



July 25, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS- 2434-P
7500 Security Boulevard
P.O. Box 8013, Baltimore, MD 21244
Attention: CMS-2439-P
Mail Stop: C4-26-05

RE: Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program

Dear Administrator Brooks-LaSure:

The Healthcare Leadership Council (HLC) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS') "Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program" proposed rule.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, homecare providers, group purchasing organizations, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

While CMS states the intent of the proposed rule is to promote efficient operation of the Medicaid Drug Rebate Program (MDRP), certain proposals will have the opposite effect, adding significant and unnecessary burdens on manufacturers when they are already working to adapt to major changes to Medicaid and Medicare, including passage of the price setting provisions in the Inflation Reduction Act (IRA) and the Average Manufacturer Price (AMP) cap removal.

CMS proposes to drastically change its Medicaid "best price" regulation to require manufacturers aggregate or "stack" price concessions to different best price eligible customers across the supply chain to reach a final price on a drug. We strongly urge CMS not to adopt this proposal as it would place substantial burdens on entities throughout the supply chain, disincentivize future discounts, and is operationally unfeasible as proposed.

The stacking proposal would require the development of a new system to track separate customers that handle a drug unit across the supply chain. It would need to collect data on every price concession to every possible best price eligible entity involved in the pharmaceutical supply chain, including 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, insurers, and others. In addition to imposing costly changes to stakeholders' contracting and business processes, developing this system would introduce health data privacy concerns, as the system would need to link a unit dispensed to a patient to that patient's insurer. CMS' proposal will have an adverse effect on recipients of discounts across the supply chain, as manufacturers will be disincentivized from continuing to offer current discounts if this stacking provision is adopted.

HLC is also concerned with the proposed "price verification survey" that would audit certain drugs and make that data public. These audits far exceed in scope CMS' stated intent to verify prices. The audits would collect data on pricing, charges, production, distribution, utilization, research, marketing, and other information at the discretion of the Secretary of the U.S. Department of Health and Human Services. Moreover, CMS proposes to post findings from this detailed audit that it determines to be nonproprietary. HLC is concerned that this will ultimately put manufacturer proprietary information at risk. We respectfully urge CMS not to adopt the proposed price verification survey.

CMS proposes to require that Medicaid Managed Care Organizations (MCOs) include Beneficiary Identification Number (BIN) and Processor Control Number (PCN) numbers on Medicaid prescription identification (ID) cards. HLC generally supports this proposal but rather than requiring ID cards list unique BIN, PCN, National Council for Prescription Drug Programs (NCPDP), and group number identifier numbers separately, HLC recommends CMS instead require ID cards have a unique BIN, PCN, and group combination.

Thank you for the opportunity to provide feedback on potential changes to the Medicaid Drug Rebate Program. If you have any questions, please do not hesitate to contact Debbie Witchey at dwitchey@hlc.org or 202-449-3435.

Sincerely,



Mary R. Greal
President