COMMUNITY ACCESS NATIONAL NETWORK

Mailing Address:

Attn: Jen Laws
PO Box 3009
Slidell, LA 70459

Chief Executive Officer:

Jen Laws
Phone: (313) 333-8534
Fax: (646) 786-3825
Email: jen@tiicann.org

June 25, 2025

Department of Health and Human Services
Centers for Medicare and Medicaid Services
Attention: Medicare Drug Price Negotiation Program Draft Guidance
IRARebateandNegotiation@cms.hhs.gov
Hubert H. Humphrey Building,
200 Independence Avenue, SW
Washington, DC 20201

RE: Comment Request (CMS-4210-N); Medicare Program; Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program Draft Guidance; Federal register Number: 2025-08607

Dear Dr. Mohmet Oz,

We write to express deep concern regarding CMS's proposed guidance on the implementation of the Drug Price Negotiation Program (DPNP), particularly the agency's decision not to require the use of a federal claims modifier for affected transactions. This omission undermines program integrity and places patients — especially those dependent on safety-net providers — at increased risk.

ABOUT CANN: The Community Access National Network (CANN) is a 501(c)(3) national nonprofit organization (formerly incorporated under the "Ryan White CARE Act Title II Community AIDS National Network") focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and supports for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking. CANN's coalition-based work is done on behalf of the patient advocacy groups, pharmaceutical partners, and government agencies.

Background: Retrospective Payments and Claims Modifiers - We've Been Here Before

In 2019 the Office of the Inspector General (OIG) audit revealed that CMS inappropriately paid acute-care hospitals **$51.6 million** for outpatient services they provided from January 2013 through August 2016 to beneficiaries who were inpatients of long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), inpatient psychiatric facilities (IPFs), and critical access hospitals (CAHs). The overpayments occurred because system edits were not working. However, after CMS modified the edits in May 2019, only $3.4 million (less than 9 percent of the $39.3 million in improper payments for the entire audit period) was

inappropriately paid to acute care hospitals from June 2019 through December 2021.[1]

Both the claims modifier or clearinghouse models offer potential mechanisms to prevent duplicate discounts between CMS and the 340B Drug Pricing Program; **we remain <u>neutral</u> on the specific approach adopted.** Each model presents distinct advantages and implementation challenges: the claims modifier provides a direct, point-of-sale solution, while the clearinghouse model offers a centralized reconciliation framework. Our priority is ensuring the selected method effectively safeguards program integrity, minimizes administrative burden for providers, and maintains access to discounted medications for vulnerable populations.

<u>Claims Modifiers are a Proven Tool to Achieve the Administration's Goals of Reducing Waste, Fraud, and Abuse;</u>

1. Failure to Mandate Claims Modifiers Jeopardizes Patient Access and Transparency

CMS's reliance on "trust" rather than a mandate for claims identification is insufficient as a mechanism for oversight. Patients bear the consequences of systemic inefficiencies and exploitation that arise from this lack of clarity. Without a standardized claims modifier, duplicate discounts—where the same drug unit receives both 340B pricing and Medicaid or Medicare rebates—are allowed to proliferate unchecked. These misallocations distort the healthcare system and, ultimately, reduce funds available for reinvestment into public health services for vulnerable populations.

2. Inconsistent Federal Standards Undermine Program Integrity and Burden Patients

CMS requires use of the "TB" claims modifier for Medicare Part B inflation rebates beginning January 1, 2025, yet it treats use of modifiers as optional under the DPNP. This inconsistent approach breeds confusion and weakens enforcement. Without clear claim identification, pharmacy benefit managers (PBMs) and covered entities can exploit system loopholes, diverting billions away from Medicaid programs and leaving patients to deal with complex, delayed, or inaccurate billing.

3. Responsibility of Manufactures to Means Test

The suggestion that Manufacturers should means test by allowing dispensing entities to choose to voluntarily and proactively indicate on a submitted claim that the claim is 340B-eligible and the MTF would pass along the 340B indication data as applicable to the Primary Manufacturer when the MTF shares the data elements with each Primary Manufacturer will add unnecessary administrative burden to all parties involved.

