

- Insulin is a critical and life-saving medication that approximately 8 million Americans rely on to manage diabetes. Likewise, injectable epinephrine is a life-saving medication used to stop severe allergic reactions.
- Health Centers are community-based health care providers that receive funds from the HRSA Health Center Program to provide primary care services in underserved areas.
 - The 340B Drug Pricing Program enables covered entities, such as health centers, to achieve average savings of 25-50% on what they might otherwise pay for covered outpatient drugs.
- This allows health centers to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services by lowering drug costs for providers and allowing them to pass along these savings to their patients and maintain and expand other health care services.
 - The NPRM seeks to remove financial barriers and improve access for low-income health center patients to life-saving medications – insulin and injectable epinephrine – at the price the health center purchased them through the 340B Program, including a minimal distribution fee.

HEALTH CENTER OVERVIEW

- [HRSA-supported health centers](#) are community-based and patient-directed organizations that deliver affordable, accessible, quality, and cost-effective primary health care to medically underserved communities and vulnerable populations, including high-need urban, rural, and frontier communities across the United States.
 - Health centers advance a model of coordinated, comprehensive, and patient-centered primary health care, integrating a wide range of medical, dental, mental health, substance use disorder, and patient services.
- Nationwide, nearly 1,400 HRSA-funded health center grantees operate approximately 13,000 sites, providing primary and preventive care on a sliding fee scale to nearly 30 million patients.
 - Over 91 percent of health center patients or families live at or below 200 percent of the Federal Poverty Guidelines and nearly 63 percent are racial/ethnic minorities.
 - Health center patients, including low-income individuals, racial/ethnic minority groups, and persons who are uninsured, are more likely to suffer from chronic diseases such as hypertension and diabetes. Clinical evidence indicates that access to appropriate care can improve the health status of patients with chronic diseases and thus reduce or eliminate health disparities.

WHAT IS THE 340B DRUG PRICING PROGRAM?

- The 340B Drug Pricing Program was authorized by the Veterans Health Care Act of 1992 and based on Congressional report language¹, the 340B Program is intended to substantially reduce the cost of covered outpatient drugs to 340B-participating eligible entities, known as “covered entities,” in order to stretch scarce federal resources. The 340B Program statute only addresses covered entity eligibility and compliance requirements. While the 340B Program statute does not specify how 340B Program savings must be used, HHS has not required entities to report on their use of savings generated by the 340B Program. However, many covered entities are HHS grantees and have specific requirements under the terms of their grants for how to use savings generated by participation in the 340B Program.

HOW WILL THIS NPRM BENEFIT HEALTH CENTER PATIENTS?

- Health centers purchasing drugs through the 340B Drug Pricing Program will be required to provide low cost insulin and injectable epinephrine to their patients with incomes below 350% of the federal poverty level and who also have health insurance with a high cost sharing requirement for either insulin or injectable epinephrine, health insurance with a high unmet deductible, or no health care insurance, addressing a key barrier to controlling diabetes and addressing life-threatening allergic reactions. Nationwide, more than 2.7 million current health center patients have diabetes.

HOW MANY HEALTH CENTERS CURRENTLY PARTICIPATE IN THE 340B DRUG PRICING PROGRAM?

- As of July 1, 2020, more than 1,300 health centers and over 9,000 associated service delivery sites participate in the 340B Drug Pricing Program.

HOW LONG IS THE PUBLIC COMMENT PERIOD?

- The NPRM will be available for public comment for 30 days.

¹The House Report accompanying the original 340B Program legislation states the following intent: “[i]n giving these ‘covered entities’ access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”