



March 20, 2024

Delivered Electronically via Bipartisan340BRFI@email.senate.gov

Re: Feedback on the Supporting Underserved and Strengthening Transparency, Accountability and Integrity Now and for the Future of 340B (SUSTAIN 340B) Act Discussion Draft

Dear Senators Baldwin, Capito, Cardin, Moran, Stabenow, and Thune:

The [Alliance for Rural Hospital Access](#) appreciates your leadership on efforts to ensure 340B program stability and oversight. We also appreciate the opportunity to submit feedback on your discussion draft, the Supporting Underserved and Strengthening Transparency, Accountability and Integrity Now and for the Future of 340B (SUSTAIN 340B Act).

The Alliance is comprised of hospitals designated as Medicare-Dependent Hospitals (MDHs), Rural Referral Centers (RRCs) and Sole Community Hospitals (SCHs) under the Medicare program. MDHs, RRCs and SCHs provide rural populations with access to a wide range of health care services. In doing so, MDHs, RRCs and SCHs localize care, minimize the need for further referrals and travel, and provide services at costs lower than their urban counterparts. These hospitals also commonly establish satellite sites and outreach clinics to provide primary and emergency care services to surrounding underserved communities, a function which is becoming increasingly important as economic factors force many small rural hospitals to close.

Summary of Comments

The Alliance is specifically commenting on the need to clarify the orphan drug exclusion enacted in 2010. Specifically, we urge you to add the provisions from **Senator Welch's (D-VT) Closing Loopholes for Orphan Drugs Act in the SUSTAIN 340B Act**. This clarification will resolve an ambiguity in current 340B policy, curtail abuse by pharmaceutical manufacturers who use the orphan drug exclusion to avoid the 340B program, and ensure that struggling rural hospitals have the resources needed to serve their patients and communities.

For the past four Congresses, then-Rep., now-Sen. Welch has introduced legislation that would clarify the orphan drug exclusion by limiting the carveout to only those uses for which the drug received orphan status. The Closing Loopholes for Orphan Drugs Act (most recently, H.R. 853 in the 117th Congress) has been a bipartisan effort in each of the last four Congresses, and Sen. Welch is working to introduce the bill again.

Senator Welch's bill would amend the orphan drug exclusion to specify that the carve-out is limited only to those uses for which the drug received orphan status. It seeks to codify exactly

what the Health Resources and Services Administration (HRSA) sought to do, before it was blocked by litigation from the pharmaceutical industry.

This change would ensure that rural hospitals are able to benefit from the 340B program to the extent that Congress intended. It is important to note that Senator Welch's legislation is not an expansion of the 340B program, as the hospitals it impacts are already participating in the program, and nothing about the bill would enable additional hospitals to enroll. Instead, it would simply bring clarity to an ambiguous issue that has been subject to litigation.

The Alliance believes this clarifying provision would be a good fit in the SUSTAIN 340B Act, given that you are seeking to ensure the program functions as intended and provide certainty in light of litigation.

2010 Changes to Rural Hospital Eligibility & Orphan Drug Exclusion

Congress enabled hospitals that treat a high rate of low-income patients to qualify based on their Medicare Disproportionate Share Hospital (DSH) payments. In 2010, Congress expanded extended 340B Program eligibility by making it easier for freestanding cancer hospitals, Critical Access Hospitals (CAHs), RRCs and SCHs to participate. Congress took this step because up to that point certain of these hospitals were barred from the program because they did not receive DSH payments, and so could not meet the DSH eligibility threshold; others were systemically incapable of meeting the DSH threshold originally established by Congress. Under this change, freestanding cancer hospitals and CAHs are eligible by virtue of their status as these providers. RRCs and SCHs are not automatically eligible, but Congress made it easier for them to qualify by lowering the DSH threshold for these facilities from 11.75 percent to 8 percent.

The RRC program was established to support certain high-volume hospitals that treat a large number of complicated cases and function as regional referral centers. The SCH program was created to maintain access to needed health services for beneficiaries in isolated communities. The populations that RRCs and SCHs serve are on average older than urban populations and therefore more dependent on the Medicare program. These facilities provide rural populations with access to a wide range of health care services, and Congress has long appreciated their significant role in the rural health care community. Congress has also continued to recognize the need to afford RRCs and SCHs special protections to ensure their continued viability.

