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340B Program Restatements and Refunds

Navigate current requirements and plan for the future

Introduction

It is a time of change in the 340B Program. Manufacturers should closely monitor 340B Program developments and prepare to respond promptly and effectively to changes in legal requirements. This may make it necessary to devote additional resources to 340B Program compliance today.

The 340B Drug Pricing Program (340B Program), which is administered by the Health Resources and Services Administration (HRSA), appears to be entering a period of possibly significant change. The effective date of the Ceiling Price and Manufacturer Civil Monetary Penalties Regulation (Final Rule), which HRSA published in January 2017, has been delayed until July 1, 2019,[1] and revisions to that regulation remain possible.

Furthermore, HRSA recently stated that the system for manufacturers to report ceiling prices to HRSA is expected once the Final Rule goes into effect,[2] which means that system may now come online by mid-to-late 2019 at the earliest.

Congressional action regarding the 340B Program also is possible and could result in further changes to the program that could affect manufacturer compliance obligations.

WHAT TO KNOW

- What existing restatement and refund requirements apply to manufacturers today, prior to the effective date of the Final Rule?
- How would the Final Rule (as published in January 2017) affect existing restatement and refund requirements, and how can manufacturers prepare for these changes?

Today's restatement and refund requirements

The 340B statute requires manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price."[3] As amended by the Affordable Care Act, the 340B statute requires HRSA to enact regulations regarding civil monetary penalties and to provide a mechanism for manufacturers to make refunds to covered entities in cases of overcharges:

> [T]he Secretary shall provide for improvements in compliance by manufacturers... in order to prevent overcharges and other violations of the discounted pricing requirements [, including] [o]versight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.[4]

HRSA published the Final Rule to comply with this statutory requirement. However, the Final Rule is not yet in effect, and this paper reviews current manufacturer obligations in two different scenarios that could trigger a 340B ceiling price restatement and refund:

- Restatement of data reported to the Medicaid Drug Rebate Program (MDRP)
- True-up of the estimated 340B ceiling price for a new drug

Restatement of data reported to the MDRP

Manufacturers report Average Manufacturer Price (AMP) and Best Price (BP) to the MDRP, which form the basis for calculating the Medicaid Unit Rebate Amount (URA). Retroactive changes to those pricing data have the potential to be viewed as impacting the 340B ceiling prices, calculated as AMP minus the URA, that were derived from those data as originally submitted. MDRP regulations require manufacturers to update BP for changes, whether driven by late-arriving data or errors, and to revise AMP for errors—in both cases within three years of when those data originally were due.[5] In practice, manufacturers routinely do restate BP to reflect late arriving data and restate AMP and BP as needed to correct errors of all types as well.

A change in AMP or BP could generate a lower ceiling price, so that the manufacturer potentially could be viewed as having overcharged covered entities that purchased at the original ceiling price. On the other hand, such a change also could generate a higher ceiling price, so that the manufacturer potentially could be viewed as having undercharged covered entities in the first instance. This raises the question of whether a manufacturer must restate the 340B ceiling price—and offer refunds in the case where the 340B ceiling price would be viewed as having been reduced—as a result of (1) AMP or BP restatements to correct errors, or (2) "routine" BP restatements for late-arriving data.

Prior to the Final Rule, the only policy guidance issued by HRSA on this topic dates from the inception of the 340B Program, in February 1993, and relates to whether manufacturers are required to offer refunds on the basis of MDRP restatements. There, HRSA stated that "[p]urchases made when a new quarterly price is in effect are governed by the new price."[6] The guidance does not distinguish between MDRP restatements to correct errors versus BP true-ups.

WHAT TO KNOW

- It is the practice of some manufacturers to restate 340B ceiling prices and provide refunds to covered entities when MDRP restatements to correct AMP or BP errors result in a lower 340B ceiling price, but to not do so if the lower 340B ceiling price is the result of a routine BP true-up for late-arriving data.

True-up of estimated 340B ceiling prices for new drugs

The 340B ceiling price is based on AMP and URA figures from two quarters prior to the current quarter, and such historic figures are not available for newly-launched drugs. Manufacturers therefore must estimate the ceiling price for new drugs. Prior to the Final Rule, HRSA addressed the 340B ceiling price estimation for new drugs in guidance issued in October 1995.[7] That Federal Register notice was not particularly clear in its direction as to the formula for the 340B ceiling price estimation or the timeline for implementing the estimated price. For example, the guidance speaks of estimating the ceiling price for three quarters after launch of the drug, but the notice also included an example table that showed an estimation period of four quarters.

