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September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted Electronically via: regulations.gov

RE: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities (CMS-1809-P)

Dear Administrator Brooks-LaSure:

The National Pharmaceutical Council (NPC) appreciates the opportunity to submit comments regarding the *Medicare Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule for Calendar Year 2025.* NPC is a health policy research organization dedicated to the advancement of good evidence and science and to fostering an environment in the United States that supports medical innovation.[1] We have rich experience conducting research and disseminating information about the critical issues of evidence, innovation and the value of medicines for patients.[2] Our research helps inform important healthcare policy debates and supports the achievement of the best patient outcomes in the most efficient way possible.

We appreciate CMS's commitment to policies which support equitable access to health care. We also appreciate CMS's continued focus on policies regarding access to and reimbursement of medicines. There is robust evidence demonstrating the value of biopharmaceuticals on public health, including associated improvements in life expectancy[3], reductions in total healthcare costs,[4] and reductions in

[1] About the National Pharmaceutical Council. National Pharmaceutical Council. 2024. https://www.npcnow.org/about
[2] About the National Pharmaceutical Council. National Pharmaceutical Council. 2024. https://www.npcnow.org/about
[3] Buxbaum JD, Chernew ME, Fendrick AM, Cutler DM. Contributions Of Public Health, Pharmaceuticals, And Other Medical Care To US Life Expectancy Changes, 1990-2015. Health Aff (Millwood). 2020 Sep;39(9):1546-1556. doi: 10.1377/hlthaff.2020.00284. PMID: 32897792.
[4] Roebuck MC, Liberman JN, Gemmill-Toyama M, Brennan TA. Medication adherence leads to lower health care use and costs despite increased drug spending. Health Aff (Millwood). 2011 Jan;30(1):91-9. doi: 10.1377/hlthaff.2009.1087. PMID: 21209444.

other poor health outcomes.[5] We aim to provide CMS with feedback and guidance on research relevant to some of the key policies outlined in the OPPS proposed rule for calendar year 2025.

Our comments are as follows:

I. Cell and Gene Therapy Payment Policies

Patient access to cell and gene therapies as a class is currently limited,[6] and outpatient administration is a pathway to increase access to these medicines. Traditionally, cell and gene therapies are administered in the inpatient setting, usually at a large academic medical center.[7] However, the geographic barriers for patients who do not live near these centers pose challenges in access. For example, patients living in rural areas and patients with incomes below the Federal Poverty Level (FPL) are particularly impacted by the travel and costs associated with going to an academic medical center for treatment.[8,9] Furthermore, infrastructure limitations may lead to a bottleneck in access to care in future years. Administering cell and gene therapies in outpatient settings, such as hospital outpatient departments, is one way to address these issues and increase uptake.

Certain cell and gene therapies can be administered in the outpatient setting, and evidence demonstrates that access to cell and gene products through this setting is increasing.[10] Increasing the outpatient administration of cell and gene therapies can significantly enhance patient access to these innovative treatments and save inpatient beds for critically ill patients. Outpatient administration of cell and gene therapies is also a pathway to improve equitable access to these treatments for patients who live in rural or underserved communities with limited access to large academic centers.

It is projected that by 2030, there will be more than 60 cell and gene therapies and indications[11] approved in the United States, approximately 10-20 per year.[12] As these therapies become more widely available, we ask that CMS recognize that not every payment method may be suitable for all payers. CMS has acknowledged the value of cell and gene therapies in its Cell and Gene Therapy Access Model, noting

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[5] Ho PM, Bryson CL, Rumsfeld JS. Medication adherence: its importance in cardiovascular outcomes. Circulation. 2009 Jun 16;119(23):3028-35. doi: 10.1161/CIRCULATIONAHA.108.768986. PMID: 19528344.

[6] Strengthening Pathways for Cell and Gene Therapies: Current State and Future Scenarios. IQVIA Institute Report. March 2024. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/strengthening-pathways-for-cell-and-gene-therapies.

[7] Elverum, K., & Whitman, M. (2020). Delivering cellular and gene therapies to patients: solutions for realizing the potential of the next generation of medicine. Gene therapy, 27(12), 537–544. https://doi.org/10.1038/s41434-019-0074-7

[8] Snyder S, Albertson T, Garcia J, Gitlin M, Jun MP. Travel-Related Economic Burden of Chimeric Antigen Receptor T Cell Therapy Administration by Site of Care. Adv Ther. 2021 Aug;38(8):4541-4555. doi: 10.1007/s12325-021-01839-y. Epub 2021 Jul 18. PMID: 34279805; PMCID: PMC8342383.