At the same time that Congress made it easier for these facilities to participate in the 340B Program, it also sought to ensure the program's discounts would not stifle investment in and development of drugs for rare diseases or conditions. Specifically, Congress included a provision that exempted from the 340B discount requirements any "drug designated by the Secretary under section 360bb of title 21 for a rare disease or condition" when purchased by one of the expansion entities. This provision effectively exempts any drug with an orphan designation.

Many commonly used drugs have orphan designations for one or more indications, even though the drug also is approved for more common indications too. In fact, a January 2017 study by Kaiser Health News (KHN) found that about one third of orphan approvals made by the FDA since the orphan drug program was enacted in 1983 have been either for mass market drugs

repurposed for an orphan designation, or for drugs that received multiple orphan designations.¹ The FDA's orphan drug program provides a number of incentives—such as market exclusivity and tax credits—to encourage development of drug therapies for rare diseases or conditions, but each of these orphan drug incentives applies only when the drug is used to treat the rare disease or condition, and not when used for other indications.

HRSA Rulemaking & Ensuing Litigation

In 2011, HRSA published a proposed rule that sought to define the orphan drug exclusion established under the 2010 law by proposing that orphan drugs would be exempt from 340B discount requirements only when used for the rare condition or disease for which that drug received orphan designation. In 2013, HRSA published a final rule that largely adhered to the proposed rule's interpretation of the orphan drug exclusion.

The pharmaceutical industry—which had been urging HRSA to interpret the exception as applying to any drug with orphan designation, regardless of the clinical condition for which the drug was prescribed—sued the agency seeking to enjoin implementation of the final rule on the grounds that HRSA did not have rulemaking authority; the federal district court sided with the pharmaceutical industry. In 2014, HRSA responded by reissuing its notice as an interpretive rulemaking, which essentially announces the agency's interpretation of the statute, but does not include regulations enforcing it. The pharmaceutical industry responded with a new lawsuit challenging the interpretive rule. This time pharma asserted that HRSA's interpretation was not supported by the statutory language. The same court again sided with the pharmaceutical manufacturers and invalidated the interpretive rule.

Congressional Action Needed

Since the court decisions, many pharmaceutical companies are restricting access to 340B Program discounts on drugs with orphan designations, thereby undermining the benefits of the program for RRCs, SCHs, CAHs and freestanding cancer hospitals. This exclusion applies only to these hospitals, and not to hospitals that qualify by hitting the higher DSH threshold.

Congress established the orphan drug program to encourage development of drugs for the diagnosis and/or treatment of rare diseases or conditions. The 340B orphan drug exclusion is, in effect, yet another incentive to promote investment in these drugs. However, Congress did not intend to extend this benefit to a drug use for which there is a substantial and lucrative market. As noted in the KHN study, seven of the ten best-selling drugs in the U.S. in 2015 were drugs with an orphan designation—even though some of these drugs were first approved for more common indications and only later received their orphan designation.

¹ *Drugmakers Manipulate Orphan Drug Rules to Create Prized Monopolies*, Kaiser Health News, January 17, 2017: http://khn.org/news/drugmakers-manipulate-orphan-drug-rules-to-create-prized-monopolies/?utm_campaign=KHN%3ADaily+Health+Policy+Report&utm_source=hs_email&utm_medium=email&utm_content=40780219&hsenc=p2ANqtz--Iz5qttLkkNBVUJN3TerDq15vXUOZzQROhDe9_cERt1nPkp_T44hddg2bb5zf1AkZB00isTyHt_xt-4PcGIhjl7UwJ0w&_hsmi=40780219

To ensure that RRCs and SCHs (as well as CAHs and cancer hospitals) benefit from the 340B program to the extent that Congress intended, we encourage you to include the Closing Loopholes for Orphan Drugs Act in the SUSTAIN 340B Act. This clarification will help ensure rural hospitals have the resources needed to continue to provide their communities with local access to important health care services.

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Thank you for your consideration of these comments. Please contact me at 202.204.1457 or ezimmerman@mcdermottplus.com if you have any questions.

Sincerely,

A handwritten signature in blue ink, appearing to read "Eric Zimmerman", written in a cursive style.

Eric Zimmerman