

Protecting Patient Access to Cancer and Complex Therapies Act (H.R.4299)

Background

The Medicare Drug Price Negotiation Program (MDPNP), created under the Inflation Reduction Act, has completed several rounds of drug negotiation for select Part D drugs. In June, the Centers for Medicare & Medicaid Services (CMS) released draft guidance for the MDPNP Initial Price Applicability Year 2028, which includes Medicare Part B infused drugs for the first time. Through the MDPNP, CMS will set a Maximum Fair Price (MFP) on select Part B medications starting in 2028.

While the Inflation Reduction Act attempted to ensure that providers can acquire MDPNP medications at the MFP price point, the statute includes no mechanism to make providers whole for their add-on payment. In fact, a recent study projects a 42-61% decrease to Part B add-on payments across infused products, a drop in reimbursement that few businesses could survive.

The CY2026 Medicare Physician Fee Schedule proposed rule, released in July, confirmed that CMS intends to reimburse providers for MDPNP Part B drugs at the MFP plus a 6% add-on payment instead of the traditional Average Sales Price (ASP) plus 6%. Furthermore, CMS intends to include the MFP within the ASP calculation, which will further drive down the ASP when used as a basis for payment in the commercial payer market.

Impact on Infusion Centers

Office-based and ambulatory infusion centers play a key role as the most efficient setting for drug administration. NICA's members administer medications to patients – including Medicare beneficiaries – with serious autoimmune conditions, such as rheumatoid arthritis, psoriasis, and lupus. These conditions are lifelong and can result in permanent disability if not managed appropriately upon diagnosis. NICA members administer Part B infused medications to patients to help them manage their disease progression and live healthy, productive lives.

Non-hospital, community-based infusion practices source their medications through "buy-and-bill" in which the medical practice purchases medications in advance and later bills the health plan for the medication once administered to the patient. The cost of these medications is based on the ASP plus 6% add-on payment, which allows NICA members to account for acquisition costs. However, these margins are incredibly slim.

Reimbursing infusion centers and providers based on MFP + 6% for MDPNP Part B selected drugs would significantly reduce the percentage-based add-on payment that infusion providers rely on to administer these essential medications. Even worse, including the MFP within the calculation for ASP will drop the ASP precipitously for Medicare and the commercial market, which also bases reimbursement for infused products based on the ASP.

Changing the calculation for Part B add-on payments could put infusion centers underwater financially and make it extremely difficult to provide care in their communities. A loss or consolidation of community-based infusion access points could drive patients to hospital outpatient departments for infusion, which are the most expensive site of care where specialty medications often cost up to 36% more. This has an impact on our overall drug spending, but it also impacts patients, whose cost-sharing reflects these differentials.

The Solution

The *Protecting Patient Access to Cancer and Complex Therapies Act* (H.R.4299) takes providers out of the middle of MDPNP drug negotiations while ensuring government and beneficiary savings.

Under this legislation, CMS would continue to select medications under the MDPNP and establish MFP for select Part D and Part B drugs. However, Medicare would receive savings via direct payments from the drug manufacturers, reflecting the difference between ASPs and MFPs on selected medications. This would restore provider payment for selected drugs or biologics under Part B to 106% of the ASP or wholesale acquisition cost (WAC) of the drug – whichever is lower. It therefore removes MFP from the add-on payment calculation and excludes MFP from the ASP calculation, thus protecting both Part B and commercial reimbursement rates. Beneficiary cost-sharing would still be assessed based on the MFPs, which will ensure immediate savings for patients.

NICA urges Congress to enact the *Protecting Patient Access to Cancer and Complex Therapies Act* before the MDPNP selects Part B drugs for negotiation.

Contact **Rep. Murphy** to cosponsor the *Protecting Patient Access to Cancer and Complex Therapies Act* (H.R.4299). Contact **Sen. Barrasso** to become an original cosponsor upon reintroduction in the 119th Congress.

Avalere Health. "Commercial Spillover Impact of Part B Negotiations on Physicians." September 2024.

[&]quot;EBRI Issue Brief No. 525. "Location, Location, Location: Cost Differences in Health Care Services by Site of Treatment — A Closer Look at Lab, Imaging, and Specialty Medications." February 2021.