February 17, 2021

The Honorable Peter Welch  
United States House of Representatives  
2187 Rayburn House Office Building  
Washington, DC 20515

The Honorable David McKinley  
United States House of Representatives  
2239 Rayburn House Office Building  
Washington, DC 20515

Dear Representatives Welch and McKinley,

The National Rural Health Association (NRHA), a nonprofit organization of 21,000 members that represents the health interests of rural Americans, applauds your bipartisan introduction of the Closing Loopholes for Orphan Drugs Act (H.R. 853). This bill provides much needed clarity for the 340B Program’s orphan drug exclusion to ensure the exclusion is limited only to the uses for which the drug received orphan designation.

In 2010, Congress sought to make it easier for Rural Referral Centers (RRCs) and Sole Community Hospitals (SCHs)—along with certain other hospital types, including Critical Access Hospitals—to participate in the 340B Program. However, many of these newly eligible hospitals are being deprived of 340B Program benefits due to court decisions invalidating regulations and broadly interpreting a provision of the law excluding drugs with orphan designation from the program’s drug discount requirements. By clarifying the 340B Program’s orphan drug exclusion to explicitly limit the carve-out only to those uses for which the drug received orphan designation, H.R. 853 will ensure that RRCs and SCHs benefit from the 340B Program to the extent that Congress intended, allowing these facilities to continue to provide rural communities with local access to important health care services.

NRHA strongly supports the Closing Loopholes for Orphan Drugs Act and commends your efforts to support RRCs and SCHs, and for sponsoring this important piece of legislation. If you have any questions, please do not hesitate to call Josh Jorgensen at 202-639-0550 or by email at jjorgensen@nrharural.org. We thank you for sponsoring this important legislation and being stalwart champions for rural America.

Sincerely,

Alan Morgan  
Chief Executive Officer