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# 340B Drug Program Year in Review and 2020 Predictions

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The past year saw a number of important developments affecting the 340B Drug Discount Program. With lawmakers and regulators continuing to focus on drug prices and price transparency, it is highly likely that 2020 will be a critical year for the 340B program.

This article provides an in-depth review of the latest developments impacting the 340B program and offers predictions for 2020. All 340B stakeholders should continue to monitor 340B program developments and provide input through the rulemaking comment process and otherwise.

**2020 Legislative Outlook**

The 116th Congress, Second Session, commenced on January 7. As the 2020 presidential and congressional campaigns get underway, Congress also faces an ambitious health care agenda in the year ahead. Below are highlights of legislation Congress is likely to consider, and as noted, reducing prescription drug costs remains a top priority. The administration will likely continue to use Executive Orders and regulations to address its key priorities, including 340B drug pricing and related matters (e.g., site neutral payments).

Major health care legislative issues include the following:

- prescription drugs costs;
- rural health;
- surprise medical billing;
- extending expiring public health programs (e.g., Community Health Centers, National Health Service Corps, Teaching Health Centers that offer Graduate Medical Education (GME);
- extending expiring Medicaid programs and funding (e.g., Community Mental Health Services Demonstration Program, temporary increase in the Federal Medical Assistance Percentage); and
- extending expiring Medicare programs and funding (e.g., funding for Quality Measure Endorsement, Input, and Selection, funding for outreach and assistance for low-income programs, and appropriations and transfers to the Patient Centered Outcomes Research Trust Fund).

The public health, Medicaid, and Medicare extenders were included in the year-end spending packages that the President signed into law as 2019 drew to a close. However, funding was only extended through May 22, 2020. The May 22 health care extenders deadline is viewed as the best possible opportunity to address both prescription drug pricing and surprise medical billing.

The White House announced the President's Fiscal Year 2021 budget request will be sent to Congress on February 10. Although budget requests depend on congressional action, they lay out the administration's spending and policy priorities for the coming year. Previous budget submissions under the Trump administration have proposed numerous changes to the 340B program. These

changes have included expanding the Health Resources and Services Administration's (HRSA's) regulatory authority over the 340B program, changing Medicare reimbursement for 340B drugs, establishing 340B user fees, and increasing covered entity reporting requirements.

In commenting on a January 2020 Government Accountability Office (GAO) report on preventing duplicate discounts under the 340B program and Medicaid drug rebate program,[1] the Department of Health and Human Services (HHS) indicated that HRSA lacks authority to promulgate regulations and enforce requirements that apply to Medicaid managed care organization (MMCO) claims for 340B drugs. The President's budget likely will attempt to tackle HRSA's lack of authority and urge Congress to take action.

**Reimbursement Round-up**

*Medicare Part B 340B Payment Reduction Litigation*

In its Calendar Year (CY) 2018 Outpatient Prospective Payment System (OPPS) Final Rule, HHS slashed Medicare Part B reimbursement for separately payable 340B drugs by nearly 30% from Average Sales Price (ASP) plus 6% to ASP minus 22.5%.

Covered entities were successful in challenging this change, with the U.S. District Court for the District of Columbia holding that the Secretary of HHS exceeded his authority in making such a drastic reduction despite Congress' statutory mandate to reimburse covered entities at ASP plus 6%.[2] HHS has appealed the decision to the D.C. Circuit, and the agency has made clear that it will continue to seek reductions in 340B reimbursement.

Despite the district court's ruling, and the complexity of unwinding payment cuts if the courts rule in the hospitals' favor, HHS reinforced its position in the CY 2020 OPPS final rule, which continues to reimburse 340B drugs at ASP minus 22.5%.

HHS also appears to be considering a substitute payment reduction should it not succeed on appeal. Proposals include an alternative payment methodology such as ASP plus 3% or tying payment to actual acquisition cost (AAC) through survey activity. The D.C. district court's opinion suggested that a roughly 3% payment reduction may be tenable compared to the nearly 30% reduction that HHS applied in 2018-2020. HHS has also proposed a data collection effort to seek AAC from hospitals. Of note, HHS indicated that it may even use the cost data to develop remedies for 2018-2020 underpayments if it loses its appeal at the D.C. Circuit. This approach would result in a significant loss of revenue for covered entities and likely trigger additional litigation.

