



May 15, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services

RE: Policy Changes to Research Data Requests and Access

Dear Administrator Brooks-LaSure:

The undersigned members of the Disability & Rehabilitation Research Coalition (DRRC) greatly appreciate the opportunity to provide comments in response to the request for information titled “Research Data Request and Access Policy Changes” issued on February 12th, 2024. As expressed in detail below, considering the potential harm to smaller institutions and the limitations of the Virtual Research Data Center (VRDC), the DRRC opposes this policy change and requests that the agency withdraw the notice or make substantial changes that meaningfully engage the research community before implementing such a large-scale policy change in 2025.

The DRRC is a coalition of 24 national research, clinical, and consumer non-profit organizations committed to improving the science of rehabilitation, disability, and independent living. We seek to maximize the return on the federal research investment in these areas, with the goal of improving the ability of Americans with disabilities to live and function as independently as possible following an injury, illness, disability, or chronic condition.

On February 12, 2024, the Centers for Medicare and Medicaid Services (CMS) announced that the agency will limit access to Medicare and Medicaid claims data and increase fees imposed on individual researchers who seek to access this data for their investigations. The new policy no longer allows CMS to disseminate physical Research Identifiable Data (RIF) for new research studies, forcing all external research partners to access data within CMS’ Chronic Conditions Warehouse Virtual Research Data Center (CCW VRDC), a secure virtual environment. Additionally, although the agency will allow ongoing research projects with approved Data Use Agreements before 2025 to continue to receive physical data files, researchers must pay an annual project fee in addition to the current file dissemination fee to continue to receive physical copies of the data. While this transition is occurring, to ensure that no physical files continue to be stored by external partners, CMS is also prohibiting physical data extracts past

2025. After receiving initial public responses, CMS decided on April 15 to delay implementation of the policy changes to 2025.

This announcement has perplexed the broader research community¹ because it appears to contradict the Administration's efforts to establish greater health data transparency and statements from the Secretary of the Department of Health and Human Services² that "transparency is the key to Biden-Harris Administration's effort to increase competitiveness and ensure that Medicare dollars are spent on first-rate health care." Given that numerous critical federal priorities depend on unimpeded access to this data, the DRRC hopes that CMS has anticipated the ramifications of this change.

The agency states that this new policy is a result of growing data security concerns and an increase in data breaches across the healthcare ecosystem. Researchers across the country, however, are aware of the sensitivity of this data and already use high-level security functions to maintain data security. For example, researchers who use Research Identifiable Files are required to have new request forms for all Data Use Agreement actions and an approved Data Management Plan Self-Attestation Questionnaire for physically shipped data. These measures force all external partners to attest that they comply with CMS' Acceptable Risk Safeguards security and privacy controls.

These Data Use Agreements exceed any requirements under the Health Insurance Portability and Accountability Act (HIPAA) that protect the privacy and security of certain health information under the HIPAA Privacy and Security Rules. To be clear, DRRC appreciates that CMS is taking steps to ensure that only authorized users are utilizing sensitive Medicare data, however, we believe that the current safeguards ensure that this data is well protected. We do not believe that the benefits of a further increase in security outweighs the negative implications this change could have on the research community and the overall Medicare program.

CMS Data is a National Resource

Access to Medicare and Medicaid claims data allows researchers to advance rehabilitation science by analyzing patterns of treatment or coverage of services that are highly effective for Medicare beneficiaries. Using this data, researchers have published numerous high-impact studies, many of which have led to breakthroughs in medical treatment or shifts in healthcare coverage that have saved taxpayer dollars.³ An example of this data at work is a groundbreaking research study⁴ published more than a decade ago that used 30-day hospital readmission rates

¹ <https://www.statnews.com/2024/02/20/cms-medicare-medicaid-research-fees-data-security/>

² <https://www.hhs.gov/about/news/2024/01/25/biden-harris-administration-launches-effort-increase-medicare-advantage-transparency.html>

³ <https://docs.google.com/document/d/1H-27k-tn3jQJ65UUvMRr1vgW3KVIvGoYdOqihzTYpG0k/edit>

⁴ <https://www.nejm.org/doi/full/10.1056/nejmsa0803563>

to demonstrate that nearly one-fifth of people enrolled in Medicare were being readmitted within 30 days after their hospital discharge. This discovery found that patients were being discharged too early, leading to their eventual readmission and higher overall medical costs. Analytics from this study are only possible when researchers have readily available access to this data via the two options that are currently available.

Negative Impacts on Under-Resourced Institutions

The health policy projects conducted using CMS data contribute to meaningful changes in best clinical practices and healthcare coverage policy. The new project fees may force many institutions, particularly those that are historically disadvantaged or under-resourced, to halt ongoing investigations and pare down research priorities. We believe that while well-resourced institutions may lose access to large quantities of physical data extracts, they are still much less likely to suffer under the new policy because of ample funding streams. Smaller universities and centers, however, may bear the brunt of the new policies. As a result, DRRC anticipates these fees having a much larger impact on the career opportunities of individuals from underrepresented backgrounds. In particular, DRRC foresees junior researchers and post-graduate students being disproportionately impacted if their institution is unable to cover the hefty fees levied on each individual who needs access to the data set.

This consequence is concerning to the research community because larger research teams create more interdisciplinary collaborations but by adding high per-user costs, teams will be limited in their capacity to work together and provide training to junior team members. If smaller research institutions are forced to cut their research teams, there may be reduced rigor and reproducibility with fewer investigators available to enhance the outcomes of the research. We are concerned that the VRDC will encourage institutions to support smaller teams rather than larger research projects that utilize multiple analysts for rigor and reliability, two crucial components to high-quality health services research.

Recommendations

The DRRC acknowledges that through this new policy, CMS seeks to increase the security of RIF, however, we believe that the agency has not sufficiently considered how the new policy will restrict data access and fundamentally alter healthcare research in the United States. Applying a large-scale change will limit the capacity of institutions to serve CMS' broader goals of improving healthcare quality, efficiency, and equity in the United States.

Therefore, the DRRC offers the following recommendations to CMS:

- Conduct listening sessions with diverse groups of researchers to understand the full ramifications of the permanent removal of physical data extracts.
- Actively work to fix the limitations in the VRDC environment.
- Create a more reasonable fee structure for research institutions of different sizes.

- Focus on elevating high-value Medicare services rather than removing ways to advance evidence-based research.

If CMS moves forward with this policy change in 2025 before considering these recommendations, the DRRC has deep concerns that this change could be detrimental to advancements and progress in disability and rehabilitation science in the United States.

We greatly appreciate your consideration of our comments, and we look forward to continuing to engage with CMS as the agency addresses the ramifications of this policy. Should you have any further questions regarding this letter, please contact DRRC Co-Coordination at Peter.Thomas@PowersLaw.com or Natalie.Keller@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of DRRC

American Academy of Physical Medicine and Rehabilitation

American Association on Health & Disability*

American Medical Rehabilitation Providers Association

American Music Therapy Association

American Occupational Therapy Association*

American Physical Therapy Association*

American Therapeutic Recreation Association

Association of Academic Physiatrists*

Association of Rehabilitation Nurses

Association of University Centers on Disabilities

Brain Injury Association of America*

Christopher & Dana Reeve Foundation

National Association for the Advancement Orthotics & Prosthetics

National Neurotrauma Society

Paralyzed Veterans of America

Rehabilitation Engineering and Assistive Technology Society of North America

Spina Bifida Association

United Spinal Association

****DRRC Steering Committee Member***