

September 29, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Room 600E
Washington, DC 20201

Ms. Krista Pedley, RADM
Director, Office of Pharmacy Affairs
Department of Health and Human Services
Health Resources and Services Administration
Healthcare Systems Bureau, 5600 Fishers Lane
Rockville, MD 20857

Dear Secretary Azar and Director Pedley:

The National Community Pharmacists Association (NCPA) writes on behalf of our membership regarding the 340B program and recent actions taken by certain pharmaceutical manufacturers which could potentially undermine the program.

NCPA represents America's community pharmacists, including 21,000 independent community pharmacies. Almost half of all community pharmacies provide long-term care services (LTC) and play a critical role in ensuring patients have immediate access to medications in both community and LTC settings. Together, our members represent a \$76 billion healthcare marketplace, employ approximately 250,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

NCPA has concerns with the recent actions taken by certain pharmaceutical manufacturers to limit delivery of 340B priced drugs to contract pharmacies, as well as steps taken by other manufacturers to require data collection from contract pharmacies. NCPA is concerned these actions will result in reducing participation of independent pharmacies in the 340B program, generally undermine the program, and has the significant potential to negatively impact patients in rural and medically underserved areas of the country served by independent pharmacies.

Established in 1992 in the Public Health Service Act, the 340B program has existed to provide discounted drugs to covered entities which serve vulnerable populations. Through subsequent guidance issued by HRSA, covered entities were permitted to establish a contractual relationship with a pharmacy to provide pharmacy services. According to data from HRSA, for most of the early history of the program, the bulk of the pharmacies in this relationship were independent, community pharmacies within a ten-mile radius of the covered entity. However, in 2001, HRSA ran a demonstration project which allowed multiple contract

pharmacies which broadened the participation of pharmacy chains. In 2010, HRSA modified guidance to permit all covered entities to contract with multiple pharmacies through additional guidance.

Since that date, many NCPA members have relied upon the guidance to build cooperative relationships with qualified entities under the 340B program to provide pharmacy services to patients and play an integral role in providing healthcare to these underserved or indigent populations. Approximately 30% of the pharmacies participating in the program are independent pharmacies.

The recent actions of some pharmaceutical manufacturers will result in limiting access to their products and negatively impact patients who are used to receiving their medication at their contract community pharmacy. Our membership, which is especially well positioned to provide services in rural and other medically underserved communities, has been a good faith participant in the 340B program and maintains a significant presence in the communities the covered entities serve. This provides a deep understanding of the patient population and the unique needs and issues facing those communities. NCPA members have long been committed to the ideals and mandates intended by Congress when the program was first established.

NCPA urges HRSA to respond promptly to these interferences with the contractual relationships by requiring these manufacturers to honor the 340B pricing for contract pharmacies. NCPA is concerned about the additional data gathering requests and the imposition of further regulatory mandates by a non-governmental entity. Importantly, and for the long term health of the 340B program, NCPA urges HRSA to adopt new guidance clarifying any ambiguous language in the definitions of covered entities and patients and to issue such guidance through a traditional rulemaking process which permits a fair, public, and transparent opportunity for all stakeholders to provide input and feedback. Finally, NCPA strongly encourages HRSA to return to a model where covered entities and their contract pharmacies are all located within a limited mileage radius of the covered entity. This limited mileage radius provision would better ensure that resources generated by local pharmacies dispensing 340B prescriptions benefit the health and welfare of the patients living in those communities.

The 340B program was created to help “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing comprehensive services” and the program has evolved significantly in the 28 years since it was enacted. NCPA stands ready to work with HRSA, the covered entities, and pharmaceutical manufacturers to return to a cooperative environment to allow eligible patients to benefit from the services of their local pharmacy and local hospital.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Douglas Hoey". The signature is fluid and cursive, with a large initial "B" and "H".

B. Douglas Hoey, RPh, MBA
Chief Executive Officer
National Community Pharmacists Association