HHS stated that it may consider stakeholder comments and suggestions submitted during the CY 2021 OPPS proposed rule comment period (likely from July-September 2020) should it ultimately be unsuccessful in its appeal. Given the significant moving parts and the potential negative impact on covered entities, stakeholder participation in the comment process for the OPPS rulemaking is critical.

***MEDICARE PAYMENT REDUCTION PREDICTIONS FOR 340B:***

- HHS will likely continue to test its legal authority under various provisions of the Social Security Act to cut reimbursement.
- If approved by the Office of Management and Budget (OMB), HHS is likely to collect 340B drug acquisition cost survey data in 2020. This will be a complicated exercise and would need to be done each year to adhere to the applicable language in the Social Security Act. This process also could be susceptible to reporting errors.
- HHS will likely use 340B covered entities' Medicare cost survey data to develop its proposed payment rates for CYs 2021 and/or 2022. This scenario appears quite possible given that the CY 2021 OPPS proposed rule typically is issued in July of the applicable year and given the

timeline of protracted litigation. HHS may also consider using this survey data to establish its remedies for the 2018-2020 340B underpayments.
- Continued site neutrality reform and risks posed by related Medicare enrollment rules (e.g., loss of grandfathered status, failure to adhere to new affiliate disclosure rule).

*Payers/PBMs Limiting Reimbursement for 340B Drugs in Certain Settings*

Since HHS issued its CY 2018 OPPS Final Rule, we've seen a number of private payers, particularly those in the Medicare Advantage space, follow suit regarding separately payable drugs. Covered entities should watch their MA and other private payer claims to assess their rights under their respective payer contracts and consider entering tolling agreements while the underlying Medicare Part B/340B litigation is pending. Covered entities also have pushed back on private payers citing to a lack of contract authority to change payment for 340B drugs based on the CY 2018 OPPS Final Rule only.

Covered entities are also reporting more plans trying to limit/eliminate reimbursement for certain services that involve the administration or dispensing of 340B drugs, including restricting hospital outpatient reimbursement for infusion services to one or two infusions, with the expectation that the covered entity refers the patient out to a freestanding setting. Covered entities should review their payer agreements, current provider-based facility and billing structures, related provider-based rules, and availability of hospital-owned home infusion models to complete a full assessment of their potential strategies. This is a significant trend that we believe will continue for the foreseeable future.

Also, as payer and pharmacy benefit manager (PBM) consolidation continues at a rapid pace, covered entities face additional challenges to treat their patients in settings that permit use of 340B drugs. Covered entities that own and operate retail and specialty pharmacies are seeing plan benefit restrictions that require the use of the plan's captive specialty pharmacy resulting in the covered entity pharmacy being out-of-network. In the specialty environment, this can result in much higher copays and deductibles for covered entities' patients, so covered entities may have to send such patients to the plans' specialty pharmacies. Covered entities should highlight the quality and cost benefits that their owned pharmacies offer to the plan in an effort to gain in-network status or consider the use of a contract pharmacy relationship as a back-up measure. The parties should also consider the impact of "any willing provider" and anti-steering laws.

***PAYERS/PBM 340B PREDICTIONS:***

- Continued reliance on Medicare Part B payment reductions as the basis to limit reimbursement for separately payable drugs, such as infused drugs.
- Continued pressure on provider-based reimbursement for infusion services; providers will need to revisit existing provider-based strategies and ensure compliance with Centers for Medicare & Medicaid Services (CMS) provider-based and related space sharing guidance throughout.
- Continued market consolidation including health plans purchasing pharmacies and other ancillary service providers.

**340B Program Compliance Remains a Top Priority**

*HRSA's authority in flux.* In 2019, HRSA questioned its own legal authority and temporarily halted audit reports, which were finally released in early December.[3] Just recently, HRSA noted its inability to issue rules and enforce such rules governing duplicate discounts in the Medicaid managed care space.[4] And those who have followed the 340B Program for many years know that HRSA retracted its controversial "Omnibus Guidance" after losing its orphan drug litigation discussed below. These developments indicate HRSA's continued internal struggle to address concerns about

its oversight of the 340B program raised by government watchdogs such as the HHS Office of Inspector General (OIG) and GAO.

