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HEALTH LAW NEWS

APRIL 05, 2019

THE 340B CRYSTAL BALL: NEW CLARITY ON 340B PRICES AND THE PROGRAM'S FUTURE

It's no April Fools' joke. On April 1, 2019, the Health Resources & Services Administration Office of Pharmacy Affairs ("HRSA") unveiled a long-awaited website that gives providers participating in the 340B drug pricing program ("340B Program") direct access to information about the maximum amounts that pharmaceutical companies may charge for certain drugs. This moves the 340B Program toward unparalleled accountability. The secured website, housed within HRSA's Office of Pharmacy Affairs Information System ("OPAIS") database, is also used to facilitate registration and verification of 340B Program covered entities ("Covered Entities"). This and other 340B Program developments on the judicial, legislative and executive fronts suggest a more favorable and dynamic outlook for the 340B Program going forward. Today, we take an operational/practice approach and address implications of the new ceiling price availability as well as the status of the lawsuit challenging Medicare's 340B reimbursement reductions. In our next article, we will address the 340B Program's future by discussing developments in the legislative and executive branches.

340B DRUG CEILING PRICE UPDATE TO HRSA OPAIS DATABASE

With the new website, covered entities enrolled in the 340B Program can verify the accuracy of the ceiling prices that pharmaceutical companies charge them for 340B Program covered outpatient drugs ("340B Drugs") for the first time. For background, every 340B Drug has a ceiling price, which is defined in statute as the maximum amount that a manufacturer can charge a covered entity for the purchase of a 340B Drug. In 2010, the Department of Health & Human Services Office of Inspector General ("OIG") investigated 340B Drug purchases by Covered Entities and found many instances where pharmaceutical manufacturers overcharged Covered Entities for 340B Drugs.

Consequently, the OIG recommended that Congress create a set of civil monetary penalties to fine manufacturers that knowingly and intentionally overcharged Covered Entities. Additionally, the OIG recommended that Congress pass a law directing HRSA to build transparency into the 340B Drug pricing information by making such information readily available to Covered Entities. The prior administration proposed rules in 2015 to formalize regulations governing these 340B Program updates, but a final rule was not issued, finalized and implemented until January 1, 2019 after related litigation. At that time, HRSA began collecting 340B Drug pricing data from manufacturers.

The culmination of this nearly decade-long process is accessible by Covered Entities' authorizing officials through the secured website on the OPAIS database. The updated website uses 340B Drug pricing data from pharmaceutical manufacturers to calculate and verify 340B Drug ceiling prices every quarter. Coupled with HRSA's civil monetary penalty authority, the availability of the 340B Drug pricing information and the potential penalties associated with overcharging create incentives for pharmaceutical manufacturers to comply with the statute. The penalties also create accountability for those entities that knowingly and intentionally overcharge safety-net providers.

The inclusion of 340B Drug ceiling price information through the OPAIS database increases the integrity of the 340B Program for the future. It provides Covered Entities with the ability to maximize the benefits under the 340B Program by ensuring that the prices paid for 340B Drugs do not exceed ceiling prices. Covered Entities should consider updating their 340B Program audit protocols to incorporate the verification of 340B Drug ceiling prices as part of their regular auditing processes.

340B PROGRAM IN THE COURTS

Separately, ongoing judicial activity regarding the Affordable Care Act ("ACA") and the 2018 and 2019 Outpatient Prospective Payment System ("OPPS") final rules could impact the 340B Program's future and its accessibility too. In early December 2018, a federal judge in the U.S. District Court in Texas held that the ACA's individual health insurance mandate was unconstitutional, and therefore the remainder of the ACA was invalid because Congress eliminated the individual mandate penalty through the 2017 Tax Cut and Jobs Act. While the lawsuit continues through the appeals process, the unraveling of the ACA could significantly impact the 340B Program eligibility of certain Covered Entities. This includes sole community hospitals, rural referral centers, critical access hospitals and children's hospitals that became eligible to participate as a result of the ACA. This lawsuit creates a flurry of uncertainly as it works its way through the appeals process, presumably up to the Supreme Court.

In late December 2018, another federal judge in the U.S. District Court in D.C., found that CMS violated its authority by implementing significant reductions to 340B Program reimbursement for hospital-administered 340B Drugs in its 2018 and 2019 OPPS final rules. The American Hospital Association and several hospitals ("Plaintiffs") challenged a payment rule that CMS implemented beginning in January 1, 2018 which effectively reduced reimbursements for certain Covered Entities under the 340B Program by nearly 30 percent, about $1.6 billion in total for 2018. We analyzed this decision's impact in a prior Health Alert, including addressing considerations for protecting potential appeal and recoupment rights in the event the CMS payment reduction is found to be impermissible.

The Court ruled in favor of the Plaintiffs, finding the reductions to reimbursement were invalid. However, the litigation continues as the parties submit additional briefings to determine the appropriate relief. On January 31, 2019, the Plaintiffs filed a brief stating that the repayments should "make whole" 340B Program hospitals and should not be applied in a budget-neutral means in the manner that CMS uses to apply the savings from the 340B Program reimbursement reductions. The plaintiffs note that a supplemental payment would be equivalent to "the difference between the amount they received and the amount they are entitled to [based on the payment methodology prior to the reductions, ASP plus 6 percent] under this Court's order, plus interest. Whether this decision holds and any potential remedies, however, remain to be seen.

PRACTICAL TAKEAWAYS

These developments speak to the increased viability of, and significant activity surrounding, the 340B Program. HRSA's new, secure website that provides information about 340B Drug ceiling prices aims to increase the effectiveness and integrity of the 340B Program. Now, Covered Entities can audit and validate that they are being offered correct 340B Drug pricing, just as drug manufacturers have been auditing Covered Entities' compliance with 340B Program requirements. Covered Entities' ability to access 340B Drug pricing information will provide greater transparency, and the enforcement of civil monetary penalties against pharmaceutical manufacturers who knowingly and intentionally overcharge for 340B Drugs will provide increased accountability.

Moving forward, Covered Entities should consider ways to use this information to assist and improve their 340B Program participation, including updating 340B Program audit protocols to incorporate 340B Drug ceiling price validation. Separately, Covered Entities should also be aware of and consider developments in the courts that may impact their reimbursement and participation in the 340B Program. Specifically with regard to the OPPS final rule litigation, Covered Entities should take steps to maintain their appeal and protect potential recoupment rights.

We will continue to monitor developments in the 340B litigation and other aspects of the 340B Program, and we will issue additional health alerts if and as those developments become relevant.

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