February 26, 2024

Chiquita Brooks-LaSure, M.P.P.
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: Research Data Request and Access Policy Changes, Announced February 12, 2024

Dear Administrator Brooks-LaSure:

We at AcademyHealth, on behalf of the health services research community, are writing to express the profound concerns the research community has about the proposed changes to the Research Data Request and Access Policies announced on February 12, 2024. We ask that CMS immediately withdraw the notice and work with the research and data communities over the coming months to design a solution that serves CMS goals while actually improving secure and affordable researcher access to data.

AcademyHealth is the professional home of health services researchers, policy experts, and practitioners, including those serving the most vulnerable and disenfranchised populations. Health services research examines how people access to health care, how much care costs, and what happens to patients as a result of this care. We additionally host the Medicaid Data Learning Network, the State-University Partnership Learning Network, the Medicaid Medical Director Network, and the Medicaid Outcomes Distributed Research Network. We represent many of the top researchers and a large proportion of users of CMS Research Identifiable File (RIF) data.

The policy changes listed in this announcement will have a profound and deeply negative impact on Medicaid and Medicare beneficiaries' access to high-quality and evidence-informed care, threaten the infrastructure of public health and health systems research, create significant barriers to lesser-funded organizations and individual researchers, including ones that are the most focused on issues of health equity, and stifle the crucial advancements in health care research, especially for junior and future scholars of Medicaid and Medicare research.

We call on CMS to immediately reverse or postpone these announced changes and engage in significant partnerships with the research community in designing the future of CMS data access.

CMS data is critical for health care research, and this proposal critically limits its access

CMS data serve as a cornerstone for research initiatives aimed at enhancing health care delivery, efficiency, and equity for all patients. The proposed policy changes threaten to severely limit researchers' access to these vital datasets. Specifically, these changes will:

- Jeopardize Public Health and Scientific Progress: The restriction on data access would hinder the development of essential evidence needed for healthcare improvements, transparency, and accountability. Vital areas of research, including health equity, healthcare quality, hospital consolidation, and drug pricing, rely on comprehensive access to CMS data for rigorous and reproducible studies. Restricting data usage to the Chronic Conditions Warehouse Virtual Research Data Center (CCW VRDC) as it is currently functioning would reduce the sophistication of research models and create potentially insurmountable challenges to data analysis and interoperability.

- Affect Training and Development of Future Scholars: The elimination of physical data access compromises the training of future health care researchers. Access to CMS data is a crucial aspect of training for graduate students, post-doctoral researchers, and junior faculty, as it facilitates hands-on learning and aids in the creation of innovative research methodologies. The proposed increased fees faced by researchers using the VRDC would create financial barriers to institutions providing CMS data access to students and research assistants. For instance, given the high per-user costs, research teams will have to limit the number of research team members with VRDC access. This creates significant restrictions for research teams to work together, check team members' code, or provide data training to junior team members.

- Compromise Equity in Research Funding and Access: The shift to VRDC-only access will disproportionately affect researchers from under-resourced institutions, including those historically disadvantaged, and from institutions that have already invested significant resources in physical data capabilities. This change risks widening the existing gap in health care research capabilities and stifling meaningful contributions to health policy, health equity, and patient care improvements. For instance, the chronic underfunding of Historically Black Colleges and Universities (HBCUs) has limited HBCU's ability to attain the distinction of being an R1 institution, thus limiting these institutions' ability to obtain the more generous external research grants needed for larger scope projects. The additional fees proposed would further existing financial barriers to HBCU's increasing their research capacity.

- Hinder Collaborative and Interdisciplinary Research: The financial and logistical barriers to accessing CMS data through the CCW VRDC will likely deter interdisciplinary collaborations, essential for addressing complex health issues. The proposed changes could inadvertently slow the pace of scientific progress that has been achieved through collaborative efforts in recent decades. Researchers face numerous logistical challenges when using the VRDC, particularly given the limits on available coding languages and open-access code, as well as slow processing speeds within the VRDC environment. Indeed, researchers report that using the VRDC can be a tedious process, and that they often encounter system errors, such as the

VRDC system itself going offline. By restricting all analysis to the VRDC, the system going offline halts the entire Medicaid and Medicare research community, leading to the loss of productive person-weeks or person years of analysis for every day of technical malfunctions, which are reported as relatively common by researchers in our community.

