

February 22, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, D.C. 20201

Dear Secretary Becerra,

On behalf of the National Rural Health Association (NRHA), I want to thank you for the work you, and the Department of Health and Human Services (HHS), have done to ensure rural providers remain stable throughout the ongoing COVID-19 pandemic. NRHA continues to have significant concerns regarding ongoing actions from large pharmaceutical manufacturers which threaten the longevity of the 340B Drug Pricing Program.

NRHA is a non-profit membership organization with more than 21,000 members that provides national leadership on rural health issues. Our membership includes nearly every component of rural America's health care, including rural community hospitals, critical access hospitals, doctors, nurses, and patients. We work to improve rural America's health needs through advocacy, communications, education, and research.

NRHA asks you to uphold the integrity of the 340B Drug Pricing Program and take action against large pharmaceutical manufacturers taking aim at the program.

The 340B Drug Pricing Program (340B program) has been a vital lifeline for providers, especially in rural America. The program helps safety-net providers across the United States, including more than 1,000 rural hospitals, stretch scarce resources to provide more comprehensive services and care for more patients. In a 2018 340B Health survey of hospitals, they found that 93 percent of rural hospitals reported using savings from the program to keep the doors of their facilities open, and half of those responders said cuts to the 340B program could trigger a closure. As America recovers from the COVID-19 pandemic, this lifeline program is needed more than ever for rural provider stability.

According to the Chartis Group, in rural America, 453 rural hospitals are vulnerable to closure. Further, Chartis reports that 40 percent of all rural hospitals are operating on negative margins. The 340B program has helped these vulnerable hospitals continue services in their rural communities. For example, in Bishop, California, the savings from the program have immensely benefited care in the community. The Northern Inyo Health Care District, a critical access hospital in Bishop, serves a community of about 4,000. Through savings from the 340B program, Northern Inyo Health Care District can fund their obstetric services. Maintaining obstetric care in rural America is vital to helping prevent maternal morbidity and mortality that disproportionately affects rural women in the United States. Bishop, California, is just one example of the 340B program keeping vital services in a community and negating the health risks often posed to rural mothers and children.



NRHA was encouraged by the Department's statements in support of the 340B program in the February 2021 brief for *Eli Lilly and Company, and Lilly USA, LLC v. U.S. Department of Health and Human Services.* In the brief, the Department said, "Lilly and its peers are engaged in a brazen attempt to effect a unilateral sea change in the settled operation of the 340B Program. Congress devised the program to provide affordable medications and much-needed revenue to vulnerable patients and safety-net healthcare providers." While NRHA emphatically agrees with the language used by the Department, the attacks on the program have not ceased.

As of February 2022, 14 pharmaceutical companies—with the latest being GlaxoSmithKline—have decided to cut sales to contract pharmacies. These actions come on top of large pharmaceutical manufacturers limiting the distribution of certain 340B drugs, the requirement of 340B covered entities to utilize a new, contracted third party database, and other limits on contract pharmacies. NRHA believes that the actions proposed by these large pharmaceutical manufacturers run contrary to the intent of the 340B program and the Health Resources and Services Administration's (HRSA) 2010 guidance on contract pharmacy arrangements.

Unfortunately, in addition to the pressures created by the drug manufacture restrictions, rural providers may be in jeopardy of losing their 340B status due to changes in their patient mix during COVID-19. For example, a Sole Community Hospital in Mississippi is concerned about their DSH requirement falling below eight percent and losing their status. Before the COVID-19 pandemic, their DSH annual average percentage was 12 percent. When the pandemic hit, their DSH dropped to 9.04 percent in Cost Report Year 2020 and will fall below eight percent for Cost Report Year 2021. They estimate that the loss of their 340B status will lead to a deficit of \$1.5 million to \$2 million per year. This would be absolutely devastating to their bottom line and result in a loss of services. NRHA urges HRSA to use the 1135 waiver process to ensure rural providers maintain 340B status by waiving the DSH percentage for qualification during COVID-19 cost report years.

NRHA is deeply concerned with the overall wellbeing of the 340B program. It is imperative that HHS and HRSA take all actions they can to uphold the integrity of this program. As the country moves beyond the pandemic, and Federal resources such as the Provider Relief Fund come to an end, NRHA believes the 340B program will be critical to ensuring important services remain in their rural communities.

NRHA appreciates HHS' continued efforts to preserve access to this valuable lifeline for rural providers. We look forward to continuing to work with the Department to ensure the integrity and longevity of the 340B program. It is simply too critical to rural health care to be undercut at a valuable time in our nation's health care system. If you would like additional information, please contact Josh Jorgensen at <a href="mailto:jjorgensen@ruralhealth.us">jjorgensen@ruralhealth.us</a>.

Sincerely,

Alan Morgan

**Chief Executive Officer** 

National Rural Health Association