[9] Socioeconomic Factors May Impact Patient Access to Cell Therapies. Avalere. April 2022. Available at: https://avalere.com/insights/socioeconomic-factors-may-impact-patient-access-to-cell-therapies

[10] Hansen DK, Liu Y, Ranhan S, et al. The Impact of Outpatient versus Inpatient Administration of CAR-T Therapies on Clinical, Economic, and Humanistic Outcomes in Patients with Hematological Cancer: A Systematic Literature Review. Cancers (Basel). 2023; 15 (24):5746. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10741664/

[11] Young CM, Quinn C, Trusheim MR. Durable cell and gene therapy potential patient and financial impact: US projections of product approvals, patients treated, and product revenues. Drug Discov Today. Jan 2022;27(1):17-30. doi:10.1016/j.drudis.2021.09.001

[12] Gottlieb S. Statement from FDA Commissioner Scott Gottlieb, M.D. and Peter Marks, M.D., Ph.D., Director of the Center for Biologics Evaluation and Research on new policies to advance development of safe and effective cell and gene therapies. FDA. Updated January 19, 2019. https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics

that these therapies "have the potential to reduce health care spending over time by addressing the underlying causes of disease, reducing the severity of illness, and reducing health care utilization."[13]

We appreciate CMS's acknowledgment of the unique innovation presented by cell and gene therapies. Our research shows that many assessments of the value of cell and gene therapies are too narrowly focused on price and the payer perspective, and thus do not comprise the full attributes of value of cell and gene and other innovative medicines.[14] New innovative curative therapies and other single administration products present challenges due to their unique set-up that may not neatly fit into existing payment policies.

We support CMS's proposal to exclude cell and gene therapies from comprehensive ambulatory payment classifications (C-APCs); such an exclusion supports innovation and equity in reimbursement. Notably, uncertain reimbursement and the potential for financial losses will discourage utilization among outpatient providers and limit patient access. Payment policies should proactively address this hurdle. In addition, policies that recognize the full benefits of these new innovative technologies can encourage future investment and avoid disincentivizing innovation, based on inadequate reimbursement**. Thus, we recommend that CMS should not create a C-APC for cell and gene therapies and related services.** A payment structure based on the average sales price (ASP), such as ASP + 6%, can encourage the availability of cell and gene therapies. This type of reimbursement helps to ensure appropriate reimbursement for the financial costs and supports their clinically appropriate use.

Lastly, we recommend that the agency should aim to ensure that clinical decisions of patients indicated to receive cell and gene therapies are not associated with the setting of care. Depending on the patient's full clinical picture, the clinician's practices, infrastructure of the care setting, and the specific therapy, an inpatient or outpatient administration setting may be preferred. Clinical decisions should be driven through shared decision making between patients and clinicians. Given the potential of these medicines to improve patient health outcomes, reimbursement should be adequate in both the inpatient and hospital outpatient settings.

II. Efforts to Expand Access to High-Cost Drugs Provided by Indian Health Services and Tribal Facilities

The CY 2000 OPPS final rule, which first implemented OPPS for hospital outpatient services, exempts outpatient services provided by hospitals of the Indian Health Service (IHS).[15] IHS and tribal facilities are reimbursed under the All-Inclusive Rate (AIR), calculated and published annually, with separate rates for Alaska as compared to the other states due to differences in costs of living. As noted in the OPPS 2025 proposed rule, IHS and tribal facilities have expanded their services over time, often providing essential

[13] Cell and Gene Therapy Access Model. Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/priorities/innovation/innovation-models/cgt#:~:text=Cell%20and%20gene%20therapies%20have,and%20reducing%20health%20care%20utilization.

[14] Wagner TD, Buelt L, Campbell JD, Westrich K. Acknowledging the Challenges in Gene Therapy: Perspectives on ICER's White Paper. April 2024. Available at: https://www.npcnow.org/resources/acknowledging-challenges-gene-therapy-perspectives-icers-white-paper

[15] Center for Medicare & Medicaid Services. Office of Inspector General; Medicare Program; Prospective Payment System for Hospital Outpatient Services. 65:68 (18434-18820) HCFA–1005–FC. Apr 7, 2000. RIN 0938–AI56. https://www.govinfo.gov/content/pkg/FR-2000-04-07/pdf/00-8215.pdf

higher-cost drugs and services.[16] However, the AIR sometimes fails to cover the full cost of these drugs, threatening these facilities' ability to offer such treatments. CMS is proposing to pay the Indian Health Service and tribal facilities separately for high-cost drugs administered in the hospital outpatient setting through an add-on payment in addition to the AIR. If finalized, an add-on payment would be effective January 1, 2025, permanently, with quarterly updates to the drug list.

