



340B Reform Update

Amgen Latest to Attack Contract Pharmacies

Date: January 7, 2021
To: 340B Health System Coalition
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The new Biden Administration and the new Congress will likely pursue some changes to the 340B program. In the meantime, there has been some significant activity impacting the program. This memo provides updates.

Additionally, as we discussed on our last conference call, we are gathering policy recommendations needed for the program, as requested by our champions in Congress. Many will be regulatory in nature, which is fine because we will also work with the new Administration to make positive changes to the program. **Please send your top five issues to me devon.seibert-bailey@shcare.net as soon as possible.** We look forward to working with you in 2021!

Contract Pharmacies Pricing

The latest manufacturer to challenge 340B pricing is biopharmaceutical manufacturer Amgen, which will end voluntary 340B pricing on orphan-designated drugs for some 340B hospital covered entities began on Jan. 1st, click [here](#).

On December 30, 2020, the HHS Office of the General Counsel released an advisory opinion concluding that drug manufacturers are required to deliver discounts under the 340B Drug Pricing Program, "when contract pharmacies are acting as agents of 340B covered entities." Unfortunately, the advisory opinion only sets forth the agency's view on the issue and does not carry the force of law, as the agency noted. This would mean that the issue could still be a source of litigation and the current lawsuits that have been filed will still need to go through the motions in the Courts. Click [here](#) for the press release from HHS, and [here](#) for the advisory opinion.

Five hospital associations, the association of hospital pharmacists, and three hospitals have sued HHS and HHS Secretary Alex Azar "to take action against" drug manufacturers "refusing to offer 340B discounts for covered drugs if a covered entity dispenses the drug through a contract pharmacy." The American Hospital Association (AHA), 340B Health, America's Essential Hospitals, the Association of American Medical Colleges (AAMC), the Children's Hospital Association (CHA), and the American Society of Health-System Pharmacists sued HHS and Azar together with Avera St. Mary's Hospital in Pierre, S.D., Riverside Regional Medical Center in Newport News, Va., and St. Mary's Medical Center in San Francisco, Calif. Click [here](#) for the suit filed in December.

Kalderos Proposal to Pay 340B Rebates in Lieu of Discounts

In a letter led by President-Elect Biden's nominee for the next HHS Secretary and current California Attorney General, Xavier Becerra, 28 state attorneys general, both Republicans and Democrats, urged current HHS leaders "to address drug manufacturers' unlawful refusal to provide critical drug discounts to covered entities, such as community health centers, under the 340B Drug Pricing Program." With Becerra leading this effort, it is thought he will be more aggressive in the new Administration protecting the program. Click [here](#) for the letter.

- Kalderos announced it has changed its 340B Pay platform to let covered entities "choose whether to use the rebate model for their own pharmacies, or maintain their existing process," while rumors swirl that at least two drug manufacturers plan to start using the platform in early 2021, click [here](#).

340B Regulations

The Health Resources and Services Administration released a final rule that "sets forth the requirements and procedures for the 340B Program's administrative dispute resolution (ADR) process" last week after it was mandated a decade ago under the Affordable Care Act. The rule, which takes effect on Jan. 13, 2021, will create a panel to manage disputes relating to the program including overcharges, audit findings, and duplicate discounts, among others. The panel would be assembled by the HHS Secretary and would include CMS and HRSA. Advocacy groups voiced concerns that the rule does not go far enough and would not help with the current actions taken by pharmaceutical manufacturers against contract pharmacies. To review the final rule, click [here](#).