

United States Senate

WASHINGTON, DC 20510

October 27, 2017

Eric D. Hargan
Acting Secretary
The Department of Health and Human Services (HHS)
200 Independence Ave, S.W.
Washington, D.C. 20201

George Sigounas
Administrator
Health Resources and Services Administration (HRSA), HHS
5600 Fishers Ln
Rockville, MD 20852

Dear Acting Secretary Hargan and Administrator Sigounas:

We write to express our concerns with the Administration's multiple decisions to delay the effective date of the HRSA 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation rule. We believe this delay contradicts the President's numerous statements that he would work to bring down the skyrocketing costs of prescription drugs.

On January 5, 2017, the Department of Health and Human Services (HHS) published this common-sense rule establishing a \$5,000 penalty for each case where a drug company knowingly and intentionally overcharges children's hospitals, safety net hospitals, federally qualified health centers, rural facilities, and other covered entities under the 340B program. Unfortunately, since that time the rule has been delayed four times, including the most recent delay to July 1, 2018. In addition, Administration officials have publically indicated there may be additional changes to the rule in its current form.


Currently, HHS has limited authority to penalize pharmaceutical companies that overcharge 340B health care providers despite significant evidence that these companies frequently and impermissibly overprice their products. Further delays or changes in the implementation of this rule contradict President Trump's repeated promises to crack down on unfair drug pricing and allows bad actors to continue enriching themselves at the expense of the American public.

Since 2003, the Department of Justice has recovered more than \$97 million from drug manufacturers and returned those funds to 340B entities. In fact, the HHS Office of Inspector General found that 68 of the 70 340B entities examined in a one-month audit had been overcharged at least one time in the past, with the monthly overpayment amount reaching as high as \$36,730. Stronger oversight of drug companies that are routinely and deliberately inflating already high drug costs is needed.

Since the Affordable Care Act passed in 2010, HHS has conducted several rounds of public comment and had more than seven years to consider this rules impact on stakeholders. We strongly urge

you to avoid implementing any changes that will weaken this important rule and ask that the Administration move forward with implementation of this rule as soon as possible.

Sincerely,



Gary C. Peters
United States Senator



Amy Klobuchar
United States Senator



Debbie Stabenow
United States Senator



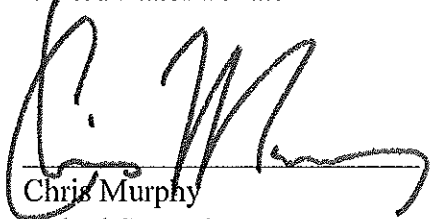
Mazie K. Hirono
United States Senator



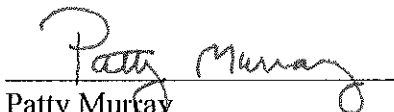
Tammy Baldwin
United States Senator



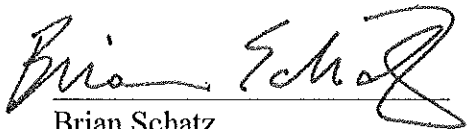
Kamala D. Harris
United States Senator



Chris Murphy
United States Senator



Patty Murray
United States Senator



Brian Schatz
United States Senator



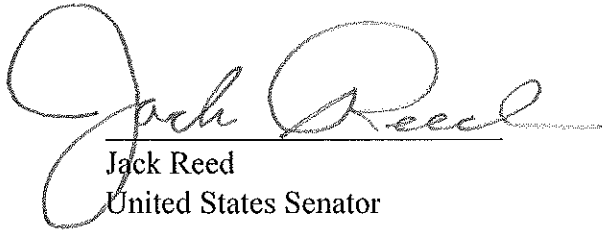
Richard Blumenthal
United States Senator



Al Franken
United States Senator



Sherrod Brown
United States Senator

A handwritten signature in cursive script that reads "Jack Reed". The signature is written in black ink and is positioned above a horizontal line.

Jack Reed

United States Senator