Statutorily, HRSA's oversight responsibilities include: (1) conducting initial eligibility checks of all entities seeking to register with the 340B program; (2) recertifying covered entities on an annual basis; and (3) performing audits of covered entities and manufacturers.[5] In 2014, the U.S. District Court for the District of Columbia ruled that HRSA lacked statutory authority to issue a final rule narrowing the exclusion of orphan drugs from the 340B program. The court interpreted HRSA's 340B program regulatory authority as limited to: (1) establishing a binding alternative dispute resolution process to resolve audits between covered entities and manufacturers; (2) establishing civil monetary penalties against manufacturers that knowingly and intentionally overcharge a covered entity for 340B drugs; and (3) issuing precisely defined standards of methodology for calculating 340B program drug ceiling prices.[6]

Most recently, HRSA's determination of 340B program ineligibility of a Federally Qualified Health Center (FQHC) based on the agency's interpretation of the definition of a "patient" was challenged in court.[7] HRSA ultimately voluntarily dropped the finding of ineligibility and readmitted the FQHC to the 340B program. We expect that HRSA will continue to ask Congress for greater authority to issue rules while looking for ways under the existing 340B statute to oversee the program.

*More sophisticated audits*. HRSA continues to use the Bizzell Group to conduct all audit fieldwork and to report its onsite observations back to HRSA. Bizzell auditors appear to have pharmacy and 340B backgrounds, resulting in higher sophistication and depth of audits with a renewed focus on complex issues such as negative split-billing software accumulations and duplicate discounts that previously were not assessed to any significant degree. Here is what we are seeing in some of those audits:

- Visibility into split-billing software. Requests to track specific drugs through split-billing software, which results in higher visibility into split-billing software and high risk of identifying problems with accumulations (that could suggest diversion or group purchasing organization prohibition violations).
- Negative accumulations. When negative accumulations are identified, HRSA is placing the onus on covered entities to further investigate and make repayments, which could have significant financial consequences.
- Child site Medicaid claims data. Requests for Medicaid claims from each child site.
- MMCO duplicate discounts. Review of Medicaid managed care claims, but with continued reluctance to issue findings.
- Disproportionate share hospital percentages and other eligibility documents. Much more attention to eligibility documentation (e.g., local government contract). Beginning April 1, 2019, HRSA announced a renewed focus on checking eligibility documents during enrollment, recertification, and random desk audits.[8] Also, as stated in a recent GAO report, "HRSA's draft procedures for fiscal year 2020 audits require auditors to specify if the hospital provided a contract that includes the names and signatures for both the hospital and government agency, effective dates that cover the entire audit period, and that requires the provision of services to the 340B-specified low-income population."[9] Additionally, HRSA published guidance in early 2019 regarding eligibility requirements.[10]

*No clear method to prevent MMCO duplicate discounts.* This was one of the hottest issues of 2019 for the 340B program and likely will remain so in 2020. There has been a significant uptick in manufacturer and state activity focused on preventing duplicate discounts. Duplicate discounts occur when a drug is subject to both a 340B discount and a Medicaid rebate paid by the manufacturer.

While covered entities assume an obligation to prevent duplicate discounts in the administration of their respective 340B programs, states must provide a method for the covered entities to prevent the

duplicate discounts. Many states have been unsuccessful in developing processes to prevent MMCO duplicate discounts, particularly in the contract pharmacy environment. Most recently, CMS issued guidance[11] following several OIG reports that suggested CMS work with states to provide tools to identify Medicaid claims for 340B drugs. Below are some notable points on CMS' commentary and guidance:

