



**Association of
American Medical Colleges**
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400 F 202 828 1125
www.aamc.org

April 19, 2024

U.S. Department of Justice
National Security Division
175 N Street NE, 12th Floor
Washington, DC 20002

Re: Docket No. NSD 104, Advance Notice of Proposed Rulemaking: National Security Division; Provisions Regarding Access to Americans' Bulk Sensitive Personal Data and Government-Related Data by Countries of Concern (89 FR 15780)

Submitted via Regulations.gov

The Association of American Medical Colleges (AAMC) appreciates the opportunity to provide comments to the Department of Justice (DOJ) Advance Notice of Proposed Rulemaking (ANPRM) entitled “Provisions Regarding Access to Americans' Bulk Sensitive Personal Data and Government-Related Data by Countries of Concern.”

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 12 accredited Canadian medical schools; approximately 400 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America’s medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened participation in the AAMC by U.S. and international academic health centers.

The AAMC recognizes that national security concerns underlie the expansion of Executive Order 13873 (“the Order”)¹, which directs the DOJ to promulgate regulations that prohibit or otherwise

¹ Executive Order on Preventing Access to Americans’ Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern. Feb. 28, 2024. <https://www.whitehouse.gov/briefing-room/presidential-actions/2024/02/28/executive-order-on-preventing-access-to-americans-bulk-sensitive-personal-data-and-united-states-government-related-data-by-countries-of-concern/>

restrict certain transactions involving access to “bulk sensitive personal data” or United States Government-related data by countries of concern. AAMC agrees with the use of risk-based safeguards when sharing or transferring sensitive data, and also strongly supports the statement in the Order that any new policies should preserve the “open, global, interoperable, reliable, and secure flows of data across borders.”

We also appreciate the Order’s explicit support for “open scientific data and sample sharing to accelerate research and development through international cooperation and collaboration.” International collaboration is a key component of the U.S. research enterprise, and greatly strengthens both our capacity and ability to advance scientific knowledge. This type of information exchange is particularly critical during quickly moving global health emergencies such as the COVID-19 pandemic. AAMC-member medical schools and teaching hospitals routinely work with biomedical and health data, conducting and managing research that is increasingly data-driven and often national or international in scope.

To the extent that regulations restricting the movement of data are deemed necessary to safeguard against identified threats to national security, AAMC urges the DOJ to ensure that the proposed regulations to be issued for community comment set practical, unambiguous, and readily implementable boundaries without negatively impacting the scientific progress that results from sharing health and biomedical data. Given the stated focus of the ANPRM “on identifying discrete classes of prohibited transactions that raise the highest national-security risks,” we would like to offer the following recommendations:

- 1) **Applying “bulk U.S. sensitive personal data” to human genomic data.** The AAMC recommends that security standards related to “human ‘omic data” (appropriately limited here to human genomic data)² be addressed separately from the other categories of information considered under the standards for protecting “bulk U.S. sensitive personal data.” Genomic data, as defined in the ANPRM captures a wide range of data types, each of which may have very different implications for security and identifiability.³ Accepted scientific practice currently examines a number of technical factors to determine the risk level of sharing genomic data and whether the resulting data should be accessible through open access or controlled access. Recommended security standards for -omics data do not primarily depend on the number of individuals represented in the data. Correspondingly, considerations of human genomic data should not be regulated using the same rules as for financial data or individual geolocation data. We do not find that the proposed estimation of “low” and “high” bulk thresholds of genomic data (100 and 1000 people, respectively) are based on any scientific rationale. Implications and potential uses of a whole genome

² “The Department of Justice currently intends for its first rulemaking to regulate covered data transactions involving human ‘omic data only to the extent that such transactions involve human genomic data.” 89 FR 15785.

³ “The term *human genomic data* means data representing the nucleic acid sequences that comprise the entire set or a subset of the genetic instructions found in a human cell, including the result or results of an individual’s ‘genetic test’ (as defined in 42 U.S.C. 300gg–91(d)(17)) and any related human genetic sequencing data.” 89 FR 15785.

sequence are substantially different than for the sequence of a single gene or small region of the genome or for the results of a genetic test. Any restrictions should be based on an in-depth assessment of risk that is based on scientific evidence and principles and determined using input from the scientific community as well as the federal agencies with the appropriate expertise (Question 8).

- 2) **Exempting federal contracts from regulation.** We support the proposed exemption for data transactions conducted pursuant to a grant, contract, or other agreement entered into with the United States Government, which would allow the Department of Health and Human Services (HHS) and other agencies to address risks related to the access to bulk sensitive personal data by countries of concern, as described in the Order in a manner that preserves the scientific intent of the grant or contract (Question 43). This flexibility is critical to develop policies and guidance for federally funded research operations and projects which are based on an evidence-based risk assessment for scientific data. We do not support the regulation of additional types of -omics data by the DOJ at this time and propose that any data security requirements for these data types be determined after input from HHS and other relevant federal research agencies (Question 5 and see answer to Question 8, above).
- 3) **Categorical exclusion for data in open access repositories.** We endorse a categorical exclusion for *sensitive personal data* to the extent that the data is lawfully available to the public via sources that are “generally available to the public through unrestricted and open-access repositories” as proposed in the ANPRM. Open access repositories are the main platform by which scientists share and access -omics data in the public domain, and their continued operation is vital for advancing collaborative science in this field (Question 11).
- 4) **Exemption for public health surveillance.** The AAMC supports the proposed exemption for data transactions required or authorized by federal law or pursuant to an international agreement, such as those which govern public health surveillance (Question 43). We also recommend the additional consideration of health-related data transfer that may not fall within the proposed exemption, such as for drug development or other medical research or clinical purposes (Question 45).
- 5) **Concerns related to the covered persons list.** The ANPRM as written focuses on “transactions that may enable access by countries of concern or covered persons” to defined categories of data. We are concerned by the proposed mechanism to keep track of these individuals through a non-exhaustive public list maintained by DOJ, which would be very challenging for academic institutions to implement and would make compliance extremely complicated. Academic institutions are not investigative bodies and do not have the tools and resources to identify covered persons (Questions 32-34).
- 6) **Ensuring regulations can be implemented by the regulated community.** We would like to emphasize to the DOJ the importance of developing regulations which are clear, specific, and implementable by the academic research community. Lack of clarity around definitions for

covered data transactions or requirements for individual institutions to conduct risk analysis or independently identify covered persons will create a regulatory framework that makes institutional compliance extremely difficult. Any unnecessary complexity will lead to a maximally restrictive approach, stifling international collaboration and research progress, and increasing undue regulatory burden in conducting research.

- 7) **Cross-agency collaboration.** The AAMC urges the DOJ to recognize in these efforts the existing and emerging federal framework for research security that is currently being finalized by the White House Office of Science and Technology Policy (OSTP) with input from across the federal government, including security and intelligence agencies. Collaborating with OSTP and other relevant agencies in order to streamline requirements and ensure their alignment is critical to ensure that institutions are not subject to dual or conflicting regulations and policies. We request that DOJ indicate in the subsequent NPRM how efforts on safely and securely working with research data are coordinated across the whole of government and specifically aligned with these research security policies.

AAMC would be glad to provide any additional comments on the proposed regulation to DOJ as the rulemaking process moves forward. Please feel free to contact me or my colleague Anurupa Dev, PhD, Director of Science Policy and Strategy (adev@aamc.org) with any questions about these comments.

Sincerely,



Heather H. Pierce, JD, MPH
Acting Chief Scientific Officer
Senior Director for Science Policy and Regulatory Counsel

cc: David J. Skorton, MD, AAMC President and Chief Executive Officer