

Congress of the United States
Washington, DC 20515

August 27, 2018

Krista Pedley, Pharm.D, MS, Captain, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Dear Captain Pedley:

As Chairmen and Ranking Members of the House and Senate health committees with jurisdiction over the 340B program, we urge you to issue or implement regulations in the three areas where the agency has explicit rulemaking authority as soon as possible.

The 340B Drug Pricing Program (340B program) is an important program that enjoys strong bipartisan support in Congress. The program helps reduce the prices of covered drugs for certain participating entities who, in turn, use such savings to provide care for patients. Numerous covered entities have stated the 340B program has helped ensure that many patients have access to needed services.

Given the important role the 340B program plays in our nation's health care safety-net, it is critical that program rules be clear and consistent for all stakeholders. Unfortunately, the agency has faced significant impediments to appropriate oversight and enforcement given recent judicial decisions that, in effect, left the agency without broad rulemaking authority.¹

The court, however, did make clear that HRSA does have regulatory authority that includes (1) establishing and implementing a binding Administrative Dispute Resolution (ADR) process for the resolution of certain disputes relating to compliance with 340B program requirements, (2) providing for the imposition of civil monetary penalties (CMPs) against manufacturers that knowingly and intentionally overcharge a covered entity for a 340B drug, and (3) issuing precisely defined standards of methodology for calculation of 340B ceiling prices. Additionally, the D.C. District Court has made clear that the agency has authority to issue guidance around other program requirements "to advise the public of its interpretation of the statute."² Unfortunately, HRSA has repeatedly delayed issuing rules and guidance regarding these important issues.

¹ Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health and Human Serv., 43 F. Supp. 3d 28, 42-5 (D.D.C. 2014); Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health and Human Serv., case no. 14-1685 (D.D.C. 2015)

² Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health and Human Serv., case no. 14-1685 (D.D.C. 2015)

Even so, HRSA has requested that Congress consider legislative action to give the agency additional rulemaking authority over the 340B program. In testimony before the Senate Health, Education, Labor and Pensions Committee this June and before the House Energy and Commerce Committee last July, HRSA stated that specific regulatory authority to conduct rulemaking for all provisions of the 340B statute would allow the agency to better oversee and manage the program. Such specific authorities have been proposed in the President's budget as well.

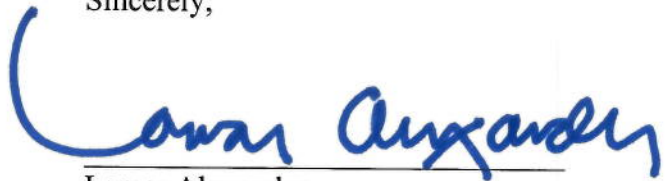
While we appreciate that HRSA has requested these additional authorities, we remain concerned that the agency is not using its existing authorities. We believe HRSA action to issue or implement final regulations in an open and transparent process, in collaboration with all relevant stakeholders, could help clarify and update program requirements in pursuit of strengthening access to necessary care and proper administration of the program.

As such, we request that HRSA take action to address these issues and issue regulations required by law for the 340B Program. Thank you for your attention to this important issue.

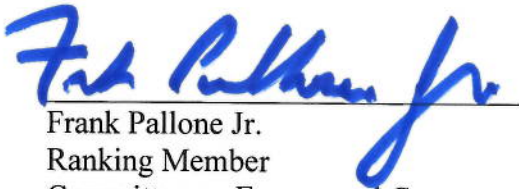
Sincerely,



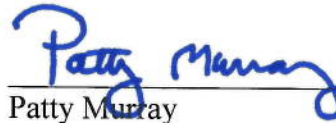
Greg Walden
Chairman
Committee on Energy and Commerce
U.S. House of Representatives



Lamar Alexander
Chairman
Committee on Health, Education, Labor,
and Pensions
U.S. Senate



Frank Pallone Jr.
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives



Patty Murray
Ranking Member
Committee on Health, Education, Labor,
and Pensions
U.S. Senate

CC: The Honorable Alex Azar, Secretary, U.S. Department of Health and Human Services