September 25, 2023

Via electronic submission: cynthia.denemark@cms.hhs.gov

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850
Attn: CMS-2434-P

Re: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program [CMS-2434-P]

Dear Administrator Brooks-LaSure:

The undersigned organizations are writing to express concerns with a recent Centers for Medicare & Medicaid Services (CMS) proposed rule which would require manufacturers to aggregate or "stack" price concessions provided to separate entities across the supply chain for Medicaid rebate Best Price purposes. Our organizations represent stakeholders across a broad spectrum of the pharmaceutical distribution chain and have serious concerns about CMS' proposal, which would make sweeping changes to current business practices. We are coming together on this Joint Stakeholder Letter to provide a unified voice on a central issue of the proposed rule and strongly recommend that CMS does not finalize this proposal.

CMS' Proposal is Not Operationally Feasible

Under this rule, CMS proposes to change the regulatory definition of Best Price, by requiring "stacking," or the aggregation of manufacturer price concessions on a drug made available to separate entities across the pharmaceutical supply chain. CMS' proposal is inconsistent with the Best Price statute, and if adopted would be unworkable to implement due to major operational barriers. The proposed rule does not address the significant challenges with this proposal.[1]

No system exists today that is capable of tracking price concessions to all of the separate customers that encounter a given drug unit across the supply chain. Such a system would need to interface with and collect data from entities involved in the pharmaceutical supply chain, including (among others) wholesalers, specialty distributors, retail community pharmacies, specialty pharmacies, mail-order pharmacies, physicians, hospitals, clinics, home infusion providers, home healthcare providers, hospices, long term care facilities, prisons, HMOs, and insurers.

Such a system would need to communicate with all of these different stakeholders across the pharmaceutical supply chain, which alone entails a massive network of connections that may surpass the technical capabilities of any given entity across the supply chain. Moreover, the system would presumably need to link all of these independent entities by reference to a single drug unit. This could require non-manufacturer entities in the supply chain to distinguish and track each unit they purchase or reimburse, and also to consent to exchange information with each manufacturer about the entity that next purchases or reimburses the unit. Connecting a unit dispensed to a patient to that patient's insurer could raise health data privacy concerns, which CMS' proposal does not address.

[1] 88 Fed. Reg. 34286 ("At this time, we cannot determine cost estimates for this item.").

CMS' Proposal Could Have Unintended Consequences on Multiple Stakeholders

Assuming a system capable of tracking individual units throughout the pharmaceutical marketplace were even possible, we urge CMS to consider the impact that the time, effort, and expense necessary to develop this type of network could have on providers, supply chain entities, patients and the industry as a whole. Diverting time and resources to this effort could limit participants' capacity to perform their core functions, whether that be developing new medicines, helping to source therapies to those who require them, or caring for patients. Supply chain entities and manufacturers are already devoting considerable time to preparing for new policies enacted under the American Rescue Plan Act and the Inflation Reduction Act that enact major changes to the Medicare and Medicaid programs.

Moreover, CMS' proposal, if finalized, would disincentivize voluntary rebates, discounts, and other price concessions to best price-eligible customers, potentially reducing beneficial supply chain discounts. This could negatively impact payers as well as providers that administer drugs to Medicaid patients.

Several organizations have submitted individual comment letters on the proposed rule and you will find further detail on this issue in our individual letters. Please feel free to contact any of the undersigned organizations if you have any questions or would like any additional information. We would welcome the chance to speak with CMS staff to provide additional technical input.

Sincerely,

Biotechnology Innovation Organization
Healthcare Distribution Alliance
Healthcare Leadership Council
Infusion Providers Alliance
Kaiser Permanente
McKesson Corporation
National Infusion Center Association
Pharmaceutical Research and Manufacturers of America