

## The Nation's Advocacy Voice for In-Office Infusion

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Eric Longnecker
Deputy Assistant Secretary, Technology Security
Bureau of Industry and Security
Department of Commerce
1401 Constitution Avenue NW
Washington, D.C. 20230

Stephen Astle
Director, Defense Industrial Base Division
Bureau of Industry Security
Department of Commerce
1401 Constitution Avenue NW
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Re: Section 232 National Security Investigation of Imports on Pharmaceuticals and Pharmaceutical Ingredients (BIS-2025-0022/XRIN 0694-XC120)

Deputy Assistant Secretary Longnecker and Director Astle:

On behalf of the infusion providers we represent throughout the country, we write to share our concerns regarding the Section 232 National Security Investigation of Imports on Pharmaceuticals and Pharmaceutical Ingredients. As a nonprofit trade association that provides a national voice for non-hospital, community-based infusion providers, we would like to request that you please consider the potential consequences of establishing tariffs on essential infusion drugs that require provider administration.

The National Infusion Center Association (NICA) is a nonprofit organization formed to support non-hospital, community-based infusion centers caring for patients in need of infused and injectable medications. To improve access to medical benefit drugs that treat complex, rare, and chronic diseases, we work to ensure that patients can access these drugs in high-quality, non-hospital care settings. NICA supports policies that improve drug affordability for beneficiaries, increase price transparency, reduce disparities in quality of care and safety across care settings, and enable care delivery in the highest-quality, lowest-cost setting.

## **Patient Out-of-Pocket Cost**

NICA would like to express concerns over the potential harm new tariffs on pharmaceuticals and pharmaceutical ingredients may have on patient drug affordability. Infusion centers administer complex,

biologic products directly to patients and are all too familiar with the challenges patients face in affording their prescription medications. This can be particularly challenging for patients with coinsurance that is based on a percentage of the medication's list price, instead of a fixed copay amount. Our members work closely with patients to navigate the financial hurdles that could prevent them from taking their prescribed medication consistently and in accordance with their prescribed treatment regimen.

Tariffs on imported pharmaceutical products and their ingredients are likely to increase the cost of these essential infused products. Patients who already struggle to afford their essential medications will find any price increase extremely challenging, which could impact the patient's ability to continue their treatment plan. The medications administered at our member facilities treat complex conditions that if improperly cared for could cause significant adverse events for the patient, including loss of productivity and complications that cause hospitalization. NICA advocates for policies at the state and federal level that *decrease* out-of-pocket costs for patients, and we are extremely concerned that these tariffs will only make the existing situation more tenuous.

## **Drug Shortages**

NICA members navigate drug shortages that may arise due to global supply chain dynamics as they work to maintain continuity of care for their patients. Biologics work best when taken on a schedule, and any interruption to that schedule can lower the effectiveness of a medication. Drug shortages present considerable challenges that may require an adjustment to the patient's prescribed infusion regimen or an increase in consumption of other medical services. When shortages reach inflection points, they may also require patients to travel to alternative sites of care in search of the medication they need. Many infusions last several hours, and requiring a patient to travel far distances to access their medications or seek care at the more costly and crowded hospital could impact that individual's ability to keep their job or care for their children.

According to the <u>United States Pharmacopeial Convention</u> (UPS), the United States currently produces about 12% of the active pharmaceutical ingredients used in prescriptions used throughout the United States, with more than half of medication ingredients sourced from Europe and India. Given manufacturers' reliance on an international pharmaceutical supply chain, we are concerned that tariffs could exacerbate supply disruptions and the frequency of drug shortages as manufacturers work to navigate new requirements. Production disruptions or ingredient shortages could make it extremely difficult for our members to secure the infused medications required by their patients. For infusion patients, even a temporary disruption in their access to these essential medications could put them at significant risk.

## **ASP Adjustment**

Under the existing "buy and bill" model for Medicare Part B drugs, infusion providers order medications, manage inventory, and handle all storage and processing. Medications are ordered based on the center's estimated needs over a certain time period, rather than ordered individually per patient. This system allows flexibility to adjust dosing and allocate inventory based on real-time needs. We are concerned that tariffs could worsen the reimbursement crisis experienced by our members if Part B provider reimbursement for administered medications is not addressed. Currently, infusion centers are reimbursed for most Part B drugs based on the Average Sales Price (ASP) plus a six percent add-on (ASP+6%), which accounts for acquisition costs. This ASP formula is calculated based on the weighted average of all manufacturer sales prices for the drug, including rebates and discounts, and is updated quarterly.

We are very concerned that tariffs will drive up the ASP, making our drugs more expensive to buy, while failing to adjust our reimbursement in a timely manner. Infusion practices run on slim margins and cannot be expected to cover this delta until the ASP calculation accurately reflects the cost of acquiring the medication. It is paramount to ensure that additional costs are factored in the ASP payment methodologies, as infusion centers will be unable to bear these additional costs. NICA strongly urges the administration to make sure that infusion centers are not held accountable for this financial difference if tariffs are imposed on pharmaceutical products and their ingredients.

NICA supports efforts to address prescription drug affordability but is extremely concerned that tariffs will only worsen the existing affordability challenges faced by patients. Thank you for your willingness to engage stakeholders in this important discussion. We look forward to working with you as you continue this investigation.

Sincerely,

Brian Nyquist, MPH

President and Chief Executive Officer National Infusion Center Association