The 1995 notice refers to adjustments by the manufacturer necessary to "reconcile" the estimated ceiling prices, but it does not address whether the manufacturer is obligated to publish such revised ceiling prices or otherwise make covered entities aware of any such revision. If the "reconciled" ceiling price is lower than the estimated ceiling price, the manufacturer potentially could be viewed as having overcharged covered entities that purchased at the estimated ceiling price.[8] On the other hand, if the "reconciled" ceiling price is higher than the estimated ceiling price, the manufacturer potentially could be viewed as having undercharged covered entities. This guidance places on the covered entities the obligation to request a refund for overcharges if the actual ceiling price is lower than the estimated ceiling price.

Current practices related to restating 340B ceiling prices and issuing refunds to 340B covered entities

Prior to the Final Rule, HRSA did not address the manner in which manufacturers should restate the 340B ceiling price or issue refunds to covered entities in connection with MDRP restatements—either as a result of the correction of errors or due to BP true-up. In the context of truing up estimated ceiling prices for new products, the 1995 HRSA guidance, which applies as HRSA policy to the period before the Final Rule becomes effective, also does not address how manufacturers are to calculate refunds that may be due to covered entities in case of 340B ceiling price restatements.

In instances where manufacturers have concluded that it is appropriate to offer refunds to covered entities, they have generally proceeded in the manner they view as consistent with their obligations under the 340B statute and Pharmaceutical Pricing Agreement. Many manufacturers are applying their standard commercial practices in the context of 340B covered entity refunds, which may include:

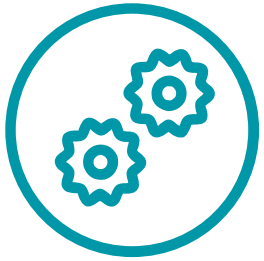
- Offsetting overcharges against undercharges (sometimes referred to as netting)
- Establishing a *de minimis*, or materiality, threshold for the amount of any refund

In structuring their approach to covered entity refunds, manufacturers typically consider HRSA's 340B non-discrimination policy, which states that the practice adopted with respect to 340B covered entities should be the same practice the manufacturer takes with respect to its commercial customers.[9]

CASE STUDY 1

Calculating restated 340B ceiling prices and refunding all covered entities

Deloitte helped a global pharmaceutical manufacturer calculate restated 340B ceiling prices and the refund amount owed to each covered entity across impacted products and the restatement time period, factoring in only the overcharges (and not undercharges), consistent with the manufacturer's assumptions. Correspondence and a refund check were sent to all covered entities owed a refund, regardless of amount, as the manufacturer opted not to set a *de minimis* threshold for payment of refund amounts.



CASE STUDY 2

Calculating restated 340B ceiling prices and setting a *de minimis* threshold for overcharges

Deloitte helped a manufacturer follow a similar process with the exception that it set a *de minimis* threshold of $1.00 and refunded overcharges to covered entities via wholesaler credits using the Manufacturer Refund Service offered by Apexus, the 340B prime vendor.[10]

CASE STUDY 3

Calculating restated 340B ceiling prices and asking covered entities to contact the manufacturer for a refund

Deloitte helped a manufacturer apply assumptions to net overcharges and undercharges when calculating the refund amount to each covered entity across products and quarters in a restatement period, set a *de minimis* threshold dollar amount above which refunds would be paid, and asked covered entities to contact the manufacturer to request a refund.

Future requirements: How can manufacturers prepare?

The Final Rule, in the form in which HRSA published it in January 2017, addresses a number of topics relating to manufacturer restatements and refunds to 340B covered entities, each of which is discussed in further detail below, including:

MDRP restatements

A requirement for manufacturers to restate 340B ceiling prices and issue refunds to covered entities within a defined time frame as a result of MDRP restatements (i.e., in the case of AMP or BP restatements for errors and in the case of BP true-ups for late-arriving data).

True-up of estimated ceiling prices

A requirement for manufacturers to true-up estimated ceiling prices for new drugs and issue refunds to covered entities within a defined timeframe.

Offsetting/*de minimis* threshold

A prohibition against offsetting overcharges against undercharges to 340B covered entities and against applying a *de minimis* threshold to refunds, absent consent from the covered entity that is due a refund.

As the Final Rule is not yet in effect, the foregoing provisions are not currently required of manufacturers. Nevertheless, manufacturers may want to evaluate if it may be appropriate or desirable to move ahead with adopting some of the Final Rule provisions, in particular with respect to the ceiling price estimation for new drugs.

