

WONDERING WHAT PATIENTS WANT AS THE GOVERNMENT IMPLEMENTS DRUG PRICING POLICIES?



PARTNERSHIP TO FIGHT
CHRONIC DISEASE



Implementation of the Inflation Reduction Act's drug pricing policies will have far-reaching implications for patients living with chronic conditions today and in the future. Organizations representing these patients want the government to prioritize several issues that are key to ensuring patients can continue to access existing and new treatments and cures.

APPROPRIATELY DEFINING UNMET MEDICAL NEED



There are many reasons patients may believe that the needs of their community are not met by current treatments and therapeutics... To protect patients, this definition must be expanded to align more closely with the needs of the Medicare population. Unmet need cannot mean only that no other treatment options exist. Instead, it must look at the nuanced factors that go into managing, treating, and curing a given condition. CMS should expand their definition of unmet clinical needs to align with that of the FDA.

**ALLIANCE FOR
AGING RESEARCH**



CMS' interpretation of unmet medical need is too narrow... We recommend CMS adopt a broader definition of unmet medical need that reflects the diversity of patient preferences and needs. This was the approach taken in the authorizing statues of the Patient-Centered Outcomes Research Institute which established a more comprehensive approach to evaluating unmet medical needs that included the consideration of "needs, outcomes and preferences" of patients.

**AUTOIMMUNE
ASSOCIATION**



Though we appreciate the guidance defined an unmet need as "treating a disease or conditions in cases where very limited or no other treatment options exist," we urge CMS to clarify how it defines limited treatment options and how it will determine unmet need overall. A too narrow definition runs the risk of disincentivizing further therapy development in a space that still requires additional treatment at the risk of not meeting the unmet need exemption.

**EVERYLIFE FOUNDATION
FOR RARE DISEASE**

ADEQUATELY REFLECTING WHAT PATIENTS VALUE



Chronic Care Policy Alliance: CMS should hear direct patient impact statements, such as how a drug has made a meaningful difference in their life and well-being... Only by factoring in patient narratives about the impact of a treatment can CMS fully grasp the value a product provides to treat chronic conditions and diseases.



Partnership to Improve Patient Care: CMS should clarify in guidance and/or regulations that it will not rely on QALYs or similar metrics. This recommendation would uphold the IRA's requirement that the comparative clinical effectiveness research factored into determinations of therapeutic benefit do not discriminate.

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ENSURING TRANSPARENCY BECOMES REALITY



National Health Council: Incorporating the voices of patients is the bedrock of the NHC's policy recommendations. The NHC urges CMS to ensure data explicitly related to the value of patients is prioritized when evaluating data. The NHC believes CMS should develop a patient engagement infrastructure to continue hearing insight from patients on the IRA's implementation.



American Cancer Society Cancer Action Network: CMS should consider undergoing rulemaking in future years to formalize the negotiation process. CMS could also use this process to establish a timeline by which the Agency intends to revisit the rules regarding the negotiation process. Using the rulemaking authority will provide stakeholders clear direction regarding the process for negotiation and will ensure an open and transparent process for any subsequent changes to the negotiation process.

PROTECTING ACCESS TO NEW INNOVATIONS



Patients' access to medicine is a crucial element in their health care experience. CMS should ensure patients access to medicine with as few barriers as possible. Although barriers such as prior authorization are often grounded in patient safety, rarely do such interventions involve patient input. In moving forward with the negotiation program, the NHC believes it is necessary that CMS clearly define coverage requirements. Defining coverage requirements in Part D and/or other payment rules will ensure patients have appropriate guardrails to assure them access to life-saving medications.

NATIONAL HEALTH COUNCIL



We urge CMS, as it implements the drug negotiation process, to monitor benefit plan design to ensure that access and affordability of Medicare drugs are not diminished.

**HIV+HEPATITIS
POLICY INSTITUTE**



Because the creation of negotiation processes will have downstream impact on research and development, we encourage CMS to work closely with the FDA, particularly on issues related to the trends in the number of new cancer therapies brought to market. Specifically, we ask CMS to closely monitor two provisions that may negatively impact research and development of new therapies - the implications on research of additional indications for new therapies and the impact on the development of small-molecule therapies since they are eligible for negotiation after only seven years on the market.

AMERICAN CANCER SOCIETY CANCER ACTION NETWORK



NORD is also concerned additional efforts are needed to meaningfully track IRA impacts on innovation. NORD encourages CMS to work closely with FDA and other public and private-sector experts to establish meaningful metrics and monitor impacts on innovation.

**NATIONAL ORGANIZATION
FOR RARE DISORDERS (NORD)**