AMERICAN COLLEGE of CARDIOLOGY

Heart House
2400 N Street, NW Washington, DC 20037-1153 | USA
202-375-6000 | 800-253-4636 | Fax: 202-375-7000
www.ACC.org

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Lee A. Fleisher
CMO, Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services (CMS)
7500 Security Boulevard, Baltimore, Maryland 21244

RE: Medicare Program; Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee

The American College of Cardiology (ACC) appreciates the opportunity to provide comment on Coverage with Evidence Development (CED) for the virtual meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) on December 7, 2022. The ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 56,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned *JACC Journals*, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions. For more, visit acc.org.

CED is an extremely powerful mechanism offering significant value to payers, clinicians, and patients. CED has been demonstrated to be an ingenious technique allowing the diffusion of diverse innovative cardiovascular technologies and services into the marketplace while simultaneously promoting timely clinical safety and effectiveness evaluations. ACC supports the use of CED to provide Medicare beneficiaries with prompt access to new technologies and services when early evidence suggests, but does not yet convincingly demonstrate, a net benefit for beneficiaries.

Registries, such as ACC's National Cardiovascular Data Registry (NCDR), provide a valuable, cost-effective mechanism to help meet the needs for CED evaluation while also fostering improvements in the quality of care. CED-mandated registry participation–when appropriate–promotes a powerful national research and data collection infrastructure capturing clinical data on large populations allowing the assessment of treatments practiced in relatively modest-sized patient subgroups not well

suited for randomized controlled trials (RCT). Since NCDR' inception in 1997, its reach has grown from the flagship CathPCI Registry into a suite of registries addressing major clinical areas, including acute myocardial infarction (AMI), EP Device implantation, lower extremity peripheral vascular interventions, atrial fibrillation (AFib) ablation, TAVR, Mitral leaflet clip, Mitral valve replacement, left atrial appendage occlusion (LAAO) procedures, and pediatric and adult treatment of adult congenital heart disease, as well as outpatient care for cardiovascular conditions. ACC's comprehensive suite of registries help measure and quantify quality improvement, identify and close gaps in evidence-based, guideline-recommended care, and optimize the implementation and use of new treatments and therapies.

NCDR has linked data from the STS/ACC TVT Registry, EP Device Implant Registry (formerly the ICD Registry) and the LAAO Registry with CMS national coverage determinations over the years to provide a tool for robust evidence development along with proof of compliance with reimbursement criteria. Our responsiveness to the CED program has allowed hospitals to participate in a meaningful and publicly responsible way, and in doing so, answer questions that are of key importance to CMS. For example, NCDR's approach to registries aligned with CEDs provide participating hospitals and practices with benchmark dashboards that report patient outcomes measures, including risk-adjusted outcomes measures to account for key differences in patient characteristics. Additionally, NCDR reports both composite measures and publicly reported measures that achieve National Quality Forum endorsement.

ACC had the opportunity to review the proposed requirements for CED in the AHRQ draft report, *Analysis of Requirements for Coverage with Evidence Development (CED)*[1]. ACC is supportive of many of the proposed updates. The College welcomes the modernization of the criteria to promote increased transparency. However, the College is concerned that the proposed update to the requirements may have unintended consequences that will add undue burden and costs to CED collaborators. Moreover, any updates to the requirements should not impede patients' access to novel therapeutics or hinder real-world evidence development. The College would like to offer the following comments on *Table 5. Amended Requirements Based on the Recommendations of the Key Informants* from the AHRQ draft report:

- Proposed new criteria A states, "The study is conducted by investigators with the resources and skills to complete it successfully." **"Resources" and "skills" are not defined. In addition, the introduction of specific "investigators" as part of a CED application**

[1] Agency for Healthcare Research and Quality. Analysis of Requirements for Coverage with Evidence Development (CED) - Topic Refinement. Sep.7, 2022. https://effectivehealthcare.ahrq.gov/products/coverage-evidence-development/draft-comment

process may cause delays in CMS achieving its objectives in evidence development since this is a very operational requirement.

- Proposed new criteria B states, "A written plan describes the schedule for completion of key study milestones." **The college is supportive of a written plan. However, there are many variables that impact projecting a timeline, including what the ramp-up phase entails and the actual adoption rate for a therapeutic in order to attain the number of patients that power a study. Therefore, it is important to provide some flexibility with written plans and schedules. Consider plan and schedule requirements be broken up into stages to provide this flexibility.**
- Proposed new criteria C states, "The rationale for the study is supported by scientific evidence and study results are expected to fill the specified knowledge gap." **ACC supports this change in language. This is an improvement from the current requirement language.**
- Proposed new criteria D states, "CMS and investigators agree on an evidentiary threshold for the study as needed to demonstrate clinically meaningful differences in key outcome(s) with adequate precision." The college believes that under the current approach to CED, whereby exclusivity is not afforded to organizations approved by CMS to meet the requirements, pre-determining evidentiary thresholds obligations for a study could prove challenging. **For this proposed criterion to be laudable, CMS would need to offer resources to organizations electing to meet the CED requirements and to the providers participating in the CED requirements necessary to support these studies.**
- Proposed criteria H states, "Data for the study comes from patients treated in the usual sites of care delivery for the product; and proposed criteria I states, "The key outcome(s) for the study are those that are important to patients. A surrogate outcome that reliably predicts these outcomes may be appropriate for some questions." **ACC supports the updated language in proposed criteria H and I.** This is an improvement from the current requirements language.
- Proposed criteria J states, "The study population reflects the demographic and clinical diversity among the Medicare beneficiaries who are the intended users of the intervention." **The college believes criteria N suffices for this purpose.**
- Proposed criteria N states, "In the protocol, the investigators describe considerations for analyzing demographic subpopulations as well as clinically-relevant subgroups as motivated by existing evidence." **This proposal appears redundant to J, and the language in criteria N is more appropriate than J.**
- Proposed criteria O states, "The investigators demonstrate robustness of results by conducting alternative analyses and/or using other data sources." **This proposal seems burdensome for studies to now include analysis of other data sources when clinical trials do not have this requirement.**

- Proposed criteria P states, "The results and analytic code are submitted for peer review using a reporting guideline appropriate for the study design and structured to enable replication." **Publishing code will not ensure replicability since CMS cannot require access to the data for replication purposes. A better proposal would be to require CEDs to include a description of how independent replication of results might be achieved.**
- Proposed criteria Q states, "The investigators commit to sharing de-identified data, methods, and analytic code with CMS or with a trusted third party. Other sharing is to follow the rules of the funder and the institutional review board." **This proposal will not achieve replicability given the limitations of de-identifying data that was used in an analysis. In addition, the suggestion of working with a trusted third party is unclear in terms of how those entities will be identified.** This may force additional expenses on CED-approved organizations both operationally with the generation of a de-identified data set and with compliance requirements in contracting, such as HIPAA obligations. In very limited cases, it may not be possible to generate de-identified data for all patients for subpopulations, such as in individuals over a certain age receiving treatment. The instances of encountering such patients are so rare that it may be possible to re-identify the patients despite de-identification in the underlying dataset.

It is essential that CED programs are designed with collaborative input from all relevant stakeholders, including clinical experts and specialties most likely to provide the services in question. The College appreciates the opportunity to provide feedback on CED criteria and thanks CMS and MEDCAC for consideration of these comments. Please direct any questions or concerns to Amanda Stirling, Regulatory Affairs Associate, at (202) 375-6553 or astirling@acc.org.

Sincerely,

Edward T.A. Fry, MD, FACC
President, American College of Cardiology