GENERAL FINAL RULE CONSIDERATIONS

- It may be advisable to move ahead with defining future processes for calculating estimated 340B ceiling prices for new products, performing the true-up of such estimated ceiling prices, restating ceiling prices following MDRP restatements, and efficiently refunding overcharges where the 340B ceiling price is reduced.
- 340B ceiling price revisions and refunds might need to be done regularly and frequently, depending on the timing and frequency of a manufacturer's planned new product launches and BP true-up schedule.
- Manufacturers should consider piloting new ceiling price restatement and refund processes prior to the Final Rule effective date to support smoother implementation, in light of the significant operational and implementation aspects to the new requirements.

Restatements of data reported to the MDRP—Post-Final Rule

The Final Rule requires manufacturers to offer refunds if a MDRP restatement results in a reduction of the 340B ceiling price on a retroactive basis.[11] A common reason for MDRP restatements is the requirement to update BP for late-arriving data. Manufacturers typically make BP true-up filings on a rolling basis, such as one year after the end of the applicable quarter. This new mandate to restate the 340B ceiling price for routine BP true-ups is a potentially significant change for manufacturers.

Final Rule considerations related to routine BP true-ups:

- Medicaid regulations give manufacturers up to three years to update their pricing data. While manufacturers typically true-up BP on a rolling basis, the obligation to true-up the 340B ceiling price and issue refunds may be a reason to consider making BP true-up filings for multiple quarters at once, to reduce the operational burden of the 340B ceiling price restatement and refund process.
- Manufacturers may take different approaches to how they calculate BP as initially submitted, 30 days after quarter end, when the data needed to calculate the actual BP for the quarter typically are not yet available. A new 340B obligation to true-up the 340B ceiling price and issue refunds and the associated operational burden may lead some manufacturers to consider other reasonable approaches to calculating the BP initially submitted to CMS.

PREPARE FOR THE CHANGES

- Stakeholders and leadership should understand the increased compliance and financial risk associated with failure to comply with the Final Rule, including civil monetary penalties (CMPs).
  - The Final Rule specifies that CMPs may be imposed on manufacturers for "knowingly and intentionally" overcharging a 340B covered entity more than the 340B ceiling price, in the amount of up to $5,000 per instance. CMPs will be in addition to repayments of overcharges to 340B Covered Entities.[12]
- 340B Program compliance should receive as much attention as other price reporting compliance matters, with effective compliance controls in place.

True-up of estimated 340B ceiling prices for new drugs—Post-Final Rule

The Final Rule for the first time introduces a clear methodology for estimating the 340B ceiling price for new drugs, namely Wholesale Acquisition Cost (WAC) minus the applicable MDRP basic rebate percentage (23.1 percent for most single-source and innovator drugs, 17.1 percent for clotting factors and products approved exclusively for pediatric indications, and 13 percent for non-innovator multiple-source drugs).

The Final Rule also requires the manufacturer to identify whether the estimated 340B ceiling price was higher than the "actual" 340B ceiling price and to proactively refund any overcharged 340B covered entities within 120 days of the determination that an overcharge occurred.[13]

PREPARE FOR THE CHANGES

- It may be appropriate for a manufacturer to adopt the Final Rule estimation methodology today, even while the Final Rule is not yet in effect, if the Final Rule methodology is simpler than the manufacturer's current approach.
- Manufacturers expecting to launch new products should make sure internal stakeholders responsible for operationalizing the Final Rule changes are well-versed in the new requirements.
- Manufacturers should determine how to implement specific Final Rule requirements related to estimated ceiling prices:
  - Establish a policy as to when the 120-day refund clock starts to run.
  - Consider whether the Final Rule WAC-based methodology can be viewed as a ceiling price, so that sub-ceiling prices are permitted if the manufacturer has more accurate estimation approaches available. A lower estimated ceiling price may obviate the need for subsequent refunds but could result in undercharges to 340B covered entities that the manufacturer cannot recoup.

