

October 28, 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  
U.S Department of Health and Human Services  
Health Resources and Services Administration  
Healthcare Systems Bureau, 5600 Fishers Lane  
Rockville, MD 20857

**Re: Implementation of Executive Order 13937, "Executive Order on Access to Affordable Life Saving Medications" (Docket No. HRSA-2020-0004)**

Dear Secretary Azar and Director Pedley:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the U.S Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA), the agency responsible for administrating the Implementation of Executive Order 13937, "Executive Order on Access to Affordable Life Saving Medications." NCPA represents America's community pharmacists, including 21,000 independent community pharmacies. 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 community independent pharmacies.

Members of NCPA participate in the 340B program as contract pharmacies – delivering pharmaceuticals and other services to patients, particularly in underserved and rural areas. As HRSA is aware, participation in the program is governed by the contract signed between the two entities and includes the fee structure for dispensing prescription medications to patients. This contracting process is independent of the participation in 340B by the covered entity and the terms can be negotiated depending on the community the entity serves.

NCPA recognizes the need to get lifesaving and sustaining pharmaceuticals in the hands of lower income, high deductible insured, or uninsured patients. The executive order and the implementing proposed

rule direct insulin and injectable epinephrine to be available at cost with an additional “minimal administration fee” at certain participating 340B covered entities- namely Federal Qualified Health Centers (FQHCs) and other 330(e)<sup>1</sup> grantees. However, NCPA raises several concerns with the proposed rule as currently drafted.

### **Administration Fees**

HRSA goes on to define a “minimal administration fee” as a fee “consistent with the stated policy of the executive order<sup>2</sup>” and not an impediment to the individual covered under the Executive Order to access their prescriptions. NCPA agrees that such costs should not be a barrier but wishes to reiterate that minimal costs must include appropriate inclusion of all related dispensing costs - which might not be captured in the list provided in the proposed rule. Continued participation in the 340B program requires the costs of delivering pharmacy services be adequately reimbursed, including any cost associated with the administration of the 340B contract and other associated fees. NCPA understands the covered entities will be applying the standard sliding scale for fees but wishes to ensure HRSA considers all the potential costs associated with pharmaceutical dispensing and consideration of participation of independent pharmacies in underserved areas, particularly those served by FQHCs and 330(e) grantees.

Additionally, NCPA requests clarification on how the fee would be apportioned for those covered entities and the contract pharmacies and if further rulemaking undertaken by HRSA on this matter would be in contradiction to the terms of those agreements. The plain language of the proposed rule leaves it unclear exactly how any administration fees would be reimbursed in the presence of a contract pharmacy arrangement, how and if any fees would be split, and how that determination of the patient eligibility for the reduced price at the point of sale is made.

### **Additional Burdens on the Pharmacy**

While the rule expressly states there would be no additional paperwork or reporting associated with implementation for health centers,<sup>3</sup> NCPA expresses concern that moving forward with this rulemaking process could provide additional paperwork, reporting, and regulatory burdens to independent pharmacies serving as contract pharmacies for these covered entities in service of this set of patients. NCPA requests HHS provide clarification in the issuance of a final rule that no additional regulatory burdens will be placed on contract pharmacies.

### **Conclusion**

NCPA appreciates HHS’ continued concern with prescription drug costs and its continued openness to considering and implementing feedback from stakeholder groups such as NCPA. We greatly appreciate

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<sup>1</sup> <https://www.federalregister.gov/d/2020-21358/p-7>

<sup>2</sup> <https://www.federalregister.gov/d/2020-21358/p-25>

<sup>3</sup> <https://www.federalregister.gov/d/2020-21358/p-40>

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the opportunity to share with HHS and HRSA our comments and suggestions on the executive order. Should you have any questions or concerns, please feel free to contact me at [ronna.hauser@ncpa.org](mailto:ronna.hauser@ncpa.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Ronna B. Hauser". The signature is fluid and cursive, with a long horizontal stroke at the end.

Ronna B. Hauser, PharmD  
Vice President, Policy & Government Affairs Operations  
National Community Pharmacists Association