David Schwartz
Head of Global Policy
Public Policy and Federal Government Affairs

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701 Pennsylvania Avenue, NW
Suite 720
Washington, DC 20004
(202) 719-6499
David.Schwartz@Cigna.com

VIA ELECTRONIC SUBMISSION TO www.regulations.gov

Jennifer Joseph
Director, Office of Policy and Program Development
Bureau of Primary Health Care
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Re: RIN 0906-AB25; HRSA-2020-0004; Implementation of Executive Order 13937, "Executive Order on Access to Affordable Lifesaving Medications."

Dear Ms. Joseph:

Cigna welcomes the opportunity to respond to the Notice of Proposed Rulemaking (proposed rule) issued by the Department of Health and Human Services (HHS) related to implementation of Executive Order (EO) 13937 of July 24, 2020. Cigna appreciates HHS's efforts to improve access to life-saving medications by low-income individuals who do not have access to affordable insulin and injectable epinephrine due to either lack of insurance or high cost-sharing requirements.

Cigna Corporation, together with its subsidiaries (either individually or collectively referred to as "Cigna"), is a global health service organization dedicated to helping people improve their health, well-being, and peace of mind. Our subsidiaries are major providers of medical, pharmacy, dental, disability, life and accident insurance, and related products and services, with over 185 million customer relationships in the more than 30 countries and jurisdictions in which we operate. Worldwide, we offer peace of mind and a sense of security to our customers seeking protection for themselves and their families at critical points in their lives.

Within the U.S., Cigna provides medical coverage to approximately 14 million Americans in the commercial segment. We also provide coverage in the individual insurance segment in several states, both on- and off-Exchange, to about 280,000 people. Additionally, Cigna, together with our Express Scripts business unit, serves more than 4 million people through our Medicare Advantage, Medicare Prescription Drug Program and Medicare Supplemental products.

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With that context as background, Cigna offers the following comments on the proposed rule.

Cigna supports efforts to make health care simple, predictable, and affordable. This proposed rule aims to make insulin and injectable epinephrine more affordable for American consumers, which is a goal Cigna shares. While improving affordability is laudable, it is important for any program with that goal to be easily implemented and executed efficiently.

In this instance, the proposal is limited to Federally Qualified Health Centers (FQHCs) that the Health Resources and Services Administration (HRSA) oversees. In order for private sector partners to support the implementation of this proposed rule, we need HRSA to clearly identify which FQHCs are participating and maintain a directory or regularly updated roster of health centers that participate in the envisioned program. HRSA is uniquely positioned to be the "source of truth" for participating FQHCs. Today, the data provided by HRSA does not include a unique code or identifier that distinguishes FQHCs.

In order to make insulin and injectable epinephrine more affordable to consumers, the proposed rule relies on FQHCs passing through 340B pricing, often referred to as "penny pricing," at the point of sale. Cigna believes it will be critical for HRSA to require FQHCs to adjudicate a prescription claim if the patient has health insurance. This is necessary to ensure those prescription claims data are available for clinical programs and care coordination services. Having a comprehensive view into medical and prescription utilization is important for whole health care coordination and identifying gaps in care that can lead to negative outcomes and increased spending. Additionally, the pharmacy provider processing the claim should adhere to 340B claim stamping by using National Council for Prescription Drug Programs (NCPDP) submission clarification code 420-DK value 20.

We also believe that in order to for this program to succeed, it needs to be simple for FQHCs, pharmacies, and patients. To achieve successful operation of the program, below are some issues we urge HHS to address in any final rule:

- **Income verification**: In order to qualify for the program, patient income will need to be verified. How will this be accomplished and by whom? Additionally, how long will income be assumed to be valid or how frequently will it need to be re-verified?

- **Insurance status**: How will insurance status be determined, verified, and tracked over time as patients move through their benefit?

- **High cost-sharing**: The proposed rule defines high cost-sharing as a cost-sharing requirement that exceeds 20% of the amount the health center charges its patients for the drug. How will this be calculated for patients with insurance who have their cost-sharing tied to a deductible or co-insurance that may change over the plan year? This fluctuation in cost-sharing may require information exchange with payers and should be resolved prior to rolling out the program.

- **High unmet deductible**: The proposed rule defines high unmet deductible as the amount a patient owes toward his/her deductible at any time during a plan year in which the outstanding deductible portion exceeds 20% of the total deductible. Does this mean once a member has reached 80% of their deductible they no longer qualify for the program? If so, that information will need to be tracked over the patient's plan year and made available at the point of sale or through the claims adjudication process. Furthermore, medical claims may need to be factored into deductible status, particularly for patients with an integrated medical/pharmacy deductible. This could be particularly challenging due to the lag in receiving and processing medical claims.

Affordable medication is a priority for Cigna and the members we serve. If FQHCs are to pass 340B discount pricing to low-income Americans, the operational and logistical challenges above must be addressed and solved for prior to implementation. Failure to do so could result in confusion among patients, frustration by providers, and, ultimately, impede the stated goal and result in little to no impact on improved access to insulin and/or injectable epinephrine.

Thank you for your consideration of these comments. Cigna would welcome the opportunity to discuss these issues with you in more detail at your convenience.

Respectfully,

David Schwartz