Current manufacturer practices with respect to issuing refunds to 340B covered entities—Post-Final Rule

The Final Rule expressly prohibits manufacturers from offsetting overcharges against undercharges and applying a *de minimis*, or materiality, threshold to refunds, even if this is the manufacturer's ordinary commercial practice, absent the consent of the covered entity due the refund.[14]

Both offsetting overcharges against undercharges and the application of *de minimis* thresholds are standard commercial practices in the pharmaceutical industry. While HRSA acknowledged in the Final Rule that it does not intend to prevent manufacturers from using standard industry practices with respect to netting overcharges and undercharges and establishing a *de minimis* threshold,[15] the Final Rule policies run counter to common industry practice by requiring manufacturers to obtain consent from **each and every** 340B covered entity due a refund prior to engaging in these standard practices. This means that in practice, manufacturers may have to maintain two separate, divergent approaches and systems with respect to refunds: one to accommodate covered entities, and another for commercial customers.

In general, manufacturers should make sure their 340B compliance-related policies and procedures are documented and aligned with the manufacturer's practices.

WHAT TO KNOW

- HRSA released its new 340B Office of Pharmacy Affairs Information System (OPAIS) in 2017 and has indicated that OPAIS in the future will include a secure pricing system component that manufacturers will be required to use to report their 340B ceiling prices each quarter.
- HRSA has not yet released that component, but manufacturers should monitor HRSA communications for any announcements as to its timing. The system also will compare the manufacturer-reported ceiling price to a price that HRSA will calculate on its own, based on MDRP data, and will provide a mechanism for reconciling the two figures if there is a discrepancy.

To prepare for the changes:

- Manufacturers should check their product attribute data on file with the MDRP to avoid issues when HRSA uses the MDRP data.
- Manufacturers should consider having an action plan in place for when ceiling price reporting begins, including engagement with HRSA as needed if there are problems.

Staying a step ahead

If the Final Rule becomes effective as published in 2017, it would transform HRSA from an agency that has historically been limited to issuing only guidance, to one with the authority to initiate civil monetary penalty proceedings against manufacturers. Statutory changes to the 340B Program remain possible as well.

Manufacturers are required to comply with existing 340B Program requirements that are in effect today under the 340B statute and Pharmaceutical Pricing Agreement, and HRSA policy statements indicate how it believes manufacturers should act in the absence of requirements. Each manufacturer should ensure it has identified how the current requirements apply to its business and products, and that existing practices support robust compliance to be well prepared for the future 340B compliance landscape, which is expected to become significantly more complex.

The pending Final Rule and other 340B changes, such as the OPAIS ceiling price reporting system, create an environment of uncertainty for manufacturers as to how to effectively prepare for upcoming 340B Program requirements. Manufacturers should proactively plan ahead now for the forthcoming changes, particularly as it is never clear how much time they will have to establish compliance once a new requirement is announced or becomes effective. Consider defining and piloting new restatement and refund processes prior to the Final Rule effective date to support timely and efficient implementation.

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If you'd like to learn more about how leading pharmaceutical manufacturers are approaching 340B Program compliance, we'd welcome the opportunity to talk with you.

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Endnotes

1. 83 Fed. Reg. 25,943 (June 5, 2018).
2. HRSA: Fiscal Year 2019 Justification of Estimates for Appropriations Committees, https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2019.pdf.
3. 42 U.S.C. § 256b(a)(1).
4. 42 U.S.C. § 256b(d)(1)(A) and (d)(1)(B)(ii)(II).
5. 42 C.F.R. § 447.510(b).
6. *See* Letter from Marsha Alvarez, Director, Office of Drug Pricing Program [previous name of Office of Pharmacy Affairs], to Joel Bobula, Manager, Public Studies, Pharmaceutical Mfr.'s Ass'n (Feb 25, 1993).
7. 60 Fed. Reg. 51,488 (Oct 2, 1995).
8. "[T]here was an attempt to evenly split the administrative burden of the process between the manufacturer and the entity. If an entity wishes a pricing adjustment, the dollar amount in question, one would expect, must be significant enough to balance the administrative burden involved in documenting and developing the request." *Id.* at 51,488.
9. *See* 59 Fed. Reg. 25,110 (May 13, 1994). *See also* 340B Drug Pricing Program Notice, Release No. 2011-1.1, Clarification of Non-Discrimination Policy, https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/nondiscrimination05232012.pdf.
10. For more information on Apexus' Manufacturer Refund Service, refer to: www.340bpvp.com/manufacturer-refund-svc/.
11. *Id.* at 1,230 (codified at 42 C.F.R. § 10.11(b)(4)).
12. 42 C.F.R. § 10.11(a).
13. 82 Fed. Reg. at 1,229 (codified at 42 C.F.R. § 10.10(c)).
14. *Id.*
15. *Id.* at 1,220, 1,225.

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