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June 25, 2025

Mehmet Oz, MD, MBA
Administrator Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Draft Guidance for the Medicare Drug Price Negotiation Program: Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028

Dear Administrator Oz:

Global Liver Institute (GLI) would like to express our sincere gratitude for the opportunity to provide feedback on the draft guidance for the Medicare Drug Price Negotiation Program for Initial Price Applicability Year (IPAY) for 2028. We were given the chance to participate in the recent CMS-hosted roundtable and appreciate the strides taken to ensure that patients impacted with liver diseases could contribute to the discussion.

Patient-centered care leads to improved outcomes¹, greater treatment adherence², and higher morale for clinical staff³. We thank you for uplifting patients' voices by including their perspectives in the IPAY process. Your inclusion of patients in the negotiation process aligns with those goals and must continue to ensure that cost-saving policies do not come at the expense of patient health and access.

¹ Yu C, Xian Y, Jing T, et al. More patient-centered care, better healthcare: the association between patient-centered care and healthcare outcomes in inpatients. *Front Public Health*. 2023;11:1148277. Published 2023 Oct 19. doi:10.3389/fpubh.2023.1148277

² Dilles T, Mortelmans L, Loots E, et al. People-centered care and patients' beliefs about medicines and adherence: A cross-sectional study. *Heliyon*. 2023;9(5):e15795. Published 2023 May 2. doi:10.1016/j.heliyon.2023.e15795

³ Lewis SE, Nocon RS, Tang H, et al. Patient-centered medical home characteristics and staff morale in safety net clinics. *Arch Intern Med*. 2012;172(1):23-31. doi:10.1001/archinternmed.2011.580

As a 501(c)3 nonprofit committed to solving the problems that matter to liver patients and improving the lives of individuals and families impacted by liver disease, GLI has long engaged in issues of access to high-value, high-quality care. We serve as a bridge between the impactful policies and the real-world experiences of the people they affect – including patients all over the country and the providers who serve them. In addition to providing comment on CMS rulemaking regarding Drug Price Negotiation Program for IPAY 2027, we have held Externally-Led, Patient-Focused Drug Development meetings with the FDA, partnered with key Congressional offices on priority legislative initiatives, and collaborated to establish ICD-10 codes to more accurately represent liver disease diagnoses. These efforts reflect our commitment to ensuring that federal health programs, including Medicare, are responsive to the needs of the communities we serve.

We commend several aspects of the IPAY process so far: CMS's facilitation of patient listening sessions ensured meetings were productive and efficient, the closed-door environment allowed for honest and comfortable dialogue, and the inclusion of both clinicians and patients in town halls allowed for a comprehensive understanding of treatment realities. Additionally, the availability of both written and verbal feedback opportunities, and clear communication about meeting purposes, contributed to the accessibility and transparency of the process.

To further strengthen these efforts, we encourage greater care in the selection and identification of meeting participants. While it is important that a variety of perspectives are represented, it is essential to ensure that those in the room suit the purpose of the meeting, and that the entities they represent are clear in order to avoid harm to patient trust, health, or understanding. Therefore, we urge CMS to fully vet participants to be sure that their participation is well-intentioned and does not undermine the perspectives of lived experience shared by others.

Additionally, we recommend CMS improve communication and clarity around how input from these meetings will be incorporated into future decisions. It is essential that patients know their advocacy is received and valued, and this can be accomplished through outlining how their advocacy impacts outcomes. We request that the CMS team reports the specific factors and evidence incorporated into calculations of maximum fair price (MFP) ceilings to demonstrate the clear role of patient testimony and public engagement in the larger process. Given the populations affected by the therapies affected, reports of this information should be linguistically accessible and readily available in multiple formats. This transparency will not only honor the stories told but also will help future participants ensure that they provide salient information in the future.

Beyond just clarity on intention, it is imperative that the current process for comment submission and participation be easily accessible and understandable to the average patient who may not be well versed in the advocacy realm and regulatory processes. Simplifying these processes and collaborating with networks like the National Health Council and the Council of Medical Specialty Societies could broaden participation and better reflect the diverse patient and provider experience.

Thank you again for your commitment to ensuring patient voices are heard and respected throughout this process. Please do not hesitate to contact Alyssa Davenport, Policy Director at adavenport@globalliver.org or Lily Benig, Associate Director of Science and Public Health at lbenig@globalliver.org if you or your staff would like to discuss these comments in greater detail. We are grateful to be able to work alongside CMS both in past and future endeavors.

Sincerely,



Larry R. Holden
President & Chief Executive Officer
Global Liver Institute

About Global Liver Institute

Global Liver Institute (GLI) is a 501(c)3 nonprofit organization founded in the belief that liver health must take its place on the global public health agenda commensurate with the prevalence and impact of liver illness. GLI promotes innovation, encourages collaboration, and supports the scaling of optimal approaches to help eradicate liver diseases. Operating globally, GLI is committed to solving the problems that matter to liver patients and equipping advocates to improve the lives of individuals and families impacted by liver disease. GLI holds Platinum Transparency with Candid/GuideStar, is a member of the National Health Council and NORD, and serves as a Healthy People 2030 Champion. Follow GLI on [Facebook](#), [Instagram](#), [LinkedIn](#), and [YouTube](#) or visit www.globalliver.org.