- Guidance is focused on state actions. CMS recapped some of the existing methods by which states work with drug manufactures, MCOs, and covered entities to reduce duplicate discount risk. Covered entities should keep in mind that the guidance does not create any new obligations for them when responding to inquiries from any drug manufacturer or vendor, such as Kalderos, about duplicate discounts.
- Option for states to opt-out of Medicaid 340B program participation. CMS instructed states that they are permitted "to limit the ability of some or all of the covered entities and/or contract pharmacies in the state to use 340B purchased drugs for Medicaid beneficiaries." CMS noted how some state Medicaid programs have elected to use the state plan amendment process to develop these parameters and encouraged states to determine whether these approaches will be effective in preventing duplicate discounts. For covered entities, this development is concerning given that an opt-out option would generally impact their ability to provide care for patients with limited income. The guidance also encourages use of BIN/PCN combinations to assist in identifying Medicaid beneficiaries and preventing duplicate discounts. Historically, the BIN/PCN method has been problematic since health plans generally do not specify which BIN/PCNs pertain to MMCOs. Therefore, pharmacies cannot distinguish between a private plan and a MMCO plan.
- Medicaid Exclusion File (MEF) limited to Medicaid Fee-for-Service Claims. While encouraging use of the MEF to prevent duplicate discounts, CMS clearly stated that "the MEF does not apply to 340B covered entities' arrangements with [MCOs] at this time." This is consistent with 2014 HRSA guidance regarding use of the MEF and prevention of duplicate discounts within Medicaid fee-for-service programs. Covered entities should remind manufacturers that the MEF only applies to FFS before engaging in substantive discussions and analysis of underlying claims data.
- 340B Claims Modifiers. The guidance promotes use of the National Council for Prescription Drug Programs (NCPDP) claims modifiers to assist in identifying 340B eligible claims at the point of service. The guidance also suggests that covered entities identify physician administered drug claims by use of the "UD" or "TB" modifiers. While the "UD" modifier is currently utilized in some states, the "TB" modifier is limited to Medicare Part B claims and is not generally used for Medicaid 340B claims identification and duplicate discount prevention purposes. Inconsistent modifier requirements could have unintended consequences, particularly when multiple payers are involved on a single claim.

***340B COMPLIANCE PREDICTIONS:***

- There will be continued tension regarding HRSA's enforcement authority and audit findings. Stakeholders should involve their legal counsel throughout the audit process to assess potential legal challenges, should the need arise.
- Auditors will continue to focus on more systematic issues and "low hanging fruit" such as negative accumulations.
- HRSA's continued reluctance to assess/issue MCO findings, but a renewed focus on working with CMS and states to develop tools to reduce MMCO duplicate discounts.
- New state plans/billing processes to use at the state level to prevent MMCO duplicate discounts.

**Covered Entity/Manufacturer Tensions Build**

*Tension and good faith inquiries increase relative to duplicate discounts.* Covered entities face mounting pressure to conduct extensive reviews and implement processes to prevent duplicate discounts in the MMCO environment. Several drug manufacturers, either directly or through Kalderos, continue to engage covered entities and/or state Medicaid agencies across the country in Medicaid duplicate discount exercises.

These exercises are coined "good faith" exercises—a term of art used by HRSA to encourage 340B stakeholders to work together informally to resolve allegations of 340B program violations. However, these exercises often yield no material findings, so we've observed covered entities and even states start questioning whether the exercises are appropriate under existing HRSA guidance. We expect this dialogue to continue as covered entities get more sophisticated in their preparations and responses to these vendors. Covered entities should have a defined process and team in place to consider the nature of the inquiry and whether a substantive response is warranted.

We also are seeing a number of state Medicaid agencies sending inquiries to covered entities regarding whether certain drugs should have been flagged as 340B drugs and removed from Medicaid Drug Rebate Program submissions to manufacturers. Again, covered entities should have a process in place to address these exercises to ensure a consistent approach. Duplicate discount questions involve analysis of a number of different complex data sets (utilization, purchase, Medicaid billing), so a measured and defined approach is critical.

Finally, we have observed a number of state Medicaid rebate agencies become overwhelmed due to the high volume of requests from an increasing number of manufacturers reaching out to them directly.

