Submitted Electronically

November 7, 2022

Joseph Ross, MD, MHS
Chair
Medicare Evidence Development & Coverage Advisory Committee
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: December 7, 2022 MEDCAC Virtual Meeting on the General Requirements for Clinical Studies Submitted for CMS Coverage Under Coverage with Evidence Development

Dear Dr. Ross:

Thank you for the opportunity to comment on the important topic of Coverage with Evidence Development.

We have general comments about the current CED landscape *representing the patient perspective* which is inadequately reflected in this process, including in the Agency for Healthcare Research & Quality analysis that informs this meeting. CED, if continued in any form, should be implemented in a patient-centered manner; not in a way which sows confusion and limits access. The lack of patient representation on MEDCAC is troubling, especially given that CMS should be viewed as a market leader in coverage decisions, not an agency whose decisions can be used as a basis for private payers to limit access and coverage.

We will also provide limited specific comments on the AHRQ analysis, of which recommendations would only serve to tweak and further complicate an already fundamentally flawed CED process. CED could serve, on a limited basis, as an important pathway for certain medical technologies if there is a clear evidence generation plan and a defined timeline for completion in place.

CMS is missing an opportunity to undertake a more comprehensive, holistic approach to addressing the underlying goal of CED; ensuring the Medicare population has access to, and coverage for, new technologies and therapies for which the agency desires additional evidence to demonstrate that the treatment is “reasonable and necessary.”

In the space in which Heart Valve Voice US operates, heart valve technologies and structural heart devices and therapies, the pivotal clinical trials leading up to Food & Drug Administration approval often center around patients of Medicare age. With this dynamic, we believe a better approach to the current CED process would be improved coordination among manufacturers, the FDA and CMS during the clinical development phase to potentially eliminate the need for CED.

We understand that the current Parallel Review regime has not worked as envisioned and would urge CMS, FDA and our industry partners to engage to strengthen this system. Also, upcoming consideration of the Transitional Coverage of Emerging Technologies pathway should address many of these issues. The underlying principle here is that all stakeholders should work from the ground up to devise the most efficient, practical approach to bringing new safe and effective technologies to patients with full, unconditional CMS coverage.

That CED, since its inception, has been imposed, on average, *less than twice per year* reinforces the need for a fundamentally different approach. The amount of administrative effort and expense, industry resources, research base, and patient angst involved to satisfy this limited process raises serious questions about the overall value of the current approach. The fact that few CED studies are ever considered finished, raises additional concerns. A scheme that essentially sets in motion a never-ending clinical trial limits access, further increases disparities, and causes confusion in the marketplace for patients, providers, manufacturers and investors. Given this limited application, does the administrative burden, economic cost, and patient uncertainty justify the current CED process?

Further, the evidence is clear that CED, in its current form and implementation runs counter to CMS' goal of advancing health equity. With many CED studies limited to large academic medical centers, for example, many Black, Hispanic and Rural patients are effectively excluded from accessing potentially life-saving new technologies. Indefinitely.

Specific Comments on AHRQ Analysis

We are confused and concerned as to why the health technology assessment schemes of countries such as Australia, Belgium, Canada, England, France, Germany, The Netherlands, Spain, Sweden and Switzerland would have been consulted. While we understand the value in accessing a broad range of research, these countries have fundamentally different healthcare systems and populations than the United States. They also may have a very different attitude toward, and acceptance of, HTAs.

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We are very troubled that the life sciences industry was not included among the "Key Informants" for the AHRQ document. We find it absurd that arguably the most affected stakeholder, other than patients, would not be included in this review and see no logical justification for the industry's omission.

We appreciate the change in language that a study is *conducted* by investigators not *sponsored* by investigators. This is a very important distinction and more accurately represents the research paradigm in the cases of CED.

The study protocol and related information should be posted under a special category on clinicaltrials.gov as well as the CMS website. Few patients would ever consult the CMS website for this type of information.

Data should be sourced from "usual sites of care delivery" wherever possible. We note that such a philosophy should also consistently be employed whenever any type of volume requirement is included in a CED to ensure that the site volume requirements are relevant to the actual procedure being conducted under CED and not used to construct an artificial barrier to care. The most glaring example is the NCD reconsideration for Transcatheter Aortic Valve Replacement (TAVR) that continued site requirements for a minimum annual volume of heart valve surgeries even though these procedures have no relation to less invasive TAVR. Also, TAVR procedures are most often performed by interventional cardiologists, not thoracic surgeons.

We agree that "the key outcome(s) of the study are those that are important to patients" but we are skeptical of the statement that "there is often existing information about what is important to patients." In our experience, there is often a serious *lack* of information about what is important to patients. In fact, CMS would be wise to consider including a patient preference component to any mandated CED study, if one is not already in place.

We agree that "the study population reflects the demographic and clinical complexity among the Medicare beneficiaries who are the intended users of the product." This should be used, however, as a means to expand access, not restrict it until representative data has been captured.

Though references to randomization, use of placebos and blinding were wisely dropped, we find it troubling that these potential components of study design were ever seriously considered. By definition, CED is analyzing a product approved by the FDA and deemed safe and effective. To use randomization, placebo or blinding would be highly inappropriate or unethical, except perhaps in some rare or extreme circumstances.

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Similarly, to the extent that informed consent may be required it must be clear to the patient that the consent is to access the patient's health data for research purposes. This has become a fairly standard consent for treatment in our healthcare system. We are concerned that an informed consent process that resembles that of a standard clinical trial would only serve to further confuse the patient and may jeopardize their care.

Regarding the use of registries, these can serve as very valuable tools in the review and analysis of real-world data. While a registry is not in itself a study design, to the extent a registry would be useful to meet the goals of a CED study, and the extent to which CMS would mandate the establishment and maintenance of a registry, best practices should apply. Chief among these best practices should be transparency, accessibility, compliance, and the inclusion of patient reported outcomes and other patient generated data.

We look forward to an ongoing dialog about how to make new, innovative technologies and treatments more accessible to Medicare patients, the shared goal of all stakeholders. Thank you for your consideration.

Respectfully submitted,

John Lewis
Executive Director