MEMORANDUM

To: **Powers' Clients and Friends**

From: **Stephen Kuperberg, Counsel**
William von Oehsen, Principal
Barbara Straub Williams, Principal
Brad Lang, Counsel

Date: **March 6, 2019**

Re: **Manufacturer Overcharges under 340B: How to Right a Wrong**

Beginning April 1, 2019, safety net providers participating in the 340B program will have a way to evaluate whether they have been overpaying for 340B drugs through HRSA's 340B ceiling price database. But will pharmaceutical manufacturers be required to make repayment when overcharges are discovered and will those repayments cover past periods? As the April 1 deadline nears, manufacturers should not evade repayment of past overcharges to participating 340B providers lest those overcharges become a "wrong without a remedy."

Background

Congress enacted the 340B program with bipartisan support over 25 years ago, stating, "[i]n giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] The law conditions a manufacturer's participation in the Medicaid program on the manufacturer's agreement to charge 340B covered entities at or below a ceiling price, which approximates the amount that the manufacturer pays to States under the Medicaid drug rebate program. [2]

Nevertheless, a series of reports by the Department of Health & Human Services Office of Inspector General (HHS-OIG) in the early 2000s[3] documented that manufacturers routinely charge more than the 340B ceiling price to covered entities. Furthermore, those reports stated that covered entities typically could not identify overcharges and that HRSA did not rectify

[1] H.R. Rep. No. 102-384, pt. II (Sept. 22, 1992).
[2] *See* Pub. L. 102-585 tit. VI § 602, 106 Stat. 4967-71 (Nov. 4, 1992), *as codified at* 42 U.S.C. § 256b(a)(1) & (2).
[3] *See* Janet Rehnquist, "Pharmaceutical Manufacturers Overcharged 340B-Covered Entities," March 2003, *available at* https://www.hrsa.gov/sites/default/files/opa/programrequirements/reports/manufacturersovercharge031003.pdf ; Daniel R. Levinson, "Deficiencies in the Oversight of the 340B Drug Pricing Program," *available at* https://www.hrsa.gov/sites/default/files/opa/programrequirements/reports/oversightdeficiencies102005.pdf ; Daniel R. Levinson, "Review of 340B Prices," *available at* https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf.

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overcharges by requiring repayment or terminating manufacturers participation in the 340B program (and thereby their participation in the Medicaid program). At this time, covered entities seeking recoupment of manufacturer overcharges (when they could be identified) had resort only to an "informal dispute process" that HRSA first announced in 1996 and which does not require the manufacturer to participate.[4]

Following these reports, Congress mandated that, "the Secretary shall provide for improvements in compliance by manufacturers … in order to prevent overcharges and other violations of the discounted pricing requirements" of the program.[5] Among those improvements were the "development of a system to enable the Secretary to verify the accuracy of ceiling prices" and the "establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge."[6] Additionally, "[n]ot later than 180 days after March 23, 2010," Congress mandated that the Secretary "shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged."[7]

The *Santa Clara* case

In 2011, the Supreme Court decided unanimously in *Astra USA v. County of Santa Clara*, 563 U.S. 110 (2011), that covered entities do not have the right to sue manufacturers for overcharges and that only the Secretary may enforce the manufacturer's obligation to change at or below the 340B ceiling price.[8] At oral argument,[9] Justice Breyer questioned the manufacturers' attorney regarding remedies available to the covered entities:

> Stephen G. Breyer: Why can't [the 340B covered entities] file a claim with the … Secretary …? Is there an administrative remedy of some kind that would be reviewable in the courts for reasonableness …? Normally under the law from Marbury v. Madison onward, where there's a wrong, there's a remedy…. And the remedy could be administrative, could be judicial, et cetera. But you're saying there's none?
>
> Manufacturers' attorney: No.

Later in the argument, Justice Ginsburg questioned the government regarding administrative remedies:

> Government's attorney: So Congress … to the extent it had concerns about enforcement … the way it reacted was … simply to give the agency enhanced authority in order to adjudicate …. to put in place this administrative remedy which will allow covered entities to bring these claims ….

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[4] 61 Fed. Reg. 65,406-13 (Dec. 12, 1996).
[5] Pub. L. 111-148 tit. VII § 7102(a), 124 Stat. 823-24 (Mar. 23, 2010), *as codified at* 42 U.S.C. § 256b(d)(1)(A).
[6] *Id.*
[7] 42 U.S.C. § 256b(d)(3).
[8] Eight justices ruled in favor of manufacturers. Justice Kagan took no part in the consideration or decision of the case.
[9] Transcripts and recordings of the oral argument are available at https://www.oyez.org/cases/2010/09-1273.