*Manufacturer follow-up on HRSA audit findings increases*. When HRSA issues a covered entity audit report with findings (as opposed to recommendations for improvement), HRSA specifies whether the particular finding requires additional analysis and repayment to affected drug manufacturers. In response, covered entities submit either (1) a notice of disagreement within 30 days, which is tantamount to an appeal of HRSA findings, or (2) a corrective action plan within 60 days. Once HRSA vets the notice of disagreements and finalizes its findings, HRSA posts a summary of its findings and corrective action steps on its program integrity page.[12]

Historically, when covered entities would offer repayment to affected manufacturers, many would not respond or simply accept repayment. However, we are seeing a trend where (1) most manufacturers will respond and engage in the repayment process and (2) a handful or more of affected manufacturers engage in very detailed data requests and analyses before agreeing to a final repayment. This can lead to complex data needs and analysis, as well as additional risk for repayments that might not otherwise have been considered during HRSA's audit. Therefore, like any audit activity, all stakeholders should carefully weigh their disclosure obligations and data in order to facilitate an appropriate approach to the scope of the issue. Confirming rights/obligations at an early stage is critical and we emphasize that stakeholders should treat all manufacturer inquiries as audits.

*Manufacturer mechanisms to limit access to 340B pricing*. As new, cutting edge drug therapies hit the market, safety net hospitals are experiencing greater restrictions on their ability to access those products at 340B pricing. Often times, these products can cost safety net hospitals tens or hundreds of thousands of dollars per treatment, and in turn, represent a tremendous cost to payers at a time when health insurance cost remains a key issue. If the products are offered at 340B prices as mandated by the 340B statute, safety net hospitals could realize significant cost savings that could be passed on to their communities via greater access to services, their patients, etc. Stakeholders need to carefully consider their legal rights and remedies in this space.

***COVERED ENTITY/MANUFACTURER PREDICTIONS:***

- Continued data analytics and inquiries regarding duplicate discounts, particularly in the MMCO space.
- Continued focus on narrowing the scope of the program at the legislative level and significant lobbying spending; more limited distribution drugs as a means to restrict access to 340B pricing to certain networks. Covered entities will continue to see a handful of drug manufacturers that push for deeper and more sophisticated dives and longer repayment windows when items are disclosed to them (e.g., diversion found during a HRSA audit).

***MAJOR DATES TO WATCH:***

- Quarter 1—Potential CMS data collection effort regarding 340B covered entity actual acquisition cost
- February 10—President Trump scheduled to submit his 2021 President's Budget to Congress
- May 22—Current health extenders for public health, Medicaid, and Medicare expire
- Early July—CMS will likely release its CY 2021 OPPS Proposed Rule
- Mid November—CMS issues its CY 2021 OPPS Final Rule

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**Endnotes**

[1] *See* GAO, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Rebate Program Needs Improvement* (GAO-20-212), https://www.gao.gov/assets/710/703966.pdf.

[2] *American Hosp. Assoc. v. Azar,* No. 18-2082 (RC) (D.D.C. Dec. 27, 2018).

[3] *See* Program Integrity: FY19 Audit Results, https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results.

[4] *See* GAO report, *supra* note 1.

[5] *See* 42 U.S.C. § 256b.

[6] *See Pharmaceutical Research & Manufacturers of Am. v. U.S. Dep't of Health & Human Servs.,* 43 F. Supp. 3d 28, 42-5 (D.D.C. 2014) (opining that HRSA did not have the authority to promulgate the orphan drug regulation and enumerating HRSA's regulatory oversight responsibilities).

[7] *See Genesis Health Care, Inc. v. Azar*, No. 4:19cv-01531-RBH (D.S.C. 2019).

[8] *See* https://www.hrsa.gov/opa/updates/2019/march.

[9] GAO, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements* (GAO-20-108), https://www.gao.gov/assets/710/703128.pdf.

[10] HRSA, 340B Program hospital registration Instruction (Updated 2/11/2019), https://www.hrsa.gov/sites/default/files/hrsa/opa/hospital-registration-instruction-details.pdf.

[11] CMS, *Best Practices for Avoiding 340B Duplicate Discounts in Medicaid* (Jan. 8, 2020), https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf.

[12] *See* https://www.hrsa.gov/opa/program-integrity/index.html.