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Submitted via email to VRDCRFI@cms.hhs.gov

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Dear Administrator Brooks-LaSure:

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The Society of General Internal Medicine (SGIM) is the leading society for academic general internal medicine physicians across the United States. SGIM represents more than 3,300 physicians including many members who conduct federally funded research that uses claims data from Medicare and Medicaid. In response to the request for information on Important Elizabeth Dzeng, MD, PhD, MPH, MPhResearch Data Request and Access Policy Changes from the Centers for Medicare & Medicaid Services (CMS), this letter describes SGIM's significant concerns related to the policy implications of changes to claims data access, cost, and pricing.

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SGIM believes that the planned changes will be detrimental to the research community at large whose use of CMS claims data is critical for the advancement of evidence-based primary care practice and policy. We believe that the changes described in the policy will drastically impede scientific progress in the study of healthcare access, utilization, disparities, and health policy. Employing the policies described in the RFI will be disruptive to existing research projects, and curtail the breadth of future projects, because of the significant costs quoted by CMS and need for Virtual Research Data Center (VRDC) seats to undertake the work. While these changes may be manageable for some extremely well-funded institutions, they will disproportionately affect early career researchers and smaller institutions who lack the funds to support their burgeoning research careers because of the considerable costs to use the valuable resource that is CMS claims data. These changes could further exacerbate inequities among clinician investigators pursuing careers in health services research, among whom are academic internists. SGIM is concerned that this policy will limit the geographical and intellectual diversity of claims-based health services research, which in turn will dampen important scientific and economic evaluation in areas that require further evaluation, including urban-rural divides in healthcare access, utilization, and cost.

Below we note these specific concerns in more detail and provide examples:

1. Disproportionate impact on early-career investigators

Early career researchers often begin their research careers with career development awards. These awards typically provide limited research resources to undertake their work, as the focus



is on applied training. For example, the typical current resource budget for a National Institutes of Health Career (K) Development Award is approximately \$25,000 per year. This budget must cover training expenses, conferences, and personnel costs, leaving little to cover increased data costs.

Thus, the considerable increase in costs will significantly reduce the available funds for early career development awardees, particularly in understudied fields such as primary care healthcare access, disparities, costs and utilization, and health service delivery. Furthermore, academic departments will be less incentivized to support early career researchers to undertake research using CMS claims, as they will likely need to supplement these costs to ensure adequate funds are available to support the development of their junior faculty's careers.

Additionally, SGIM has three specific concerns. First, SGIM is concerned that because of these added costs, academic internists will turn away from claims-based research of both older adults and means-tested Medicaid beneficiaries. Second, SGIM expects that the research pipeline of capable individuals will decline – particularly those who possess the required skills and expertise to undertake claims-based research. Third, as a result of this, fewer investigators will use this important resource to undertake this work.

2. Disproportionate impact on smaller institutions and those with less well-developed health services research programs that lack supplemental funds to support cost increases

SGIM expects that the changes specified will limit research opportunities for small academic institutions. Thus, the effect of this work will be to limit the pool of researchers from a variety of institutions outside of the traditionally, well-funded academic centers. These smaller institutions provide valuable insights as academic colleagues, typically in geographical locations where changes to hospital and primary care policy may have differential effects. For example, new policies that may detrimentally impact rural hospital access or disproportionately penalize primary care practices in certain states due to their Medicaid policies will be harder to analyze, and less likely to be investigated by the communities of researchers where these events take place.

The implications of this will be important for patients, physicians, and healthcare systems, as well as state and federal authorities. The vital feedback loop that brings evidence to support or change existing policies is likely to be weakened by these new data access and cost policies.

3. Decline in primary care-focused research using claims data

SGIM's key advocacy focus is on primary care practice. Claims-based research has a proud history of providing important insights into the state of primary care in the United States. The implementation of physician value-based payment systems and unique integrated primary care models (e.g., Patient Centered Medical Home, Accountable Care Organizations) are active laboratories of healthcare delivery that require ongoing independent, rigorous investigation.



Claims-based research has been and will continue to be essential to examining the implications of policies as CMS seeks to improve primary care for millions of Americans nationwide. Increasing data costs and restricting access to the data via the VRDC will have a significant negative impact on the evaluation of primary care at scale, at a time when more evidence-based policy approaches are necessary coming out of the COVID-19 pandemic. Important policies such as the evolution of telehealth and its impact on healthcare outcomes, access to care, and differences by Medicare and Medicaid beneficiaries will need to be better understood, evaluated, and modified in the coming years. The success of such endeavors will be severely curtailed by these changes.

Conclusion

In summary, SGIM is deeply concerned about the suggested changes described in the RFI. They will limit the future pipeline of CMS claims-based research and researchers, worsen inequity in academic practice, and have considerable negative impact on understanding the implications of healthcare policy, particularly in primary care. We believe that CMS should pause these plans to seek further input before considering next steps. SGIM believes that widening accessibility of claims data would be a step in the right direction. Nonetheless, consultation with the communities of researchers, users of CMS claims data, and other stakeholders will be critical to ensure the viability of claims-based research and to prevent changes that will be to the detriment of the provision of US healthcare, its providers, and most importantly, beneficiaries themselves.

Thank you for considering these comments. Should you require further information, please contact Erika Miller at emiller@dc-crd.com.

Sincerely,

Martha Gerrity, MD, MPH, PhD, FACP

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President, Society of General Internal Medicine