We appreciate CMS's aim to improve equitable access to medicines reimbursed at IHS and tribal facilities. Given the current inequities that American Indian and Native Alaskan populations face in receiving access to health care,[17] receiving medicines in a local tribal facility could improve health outcomes. We encourage CMS to closely and consistently monitor whether adoption of this policy will adequately facilitate equitable patient access to medications administered in hospital outpatient facilities in tribal communities. We request that CMS consider reporting on access to medicines within American Indian/Alaskan Native and other racial and ethnic communities within Health and Human Services Dashboards, such as those produced by the Indian Health Service.[18]

III. Patient Access to Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention

CMS expects to finalize the National Coverage Determination for PrEP in late September 2024 under which PrEP medicines and related services will be covered under Medicare Part B as a preventative service, without any copayment. In this proposed rule, CMS has outlined a proposed payment methodology for PrEP drugs under Medicare Part B. CMS proposes to set payment amounts for these drugs using the ASP methodology. If ASP data were not available for a given drug, the fee for the administered PrEP drug would be set using the most recent amount published in the National Average Drug Acquisition Cost Survey. **We propose that CMS consider employing a publicly available source of drug pricing information, such as the wholesale acquisition cost (WAC), if ASP is not available to promote transparency and is subject to less variability. WAC is also commonly used as a pricing benchmark in Medicare Part B and should be considered as a preferred pricing benchmark for PrEP preventive therapies in the absence of ASP data.**

NPC supports CMS's efforts to promote access to HIV PrEP drugs with no cost-sharing, which may improve medication adherence. Our prior research has shown that utilization management and out-of-pocket costs worsen adherence to medicines.[19] Although CMS has taken steps to prepare providers and pharmacies for this potential change and has noted the critical importance of interrupted access to HIV

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[16] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities. 2024. [CMS-1809-P] RIN 0938-AV35. https://public-inspection.federalregister.gov/2024-15087.pdf

[17] Singh, G. K., Lee, H., Kim, L. H., & Williams, S. D. (2024). Social Determinants of Health Among American Indians and Alaska Natives and Tribal Communities: Comparison with Other Major Racial and Ethnic Groups in the United States, 1990-2022. International journal of MCH and AIDS, 13, e010. https://doi.org/10.25259/IJMA_10_2024

[18] Indian Health Service. (n.d.). *National accountability dashboard for quality: Quality at IHS*. National Accountability Dashboard for Quality (NAD-Q). https://www.ihs.gov/quality/national-accountability-dashboard-for-quality/

[19] Fusco N, Sils B, Graff JS, et al. Cost-sharing and adherence, clinical outcomes, health care utilization, and costs: A Systematic Literature Review. J Manag Care Spec Pharm. 2023;29(1):4-16. https://doi.org/10.18553/jmcp.2022.212

PrEP drugs and treatments, we urge CMS to take steps to prevent patient access challenges throughout the transition over coverage, if the proposals are finalized.[20] **Given the clinical and public health considerations related to the prevention of HIV, we suggest that the agency continue to ensure that HIV medicines administered under Medicare Part B have adequate coverage and protections.** Medicare Part D plans are limited in their ability to impose utilization management tools for medicines in the six protected classes. We recommend that similar protections be ensured as preventive HIV medicines transition to coverage under Medicare Part B.

IV. Modifications to the Packaging Policy for Diagnostic Radiopharmaceuticals

Currently, diagnostic radiopharmaceuticals, including contrast and stress agents, are packaged under the OPPS based on their use in diagnostic tests or procedures, which can create barriers for beneficiaries requiring higher-cost radiopharmaceuticals. CMS believes that providing separate payments for diagnostic radiopharmaceuticals that have a per day cost greater than $630 would maintain beneficiary access without disincentivizing the use of clinically appropriate, high-cost, low-utilization agents in under-resourced areas.

Diagnostic radiopharmaceuticals are important for the detection of many diseases, including Alzheimer's disease, Parkinson's disease, heart disease, and cancer.[21,22] **NPC supports separate payments for diagnostic radiopharmaceuticals above a certain cost threshold.** NPC believes that timely diagnosis is important for preventing disease progression, and financial incentives for reimbursement should not interrupt the best clinical diagnostic procedure as outlined by a patient and clinician.

