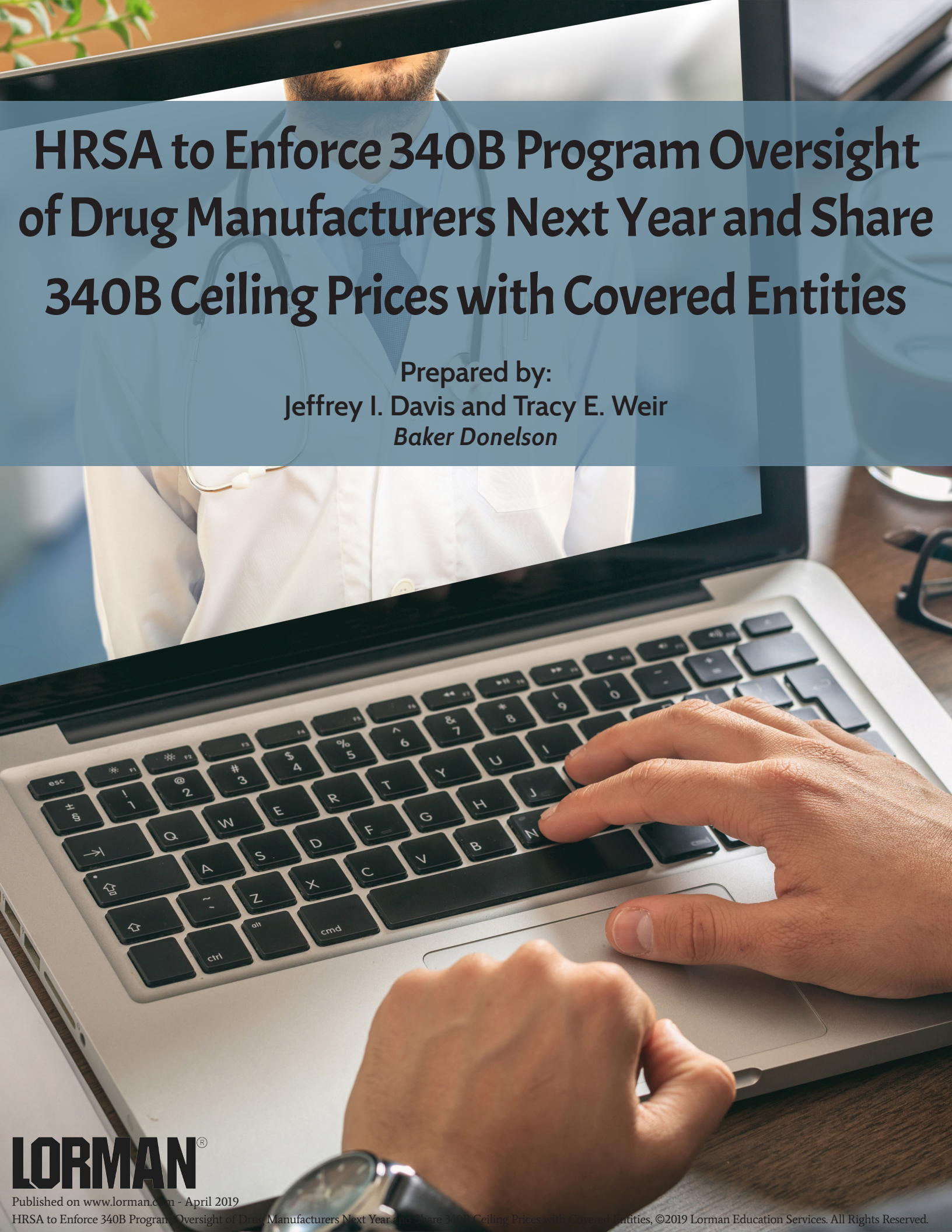

HRSA to Enforce 340B Program Oversight of Drug Manufacturers Next Year and Share 340B Ceiling Prices with Covered Entities

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HRSA to Enforce 340B Program Oversight of Drug Manufacturers Next Year and Share 340B Ceiling Prices with Covered Entities

Written by Jeffrey I. Davis and Tracy E. Weir – 12/13/18

Two recent announcements by the Health Resources and Services Administration (HRSA) highlight the agency's plans for increased oversight in the next year of drug manufacturers under the 340B drug pricing program and transparency into 340B ceiling prices for health care providers participating in the program, referred to as covered entities. Hospitals and other providers should monitor these developments, as they will offer covered entities opportunities to ensure they are being charged the correct drug prices.

