

CMS Should Not Minimize Unmet Need in IRA's Medicare DPNP

A new study from NPC & CU finds crucial elements of unmet medical need unaccounted for in current FDA guidelines which inform the IRA's Medicare DPNP.

WASHINGTON, DC, UNITED STATES, October 27, 2025 /EINPresswire.com/ -- Leaders at the Centers for Medicare & Medicaid Services (CMS) appear to be taking a narrow approach when considering how prescription drugs selected for the Inflation Reduction Act (IRA)'s Medicare Drug Price Negotiation Program (DPNP) address unmet medical needs, according to a [targeted literature review](#) co-authored by the National Pharmaceutical Council (NPC) and published in Applied Health Economics and Health Policy. Unless CMS expands its framework to include a wider perspective of unmet need, the DPNP risks undervaluing medicines and disincentivizing future medical innovations.

"Opportunities for CMS to Further Specify and Broaden Its Approach to Assessing Unmet Medical Need in the Context of the Medicare Drug Price Negotiation Program" compares the elements of unmet need in the IRA's Medicare DPNP with FDA guidelines to identify areas where CMS administrators could benefit from additional specification. The study is authored by Michael J. DiStefano, PhD, R. Brett McQueen, PhD, Harry Gyimah Gyamfi, MSc, David Ameyaw, MSc, and Antal Zemplenyi, PhD, of the University of Colorado (CU) and NPC's Hanke Zheng, PhD, and Jon D. Campbell, PhD.

Established in 2022, the IRA's Medicare DPNP requires CMS to consider several criteria — including the extent to which a selected drug addresses an unmet medical need. Recently, CMS stated that the agency will use [guidance from the FDA](#) to make this assessment of unmet need, prompting concerns that CMS's approach is too narrowly focused on aspects of conventional clinical benefit.

"At present, CMS's narrow focus in evaluating unmet need risks blunting incentives to develop innovative medications with meaningful benefits to patients, their families, and society," said Dr. Zheng, NPC Research Manager and study co-author. "Stakeholders in the program are left confused as to how CMS is navigating its statutory directives."

Researchers concluded that CMS should expand its framework for assessing unmet medical need to clearly specify additional elements of need that are not appropriately captured by current FDA guidelines — particularly factors from the patient, caregiver, and societal

perspectives. Examples include patient quality of life, caregiver and societal economic burden, and elements of treatment administration.

"By explicitly incorporating all elements of unmet medical need, CMS leaders can prompt more accurate and robust evidence through targeted feedback from manufacturers, researchers, and patient groups," said Dr. Campbell, NPC Chief Science Officer and study co-author. "It's critical that patient voices are effectively included and selected drugs are not undervalued."

This study, which is part of an ongoing collaboration between NPC, CU, and the National Health Council, specifically focuses on the context of the IRA's Medicare DPNP, but the findings have broader implications on our understanding, as a society, of unmet medical need. Future publications in this series will explore stakeholder perspectives on unmet need.

The work builds on [previous NPC research](#) about how the IRA may have unintended consequences on pharmaceutical investor strategy — particularly among small molecule drugs and launch indications within a small population. NPC recently addressed these concerns in comments submitted to the Centers for Medicare & Medicaid Services.

□About the National Pharmaceutical Council□

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