4. Data Confirms Widespread Duplicate Discount Abuse and Its Financial Toll

---

[1] https://oig.hhs.gov/reports/all/2022/cmss-system-edits-significantly-reduced-improper-payments-to-acute-care-hospitals-after-may-2019-for-outpatient-services-provided-to-beneficiaries-who-were-inpatients-of-other-facilities/

IQVIA estimates between $20 and $25 billion in duplicate discounts occur annually. A Government Accountability Office (GAO) audit found a 25% error rate in audited 340B programs, often due to systemic flaws such as the inaccurate Medicaid Exclusion File (MEF). These are not isolated incidents—they reflect systemic issues that CMS's inaction allows to continue.

5. Retrospective Payment Models Create Uncertainty and Delay Care

CMS's proposal to rely on retrospective identification and clawbacks, rather than prospective prevention, shifts undue administrative and financial burdens onto providers—particularly small and rural hospitals. These facilities are often already operating at a loss; nearly 45% of rural hospitals report negative margins, and over 90% depend on 340B savings to continue operations. Delays in payment or complex compliance requirements will result in delayed care, reduced services, or facility closures—placing patients at risk of losing essential access to care.

I. Automation Reduces Manual Oversight

- **Claims modifiers enable automated detection** of duplicate discounts and improper billing.
- Without a standard modifier, agencies must **manually audit records**, cross-reference multiple data sources, or rely on self-reported data—which is costly, labor-intensive, and prone to error.
- Automating compliance through modifiers reduces the need for extensive human review and streamlines oversight operations.

II. Centralized Data = Lower Administrative Costs

- A universal claims modifier creates a **centralized and standardized dataset** for identifying which transactions are eligible for 340B pricing or DPNP pricing.
- This **simplifies data validation** across Medicare, Medicaid, and Manufacturer rebate programs, reducing the complexity and cost of reconciling mismatched data from fragmented systems.

III. Improved Accuracy = Fewer Investigations and Penalties

- Modifier use reduces billing errors and noncompliance, meaning:
  - **Fewer investigations** by the Office of Inspector General (OIG) or GAO.
  - **Fewer whistleblower cases or False Claims Act penalties** requiring lengthy litigation or settlements.
- This leads to **cost savings in legal fees, settlements, and recovery actions**, which are expensive for both government and providers.

IV. Reduces Fraudulent Claims at the Source

- By clearly flagging which claims are 340B-eligible, a modifier helps **prevent improper rebate claims before they occur**, rather than trying to recoup funds after the fact.

- This **proactive compliance model** is far more efficient—and less expensive—than retrospective enforcement.

V. Reduces Burden on State Medicaid Agencies

- CMS currently delegates duplicate discount prevention to **state Medicaid agencies**, many of which are under-resourced.
- A federal claims modifier standard would **relieve states from having to build duplicative infrastructure**, lowering state and federal administrative costs simultaneously.

VI. Enables Risk-Based Oversight Models

- With clean, tagged claims data, CMS and HRSA can adopt **risk-based oversight**, focusing audits and enforcement where problems are most likely—rather than conducting blanket reviews.
- This is more efficient, more targeted, and **dramatically reduces the cost per audit**.

High Administrative Overhead and Time Lag
Retrospective reconciliation involves multiple stages:

- Staff must extract and validate claims.
- Claims are matched retroactively to cost reports or utilization thresholds.
- Discrepancies trigger reviews, recoupments, and possible appeals. This process is:
  - **Slow**: Timeliness is delayed by claims run-out and processing pipelines.
  - **Expensive**: Personnel and contractor costs accumulate.
  - **Error-prone:** High administrative stress increases risk of oversight and inconsistent enforcement.

Bottom Line:
Yes—a standardized, mandatory claims modifier would reduce government oversight costs by enabling automation, improving data accuracy, preventing fraud, streamlining audits, and minimizing administrative burdens at both the federal and state levels.

It's a smart, cost-effective policy tool that supports compliance, reduces waste, and ensures taxpayer dollars are used as intended—to benefit patients, not bureaucratic inefficiency or corporate exploitation.

