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Centers for Medicare & Medicaid Services
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Sent electronically to IRAREbateandNegotiation@cms.hhs.gov

**Re: Medicare Drug Price Negotiation Program: Initial Memorandum,
Implementation of Sections 1191 – 1198 of the Social Security Act for Initial
Price Applicability Year 2026, and Solicitation of Comments**

Dear Deputy Administrator Seshamani:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 220 institutions from across the health care spectrum, thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments on the *Medicare Drug Price Negotiation Program Initial Guidance* for the initial price applicability year (IPAY) of 2026.¹ CMS' implementation of the drug price negotiation program established by the *Inflation Reduction Act (IRA)* represents an unprecedented new federal authority that will significantly alter how personalized medicine will be evaluated and incentivized under Medicare. We believe the initial guidance lacks clear descriptions for CMS procedures and methodology that will be used to negotiate a drug's maximum fair price (MFP). Because few details are provided on how personalized medicine will be considered, we are concerned about how CMS' implementation of the new program may impact patient access to new and existing treatments underpinning this approach to care.

Personalized medicine is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients. Personalized medicine is playing an important role in transforming care and patient outcomes for a range of serious and life-threatening diseases and conditions, helping to shift patient and provider experiences away from trial-and-error toward a more streamlined process for making clinical decisions.

After initial approval of a targeted therapy by the U.S. Food and Drug Administration (FDA), further research provides greater understanding of patients' responses to treatment based on results from molecular diagnostics and other biomarkers. This

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research leads to new or improved treatment indications that contribute to progress in personalized medicine. Of particular importance is the role that research conducted after approval of a new drug plays in advancing the frontiers of personalized medicine and the potential downstream impacts of the negotiation program on this research.

We believe PMC and CMS share the goal of achieving better health outcomes and lowering costs for patients. The following comments express concerns over how the drug price negotiation program could disrupt the innovation ecosystem for and patient access to personalized medicine. As overarching priorities, PMC urges CMS to refine its negotiation process to ensure:

- CMS' methodology to determine a selected drug's MFP recognizes the clinical and societal benefits of personalized medicine and incorporates patients' perspectives on care value;
- CMS' methodology and negotiation process establish consistency and transparency by communicating how factors considered are weighed and how external data is factored into its decisions;
- CMS establishes procedures that allow a robust exchange of information with manufacturers, patient organizations, and other stakeholders in determining the MFP throughout the negotiation process, as well as procedures that allow information about negotiations to be shared publicly to help establish precedents and consistency across negotiations;
- Patients do not face additional barriers in accessing negotiated medicines and their treatment alternatives, as well as non-negotiated medicines; and
- CMS establishes processes to monitor any unintended, downstream impacts of the program on patient access to personalized medicine and on pipelines for new personalized medicine treatments and expanded indications.

Statement of Neutrality

Many of PMC's members will present their own responses to the *Medicare Drug Price Negotiation Program Initial Guidance* and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the initial guidance and/or any that follows.

Recognizing the Clinical and Societal Value of Personalized Medicine

Drugs with personalized medicine treatment strategies create considerable benefits for patients and society since they are used in a manner that directs them toward patients who are most likely to benefit and away from those who are not. Value assessment frameworks (VAFs) often draw sweeping conclusions, however, about the economic worth of a particular treatment, typically based on analysis of its safety and effectiveness at a population level. In many cases, value assessment methodologies fail to adequately account for the safety and effectiveness benefits that may be realized by individual patients or patient subpopulations. When assessing value, it is important to consider the holistic benefits of a treatment at the patient, subpopulation, and societal levels.

