ACRO Innovate Advocate Collaborate

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Centers for Medicare & Medicaid Services

RE: CMS-1848-P: Support for Proposed HCPCS G-Code for Clinical Trials Counseling as part of CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program [Docket No. CMS-2026-2377]

Founded in 2001, the Association of Clinical Research Organizations (ACRO) is a non-profit trade association representing the world's leading clinical research and technology organizations, which provide specialized services integral to the development of drugs, biologics, and medical devices that enable patients to live longer, healthier, and more productive lives. ACRO members are involved in the majority of FDA-regulated clinical trials and provide a wide range of specialized services across the entire spectrum of drug development—from preclinical, proof of concept, and first-in-human studies through post-approval, pharmacovigilance, and health data research. ACRO member companies employ more than 470,000 people worldwide and conduct research in every global reason.

General Comments

ACRO thanks CMS for raising these important questions around physician reimbursement for clinical trial consultations. Increasing clinical trial access and participation, both from patients and providers, is a core tenant of the work undertaken by ACRO and its members and we are therefore very supportive creating a new G-code to reimburse physicians and Qualified Healthcare Professionals (QHPs) for time spent counseling patients about clinical trials.

Clinical trial details, like study protocols, inclusion/exclusion criteria, etc., are very complex and require a significant amount of provide time to communicate effectively to patients. A dedicated code for such counseling would allow more providers to spend this necessary time discuss clinical trial options with patients and would likely result in higher rates of clinical trial involvement, both from patients and providers.

We would be remiss not to mention the macrolevel benefit to the healthcare system that would be provided by having more patients in clinical trials. Not only does better access and participation lead to improved timelines for new medicines, but the cost to the government for reimbursing for provider time would be offset by the costs that are covered by trial sponsors for patients receiving care as part of the clinical trial in which they are enrolled.

Specific Comments

Creation of HCPCS G-code for Clinical Trial Counseling

ACRO strongly supports the creation of a dedicated HCPCS G-code for clinical trial counseling. Given the complexity of such discussions, we would suggest the creation of a standard code that covers the first 20 minutes and would be available to be used in combination with an E/M or other routine wellness visit, and a modified code to cover an additional conversation that can range up to 45 minutes. For

example, Advanced Care Planning has CPT 99497 as the parent code and +99498 as the add-on code. We believe CMS should consider a similar approach here for clinical trial counseling. Often times, providers first speak to a patient about the general availability of clinical trials, in most cases during a broader visit to manage the patient's active disease, and then, depending on a patient's receptiveness, would hold a second, longer conversation about trials the patient might be eligible for specific to their disease or condition.

If clinical trial counseling is not able to be billed in combination with a regular E/M or other visit, we run the risk of creating a system where providers are forced to choose between not having a discussion about clinical trials or having that discussion and not billing for it, or having to wait until a follow up visit to have the conversation. An add-on structure would ensure fair compensation for provider time.

Accurate RVU Value for Clinical Trial Counseling
ACRO recommends adopting a minimum wRVU of 1.5 for clinical trial counseling. This level is similar to values currently set for other counseling services like Advance Care Planning (CPT 99497) and Chronic Pain Management (G3002). Given the complexity of the conversation(s)— which includes sorting through inclusion/exclusion criteria, communicating safety risks, differentiating between different types of trials—we feel setting the wRVU at this level is appropriate given the time and resources required.

Availability as a Medicare Telehealth Service
ACRO supports clinical trial counseling being made available as a Medicare telehealth service. Allowing patients this flexibility—particularly for patients who live in rural settings where care options might not be conveniently located—will help to improve clinical trial access and participation.

Documentation Requirements
ACRO supports requiring a level of documentation that guards against potential fraud but also does not result in further administrative burden on the part of providers. Keeping the documentation requirement focused on the trial name, the total time spent counseling the patient, and the patient's decision should be sufficient.

Conclusion

ACRO commends CMS for their attention to the importance of improving clinical trial access and participation. ACRO is very supportive of the creation of a HCPCS G-code for clinical trial counseling and feels it would be paramount to add as a Medicare telehealth service. To properly cover provider time for such counseling, we propose a wRVU of at least 1.5.

We thank CMS for this opportunity to provide feedback and look forward to continued collaboration to expand access to clinical trials for patients around the country.

Respectfully submitted,

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ACRO