> Ruth Bader Ginsburg: It just went into effect in January 1, right? But are there -- are there plans to implement it?
>
> Government's attorney: Yes. The agency is moving ahead with that. The agency has already issued an advanced notice of proposed rulemaking back in the fall. And it has solicited comments about how the -- the administrative scheme should look. That comment period has closed, and so now the agency is in the process of -- of moving forward ….

Justice Ginsburg's opinion took note:

> If a manufacturer overcharges a covered entity, HRSA may require the manufacturer to reimburse the covered entity; HRSA may also terminate the manufacturer's PPA, which terminates as well the manufacturer's eligibility for Medicaid coverage of its drugs. Currently, HRSA handles overcharge complaints through informal procedures. The [2010 addition] provides for more rigorous enforcement [and] directs the Secretary to develop formal procedures for resolving overcharge claims. Under those procedures, which are not yet in place, HRSA will reach an 'administrative resolution' that is subject to judicial review under the Administrative Procedure Act (APA).[10]

Because it appeared, based on the Government's representations, that the publication of the new regulations implementing a formal administrative resolution process was imminent, the Court decided that covered entities could not seek recovery against manufacturers outside the procedures in those soon-to-be implemented regulations.[11]

Current administrative landscape

Notwithstanding the government's assurances to the Supreme Court, however, HRSA failed to implement the rules that Congress mandated even many years after the statutory deadlines for doing so. It was not until a group of 340B covered entities sued in 2018 that HRSA implemented some, but not all, of the long-overdue regulations.[12] The regulations that HRSA implemented, effective January 1, 2019, include requiring manufacturers to submit 340B ceiling prices and the imposition of civil monetary penalties (CMPs) on manufacturers who knowingly and intentionally overcharge covered entities. Significantly, the regulations also adopt HRSA's long-standing "penny pricing" policy, under which manufacturers must charge covered entities a penny when the ceiling price calculation results in an amount less than $0.01. Subsequently, HRSA announced that it would publish ceiling prices for January 1, 2019 and subsequent periods in a database to be available to covered entities beginning in April 2019. Significantly, however, HRSA still did not implement the mandatory Administrative Dispute Resolution

[10] *Santa Clara*, 563 U.S. at 116 (citations omitted).
[11] *Id.* at 121-22 (citations omitted).
[12] 83 Fed. Reg. 61,563 (Nov. 30, 2018); *see also* 82 Fed. Reg. 1210 (Jan. 5, 2017).

process that Congress had directed be promulgated by September 20, 2010,[13] leaving only the voluntary, informal dispute process as the administrative vehicle by which covered entities may seek recoupment of overcharges.

The informal dispute process

Despite its "voluntary" and "informal" descriptors, HRSA's informal dispute process does provide a clear procedure by which covered entities may raise claims of manufacturer overcharges and seek relief from the Secretary:[14]

1. First, the covered entity must notify the manufacturer of the overcharge and attempt in good faith to resolve the dispute.[15]
2. If the parties are unable to resolve the dispute, the covered entity must submit a written request for review to the Director of the Office of Pharmacy Affairs (OPA) within 30 days, setting forth specific facts that are in dispute, including copies of any documents supporting the claim, and evidence of the good faith effort to resolve the dispute.[16]
3. HRSA's Director of the Bureau of Primary Health Care must then appoint a committee of at least three people (with a chairperson from OPA and members from other sections of the Public Health Service) to review the dispute. The chair must send a letter to the manufacturer within 30 days of receipt of the request for review, requesting a response or rebuttal. The manufacturer then has 37 days to respond.
4. Upon receipt of the manufacturer's response or rebuttal, the review committee must review all of the documentation and may, at its discretion, invite the parties to "discuss" the issues with the committee, to submit additional material, or both.

[13] Although outside Congress's September 20, 2010 deadline, HRSA proposed rules governing its binding Administrative Dispute Resolution process in 2016, 81 Fed. Reg. 53,381 (Aug. 12, 2016), but later withdrew those rules, *see* https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AA90.
[14] 61 Fed. Reg. 65,406 (Dec. 12, 1996).
[15] Apexus, HRSA's prime 340B vendor, suggested in an FAQ posted on February 8, 2019 that the covered entity should check the labeler code on 340B OPAIS, check the Medicaid Drug Rebate Program labeler code, validate the correct price using the 340B OPAIS pricing system, verify price accuracy using the Prime Vendor Program website if applicable, work with the entity's wholesaler or directly with the manufacturer to resolve the pricing issue, and if necessary, contact OPA by completing a Price Unavailable form for further investigation by OPA. *See* https://www.340bpvp.com/resourceCenter/faqSearch.html?category=content&Ntt=1239. To date, HRSA has indicated that it intends to restrict access to the ceiling price database to the Authorized Official or contact person for each covered entity, on a view-only basis, without opportunity to download data or permit other users access. These policies appear overly restrictive in light of the Congressional mandate to provide meaningful access to the ceiling price data and counterproductive to HRSA's interests in efficient administration of the 340B program.
[16] The HRSA guidance references the Office of Drug Pricing, which is the predecessor agency to OPA.