PMC appreciates CMS' reference to patient experiences in its discussion of the clinical benefits of selected drugs and their therapeutic alternatives in Sec 60.3.3. However, as we discuss later in this letter, it is still unclear how patients, caregivers, and providers will influence the selection of therapeutic

alternatives or if CMS will seek guidance throughout the MFP-setting process from these key stakeholders. Considering patient experiences in this context is paramount to ensure that patient perspectives of value are appropriately accounted for during the drug price negotiation process. In 2017, PMC published a white paper titled [*Personalized Medicine and Value Assessment Frameworks: Context, Considerations, and Next Steps*](#).ⁱⁱ The paper outlines factors that value assessment frameworks should consider to help ensure a focus on patient experiences and patient access to optimal care. **In general, PMC urges CMS to consider the following aspects of clinical and societal value related to personalized medicine that advance patient-centered care, ensuring that the value of personalized medicine to direct patients toward or away from treatments based on their likelihood to benefit from them is factored into determining the MFP for a selected drug:**

- 1. Diagnostic testing strategies:** Diagnostic tests can help guide treatment decisions and determine which treatments will be most effective and safest to use in any given patient and are a crucial element of the personalized treatment regimen. For example, the use of companion diagnostics can help define subpopulations of patients who may benefit from a treatment, and those that will not. The availability of diagnostic tests and consideration of test results that help inform treatment decision-making for drugs with biomarker implications must be figured into the value assessment methodology for personalized medicines. **PMC encourages CMS to consider the value of applicable diagnostic strategies in its evaluation of unmet medical need and clinical effectiveness.**
- 2. Heterogeneity of treatment effects:** Some patients will experience more or less benefit from a treatment than suggested by the averages reported within clinical trials and population-based data. Health care policies based on average, population-based rates for treatment response may unduly restrict access to treatments that could be the most effective option for some patients. Thus, personalized medicines may be misjudged or undervalued simply because the data required for value-based decision-making do not account for patient subpopulations or because long-term efficacy data is not yet available. **PMC encourages CMS to consider the full range of patient outcomes and benefits that may not be represented in population average-based data.**
- 3. Patient values and circumstances:** Personalized medicine depends not only on the consideration of a patient's molecular characteristics and biological characteristics but also on individual values, clinical and economic circumstances, and the potential impact of a therapy for that patient over the long term. Fundamental patient values and preferences, including the impact of treatment on quality of life, quantity vs. quality of time, functional ability related to illness or treatments, cost of supportive care, and other patient costs of treatment are weighed by patients and their caregivers when deciding on a treatment in consultation with health care providers. **To appropriately assess the value personalized medicines provide to patients with unmet medical needs, PMC encourages CMS to not use the narrow definition of "unmet medical need" proposed in guidance and instead formally consider a broad range of patient outcomes and impacts, including unmet medical needs unique to individual patients and to patient subpopulations.**
- 4. Treatment efficiency:** Although value assessments generally focus on improvements in effectiveness, they do not generally consider treatment efficiency. Treatment efficiency involves avoiding ineffective or harmful treatment options and reducing the downstream expenses

associated with rapid disease progression and/or adverse events. In order to capture economic as well as clinical value, value assessments need to consider costs and outcomes across health care. **As CMS evaluates the costs and benefits of personalized medicines to society, PMC encourages the agency to formally consider a broad range of economic impacts, including broader cost offsets and societal benefits.**

As discussed in the following section, we recommend that when these factors are taken into consideration, the MFP for a selected drug, including any selected personalized medicines or targeted therapies, be set at the ceiling if it demonstrates significant clinical and societal benefit.

It is clear both in the statute and in CMS' initial guidance that quality-adjusted life years (QALYs) will not be used as a basis for evaluations. The QALY does not sufficiently account for the broad heterogeneity of clinically relevant characteristics and preferences across patients and diseases, nor does it consider aspects of value defined by patients and their families. The measure relies on population averages that do not consider the heterogeneity of patient populations, even within the same condition.

