October 29, 2020

The Honorable Lamar Alexander
Chairman
Health, Education, Labor and Pensions Committee
U.S. Senate
Washington D.C. 20510

The Honorable Greg Walden
Ranking Member
Energy and Commerce Committee
U.S. House of Representatives
Washington D.C. 20515

Dear Chairman Alexander and Ranking Member Walden,

On behalf of the Rural Hospital Coalition (the Coalition), we appreciate the opportunity to provide feedback on the House Energy and Commerce and Senate Health, Education, Labor and Pensions committees' Request for Information on how to improve the 340B Drug Pricing Program (340B).

The Coalition is comprised of hospitals designated as Medicare-Dependent, Small Rural Hospitals (MDHs), Rural Referral Centers (RRCs) and Sole Community Hospitals (SCH) under the Medicare Program. The Coalition shares the common goal of ensuring that federal policies recognize the unique and important role and contributions of these hospitals to the Medicare program and its beneficiaries. Consistent with this mission, the Coalition is pleased to provide a response highlighting some of the challenges rural safety net facilities face and offering a specific policy to improve 340B and the role it plays in the safety net.

Rural Hospital Designations: Overview

Medicare Dependent Hospitals: The MDH program was established by Congress in 1990 with the intent of supporting small rural hospitals for which Medicare patients make up a significant percentage of inpatient days and discharges. Because they primarily serve Medicare beneficiaries, MDHs rely heavily on Medicare reimbursement to sustain hospital operations. Consequently, these hospitals are more vulnerable to inadequate Medicare payments than other hospitals because they are less able to cross-subsidize inadequate Medicare payments with more generous payments from private payers. As such, Congress acknowledged the importance of Medicare reimbursement to MDHs and established special payment protections to buttress these hospitals. Congress recognized that if these hospitals were not financially viable and failed, Medicare beneficiaries would lose an important point of access to hospital services. Many of these hospitals also have substantial Medicaid patient populations.

Sole Community Hospitals: Congress created the SCH program nearly 40 years ago to maintain access to needed health care services for Medicare beneficiaries in isolated communities. Congress was concerned that as it moved Medicare to fixed, per-service payments under the IPPS, hospitals whose costs exceeded IPPS payments could be financially threatened, and that the Medicare program and its beneficiaries would suffer if hospitals serving isolated, rural populations failed because of this financial shortfall. The SCH program is intended to maintain the viability of hospitals providing critical health care services to their communities.

Rural Referral Centers: Congress established the RRC program to support rural hospitals that treat a large number of complicated cases and function as regional referral centers. Generally, to be classified as an RRC, a hospital has to be physically located outside a Metropolitan Statistical Area (indicating an urban area) and either have at least 275 beds or meet certain case-mix or discharge criteria.

MDHs, RRCs and SCHs provide rural populations with local 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. Congress and CMS have reconfirmed their commitment to these hospitals repeatedly over the years by providing new protections to ensure their viability and access to hospital services in rural communities.

Challenges for Safety Net Hospitals

It is important to examine the challenges facing MDHs, RRCs, and SCHs that may impact the quality of, and access to essential health care services in rural communities across the country. First, many MDHs, RRCs, and SCHs are the sole source of care within and around a community. Many patients that live in rural and underserved communities depend on these facilities for a full complement of health care services, from primary care to sophisticated inpatient treatment. More and more rural hospitals are struggling and closing, causing access problems for residents of rural communities.

Second, providers in rural and underserved communities treat more challenging and unique patient populations. For example, individuals who live in rural areas have higher rates of chronic or life-threatening diseases, such as diabetes and coronary heart disease.[1] Additionally, rural residents are more likely to face significant mental health issues including substance abuse and seasonal affective disorder.[2] By serving a disproportionate number of Medicare beneficiaries, MDHs also manage a challenging patient population: the elderly and aging.

Third, providers in rural and underserved communities are increasingly confronting extremely difficult financial circumstances. Hospitals in these communities (including MDHs, RRCs, and

[1] O'Connor, A., & Wellenius, G. (2012, April 24). Rural-urban disparities in the prevalence of diabetes and coronary heart disease. The Royal Society for Public Health, 126(10), 813-820. doi:10.1016/j.puhe.2012.05.029.
[2] Health Status and Behaviors, Stanford Medicine, eCampus Rural Health.

SCHs) tend to have negative or very small operating margins, making them financially vulnerable. These hospitals also often do not have the same flexibility as other hospitals to discontinue lower margin or unprofitable services. As mission driven organizations, and the only source of hospital services for their community, these hospitals often will continue to offer services, even at great financial loss, because there are no other providers offering those services. Unnecessary restrictions on 340B impose further financial strain and compromise their ability to serve rural communities.

Background on Changes to Rural Hospital Eligibility & Orphan Drug Exclusion

Since 1992, 340B has provided certain health care providers that treat low-income and indigent populations, or that otherwise fulfill a health care safety net role, with financial relief from high prescription drug costs. In 2010, Congress sought to make it easier for certain safety net rural hospitals to participate in the program, including RRCs and SCHs. At the same time that Congress made it easier for rural safety net facilities to participate in 340B, 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 orphan drug designation from the 340B discount.

This is problematic because, as you may know, many commonly used drugs have orphan designation for one or more indications, even though the drug also is approved for more common indications too. Indeed, a January 2017 study by Kaiser Health News found that about one-third of orphan approvals made by the Food and Drug Administration (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.[3] 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.

Congressional Action Needed on the Closing Loopholes for Orphan Drugs Act

To address this issue, Representatives Peter Welch (D-VT) and David McKinley (R-WV) introduced H.R. 4538, the Closing Loopholes for Orphan Drugs Act. This bipartisan bill seeks to clarify 340B's orphan drug exclusion to explicitly limit the carve-out only to those uses for which the drug received orphan designation. This clarification seeks to ensure that safety net hospitals benefit from 340B to the extent that Congress intended, allowing these facilities to continue to provide underserved communities with local access to health care services. H.R. 4538 is one of the few bipartisan 340B bills currently pending in Congress. It has been endorsed by the National Rural Health Association, America's Essential Hospitals, the American Society of Health-System Pharmacists, and 340B Health, among others. Passing this bipartisan legislation will ensure that RRCs and SCHs (as well as critical access hospitals and cancer

[3] *Drugmakers Manipulate Orphan Drug Rules to Create Prized Monopolies*, Kaiser Health News, January 17, 2017: https://bit.ly/3e8WOh9

hospitals) benefit from 340B to the extent that Congress intended, allowing these rural facilities to continue to provide their communities with local access to important health care services.

To the extent you are contemplating introducing legislation as a result of this inquiry, we urge you to include the provisions of H.R.4538 in that bill.

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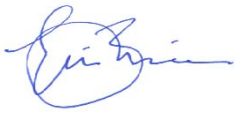
We are hopeful that this response is helpful to the committees.

The Coalition thanks you again for the opportunity to be part of this important discussion, and we look forward to serving as a resource.

Please do not hesitate to contact me at 202.204.1457 or ezimmerman@mcdermottplus.com if you have any questions.

Sincerely,



Eric Zimmerman