- <u>Stifle Methodological and Analytical Innovation</u>: Access to individual-level data is crucial for employing and developing a range of research methodologies, including machine learning and microsimulation modeling. The VRDC environment could impede innovation by limiting researchers' ability to engage in such methodologies, effectively constraining health services research.

- <u>Surprise Researchers with Unexpected and Potentially Unworkable Added Data Costs:</u> The transition period is unworkable for many researchers to comply with data access policy changes within the framework of existing grants or projects. Many research grants, including those from federal agencies like NIH and philanthropic nonprofits, are funded in multi-year windows, which will require researchers to transition in the midst of a study. Research organizations may have also made significant investments in data that they planned on reusing for multiple projects, and budgeted the savings into grant applications. Additionally, these grants may not have the capacity to absorb the dramatic increases in user fees, which can easily be more than six figures. Grantees with smaller grants, many of whom may be early-career researchers, may suddenly be completely cut off from using government data altogether.

- <u>Impact Healthcare Costs and Trust Fund Viability</u>: The inability to conduct comprehensive research using CMS data risks increasing healthcare costs and jeopardizing the Medicare trust funds. Research driven by CMS data plays a crucial role in identifying efficiencies and improvements that can contain costs and enhance care delivery.

<u>Recommendations for CMS to support researchers and patients</u>

In light of these concerns, AcademyHealth urges CMS to consider the following recommendations:

- <u>Immediately Withdraw the Notice:</u> We call on CMS to take a step back and further consider the problem scope and potential solutions that stakeholders will be providing the agency. The most effective way to ensure a thoughtful and deliberative process is to suspend the February 12 notice.

- <u>Constructive Engagement with the Research Community</u>: We recommend that CMS engage in meaningful dialogue with stakeholders, including researchers, academic institutions, data and security experts, and professional organizations to ensure the VRDC environment meets researchers' needs and provides opportunities to perform timely, quality analysis while maximizing data security. CMS should work with the research community to identify specific areas within the VRDC in need of improvement, such as processing times, system reliability,

and the use of open-source code and workable solutions to these challenges. Given the concerns about the current computing infrastructure and the substantial increase in users and computational power that would be required with such a transition, CMS should ensure that the VRDC environment and infrastructure are expanded to meet these needs before transitioning users to it. These improvements should include additional RFI opportunities and public listening sessions. Through such a dialog, the research community can become more fully aware of concerns that may have driven CMS to issue the February 12 notice. Together we can find new ways to effectively balance needed data security and research access.

- <u>Phased Implementation and Support for Transition:</u> To minimize disruption, a phased implementation of any policy changes, accompanied by adequate financial and logistical support for researchers transitioning to the VRDC is critical. This could include financial assistance, training, and technical support to facilitate the transition to and effective use of an improved virtual environment. CMS should ensure that the specific concerns of individual institutions moving from physical data to the VRDC are addressed, such as uncertainty on access to previously purchased physical data or the potential to import developed physical datasets into the VRDC. The window for full transition should be significantly extended to allow for compliance.

- <u>Reconsideration of Physical Data Access Policies</u>: Given the significant investments in data security and privacy already made by research institutions, we encourage CMS to reconsider the complete discontinuation of physical data extracts. A more nuanced approach, possibly involving enhanced security measures or selective access based on demonstrated compliance with data privacy standards, could preserve the integrity of research while ensuring data security. Research organizations should have an option to create secure data environments that pass regular security inspections. We believe that protecting patient data is critical, but it must be done in a manner that is both effective and with minimized negative externalities on research.

Conclusion

The proposed changes to the CMS research data request and access policies pose critical burdens to the research community and the broader goals of improving health care quality, efficiency, and equity in the United States. It also is a dramatic and unnecessary step back in the work that CMS has done towards accessible data and the implementation of the Foundations for Evidence-Based Policymaking Act of 2018 (Evidence Act) and the FY2023-2026 Evidence-Building Plan [released](#) by the Department of Health and Human Services. AcademyHealth is committed to engaging with CMS and other stakeholders to find balanced solutions that maintain equitable, affordable access to these critical data resources. We believe that through collaborative efforts, it is possible to address security concerns without unduly restricting the research essential for advancing public health and health care policy.

Thank you for the opportunity to discuss the perspectives and concerns of the health services research community. For further comment, clarification, or inquiry, please email Josh Caplan at Josh.Caplan@AcademyHealth.org.