While CMS states it will follow statute, the guidance indicates that CMS still plans to separate and exclude QALY metrics from evaluations of research that otherwise factor in QALYs. PMC is concerned that this approach may not effectively separate QALYs from CMS' analysis because CMS may continue to rely on studies that employ QALY-related data from secondary sources, or that CMS may exclude analyses that are otherwise helpful in establishing the value of a drug for a patient. **Therefore, PMC requests that CMS make clear how it will exclude QALY-based metrics from its analysis of such evidence, when this evidence may be used, and how this evidence would be weighed. PMC also requests that CMS highlight when and how the agency removed QALY-based metrics from consideration in its public explanation of a drug's MFP. In addition, regarding CMS' *Negotiation Data Elements Information Collection Request* that asks the public to submit information on a selected drug, PMC asks CMS to make sure that data submitters attest to removing the QALY and other potentially discriminatory metrics from their submission, instead of using the proposed checkbox.**

CMS requests input on what alternative measures to QALYs might be appropriate or inappropriate. PMC believes the agency would be better served by focusing on the factors related to comparative clinical outcomes and unmet need that are described in statute, which can better capture the benefits of personalized medicine, rather than seeking an alternative to the QALY. There is not one measure of value or one VAF that holistically captures the value of a treatment and the benefits of any medical treatment including personalized medicine. VAFs have strengths and limitations relative to different stakeholder perspectives and circumstances that can bolster or undermine their usefulness and applicability to personalizing patient care. A single measure will not be sufficiently comprehensive. **We encourage CMS to consider a wide variety of measures consistent with CMS' statutory focus on comparative effectiveness research and unmet need, especially those driven by patient experience data, patient input, and patient-centeredness.**

Establishing a Consistent and Transparent Process for Gathering and Evaluating Evidence

PMC appreciates that CMS will consider real-world evidence (RWE), evidence from peer-reviewed research, white papers, expert reports, clinician expertise, patient experiences, intermediate outcomes, surrogate endpoints, and patient-reported outcomes when reviewing the clinical benefit of a selected drug

and its therapeutic alternatives (Sec. 60.3.3). Considering that all medicines for which CMS will set an MFP will have a minimum of nine years since their original FDA approval, **PMC encourages CMS to consider as broad an array of evidence sources and outcomes as possible to help fill gaps in population-based data sources and capture the full range of benefits and impacts from personalized medicine discussed above.**

Although CMS' initial guidance lists aspects related to the quality and completeness of evidence sources it will consider, such as peer review, study limitations, risk of bias, and study population, among others, CMS does not describe requirements for the quality and completeness of this data, nor how CMS would consistently evaluate this evidence in determining the MFP. For example, since studies using RWE are designed fit-for-purpose, CMS' methodology should consider the extent to which the evidence it considers was designed to answer the value questions it is asking. The approach outlined in the initial guidance is too vague to create consistency across negotiations. **To ensure that the agency is evaluating these elements in a way that considers the value of personalized medicine to patients, CMS should refine its methodology through notice and comment rule-making to provide more clarity on how the agency intends to leverage negotiation data elements outlined in Sec. 50.2.** For RWE in particular, CMS should describe what data sources they plan to use and create guidelines to ensure that the data used is robust and correctly utilized.

Specifically, CMS should outline a consistent methodology for how it will synthesize evidence and for how data related to therapeutic alternatives will result in changes to an initial offer or final negotiated MFP. In addition, CMS should leverage clinicians' and patients' expertise and not use cost as a criterion for selecting therapeutic alternatives. While multi-criterion decision analysis (MCDA) may not be feasible for CMS because it requires extensive time, resources, and expertise, CMS may be able to incorporate elements from, for example, the cost-consequence approach model to compare evidence on outcomes for certain therapies. As part of CMS' methodology, we ask CMS to prioritize data related to the factors described above for recognizing the full range of personalized medicine's benefits to patients and the health care system. Given the discount already reflected in a selected drug's ceiling price, **we recommend that when these factors are taken into consideration, the MFP for a selected drug be set at the ceiling if it demonstrates significant patient benefit.**

Furthermore, CMS' methodology should clearly explain how each data element is weighted in determining the initial offer and final MFP. **To account for the clinical and societal benefits of personalized medicine and incentivize continued research and development for this field, CMS should place more weight on the factors related to the benefits of the selected drug for patients, caregivers, and society over, for example, non-clinical manufacturer-specific data elements.**

Establishing a consistent process for gathering and evaluating evidence can help manufacturers, patient groups, and other third parties better understand the evidence they may need to discount, prioritize, or collect for CMS' future consideration. Transparency can also build beneficiaries' confidence that their preferences and values are important to the agency.

