



November 7, 2022

Submitted electronically.

Tara Hall
MEDCAC Coordinator
Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

**Re: MEDCAC Virtual Meeting on the General Requirements for Clinical Studies
Submitted for CMS Coverage Under Coverage with Evidence Development**

Dear Ms. Hall:

The Society for Women's Health Research (SWHR) appreciates the opportunity to provide comments to the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) panel in advance of its December 7, 2022 meeting to discuss the Centers for Medicare & Medicaid Services (CMS) general requirements for clinical studies under Coverage with Evidence Development (CED).

SWHR would like to comment in particular on the Agency for Healthcare Research and Quality's (AHRQ) September 2022 Analysis of Requirements for CED that recommended CMS update the CED study design requirements with a particular focus toward the efficient completion of CED studies.¹ In September, SWHR joined a letter spearheaded by the Alliance for Aging Research (AAR) to AHRQ highlighting underlying factors present under the current CED process that may contribute to disparities in access and recommending that AHRQ require all CED trials to be listed on ClinicalTrials.gov, ensure study proposals are consistent with good science and procedure, and remedy certain procedural defects in its process, such as ensuring that the improper use of QALYs or other metrics that may discriminate against certain populations be excluded from consideration.

Reiterating those points, AAR, within its November 2022 letter to MEDCAC, discussed how the CED process can be troubling for access:

“The CED process indefinitely and effectively prevents hundreds of thousands of Medicare beneficiaries from accessing potentially disease-modifying therapies. Under

¹ Agency for Healthcare Res. & Quality, *Analysis of Requirements for Coverage with Evidence Development (CED) – Topic Refinement* (Sept. 2022), <https://effectivehealthcare.ahrq.gov/products/coverage-evidence-development/draft-comment>.

CMS' terms, CEDs restrict coverage only to those few Medicare beneficiaries who are fortunate enough to be able to participate in approved clinical studies. These studies are small in number, limited in size, and available in only limited geographic areas. This means that, for example, only a select few beneficiaries are able to access anti-amyloid mABs for the treatment of AD even though an FDA-approved treatment is already available and other treatments may soon be approved and available to those with sufficient private resources to access treatment.²

The CED process also enables CED trials to continue in perpetuity without a clear end in sight. According to an April 2022 study published in the *American Journal of Managed Care* (AJMC) on the CED process, only six out of the total 27 CED trials initiated over the past 15–20 years have been retired and have taken between 4–12 years to be retired.² Two of the six retired CED trials resulted in deferral to the Medicare Administrative Contractors for local coverage decisions.³ Meanwhile, the other CED trials remain ongoing and one CED trial never even commenced.⁴ The inherent lack of rhyme or reason as to how or when CMS decided to retire 6 of the 27 CEDs was noted and suggests that there are bigger problems with the process than refinement of clinical study requirements: "In summary, on review of the 6 therapies with CED requirements removed, there were no clear programmatic characteristics suggesting greater or less likelihood of progressing to an NCD without CED requirements versus revocation of the NCD."

Additionally, SWHR has concerns that the CED process can disproportionately harm certain communities, including underrepresented communities of color, and in particular women of color, and low-income communities. SWHR has long advocated for meaningful, diverse representation in clinical trials. As these individuals may not have access to trial sites, SWHR has reservations about CMS being able to meet the CED trial recruitment goal and initiate a sufficient number of trials in a timely manner.

Finally, SWHR encourages MEDCAC to update CED criteria to ensure that CED-approved studies be required in a timely manner as well as require that they are reported on ClinicalTrials.gov. Currently, as noted in the AAR letter, "CMS is not reevaluating the adverse implications of CED coverage policies because some CED studies are never stated, others have no end dates, and even when concluded and additional data are available, the CED process remains open." Having established start and end dates would provide additional clarity to the process, provide transparency and predictability to stakeholders, and ensure prompt analysis of data upon trial completion. Disclosing core elements of the CED protocol, including key

² See Emily P. Zeitler et al., *Coverage With Evidence Development: Where Are We Now?*, 28 AM. J. MANAGED CARE 382, 382–89 (Aug. 2022). Dr. Zeitler's conclusions are not new. Other studies have similarly concluded that "CED schemes . . . are often costly, complex, and challenging." Carlo Federici et al., *Coverage with evidence development schemes for medical devices in Europe: characteristics and challenges*, 22 EUR. J. HEALTH ECON. 1253, 1253–73 (Nov. 2021).

³ Zeitler.

⁴ *Id.*

outcomes and elements of design, should be housed on ClinicalTrials.gov, which is not limited to “applicable clinical trials” and would provide a unique permanent identifier to each study.

Thank you for your consideration of the above comments. SWHR looks forward to engaging with CMS on this process. If you have questions or need any additional information that would be helpful, please contact me at kathryn@swhr.org or Lindsey Horan, Chief Advocacy Officer, at lindsey@swhr.org.

Sincerely,

A handwritten signature in black ink that reads "Kathryn G. Schubert". The signature is fluid and cursive, with "Kathryn" on top and "G. Schubert" below it.

Kathryn G. Schubert, MPP, CAE
President and CEO
Society for Women's Health Research