<u>Opposition Arguments are *not* about Patients</u>

.

1. **Claims Modifiers Do Not Jeopardize Privacy and Are Already in Use**

Contrary to some misinformation, claims modifiers use de-identified digital markers that do not compromise patient privacy. These tools are widely used in Medicare and Medicaid billing processes and are essential for automating compliance and protecting rebate integrity. By failing to extend this existing infrastructure to the DPNP, CMS forces stakeholders to navigate complex, manual, and error-prone alternatives—again to the detriment of patients.

2. Vulnerable Patient Populations Will Suffer Most

When duplicate discounts and exploitative pricing practices reduce available public funds, patients lose access to programs that provide critical medication, preventative care, and emergency services. For example, a legislative analysis in Texas projected a $72 million shortfall in its HIV Medication Program if 340B expansion lacked adequate oversight. This illustrates how poor federal policy choices can directly translate into reduced care or financial hardship for patients.

The Case for a Mandatory Federal Claims Modifier or Clearinghouse Is Clear

CMS must reconsider its position. A mandatory federal claims modifier is a straightforward, existing solution to a complex, high-risk problem. It would:

- Prevent duplicate discounts that siphon funds from safety-net services.
- Provide consistency across state and federal programs.
- Enable automated compliance and enforcement.
- Protect the sustainability of rural and small-scale safety-net providers.
- Safeguard patients from the downstream impacts of financial exploitation.

CMS's decision to "not assume responsibility for deduplicating discounts at this time" effectively abandons the patients and providers most in need of federal protection. Rather than enabling a fairer, more transparent healthcare system, this inaction invites confusion, abuse, and harm.

States Are Hamstrung by Legal Constraints and Inadequate Oversight Tools

At least 12 states have enacted laws restricting the use of 340B claims modifiers or data-sharing with Manufacturers. CMS's decision not to require a federal solution creates a patchwork of rules and a regulatory vacuum. This lack of uniformity enables duplicate discounts that drain state Medicaid programs, undermining services that are critical to patients such as HIV treatment, chronic disease care, and rural hospital services. These are not abstract policy failures—they represent real harms to individuals relying on safety-net systems to survive.

Appropriate CMS guidance would resolve these disparities in state policies via Supremacy Clause application.

Recommendation:

CMS should immediately revise the proposed DPNP guidance to mandate a standardized, federal claims modifier or for all DPNP-related transactions. This reform is essential to protecting patient access, ensuring program compliance, and maintaining the financial sustainability of providers who serve the nation's most vulnerable.

Conclusion: Putting Patients First with a Mandatory Claims Modifier

At its core, this debate is not just about administrative codes, billing systems, or financial reconciliations—it is about people. It is about the cancer patient in a rural town who depends on a safety-net hospital for treatment. It

is about the parent of a child with a rare disease who relies on 340B-discounted medications to stay afloat. And it is about the countless individuals living with chronic conditions who face barriers to care every day.

When duplicate discounts go unchecked and safety-net resources are drained, patients are the ones who suffer—through delayed treatment, reduced services, and closures of the very facilities that serve as their lifelines. Allowing fragmented oversight to continue without a standardized claims modifier creates confusion, fuels inequity, and leaves the most vulnerable at risk.

A mandatory, standardized federal claims modifier is not just a smart policy choice — it is a patient-centered solution. It ensures that public funds are used efficiently, that life-saving medications remain accessible, and that safety-net providers can continue serving communities in need. CMS has the opportunity — *and the responsibility* — to act now, not later, to build a system rooted in clarity, fairness, and care.

We urge CMS to adopt this critical reform and put patients at the center of its policy decisions.

Thank you for the opportunity to comment. We invite you to meet with us to discuss this matter further, we can be reached by email or phone at kalvin@tiican.org , 913-954-8816, or jen@tiicann.org, 313-333-8534.
Sincerely,

Respectfully submitted,

Jen Laws
CEO
Community Access National Network (CANN)

Kalvin Pugh
Director of State Policy, 340B
Community Access National Network (CANN)