Facilitating Meaningful Stakeholder Engagement

We recognize that CMS has a tight timeline for drug selection and price negotiation. But in order to ensure MFPs adequately reflect the value of selected treatments for patients and to limit unintended consequences on patients' access to personalized medicine, CMS must provide ample time for third

parties, including patients and patient organizations, to share data and experiences related to selected drugs.

CMS' initial guidance only allows 30 days from when the list of selected drugs is announced for the public to provide information on the selected drug and therapeutic alternatives to inform CMS' initial offer. We believe this short and singular timeframe for public input does not allow a sufficient window for stakeholders who may have information on the value of a treatment to their patient population to collect and provide information that could improve CMS' decision-making. In addition, this timeframe will disadvantage patients and caregivers from or organizations working with underserved communities who have fewer resources and may find it challenging to respond in such a short timeframe. **CMS should consider the burden of data collection and submission on stakeholders. We ask CMS to allow patients, caregivers, clinicians, and organizations representing these groups additional time to submit the requested data after the list of selected drugs is published. In addition to informing CMS' initial offer for a selected drug, CMS should allow this information to be submitted during subsequent steps of the negotiation process, if initiated, to inform CMS' decision-making.** Flexibility with the submission of public information would facilitate the inclusion of a broad range of patient perspectives, including those of communities underrepresented in existing studies and published literature.

Noticeably, the proposed negotiation process does not allow for additional engagement with third parties beyond the initial 30-day window to submit data. CMS' final public explanation of the MFP is released six months after the only opportunity for public input. This does not build confidence that patient and stakeholder input will be reflected in the final MFP. **Patients, caregivers, providers, manufacturers, and regulators should all be engaged meaningfully throughout the negotiation process. These parties should be allowed ample opportunities to submit relevant information. And they should be informed by CMS about how their input is being used during the negotiation process.** In addition, although we appreciate CMS' intention to consult with clinical and academic experts to help evaluate clinical benefit of a selected drug, **we ask CMS to outline how clinical and academic experts would be identified and consulted during the negotiation process.** For example, CMS could establish a panel of patients, clinicians, and other stakeholders to provide feedback throughout each drug negotiation.

We appreciate CMS' request for input on striking the proper balance between the public's interests in transparency and the protection of confidential business information. CMS' initial guidance proposes that any information the manufacturer receives from CMS about the initial offer and negotiation factors during the negotiation process must be kept confidential and must later be destroyed (Sec. 40.2). Although we agree CMS needs to preserve the confidentiality of a manufacturer's proprietary information, the confidentiality and compliance requirements around the information manufacturers receive from CMS creates an opaque negotiation process. These requirements would prevent setting precedents and sharing lessons learned across negotiations, potentially undermining manufacturers' and the public's confidence in the consistency of negotiations and the determination of MFPs across selected drugs. **We ask CMS to allow manufacturers to publicize information related to the negotiation while still protecting private trade information.** This will not only help build public trust in the process, but will ensure transparency and predictability that will help inform stakeholder data submissions during future years of the negotiation program.

In order to improve their ability to participate in the negotiation process, stakeholders must understand how the information they submit was considered. We thank CMS for intending to publish an explanation

of the factors that had the greatest influence in determining a drug’s MFP (Sec. 60.6.1). We are concerned, however, that the explanation may not provide adequate detail to be meaningful to the public and that its timing, six months after the initial opportunity for public input, may make it irrelevant for stakeholders. **In CMS’ explanation for the MFP, we ask the agency to explain which information submitted by the manufacturer and the public was or was not considered in the final MFP; the benefits and impacts considered; the data sources considered; how evidence influenced the MFP up or down, including the extent to which RWE and patient-centered data elements like patient experience data were used; which third parties were engaged, both formally and informally by CMS; and, as discussed above, the extent to which and how any evidence used to inform the MFP was separated from a QALY-based metric. In addition, we recommend CMS make explanations for the MFP clear, accessible, and transparently available for the public.**