As CMS considers how payment policy can address concerns related to access, we encourage CMS to monitor the impact of this policy, particularly on the growing, underdiagnosed elderly population with Alzheimer's disease.[23] Improving access to diagnostic radiopharmaceuticals through payment structures that align with innovation would be an important step in the right direction.

V. Collection of Patient-Reported Outcomes Measures and Social Drivers of Health Data

A. Patient-Reported Outcome Measures

Decisions made by both public and private payers can critically impact patients and their caregivers, with the power to impact a patient's overall quality of life. As CMS continues to consider how to best solicit the patient perspective related to recovery after a facility-based outpatient procedure or surgery,

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[20]Centers for Medicare & Medicaid Services. Fact Sheet: Potential for Medicare Part B Coverage of Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy (oral or injectable) to Prevent Human Immunodeficiency Virus (HIV). July 2024. Available at: https://www.cms.gov/files/document/fact-sheet-potential-medicare-part-b-coverage-preexposure-prophylaxis-prep-using-antiretroviral.pdf

[21] World Nuclear Association. Radioisotopes in Medicine. Apr 30, 2024. Website: https://world-nuclear.org/information-library/non-power-nuclear-applications/radioisotopes-research/radioisotopes-in-medicine#notes-amp-references

[22] Hong AS, Levin D, Parker L, Rao VM, Ross-Degnan D, Wharam JF. Trends in Diagnostic Imaging Utilization among Medicare and Commercially Insured Adults from 2003 through 2016. Radiology. 2020 Feb;294(2):342-350. doi: 10.1148/radiol.2019191116. Epub 2019 Dec 31. PMID: 31891320; PMCID: PMC6996668.

[23] Alzheimer's Association. 2024 Alzheimer's Disease Facts and Figures. Alzheimers Dement 2024;20(5).

the agency should continue to evolve towards best practices[24,25] for patient engagement. We are encouraged to see that CMS has proposed to implement a patient-reported measure, the Information Transfer Patient-Reported Outcome-Based Performance Measure (PRO-PM), to allow patients to report the level of "clear, personalized recovery information" shared with them upon discharge after a surgery or procedure at a hospital outpatient department. [26]

As cited in prior literature, patient-reported outcomes are critical to improving the healthcare ecosystem toward patient-centered care.[27] **We encourage CMS to review and, wherever possible, utilize the guiding principles listed below to continue to assess the transparency and validity of the proposed patient-reported outcome measure.** We also encourage CMS to broadly consider how these methodologies can be applicable to the agency's goals of promoting a patient-centered healthcare system. NPC has developed or recommends the following resources:

- *NPC's Guiding Practices for Patient-Centered Value Assessment* includes 33 specific elements surrounding six key aspects of value assessment, including the assessment process, scientific methodology, benefits, costs, evidence, and dissemination and utilization.[28]
- *Principles for planning and conducting comparative effectiveness research*, published by NPC researchers alongside a team of international collaborators, highlights thirteen principles for planning and conducting comparative effectiveness research.[29]
- *The Myth of Average: Why Individual Patient Difference Matter*, published by NPC, provides recommendations for ways to improve the patient-centeredness of value assessment.[30]

NPC and others have emphasized the need for CMS to prioritize diversity and a multi-modal approach in patient outreach in other areas of implementation, such as the Medicare Drug Price

[24] Harrington RL, Hanna ML, Oehrlein EM, Camp R, Wheeler R, Cooblall C, et al. Defining Patient Engagement in Research: Results of a Systematic Review and Analysis: Report of the ISPOR Patient-Centered Special Interest Group. Value in Health. 2020; 23 (6). Available at: https://www.sciencedirect.com/science/article/pii/S1098301520301418
[25] Guiding Practices for Patient-Centered Value Assessment (2024). National Pharmaceutical Council. Jan 2024.
[26] Center for Medicare & Medicaid Services. Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO-OP) Program; and Basic Health Program; 88 FR 82510; 2023-25576; Proposed Rule (82510-82655) Nov 24, 2023. RIN: 0938-AV22.
[27] Perfetto, E. Patient Reported Outcomes and Patient Centered Outcomes. Webinar Series. Accessed Aug 23, 2024. https://nationalhealthcouncil.org/webinars/clinical-outcome-assessment-webinar-series-patient-reported-outcomes-and-patient-centered-outcomes/
[28] National Pharmaceutical Council. Guiding Practices for Patient-Centered Value Assessment. 2024. Washington, DC. Available at: https://www.npcnow.org/sites/default/files/2024-01/2024%20Guiding%20Practices%20for%20PatientCentered%20Value%20Assessment%20January.pdf
[29] Luce BR, Drummond MF, Dubois RW, Neumann PJ, Jönsson B, Siebert U, Schwartz JS. Principles for planning and conducting comparative effectiveness research. J Comp Eff Res. 2012 Sep;1(5):431-40.
[30] National Pharmaceutical Council. The Myth of Average: Why Individual Patient Differences Matter. 2022. Washington, DC. Available at: https://www.npcnow.org/sites/default/files/2022-01/The_Myth_of_Average_01.2022.pdf

