



August 21, 2023

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
P.O. Box 8013  
Baltimore, MD 21244-8013

*Submitted electronically via cms.gov*

Re: Coverage with Evidence Development Proposed Guidance

Dear Administrator Brooks-LaSure:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the proposed guidance titled “Coverage with Evidence Development” (Proposed Guidance) published on June 22, 2023.

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP’s nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

AMCP supports providing patients with timely access to valuable and potentially lifesaving treatments. The use of the Coverage with Evidence Development (CED) pathway encourages evidence development, permits coverage of innovative drugs for people with Medicare who are participating in controlled trials. This pathway provides Medicare beneficiaries with vital access to promising treatments that would not otherwise be covered.

### **Clinical Study Standards for CED – Study Population**

The Proposed Guidance includes the following clinical study standard:

The study population reflects the demographic and clinical diversity among the Medicare beneficiaries who are the intended population of the intervention. At a minimum, this includes attention to the intended population’s racial and ethnic backgrounds, gender, age, disabilities, important comorbidities, and dependent on data availability, relevant social determinants of health.<sup>1</sup>

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<sup>1</sup> Proposed Guidance at p. 8.

AMCP is committed to addressing health disparities in medication use and access.<sup>2</sup> Clinical trials need to include people from diverse backgrounds given that people of different ages, races, and ethnicities may have different outcomes from medical treatment.<sup>3</sup> Without greater diversity in these trials, valuable evidence about potentially divergent outcomes is not being captured. Despite the growing awareness of the need for inclusivity in clinical trials, people from racial and ethnic minority and other diverse groups remain underrepresented in clinical research.<sup>4</sup>

While AMCP applauds CMS for addressing diversity in clinical trials, AMCP urges CMS to consider more stringent standards for health equity in CED clinical trials. CED clinical trials should take more concrete action to address the root causes of the lack of diversity, such as robust data collection, careful consideration of the potential biases inherent in the selected inclusion or exclusion criteria for the trial, countering mistrust in clinical trials due to historical atrocities, or considering how best to assist participants struggling with economic barriers to participation such as lack of transportation.<sup>5</sup> AMCP believes that requiring concrete action would increase the likelihood of ensuring that the study population reflects the diversity of Medicare beneficiaries.

## Conclusion

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact AMCP's Director of Regulatory Affairs, Geni Tunstall, at [etunstall@amcp.org](mailto:etunstall@amcp.org) or (703) 705-9358.

Sincerely,



Susan A. Cantrell, MHL, RPh, CAE  
Chief Executive Officer

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<sup>2</sup> See, e.g., AMCP's strategic priorities at <https://www.amcp.org/about/about-amcp/amcp-strategic-priorities>.

<sup>3</sup> <https://www.fda.gov/consumers/minority-health-and-health-equity/clinical-trial-diversity>

<sup>4</sup> <https://www.fda.gov/media/168662/download?attachment>

<sup>5</sup> See, e.g., <https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html#:~:text=Historically%2C%20clinical%20trials%20did%20not,on%20White%20male%20study%20participants>.