5. Within 30 days of the manufacturer's response, the committee must prepare a written decision, either dismissing the dispute or providing its proposed decision.
6. Within 30 days of receiving the committee's determination, either party may appeal to the HRSA Administrator, who must appoint a review official or committee, and who must respond to any appeal requests within 30 days from the receipt of the request.
7. If the final determination is that a manufacturer violated the 340B statute or its agreement to provide drugs at 340B ceiling prices, HRSA may terminate the manufacturer's participation in the 340B program (and, therefore, the Medicaid program) *or take other actions, as deemed appropriate*. After the dispute is resolved, the manufacture must pay any amounts owed no later than 30 days following a final determination.[17]

Several important points emerge from HRSA's "informal" and "voluntary" dispute process policy. First, prior to April 1, 2019, covered entities did not have the evidence of demonstrate overcharges under the process[18]—the new HRSA ceiling price database will give them that information. Second, although the process is described as "informal" and "voluntary," the policy provides for specific and mandatory dates by which the agency will act, irrespective of the manufacturer's choice to respond and participate. Third, the process requires the agency to make a determination and provides that the agency will take action, including terminating the manufacturer's participation with 340B and Medicaid, or other action "as deemed appropriate." This other action could include ordering a repayment. In addition, beginning in January 2019, the penalties should include referral to HHS-OIG for imposition of CMPs to redress knowing and intentional overcharges. Fourth, in light of the *Santa Clara* case establishing that covered entities do not currently have the right to bring an action against manufacturers for overcharges, the agency has an obligation to act on overcharge claims or covered entities will be left in precisely the circumstance that the government assured the Supreme Court would not occur—suffering a "wrong without a remedy."

"Retroactivity" and past overcharges

Covered entities should be able to identify and seek repayment for any ceiling price data on the HRSA database, which will include data beginning with the first quarter of 2019 forward. The question becomes whether covered entities will be able to recoup past overcharges. Despite statements by HRSA in 2017 that it would not enforce manufacturer reporting

[17] *See* 61 Fed. Reg. at 65,412-13 (emphasis added).
[18] *See, e.g.*, Brief of a Coalition of 340B Entity Groups as *Amicus Curiae* in Support of Respondent in *Astra USA, Inc. v. County of Santa Clara*, No. 09-1273 (Dec. 20, 2010) (outlining history of HRSA unresponsiveness to requests by covered entities to investigate overcharges), *available at* https://www.americanbar.org/content/dam/aba/publishing/preview/publiced_preview_briefs_pdfs_09_10_09_1273_RespondentAmCuCoalitionof340BEntityGrps.pdf. To the best of our knowledge, HRSA's informal dispute process has only been invoked once—and then by a manufacturer, not a covered entity.

requirements and CMPs retroactively,[19] HRSA also made clear that the obligation to charge at or below ceiling prices has been effective, and the ceiling price calculation has been statutorily defined, since the start of the 340B program.[20] Furthermore, HRSA has access to the historical ceiling prices even if the manufacturers did not report them, or reported them inaccurately.[21] HRSA also noted that its "penny pricing policy has been in place for many years"—and that the alternative to charging a penny would be to have a 340B ceiling price of zero.[22] Accordingly, while manufacturers' reporting obligations, and potential liability for CMPs for knowing and intentional overcharges, would begin January 1, manufacturers have always been responsible, and will continue to be responsible, to repay past overcharges.

Past overcharge look-back and potential statutes of limitations

If a covered entity discovers an overcharge through the new HRSA database, and it has records showing the same or similar pricing from prior quarters, it is reasonable to assume that an overcharge occurred in those earlier periods, particularly for drugs subject to the penny pricing policy. The HHS-OIG stated in May 15, 2018 "that 14 percent of all purchases by 340B entities were in fact over the ceiling price…. So, we do in fact have evidence that overcharging has taken place."[23] Furthermore, HRSA has previously acknowledged that "a small number of manufacturers have informed HHS over the last several years that they charge more than $0.01 for a drug with a ceiling price below $0.01" and that it "believes" that a majority of—but far from all—manufacturers follow the "long-standing HHS policy" on penny pricing.[24]