Ensuring Coverage Policies Facilitate Patient Access to Negotiated Drugs

PMC requests CMS clarify how it will interpret the requirements identified in Sec. 110 that negotiated drugs be covered by plans, specifically the extent to which any utilization management will be permitted for negotiated drugs. PMC has previously submitted comments to CMS on the difficulties utilization management practices, such as prior authorization and step therapy, can create for patients in accessing the latest treatments and standards of care informed by personalized medicine.^{iii,iv} Without additional clarification and guardrails, PMC is concerned that plans could use utilization management to prefer non-negotiated drugs or deny coverage for negotiated products vital to a patient’s personalized health care. Because negotiated drugs are being offered to plans at a lower price, **PMC believes negotiated drugs should not face additional cost-control practices that could limit eligible Medicare beneficiaries’ access to them. To ensure patients are protected from plan attempts to offset costs, CMS should establish robust guardrails and conduct oversight to ensure the clinical appropriateness of any utilization management and formulary changes and to mitigate unintended consequences on beneficiaries’ access to both negotiated and non-negotiated drugs and the narrowing of patients’ treatment options.**

Monitoring Unintended Impacts on Personalized Medicine

Now an important part of health care, personalized medicines have accounted for at least a quarter of new drug approvals for each of the past eight years.^v Over the past eight years, PMC has also identified more than 120 expanded indications significant to advancing personalized medicine.

Multiple analyses, including those from the Congressional Budget Office, have called attention to the potential consequences of the Medicare drug price negotiation program, such as canceled research and development and disincentives to invest in small molecule medicines and therapeutic areas that require incremental innovation.^{vi,vii,viii,ix} Due to smaller patient subpopulations, personalized medicines that address the root causes of disease can be expensive and riskier to develop. In 2022, over half of FDA-approved personalized medicines were indicated for certain cancers, and over one-third were indicated for rare diseases.^x Treatment pipelines in both therapeutic areas are expected to be impacted by Medicare’s drug price negotiation program.^{xi,xii} In addition, over the past eight years, the expanded indications listed in PMC’s annual analyses of FDA approvals have had an upward trend in the average time since a drug’s initial approval. Given this trend, PMC is concerned that implementation of the negotiation program, which by statute makes drug products eligible for negotiation after nine years (or

13 years for biological products), could curtail post-approval research for expanded indications that provide patients with personalized medicine treatment options.

Since Medicare’s drug price negotiation program could have an outsized effect in discouraging the pharmaceutical industry from bringing additional personalized medicines and expanded indications to the market, CMS should take every step possible to prevent and monitor for potential unintended impacts of the program on patients and the health care system. **PMC asks CMS to collect information on unintended impacts to ensure the negotiation program does not create disincentives to develop new treatments for unmet medical needs; disincentives to conduct research on expanded indications that provide additional benefits to patients; or barriers for patient access to personalized medicine.** Related data CMS could consider tracking include changes in new drug applications (NDAs) and supplemental NDAs; changes in formulary placement and utilization management for negotiated versus non-negotiated drugs; and other barriers to patient access.

Conclusion

PMC appreciates CMS’ commitment to lowering health care costs for Medicare beneficiaries. As the agency implements the drug price negotiation program, we urge CMS to carefully consider these comments for this and future guidance. We look forward to working with you and your colleagues to ensure the program maintains the ecosystem for innovation in personalized medicine and fosters patient access to needed personalized medicine treatments. If you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org, or David Davenport, PMC’s Manager of Public and Science Policy, at ddavenport@personalizedmedicinecoalition.org or 804-291-8572.

Sincerely yours,



Cynthia A. Bens
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ⁱ Center for Medicare. *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments*. March 15, 2023. <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf>. (accessed April 13, 2023).

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