ISPOR
The professional society for health economics and outcomes research

Improving healthcare decisions

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Dear The Centers for Medicare & Medicaid Services (CMS):

ISPOR – The Professional Society for Health Economics and Outcomes Research - is pleased to respond on behalf of its membership to your consultation entitled "Important Research Data Request & Access Policy Changes."

ISPOR is a scientific and educational society with many of its members engaged in evaluating health technologies, including pharmaceuticals, medical devices, and other interventions. We have a large membership living and working in over 100 countries globally, across a range of disciplines, including health economics, epidemiology, public health, pharmaceutical administration, psychology, statistics, medicine, and more, from a variety of stakeholder perspectives, such as the life sciences industry, academia, research organizations, payers, patient groups, government, and health technology assessment bodies. The research and educational offerings presented at our conferences and in our journals are relevant to many of the issues and questions raised in this request for information.

The response to this consultation was led by the Policy Outlook Committee of our most senior advisory body, the Health Science Policy Council. We solicited comments from the ISPOR Institutional Council, Real-World Evidence (RWE) Steering Committee, the ISPOR Faculty Advisory Council, and several ISPOR Special Interest Groups. We also consulted with the International Society for Pharmacoepidemiology (ISPE). Collectively, ISPOR and ISPE's interests represent approximately 20,000 researchers and research stakeholders globally, many of whom are directly involved in the planning or execution of real-world data analyses. The attached document provides a summary based on their comments. We hope they prove useful.

ISPOR would be happy to answer any questions about our response, to serve as a partner, or to participate in any follow-up consultations on the relevant program items mentioned within the report.

Sincerely,

Robert Abbott
CEO & Executive Director
ISPOR

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Important Research Data Request & Access Policy Changes

The Centers for Medicare and Medicaid Services (CMS) announced two policy changes in February 2024 concerning access to CMS data. One required all new data requestors to gain access via the Virtual Research Data Network Center (VDRC). The other required all uses to transition their access to CMS data via the VDRC.

As members of ISPOR - the professional society for health economics and outcomes research, we are concerned about the unintended harmful impacts of these policies. We agree with and fully support the comments from our colleagues with the International Society for Pharmacoepidemiology (ISPE), who have submitted a separate response letter to CMS regarding the harmful impacts on researchers, research teams, and institutions to use CMS data – both those currently using physically delivered data and those already using the VRDC. Much of their focus is on the potential impact on academic researchers and trainees.

We add to this the potential negative impact on other researchers including those employed by the healthcare industry broadly, and specifically those employed by pharmaceutical and device developers. Given the FDA's commitment to furthering real-world data (RWD) to generate credible real-world evidence (RWE) that will advance the development of therapeutic products and strengthen regulatory oversight of medical products across their lifecycle, the new policies may impede these regulatory efforts, since timely access to CMS data by industry researchers and their academic partners. Further, impediments to access to Medicare data could hinder industry's ability to generate the comparative effectiveness evidence needed to inform the drug price negotiations under the Inflation Reduction Act. We also argue that the access impediments posed by the VRDC may impede progress towards a learning health system, which is a central goal of federal efforts as defined by the Agency for Healthcare Research and Quality (AHRQ).

With respect to the harmful immediate impacts of the new policies, we highlight two predictable consequences:

- Requiring access through the VRDC will impede if not prevent linkage of CMS data to other data sources. Many such linkages are not possible within the VRDC due to restrictions in data use agreements and other technical challenges. To generate credible RWE, it is well recognized that linkage of multiple data sources is critical including administrative, clinical record, laboratory, patient-reported outcomes, death, and others. Further, to identify and address healthcare inequities, linkage of Medicare data to non-healthcare data (for example neighborhood data) is becoming increasingly important. Thus, the new policies may negatively impact the rigor and quality of RWD research.

- There are technical challenges with expanding the capacity of the VDRC. We suggest that, in its current form, it may be unlikely to be able to handle the volume of researchers and their projects, nor is there sufficient CMS capacity to train the new influx of Medicare researchers on how to use the VRDC. At the very least, requiring the use of VDRC should be piloted while the information technology infrastructure is tested on larger and broader constellations of researchers.

We acknowledge ISPOR member Marc Berger for his assistance in assembling these comments, as well as ISPOR staff Richard Willke, Laura Pizzi, Kelly Lenahan, and Madeline Shipley.