340B ADR Rule Should Not Be Finalized Until HRSA And CMS Have Issued Guidance/Rulemaking Affirming Manufacturer Protections

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The 340B Program Generates Significant Profits for Covered Entities & For Profit Partners

- The 340B program continues to grow at a fast rate
  - Total purchase in 2022 = $53.7 billion, a 22.3% increase over 2021
- CEs use the steep discounts they receive to generate profits, not to pass through savings to patients
- Example – Lilly asked pharmacies what they charge for Humalog U100 Kwikpens, for which CEs pay 1 penny per mL through 340B

	Covered Entity 1 (DSH-69 Child Sites)	Covered Entity 2 (RRC-19 Child Sites)	Covered Entity 3 (DSH-15 Child Sites) *Contract Pharmacy*
340B Price (Acquisition Cost)	15¢	15¢	15¢
Covered Entity Price to an Uninsured Patient	$850	$120 But only fill prescriptions for employees and their families	Greater Than $509
Covered Entity Mark Up Percentage	566,567%	79,900%	Greater Than 339,233%
Contract Pharmacies (Number/No. of States)	123 (20 states)	46 (19 states)	61 (23 states)

Manufacturer Protections, In Statute

- Under the statute, manufacturers are supposed to be protected from two types of CE infractions

Duplicate 340B/Medicaid Discounts

- Relies on "Fee for Service" (FFS) HRSA/CMS Guidance
  - 14.8% of Medicaid utilization
- Requires HRSA/CMS guidance for Medicaid Managed Care
  - 85.2% of Medicaid utilization

Diversion

- Requires a HRSA/CMS definition of "patient"
  - 100% of 340B claims

HRSA/CMS Guidance on Protections Only Covers Fraction of Potential Entity Misconduct

- As HRSA/CMS has only ever provided guidance to covered entities on Medicaid FFS utilization, statutory protections for manufacturers only cover small percentage of 340B program
  - Under the 340B statute, if HRSA does not establish a mechanism for duplicate discounts, CMS is obligated to act (42 U.S.C. 1396r-8(a)(5)(C))
  - But CMS has not undertaken any such efforts and HRSA and covered entities seem to be unaware of the need to make this a meaningful process
- Covered entities are aware of this and resist manufacturer efforts to exercise these provisions of the statute designed to protect manufacturers

Duplicate Discounts in Medicaid Managed Care

- The covered entity community believes Medicaid Managed Care cannot be audited by manufacturers

> Drug manufacturers have a statutory right to seek permission from HRSA to conduct an audit to determine whether a covered entity is in violation of Section 340B(a)(5)(A) or (B). Neither are applicable to 340B drugs billed to managed care organizations ("MCOs"). Section 340B(a)(5)(A) prohibits duplicate

- HRSA recently told Lilly the same, even though it later relented

> HRSA also notes, for Lilly's consideration, as stated in HRSA's December 2014 Policy Release 2014-1 (https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/clarification-medicaid-exclusion.pdf), the HRSA Medicaid Exclusion File (MEF) is the mechanism for preventing duplicate discounts with regard to Medicaid Fee for Service (FFS) claims. The MEF does not apply to Medicaid Managed Care claims. As Lilly is aware, HRSA published a 340B Omnibus Guidance that proposed a mechanism for preventing duplicate discounts for both Medicaid FFS and Medicaid Managed Care claims. However, the 340B Omnibus Guidance was not finalized and HRSA does not have published guidance on how covered entities should exclude Medicaid Managed Care claims. Lilly may want to consider this information in deciding whether to initiate an audit of [redacted].

- 340B experts state that Medicaid Managed Care has never been audited by either HRSA or manufacturers

Diversion Issues a Result of HRSA's Lack of "Patient" Definition

- The term "patient" is not defined in statute
- While many entities may subscribe to HRSA's 1996 definition of "patient," more and more covered entities (encouraged by consultants/vendors) have expanded definition
  - Creative attempts to expand program include "Patient capture" "Referral capture" "Claims harvesting"
  - Many covered entities understand recent *Genesis* decision to support further expansion of "patient"
- Even *Genesis* decision recognized that HRSA "does possess authority to implement its interpretations of the statutory term 'patient'"
- Manufacturers have told HRSA the same for years
  - 2020 PhRMA petition for rulemaking
  - 2023 Lilly ADR comment letter

HRSA Guidance Shields Contract Pharmacies From Audit

- HRSA has instructed manufacturers that they should use the audit process to address any concerns related to contract pharmacies:

> Lilly purports that the rationale for its restrictive action is to prevent diversion and duplicate discounts. The 340B statute provides a mechanism by which a manufacturer can address these concerns. Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A) of the PHS Act. The 340B statute does not permit a manufacturer to impose industry-wide, universal restrictions.

- But HRSA then relies on its outdated Audit Guidelines to deny manufacturer audit of contract pharmacy relationships:
  - Section 4 of the "340B Policy, Contract Pharmacy Agreement, Process & Control Environment Review Related To 340B Drug Diversion & Duplicate Discounts" field seeks to review if contract pharmacies have been independently audited each year. This review is outside of the manufacturer audit guidelines and should be removed.
- HRSA eventually relented and permitted Lilly to audit these contracts, but with caveat that failure to audit pharmacies "not an indicator of non-compliance"

Manufacturer Audit Rights are Illusory

- While manufacturers are granted the right to audit for duplicate discounts and diversion in statute, in reality HRSA/CMS guidance has rendered those rights meaningless
  - The covered entity community knows this and acts accordingly
  - HRSA stated as much: “The historical infrequency of manufacturer audit requests along with the requirement that manufacturers audit covered entities prior to filing an ADR claim suggests that the number of manufacturer ADR claims will be low.” 87 Fed. Reg. 73516, 73518 (Nov. 30, 2022)
- Lilly presented hurdles to audits in its comment letter
  - Burden and expense of complying with extra-statutory requirements
  - Lack of clear audit standards
  - High burden of proof
  - Inability to recover even upon findings of violations

Recent Audit Attempts

Lilly's recent experiences with two audits only confirms their lack of availability in practice

Covered Entity #1

- During good faith resolution exchange, CE told Lilly it had reviewed sample and determine no duplicate discounts occurred
- 9 months later, after HRSA approved the audit, CE informs Lilly that sampled claims labeled as both 340B and Medicaid MCO
- Nearly 2 months into audit and no documents have been produced

Covered Entity #2

- Ignored Lilly's good faith resolution letters for 4 months
- Responded through legal counsel who claimed Lilly had no right to audit and was criminally liable for attempting to do so
- Continues to challenge right to audit even after HRSA approval
- Nearly 2 months into audit and no documents have been produced

Conclusion

- HRSA/CMS's lack of guidance on the Medicaid Managed Care duplicate discounts and diversion prohibitions means manufacturers do not have any practical audit rights over those topics
- Even if they did have audit rights, HRSA policies have made these audits expensive, onerous, and without the prospect of recovery
- Using ADR process to define these terms as HRSA has proposed is problematic
  - Deprives stakeholders of ability to comment
  - Unfair to manufacturers who would only learn retrospectively of HRSA standards
  - Burdens the federal court system
- Finalizing the ADR final rule without first ensuring the underlying manufacturer rights puts the cart before the horse so the final rule should be returned to HRSA