Below we outline HRSA's two recent announcements and their implications for covered entities.

Drug Manufacturer Civil Monetary Penalties

HRSA published a final rule on November 30, 2018, moving up the effective date of a long-awaited regulation that will assess civil monetary penalties (CMPs) against drug manufacturers that knowingly and intentionally overcharge covered entities for drugs purchased under the 340B program. The rule also addresses how manufacturers

should calculate 340B prices for new drugs and codifies in regulation HRSA's longstanding "penny price" policy, under which manufacturers must charge $0.01 when a drug's price increases faster than the rate of inflation, causing the 340B ceiling price to otherwise be zero. HRSA will begin enforcement of the regulation January 1, 2019.

The regulation, first published by the last Administration on January 5, 2017, was originally scheduled to go into effect April 1, 2018. The current Administration delayed enforcement of the rule five times, most recently to July 1, 2019. Congress directed HHS to implement CMPs in cases of overcharges in 2010, and providers have repeatedly called on HHS to move forward with implementation.

HHS's decision to move up enforcement of the rule follows a hospital lawsuit challenging the legality of the delays. On September 11, 2018, hospital associations and hospital co-plaintiffs filed a lawsuit in the U.S. District Court for the District of Columbia against the Department of Health and Human Services (HHS). The plaintiffs argued the delays were unlawful under the Administrative Procedures Act, as the Administration had not put forward a plausible explanation for the delay, making it both arbitrary and capricious and an unreasonable delay of an agency action. HHS asked the court to stay the lawsuit after the agency announced plans to move the effective date up to January 1, 2019. The court denied the request.

HHS continues to ask the court to dismiss the case as moot now that the agency will enforce the rule January 1. The plaintiffs, however, have asked that the court order HHS to make 340B ceiling prices

available to covered entities no later than April 1, 2019. Below, we discuss the status of HRSA's publication of 340B ceiling prices.

340B Ceiling Price Website

On November 30, 2018, HRSA announced on its website that, beginning April 1, 2019, the agency plans to publish HRSA-verified 340B ceiling prices for covered entities to access and determine whether manufacturers are charging the correct prices. Congress directed HHS to verify 340B prices and develop a ceiling price website for covered entities in 2010. In its announcement, HRSA said it will be implementing a "secure pricing component" of the 340B Office of Pharmacy Affairs Information System (OPAIS) in the first quarter of 2019. Under the secure pricing system, manufacturers will submit pricing data for HRSA to use to calculate and verify 340B ceiling prices. The announcement states that covered entities will be able to access the ceiling prices beginning April 1, 2019.

340B Covered Entity Implications

HRSA's recent announcements are welcome news for 340B covered entities, which have been calling on HHS to implement 340B program integrity provisions enacted by Congress in 2010, as part of the Affordable Care Act (ACA). Congress directed HHS to implement manufacturer oversight provisions in response to a series of HHS Office of the Inspector General (OIG) reports in the 2000s finding instances of overcharges. OIG recommended that Congress authorize HHS to penalize manufacturers for instances of knowing and intentional overcharges and to verify 340B prices and make them available to covered entities.

Access to HRSA-verified 340B ceiling prices should assist covered entities in evaluating whether manufacturers are overcharging them for 340B drug purchases. Covered entities should monitor HRSA's actions in the first quarter of 2019, particularly regarding information on the process for covered entities to access 340B ceiling prices through the OPAIS.

HRSA's announcements could also have broader implications for Congressional and Administrative oversight of 340B covered entities. The chairmen and ranking members of the Senate Health, Education, Labor, and Pensions (HELP) Committee and House Energy and Commerce Committee sent a letter to HRSA on August 27, 2018, calling on the agency to issue regulations in the areas where HHS has authority, including manufacturer CMPs. The letter also noted, however, that HHS has the authority to issue sub-regulatory guidance in other areas to inform stakeholders of the agency's interpretation of the 340B statute. Covered entities should monitor HRSA's actions, including guidance or program updates published on the Office of Pharmacy Affairs (OPA) website addressing covered entity compliance under the 340B program.

For further information, please contact the authors, Jeff Davis and Tracy Weir, or any member of Baker Donelson's Reimbursement Team.