September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (CMS-1809-P)

Dear Administrator Brooks-LaSure:

Our organizations, which include patient advocacy organizations, provider associations, and other key stakeholders, appreciate the opportunity to comment on the "Medicare and Medicaid Programs; CY 2025 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule" (OPPS/ASC rule).[1]

This letter addresses two areas of discussion within the rule: 1) the Centers for Medicare and Medicaid Services' (CMS) proposed payment policy related to drugs/devices with Medicare Coverage with Evidence Development (CED) designation, and 2) the provision of separate payment for some diagnostic radiopharmaceuticals. Signatories may submit letters to CMS on other sections of the OPPS/ASC rule that are important to their organizations.

Payment Policy for Drugs/Devices with Medicare Coverage with Evidence Development (CED) Designation

Our comments do not pertain to the rationale or methodology of CMS's proposed "blended" payments to clinical trial sites for qualifying Category B Investigation Device Exemption (IDE) trials of qualifying medical devices, but comment on the expansion of that policy to so-called "Coverage with Evidence" (CED) clinical trials. This letter does not speak to broader concerns about the underlying legality[2] of CMS's use of the CED framework.

[1] 89 Fed. Reg. 59186 (July 22, 2024).
[2] Alliance for Aging Research. Façade of Evidence: How Medicare's Coverage with Evidence Development Rations Care and Exacerbates Inequity. 13 Feb 2023. https://www.agingresearch.org/wp-content/uploads/2023/02/Facade-of-Evidence-CED-2-13-2023.pdf

We object to the proposed policy as (1) the proposed payment change will disincentivize provider participation in CED studies and (2) the CED policy is unethical. These issues are explored below.

Proposed CED Payment Disincentivizes Site Participation

CMS's proposal to reduce payment for products the agency makes subject to CED will disincentivize site participation in CED studies. Providers already face significant costs and additional workflow requirements related to CED studies, such as subscription fees to submit data to data registries and enhanced collection and submission requirements on data elements of potential research interest. **By reducing payment for providers for whom participating in CED already incurs additional costs and burden, CMS will disincentive provider participation in CED trials.**

This would build upon existing restrictions in the form of provider or site criteria that CMS often uses to limit the universe of providers eligible to participate in CED studies.[3] The practical application of these policies reduces the pool of eligible providers to those participating in settings such as academic medical centers (AMCs) and facilities that are already performing a high volume of procedures. These restrictions often mean that communities of color and individuals residing in rural areas disproportionately face access restrictions due to CED.[4]

Reduced provider participation in CED studies because of lowered payment is not theoretical; the agency's experience with registry studies for amyloid beta positron emission tomography (PET) proves the case. The original CED study for AB PET – the IDEAS Study – enrolled over 140 clinical trial sites, whereas the extension of that trial (the NEW IDEAS study) had enrolled only 17 sites as of 2022; this is largely attributable to CMS dramatically lowering payment for providers and for PET scan agents in New IDEAS.[5] As reported by the Government Accountability Office "[t]he study organizers said that those hospitals, which had all participated in the original IDEAS Study, declined to participate because the packaged payment would cause them to incur a financial loss for each procedure performed."[6]

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[3] For example, volume of heart valve replacement procedures AND volume of open-heart surgeries in the case of transcatheter edge-to-edge repair of the mitral valve.

[4] Vemulapalli, Sreekanth, et. al. Mitral Valve Surgical Volume and Transcatheter Mitral Valve Repair Outcomes: Impact of a Proposed Volume Requirement on Geographic Access. Journal of the American Heart Association. Vol. 9, No. 11. 27 May 2020. https://www.ahajournals.org/doi/10.1161/JAHA.119.016140

[5] Letter from Eli Lilly and Company to CMS. Re: 2024 Hospital Outpatient Prospective Payment System Proposed Rule (CMS-1786-P). 8 Sept. 2023. https://downloads.regulations.gov/CMS-2023-0120-2305/attachment_1.pdf

[6] U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-252, MEDICARE PART B: Payments and Use for Selected New, High-Cost Drugs (Mar. 2021), *available at* https://www.gao.gov/assets/gao-21-252.pdf.

The CED Proposal is Unethical

Medicare's proposal to utilize randomized controlled clinical trials (RCTs) involving placebos is unethical and illustrates an excessive focus on reducing expenditures. CMS would contravene medical ethics by requiring patients to take the chance of receiving a placebo when the drug or device has already been approved or cleared by the FDA based on its safety and efficacy profiles. While the ethics of using placebo are acceptable for product development purposes, there is no acceptable ethical way to ration such care through placebos once the treatment has been approved or cleared by the FDA.

Further, there is a second ethical flaw with the CMS proposal. Under CMS' s proposal – and indeed, under existing Medicare policy - Medicare charges a co-payment for patients who receive placebo (i.e., payment for nontreatment). While CMS's proposed policy attempts to save the program money, the agency has not endeavored to address this key ethical consideration that also can result in financial harm to beneficiaries. To be direct, failure to provide a product despite receiving payment would be considered breach of contract in other contexts.

We encourage the agency to instead uphold its contract to the beneficiaries the program exists to serve. **As such, we oppose this proposed CED payment policy on ethical grounds and urge CMS to abandon it.**

Separate Payment for Diagnostic Radiopharmaceuticals

We also write to support CMS's proposal to separately pay for diagnostic radiopharmaceuticals with a mean unit cost above the $630 threshold. As the Agency correctly notes, the Agency has subjected diagnostic radiopharmaceuticals to packaged payment since 2018, resulting in serious and significant harm to patient access to needed treatment. Many stakeholders have long called for CMS to separately pay for these important medications, which are particularly important in the diagnosis and treatment of Alzheimer's and Parkinson's disease.

CMS has long understood that package payment for certain drugs (and devices) can lead to hospitals refusing to provide these treatments to Medicare beneficiaries, as the cost of providing these diagnostics exceeded Medicare reimbursement. We appreciate that CMS has acknowledged that to be the case for diagnostic radiopharmaceuticals and has agreed to separately pay for such products which exceed the calculated threshold. **We support the CMS proposal, as well as the CMS methodology to derive the payment threshold amount and urge the Agency to finalize the separate payment proposal in the Final Rule**.

Conclusion

Thank you for your consideration of the above comments. If you have questions or wish to discuss our comments, please feel free to contact Sue Peschin, President and CEO of the Alliance for Aging Research, at speschin@agingresearch.org.

Sincerely,

Alliance for Aging Research
Alliance for Patient Access
Alliance for Women's Health and Prevention
American Academy of Neurology
Black Women's Health Imperative
Caregiver Action Network
Conquering CHD
Global Coalition on Aging Alliance for Health Innovation
HealthyWomen
Lupus and Allied Diseases Association, Inc.
National Grange
National Minority Quality Forum
Partnership to Fight Chronic Disease
Patients Rising
RetireSafe
Society for Women's Health Research
UsAgainstAlzheimer's
Voices of Alzheimers