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340B Rebate Guidance Coalition Call

Issues:

- PHI information
- Multiple rebate IT programs
- Perceived Patient Definitions by Drug Companies
- Funding Difficulties
- Upfront payment of WAC
- Mixed-use drugs
- Claims data
- Disputed claims
- IRA drug classification
- Varying billing styles (hospital v. pharmacy, etc)
- Administrative costs

Analysis of Comments Already Submitted

(Click here to access all comments)

Top Concerns About the 340B Rebate Model Pilot

1. Undermining the Intent of the 340B Program

- The rebate model reverses the original purpose of providing **upfront discounts** to safety-net providers.
- It shifts financial and operational burdens from manufacturers to providers.
- Many commenters argue this contradicts congressional intent and decades of precedent.

2. Severe Financial Burden and Cash Flow Disruption

- Covered entities must pay **full drug prices upfront** and wait for rebates, creating **unsustainable cash flow gaps**.
- This is especially harmful for **rural hospitals, FQHCs, and small providers** with thin margins.

- Some facilities projected millions in additional upfront costs.

3. Increased Administrative Complexity

- The rebate model introduces **new IT systems**, **data tracking**, **claim reconciliation**, and **staff training** requirements.
- Many commenters noted that this would **divert resources from patient care**.
- Concerns about **multiple manufacturer-specific platforms** and lack of standardization were common.

4. Delayed or Uncertain Rebates

- Rebates are not guaranteed, and delays or denials could destabilize budgets.
- Lack of enforcement mechanisms for timely rebate payments was widely criticized.
- Some commenters requested **interest penalties** for late payments and **binding dispute resolution processes**.

5. Lack of Transparency and Manufacturer Accountability

- Manufacturers would gain control over rebate eligibility and data, raising concerns about fairness and misuse.
- Many called for **public disclosure of rebate terms**, **standardized data formats**, and **HRSA audit authority**.
- There were calls to prevent manufacturers from using rebate data to enforce contract pharmacy restrictions.

6. Threat to Patient Access and Safety-Net Services

- Delays in savings could lead to **reduced medication access**, **cutbacks in services**, and **clinic closures**.
- FQHCs and CHCs warned of losing wraparound services and care for uninsured patients.
- Some commenters requested **exemptions for CHCs** or **voluntary participation** for covered entities.

7. Compressed and Unrealistic Implementation Timeline

- The proposed timeline (comment deadline, manufacturer application, and January 1 launch) was deemed **too short**.
- Many requested **extensions** to allow for meaningful stakeholder engagement and operational readiness.

8. Legal and Statutory Concerns

- Several associations argued that rebate models are **inconsistent with the 340B statute**, which requires discounts at the time of sale.
- Concerns were raised about **regulatory reversals** and **lack of Congressional authorization**.

9. Data Security and Privacy Risks

- Submitting sensitive patient data to third-party platforms (e.g., Beacon) raised **HIPAA and cybersecurity concerns**.
- Commenters demanded **manufacturer liability for breaches** and **HRSA vetting of platforms**.

10. Risk of Program Expansion Without Evaluation

- Many feared the pilot could expand to all drugs without proper analysis.
- Requests were made for **impact studies**, **published findings**, and **stakeholder input before expansion**.

Suggestions and Alternatives Offered

- **Centralized clearinghouse model** to streamline data submission and reduce burden.
- **Voluntary participation** for covered entities.
- **Manufacturer-funded administrative fees** to offset costs.
- **Preservation of the upfront discount model** with enhanced oversight.
- **Pilot limited to contract pharmacy arrangements**, not mixed-use or physician-administered drugs.