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HealthCare Institute of New Jersey
ADVANCING GLOBAL HEALTH • LEADING NEW JERSEY'S ECONOMY

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September 10, 2025

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1832-P
P.O. Box 8016
Baltimore, MD 21244-8016

Dear Sir or Madam:

The HealthCare Institute of New Jersey (HINJ) is a trade association that serves as the leading voice for our state's research-based biopharmaceutical and medical technology companies. HINJ strives to raise awareness and understanding of New Jersey's and America's global leadership on innovation, expand patient access to the life-saving medical advances our member companies produce, and preserve New Jersey's and America's workforce, economy and jobs.

I write to submit comments regarding CMS' CY 2026 Physician Fee Schedule Proposed Rule, CMS-1832-P (the "Proposed Rule"), and its impacts on biopharmaceutical companies working tirelessly to save lives and cure diseases.

Researching, discovering, and manufacturing new, life-saving treatments and cures for patients is a highly complex process that depends on an entire ecosystem of researchers, manufacturers, government agencies, vendors, and additional partner stakeholders. This ecosystem interconnectedly involves R&D and manufacturing facilities, raw materials, FDA-approved suppliers, regulatory reviews and inspections, critical transportation and delivery logistics, infrastructure, and many other vital components. Maintaining the precise and delicate balance of these numerous elements is extremely challenging, but it is essential to meet these challenges to ensure American patients receive the critical care our companies provide every hour.

However, the Proposed Rule would greatly disturb this fragile balance, risking patient access, America's leadership in global innovation, our innovation economy, and jobs in the United States.

In the Proposed Rule, CMS presumes that any Bona Fide Service Fee (BFSF) based on a percentage of a Part B drug's price is a reportable price concession, at least when the BFSF exceeds a "reasonable markup to the total cost." This presumption would disrupt a long-standing industry practice, which has been imposed on manufacturers by entities such as wholesalers, distributors, and others that charge service fees related to the supply chain for life-saving and life-improving medicines. Some services, like product distribution, inventory management, data reporting, and other logistics, can be valued based on costs that are not necessarily affected by the drug's price or volume (notable examples include drugs requiring cold chain handling, radiopharmaceuticals, etc.).

However, distributors also face variable costs, including opportunity costs and capital investments when deciding which drugs to buy and in what quantities. To manage these costs, wholesalers, pharmacies, insurance plans, group purchasing organizations (GPOs), storage and logistics facilities, pharmacy benefit managers (PBMs), and other entities consider the value of the product when making purchasing and contracting decisions. Many of these purchases and contracts are necessarily based on the overall value of the drugs rather than a cost-plus model. It is unlikely that the industry will be able to change this model—certainly not by January 1, 2026, as proposed.

Furthermore, the Proposed Rule puts the entire burden of reversing this long-standing practice solely on manufacturers. These supply, storage, and distribution contracts, partnerships, and collaborations take years to establish and integrate under normal circumstances. Implementing such a significant change with this little lead time—and without incentives for supply chain partners to negotiate and adapt—will most likely cause major disruptions to patient access, innovation, American jobs, and future treatments and cures.

Without our distribution partners, we cannot provide current levels of access to patients. Manufacturers lack the logistics capabilities to distribute *en masse*. For example, each state has different licensure requirements for distributing medicinal products to patients. Most manufacturers do not hold the necessary pharmacy licenses to sell directly to patients and must, therefore, rely on the distribution chain of wholesalers, retail pharmacies, and health clinics. As a result, manufacturers are compelled to accept the system imposed by that supply chain just to make their products available. The Proposed Rule does nothing to impose any requirements or restrictions on any other entity in the supply chain and does not improve manufacturers' bargaining power regarding these entities to facilitate such a change.

As a result, manufacturers will be required to report as discounts (at least a portion of) payments that previously qualified as BSFs. Such reporting would, in turn, negatively affect physician reimbursement through a reduction in the drug's Average Sales Price (ASP), potentially causing the Part B ASP reimbursement rate to fall below a physician's acquisition cost. Because of the cyclical nature and two-quarter lag of ASP reporting, any potential price decreases may never align with the ASP reimbursement rate, forcing physicians to choose between accepting losses on every medication they prescribe or basing their prescribing decisions on financial considerations rather than clinical ones, such as prioritizing pharmacy benefit drugs regardless of whether they are more economical or clinically better for the patient.

Furthermore, if enacted, this rule would take effect in January 2026, leaving little time for companies to renegotiate BFSF contracts. As mentioned above, many of the industry's administrative and data fees are percentage-based, which requires significant time to renegotiate. Additionally, the rule would mandate that companies reevaluate these contracts every year, an extremely burdensome requirement since our industry typically engages in multi-year contracts. These complex negotiations and renegotiations would need at least one year's lead time to implement, making a January deadline nearly impossible to meet.

America's patient community relies on New Jersey's life sciences to continue doing what we do best – saving lives around the world by discovering new treatments and cures right here in New Jersey. Our comments are provided to preserve that ability and protect America's national interests, global leadership, and patient community.

Respectfully,

Christine Buteas

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President and Chief Executive Officer