Covered entities could and should be able to seek repayment for historical overcharges. Because HRSA has access to historical ceiling price data, it need not have the "voluntary" participation of the manufacturer to determine the scope of an overcharge once the covered entity meets the threshold requirements of the informal dispute process.[25] Significantly, although the proposed mandatory Administrative Dispute Resolution process included a three-

[19] *See* 82 Fed. Reg. 1210, 1211 ("Other commenters asked HHS to revise the effective date of the final rule to 180 days after March 23, 2010, which would allow HHS to impose CMPs retroactively…. The final rule is effective March 6, 2017 …. HRSA plans to begin enforcing the requirements of this final rule at the start of the next quarter, which begins April 1, 2017. Manufacturers that offer 340B ceiling prices as of the quarter beginning April 1, 2017 must comply with the requirements of this final regulation. HHS believes that this timeframe provides manufacturers sufficient time to adjust systems and update their policies and procedures. HHS disagrees that the rule should be implemented retroactively.").
[20] *See* 82 Fed. Reg. at 1214.
[21] *Id*.
[22] 82 Fed. Reg. at 1216, 1214.
[23] Examining Oversight Reports on the 340B Drug Pricing Program, Spoken Testimony of Ann Maxwell, Assistant Inspector General for Evaluation and Inspections, Office of the Inspector General Before the United States Senate Committee on Health, Education, Labor and Pensions (May 15 2018).
[24] 83 Fed. Reg. at 20,009.
[25] Although it does not widely publicize the service, HRSA also will confirm for covered entities on a case-by-case basis whether the ceiling price for a past quarter resulted in an overcharge to the entity for that quarter. Covered entities may be able to avail themselves of this service concurrently with the process of resolving historical overcharges through the informal dispute process.

year look-back period for resolving overcharges,[26] neither the informal dispute process, nor the 340B statute, contains such a limitation.[27]

Potentially, HRSA might decide that its authority to enforce penalties on a manufacturer for overcharges is limited by the general federal statute of limitations governing enforcement of a "civil fine, penalty or forfeiture, pecuniary or otherwise."[28] However, Courts have held that "[s]tatutes of limitation sought to be applied to bar rights of the government[ ] must receive a strict construction in favor of the government,"[29] and so whether the five year default statute of limitations would apply to a HRSA enforcement action would likely depend on whether HRSA's enforcement against the manufacturer imposes a "civil fine, penalty or forfeiture" under a strict construction of those terms. Even if a five-year limit were applicable, if the manufacturer's overcharges were continuous, part of a pattern of fraudulent concealment, or both, the five-year limit could be extended or tolled.[30] Alternatively, HRSA might adopt the same 10-year look-back that CMS and other parts of HHS impose for repayment of overpayments, on the theory that 10 years is the outer limit of the False Claims Act statute of limitations.[31] Significantly, because there is no statute of limitations for manufacturers having to repay Medicaid rebates under the Medicaid Drug Rebate Program, HRSA could reasonably apply the same logic to the 340B program. Whether HRSA pursues a five-year look-back, a ten-year look-back, or one that dates back to the establishment of the program, it is clear that manufacturers should not be able to evade repayment of overcharges to 340B safety-net providers participating in the program.

We will continue to monitor the roll-out of HRSA's ceiling price database, including further modifications to access and manufacturer compliance.[32] If you have any questions on how the ceiling price database or recoupment of past manufacturer overcharges may affect your organization, please contact Steve, Bill, Barbara, or Brad, or the Powers attorney with whom you normally work.

[26] *See* 81 Fed. Reg. at 53,387 ("A covered entity … must file a claim for administrative dispute resolution in writing to HRSA within 3 years of the date of the alleged violation.").
[27] *See generally* 42 U.S.C. § 256b.
[28] *See* 28 U.S.C. § 2462.
[29] *3M Co. v. Browner*, 17 F.3d 1453, 1455-58 (D.C. Cir. 1994); *see also United States v. Meyer*, 808 F.3d 912, 914 (1st Cir. 1987).
[30] *See, e.g., SEC v. Koenig*, 557 F.3d 736, 739-40 (7th Cir. 2009); *SEC v. Huff*, 758 F. Supp. 2d 1288, 1341-42 (S.D. Fla. 2010); *Harmon Indus., Inc. v. Browner*, 19 F. Supp. 2d 988, 998-99 (W.D. Mo. 1998).
[31] *See, e.g.,* 77 Fed. Reg. 9179, 9184 (Feb. 16, 2012).
[32] In fact, since January 2019 Apexus has added over 70 FAQs, many of which relate to manufacturer compliance.