EACH/PIC COALITION

The EACH/PIC Coalition submitted the following comments to CMS via their ICR on IPAY 2027 on each of the 15 drugs selected for negotiation.

The Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) is a two-part coalition that unites patient organizations and allied groups (EACH), as well as patients and caregivers (PIC), to advocate for drug affordability policies that benefit patients.

Therapeutic Alternatives

While we understand why CMS is seeking information on therapeutic alternatives, we urge CMS to bear in mind that for many patients with chronic conditions, therapeutic alternatives are not easily exchangeable.

Once diagnosed with a chronic condition, each patient starts an often life-long journey to identify the correct treatments and regimen to successfully manage their symptoms and improve their health. Many will also face multiple chronic conditions or need medications to treat specific symptoms or even side effects of their preferred treatment. For these reasons, patients with chronic conditions often rely on a complicated and personalized course of treatment that is not easily altered.

For these patients, therapeutic alternatives may not be alternatives at all. Very often drug interactions or other health conditions would prevent individual patients from being able to switch to an alternative medication that, on paper, seems like it would be an appropriate treatment. Further, patients with chronic conditions can build up a tolerance to medications over time, so they must retain access to all treatments in a class of drugs to prolong their treatment.

Substituting or requiring patients to change drugs based on cost considerations instead of medical needs can disrupt continuity of care and result in complications and higher overall medical costs. We urge CMS to seriously consider the unique circumstances faced by these patients and work diligently to ensure that access to all treatments is protected.

Protect Patient Access to Medications

We share with CMS the goals of lowering patient out-of-pocket costs and ensuring that Americans can access the medications they need to maintain their health. However, we are concerned that the Medicare Drug Price Negotiation Program (MDPNP) is not the most effective way to lower patient costs and could ultimately cause harm by creating added barriers between patients and their medically necessary treatment. We respectfully urge regulators to consider the concerns of patient organizations outlined in these comments.

We are concerned that MDPNP could further complicate an already complex healthcare marketplace and result in worse outcomes for patients. At its core, MDPNP necessitates CMS selecting individual drugs for market interventions. This alone puts CMS in a position of creating inequities between patient populations by selecting and reviewing individual drugs, rather than evaluating systemic health costs.

EACH PIC COALITION

Additionally, as CMS has acknowledged in published guidance on the program, the MDPNP could create a new incentive structure for payers that could compromise patient access to the selected medications due to increased utilization management or reshuffling of formularies:

> *"CMS is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs." (CMS, "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027," May 3, 2024)*

Ultimately, this could mean insurers and PBMs place drugs selected for negotiation on higher tiers of the formulary. This could ultimately lead to higher OOP costs for patients who could face higher copay or coinsurance rates to retain access to that drug or alternatively be forced to switch to a different medication that may or may not be as efficacious for the patient.

Additionally, non-medical switches in medication can cause unnecessary complications for patients. At a minimum, a switch should require more doctor visits to monitor the efficacy of a new medication. Further, if the switch results in side effects or worsened outcomes, patients could face medical interventions or hospitalization and the additional costs borne out by both.

We encourage CMS to proactively implement patient protections against harmful and abusive utilization management practices, rather than wait for plans to act against patient interests before stepping in. In the interest of patients, we also encourage CMS to create a dedicated portal and/or methodology for patients to provide immediate and direct feedback to CMS on any detrimental policies they experience as a result of the MDPNP. We also encourage CMS to incorporate utilization management as a topic in future patient-focused events (such as listening sessions or roundtables) to ensure the issue is being monitored and patients have opportunity to provide direct feedback to regulators.

Identify and Resolve Patient-Reported Obstacles to Care

While our health system is complicated, one principle is simple: every change and policy we implement should ultimately benefit patients. We urge legislators to keep this principle as a singular focus as it evaluates health reform proposals and new legislation.

Although well-intentioned, MDPNP fails to address many of the underlying causes and complicated factors that result in higher prescription drug costs for patients. Therefore, we urge regulators to focus their time on identifying and addressing patient-reported obstacles to drug affordability.

Failing to resolve the underlying factors that lead to higher costs for patients can result in short-term relief and uneven benefits – aiding some but potentially leaving others with higher costs and drug accessibility challenges.