information, we ask for the opportunity to explain our strong belief that imposing additional limitations on the use of de-identified data will have adverse long-term effects that will harm patients by creating barriers to accessing information that provides critical insight to care delivery and health outcomes.

¹ For more information about the Coalition, see <https://www.registrycoalition.net/>.

With the primary goal of advancing high-quality care for every patient, our professional medical societies have invested heavily in creating and sustaining clinical data registries that, collectively, can change the face of health care. Appropriate use of health information is the foundation of any rapid learning health system—a goal strongly and consistently promoted by the Institute of Medicine.

In 2018, the AMA reaffirmed Policy H-450.933, Clinical Data Registries. This policy states, in part, that “[o]ur AMA encourages multi-stakeholder efforts to develop and fund clinical data registries for the purpose of facilitating quality improvements and research that result in better health care, improved population health, and lower costs”; “[o]ur AMA supports flexibility in the development and implementation of clinical data registries”; and “[r]egistries and electronic health records should be interoperable, and should be capable of sharing and integrating information across registries and with other data sources in a HIPAA-compliant and confidential manner.” Drawing new limits around the use of de-identified data could hamper these efforts and forestall discoveries and insights that could lead to improved patient care.

We agree completely with this AMA Policy H-450.933 and Report 26’s conclusion that “access to de-identified patient data is important for the future of health care.” It fuels quality improvement and research efforts with, as the Report states, “significant implications for our ability to make progress in refining the practice of medicine, reducing health care costs, reducing and preventing chronic disease, identifying cures for deadly conditions, and much more.” However, we are deeply concerned that Report 26 calls for the imposition of unprecedented limitations on the use of wholly de-identified data. This suggestion runs counter to HIPAA and other well-established privacy and research protection laws and will curtail improvements in quality of care. Providing appropriately de-identified real-world evidence is a legitimate function of medical specialty society registries and helps to support our members’ quality improvement efforts as well as research projects.

On close examination, it is apparent that a system in which individual patients could influence the creation, use or disclosure of a de-identified data set would exceed any current legal boundaries or authorities and would threaten the viability of the clinical data registries that hold so much promise for improving the quality of care. The premise that patients could veto the use of their de-identified data confuses patient rights in their individually identifiable information with the well-established property rights of physicians, hospitals, and other health care providers in the medical records they create from such data.

Likewise, we are troubled by Report 26’s brief but sweeping reference appearing to question the propriety of “patient record licensing contracts with exclusive rights.” We respectfully ask for the opportunity for further dialogue to better understand the nature of the concerns that prompted this remark. Our registries are dedicated to advancing quality improvement and stimulating medical research throughout our respective medical communities. Our pursuit of these goals may well be enhanced, rather than undermined, by the fact that a registry might choose to license de-identified data sets to commercial entities, with or without some degree of exclusivity. Such license agreements should not automatically be cause for concern as long as they are accompanied by appropriate safeguards and accountability to prevent re-identification and to allow our registries to continue to advance their core missions. The use of de-identified, health data by government agencies, pharmaceutical and device companies, insurance companies,

hospitals, and business analysts for population health management, health economics, forecasting of health care trends, assessing health outcomes over time, understanding adverse events, and other so-called “commercial” purposes has long been a part of the healthcare landscape and itself has the potential to contribute to access, value, and quality of care.

As noted in Report 26, many of the studies² assessing the risk of re-identification of de-identified data were small and did not use data that had been de-identified according to existing standards set forth in the HIPAA Privacy Rule. As such, Report 26 suggests, “caution should be taken when making generalizations based on the few cases identified in the studies.” We agree that registries and their collaborators must act responsibly to mitigate against the risk of re-identification of de-identified data. We submit that these risks are sufficiently addressed through strict compliance with the existing standards for de-identification set out in the HIPAA Privacy Rule, which specifically address strategies to reduce the risk of re-identification.³

As medical professionals, we are committed to protecting the best interests of patients we serve and this includes using appropriate resources to improve quality of care. We believe policies that encourage the development and sustainability of a rapid learning health system are consistent with this goal. We look forward to working with the AMA to help ensure appropriate protections for personal health information are in place, while supporting a strong registry environment that leads to critical insights about quality and patient outcomes.

Thank you for the opportunity to submit these comments. If you have any questions, please contact Rob Portman at Powers Pyles Sutter & Verville PC (rob.portman@powerslaw.com or 202-872-6756).

Respectfully submitted,

AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION
AMERICAN ACADEMY OF NEUROLOGY
AMERICAN ACADEMY OF OPHTHALMOLOGY
AMERICAN ACADEMY OF OTOLARYNGOLOGY - HEAD AND NECK SURGERY
AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION
AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS
AMERICAN COLLEGE OF EMERGENCY PHYSICIANS
AMERICAN COLLEGE OF GASTROENTEROLOGY/GIQUIC
AMERICAN COLLEGE OF RADIOLOGY

² See, e.g., El Emam, K., et al., *A Systematic Review of Re-Identification Attacks on Health Data*. PLoS ONE, 2011. 6(12): p. e28071.

³ The Coalition is also concerned that Report 26 (at p. 4, lines 26-27) appears to identify biologic specimens as a form of de-identified data. While biologic specimens may have patient data in the records associated with such specimens, the specimens themselves do not constitute data. More importantly, we are concerned that the Report appears to conflate issues surrounding patient consent for use of biologic specimens with the need for patient consent for the use of de-identified data. The use and availability of de-identified biologic specimens (as compared to de-identified data) present unique concerns and challenges that should be addressed separately from the use of de-identified patient data.

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AMERICAN COLLEGE OF RHEUMATOLOGY

AMERICAN COLLEGE OF SURGEONS

AMERICAN GASTROENTEROLOGICAL ASSOCIATION

AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY/GIQUIC

AMERICAN SOCIETY FOR RADIATION ONCOLOGY

AMERICAN SOCIETY OF ANESTHESIOLOGISTS/ANESTHESIA QUALITY INSTITUTE

AMERICAN SOCIETY OF CLINICAL ONCOLOGY

AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY

AMERICAN SOCIETY OF PLASTIC SURGEONS

AMERICAN UROLOGICAL ASSOCIATION

COLLEGE OF AMERICAN PATHOLOGISTS

NORTH AMERICAN SPINE SOCIETY

SOCIETY OF INTERVENTIONAL RADIOLOGY

SOCIETY OF NEUROINTERVENTIONAL SURGERY

THE SOCIETY OF THORACIC SURGEONS