

Years in the Making: The Health Resources & Services Administration Launches a Website to Increase Pricing Transparency in the 340B Program

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If you overheard Medicaid providers breathe audible sighs of relief on April Fool's Day, it may be because on April 1, 2019, the Health Resources & Services Administration of the Department of Health and Human Services (“[HRSA](#)”) finally updated the [Office of Pharmacy Affairs 340B Information System website](#) (the “[340B Website](#)”) to allow 340B Drug Pricing Program (the “[340B Program](#)”) providers – including 340B Program-eligible hospitals and other eligible healthcare providers– to use the 340B Website to verify the accuracy of the ceiling prices that they are being charged by manufacturers of 340B Program-covered drugs.

More than two years ago, on January 5, 2017, the Centers for Medicare & Medicaid Services (“[CMS](#)”) issued a final rule setting forth: (i) the ceiling prices for drugs sold as part of the 340B Program, and (ii) civil monetary penalties for drug companies that “intentionally and knowingly” charge 340B Program providers more than the ceiling price for a covered drug (the “[Final Rule](#)”). The Final Rule was produced in response to a push by Congress to have drug ceiling prices listed and made publicly available on a website in response to a report issued by the U.S. Department of Health & Human Services, Office of the Inspector General, which indicated that there were reports of drug companies overcharging for drugs purchased as part of the 340B Program.^[1] The Final Rule was supposed to take effect on March 6, 2017, but it was delayed five times until its final effective date – January 1, 2019.

As required by the Final Rule, HRSA was directed to provide 340B Program providers with greater transparency into the pricing of 340B Program-covered drugs. The updated 340B Website is the means by which HRSA is providing such additional transparency. So that the 340B Website has the necessary pricing data to fulfill its objectives, 340B Program-participating drug companies are required to upload their quarterly pricing data for their 340B Program-covered drugs to the secure 340B Website. With this information, the 340B Website then (i) calculates the applicable 340B Program ceiling prices,^[2] and (ii) verifies that the amounts being charged by the posting drug manufacturer do not exceed the applicable 340B program ceiling price. To verify the posting manufacturer's compliance with the 340B Program's drug pricing rules, the 340B Website compares the data uploaded by the drug manufacturer with the 340B ceiling prices as calculated by the HRSA.

As described by the HRSA, by giving 340B Program-participating providers the ability to view the 340B ceiling prices on the 340B Website, the providers are able to ascertain whether they are overpaying for covered drugs.^[3]

Hospital groups and advocates are clearly supportive of the Final Rule and the 340B Website. According to Tom Nickels, Executive Vice-President of the American Hospital Association (“AHA”), “[the] website will help make sure hospitals participating in the [340B Program] are not being overcharged by drug companies and that instances of price gouging can be uncovered and penalties enforced.”^[4] In addition, Mr. Nickels is quoted as saying, “[a]s prescription drug prices continue to skyrocket, the 340B program is as crucial as ever in helping hospitals provide access to health care services for patients in vulnerable communities.” The AHA’s enthusiastic greeting of the new 340B Website is not surprising since the 340B Website comes as a result of a lawsuit filed on September 11, 2018, by the AHA and other trade associations and 340B Program providers against the HRSA to force the HRSA to implement the Final Rule – the implementation of which was first scheduled to take place on March 6, 2017.

[1] Jack O’Brien, “HRSA Launches 340B Drug Pricing Website” (April 1, 2018), <https://www.healthleadersmedia.com/finance/hrsa-launches-340b-drug-pricing-website>.

[2] The 340B ceiling price is calculated by subtracting the rebate percentage, or Unit Rebate Amount (“URA”), from the Average Manufacturer Price (“AMP”). This per pill ceiling price is then multiplied by the number of pills provided in the bottle in order to get the drug ceiling price for the package.

[3] “340B Ceiling Price Calculation,” <https://www.hrsa.gov/opa/updates/2015/may.html>

[4] “As urged by AHA, HRSA launches website for checking 340B maximum prices,” American Hospital Association (April 1, 2019), <https://www.aha.org/news/headline/2019-04-01-urged-aha-hrsa-launches-website-checking-340b-maximum-prices>.

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