Negotiation process.[31,32] Robust engagement with underrepresented communities through outreach and ongoing dialogue is needed to promote an equity-focused implementation process.[33]

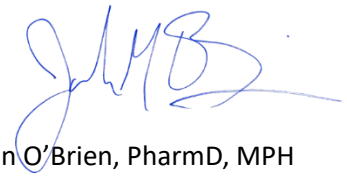
As CMS moves towards mandatory reporting of the patient-reported outcomes measure, we encourage CMS to continue to examine how well the survey reports on the domains important to patients. **We also urge CMS to consider implementing additional patient-centered surveys and metrics to seek voluntary feedback from patients on their experiences within additional points of care.** Integrating more holistic patient-reported data into hospital outpatient clinic and other workflows can help to highlight the gaps in care most important to patients and caregivers.

B. Social Drivers of Health Data

NPC appreciates that CMS is collecting evidence on social drivers of health. CMS's Health Equity Framework outlines that improved collection of data on disparities is critical to improving health equity.[34] In this proposed rule, CMS proposes to require hospital outpatient facilities to screen for and collect evidence on social drivers of health. **We are encouraged by CMS's collection of broad data on social drivers of health, given patient consent. We also encourage CMS to publish standards on how social data will be protected.** Documented heterogeneity in treatment preferences[35] and effects,[36] as well as disparities in health status and access to care, further underscore the need for continued focus on social drivers of health and equity.

Conclusion

The National Pharmaceutical Council appreciates the opportunity to comment on this proposed rule. We would be happy to meet to expand upon our comments and share our research. Please contact me at john.obrien@npcnow.org or (202) 827-2080 if we may provide any additional information.



John O'Brien, PharmD, MPH
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[31] National Organization for Rare Disorders. NORD Recommendations: Future Medicare Drug Price Negotiation Program Patient and Provider Listening Sessions [Internet]. 2024.
[32] Miller M, van Geertruyden S, Saxton MC, Savage CY, Weir D, Werner S. A summit on amplifying voices of patients, caregivers, and people with disabilities in Inflation Reduction Act drug price negotiations. J Manag Care Spec Pharm. 2024 Mar 1;30(3):247-251. doi: 10.18553/jmcp.2024.23278. Epub 2024 Jan 30. PMID: 38289281; PMCID: PMC10906444.
[33] The Center for Innovation & Value Research (formerly Innovation and Value Initiative). Comments on the draft guidance for implementation of the Medicare Drug Price Negotiation Program (DPNP) for initial price applicability year 2027 and manufacturer effectuation of the maximum fair price (MFP) in 2026 and 2027. Available at: https://valueresearch.org/the-center-formerly-ivi-provides-comments-on-cms-drug-price-negotiation-program/
[34] CMS. CMS Framework for Health Equity 2022-2023. https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf
[35] Hollin IL, González JM, Buelt L, Ciarametaro M, Dubois RW. Do Patient Preferences Align With Value Frameworks? A Discrete-Choice Experiment of Patients With Breast Cancer. MDM Policy Pract. 2020;5:238146832092801; Groothuis-Oudshoorn CGM, Flynn TN, Yoo H Il, Magidson J, Oppe M. Key Issues and Potential Solutions for Understanding Healthcare Preference Heterogeneity Free from Patient-Level Scale Confounds. The Patient - Patient-Centered Outcomes Research. 2018;11:463–6.; Whitty JA, Fraenkel L, Saigal CS, Groothuis-Oudshoorn CGM, Regier DA, Marshall DA. Assessment of Individual Patient Preferences to Inform Clinical Practice. The Patient - Patient-Centered Outcomes Research. 2017;10:519–21.
[36] National Pharmaceutical Council. The Myth of Average Why Individual Patient Differences Matter [Internet]. Washington, DC; 2022 Jan. Available at: https://www.npcnow.org/sites/default/files/2022-01/The_Myth_of_Average_01.2022.pdf