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Submitted via email to VRDCRFI@cms.hhs.gov

April 16, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

Re: Research Data Request and Access Policy Changes

Dear Administrator Brooks-LaSure:

On behalf of the Association of American Medical Colleges (AAMC), I am writing to express significant concerns with changes proposed to the Research Data Request and Access Policies for research identifiable files that were announced on February 12, 2024. This policy, especially related to the discontinuation of physical data extracts to support external research projects, will significantly jeopardize future research focused on access to high quality, evidence-based, cost-effective, equitable care. While we appreciate CMS's extension of its RFI comment deadline and delay in implementation, we ask that CMS withdraw these policies and instead work with the research community to develop an alternative approach to enable equitable, affordable access to CMS data while addressing concerns regarding data security.

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; 13 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. Many researchers at academic medical centers work extensively with CMS research data to study and inform policies related to payment and care delivery for Medicare and Medicaid beneficiaries.

While we understand CMS's concerns with security of data, we believe that eliminating the use of physical data access and requiring use of the Virtual Research Data Center (VRDC) for

research identifiable files will create significant barriers to research that is critical to provide evidence and answer questions that will enable progress on critical issues, such as health equity, health access, health care quality and safety, cost, drug pricing, and many other federal policy priorities. Specifically, these changes jeopardize the ability to conduct research in the following ways:

- **The Pricing Structure of the VRDC would Stifle Research Projects:** Under the current pricing structure of the VRDC, many research projects would not be feasible. Collaborative efforts where multiple roles are required for data analysis are commonplace. Many projects are not externally funded, and internal funds would not be sufficient to cover per user fees of approximately $20,000 per year plus additional fees (e.g. start up). As an example, one university informed us that it has approximately 194 current users on 97 data use agreements (DUAs) and would incur an estimated $3,880,000 in user seat fees and $1,455,000 in project fees to move the current research work to the VRDC in the first year of the transition.

- **Development of future researchers**: Given the high per user costs to use the VRDC, institutions would need to limit access to the number of users on the research team with access. These limitations on access to data are most likely to affect graduate students, post-doctoral researchers, and junior faculty, thereby jeopardizing the training of future health care researchers.

- **Disproportionately Affect Organizations**: The requirement to use VRDC only will disproportionately affect researchers at organizations with less funding, including those that have been historically disadvantaged.

- **VDRC has technical limitations:** Researchers have experienced challenges when using the VRDC, such as limits on available coding languages and open-access code and slow processing speeds. They report frequent system errors. The VRDC is unable to support technically demanding analyses. Technical malfunctions result in delays in productivity and completion timelines of analyses.

- **VRDC Does Not Enable Linkages of Data Sets:** Many researchers work with a number of datasets that they are able to merge at their university using security protections to study topics that require linking Medicare claims data with other types of non-CMS datasets, such as electronic health record data, or registry data. VRDC does not have the storage available or the security in place for transfers to link these large data sets. This merger of datasets is essential as there are many topics that cannot be understood using claims data alone.

- **Added Data Costs Jeopardize Existing Grants:** Many existing research grants have been funded for a period that includes multiple years. The funding from these grants and associated budgets were established at a time when use of physical extracts was allowed; therefore, the funding from these existing grants is most likely not sufficient to absorb the significant increase in user fees.

CMS Should Seek Better Solutions to Protect Security

While we understand that CMS has concerns with the security of physically distributed data files, we urge CMS to take time to seek input from stakeholders on how to balance security priorities with data access policies that inform policy and advance equity. Potential options to consider in order to mitigate the negative impact on research could include (a) safeguards around existing data processes, and (b) ways to make the VRDC environment more accessible and thus more widely used (listed below):

- Establishing requirements and safeguards that researchers must meet to protect the data (e.g. requiring data breach insurance with a policy size that is correlated with the amount of data used.)
- Ensuring that each RIF data set has a Limited Data Set (LDS) counterpart by creating new LDS purchase options where currently unavailable (for example, for the Shared Savings Program Provider-level RIF).
- Changing the pricing structure for VRDC so that additional users at the same organization do not incur additional fees by allowing user seats to be designated to the institution (rather than individuals) so that they can be shared by researchers rather than belonging to one individual. This would allow flexibility for organizations with varied staffing demands (e.g. several part-time researchers who work on the same type of project may share a seat).
- Reducing the overall fees associated with use of VRDC.
- Improving the capabilities of VRDC to mitigate technical problems and allow linkages of data sets.

Should CMS move forward with these policies despite our concerns, we recommend further delay as additional time is needed for the transition. Thank you for your consideration of our concerns. We would welcome the opportunity to discuss these concerns further with you. If you have any questions or need any additional information, please do not hesitate to contact Gayle Lee at galee@aamc.org.

Sincerely,

Jonathan Jaffery, MD, MS, MMM
Chief Health Care Officer
AAMC

cc: David Skorton, MD, AAMC President and CEO