# DHS Responses to Public Comments Regarding 340B Modifiers on Physician Administered Drugs

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**Biotechnology Innovation Organization (BIO)**

**Comment:** I am writing to submit comments on behalf of the Biotechnology Innovation Organization (BIO) regarding the Department of Medical Services' proposed rule to implement "340B Modifiers on Physician-Administered Drugs."

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics yield not only improved health outcomes, but also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

The 340B Program is now the second largest pharmaceutical program in the federal government behind Medicare, totaling $44 billion in 2021. By some conservative estimates, duplicate discounts amount to 3% to 5% of total 340B claims. *(1)* This means that these conservative estimates indicate that duplicate discounts could total more than $1.32 Billion to $2.2 Billion. Minimizing diversion and duplicate discounts is essential to program integrity to protect against waste and abuse. While BIO strongly supports the use of 340B modifiers to identify all 340B claims, we have some concerns that part of this rule, as drafted, is confusing and should be deleted.

Specifically, in 142.200 (H), the proposed rule states,
*". . . A covered outpatient drug includes outpatient drugs and drugs used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), and (O)."*
BIO believes the sentence above should be deleted from the proposed rule as it is unnecessary and confusing, and more importantly is inconsistent with federal law.

Section 1927(k) of the Social Security Act defines "covered outpatient drugs," and specifically excludes, among others, drugs used in inpatient settings. Therefore, the reference to "inpatient" in the proposed rule contradicts federal law and should be removed from the proposed rule.

*Reference:*
*1 Mundra, Ashwin, "The 340B Noncompliance Data Gap Leaves Drug Manufacturers in the Dark," The Drug Channels Institute, Blog, March 18, 2022. https://www.drugchannels.net/2022/03/the-340b-noncompliance-data-gap-leaves.html*

**Response:** The State of Arkansas included full definitions of entities from the Federal guidance to define various facilities. However, only covered outpatient physician administered drugs will be required to be billed with the modifiers. The modifiers would not apply to inpatient drugs or per diem billing. The

Arkansas 340B facilities are aware of the intent for outpatient drugs only, as they have been working with the state regularly to prepare for this change.

**Comment:** Secondly, the reference to "subparagraph (L), (M), (N), and (O)" does not appear to attach to corresponding subparagraphs in the provider manual the proposed rule is amending. These subparagraphs appear to be in reference to 340B covered entity types in the federal statute, but the proposed rule does not indicate this, and such a reference would be inappropriate and unnecessary for the purposes of requiring modifiers on 340B-purchased physician-administered drugs. *(2)*

Notwithstanding these concerns, as noted, BIO strongly supports the use of 340B modifiers on all appropriate claims. Program integrity is of the utmost importance to BIO and its members. We believe claim modifiers are essential mechanism to reduce the incidence of duplicate discounts and diversion, which are prohibited by federal statute. Thank you for the opportunity to comment on this proposed rule.

*Reference:*
*2 42 U.S.C §256b(b)(2)*

**Response:** Several Official Notices have been provided to all providers for best practices for use of the modifiers on the covered outpatient physician administered drugs. Also, the State of Arkansas has met and communicated with 340B providers regularly to make sure that covered entity billing departments are ready and understand the changes. The state also intends to hold billing clinics to help 340B providers be ready for the changes.