

September 7, 2021

The Hon. Frank Pallone, Jr., Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Hon. Cathy McMorris Rodgers, Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
2322 Rayburn House Office Building
Washington, DC 20515

The Hon. Anna G. Eshoo, Chair
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
272 Cannon House Office Building
Washington, DC 20515

The Hon. Brett Guthrie, Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2434 Rayburn House Office Building
Washington, DC 20515

RE: Please Support Section 90006 of H.R. 3684 to Delay of the “Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees” Final Rule to January 1, 2026

Dear Chairman Pallone, Ranking Member McMorris Rodgers, Chairwoman Eshoo, Ranking Member Guthrie, and distinguished members of the Committee:

Navitus Health Solutions writes to provide these comments regarding Congress’ proposed delay of the “Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees” Final Rule¹ until January 1, 2026 through Section 90006 of H.R. 3684, the Infrastructure Investment and Jobs Act.

As background, Navitus Health Solutions is a 100% pass-through, fully transparent, pharmacy benefit manager (PBM). Since the founding of our company in 2003, Navitus has relentlessly worked to reduce the overall drug costs paid by our clients, while improving member health, providing superior customer service, and ensuring regulatory compliance. Navitus administers pharmacy benefits to over 750 clients with more than seven million members across our commercial, ACA/Exchange, Medicaid, Medicare Part D, and discount card lines of business.

Navitus urges you to support passage of Section 90006 “Moratorium on implementation of rule relating to eliminating the anti-kickback statute safe harbor protection for prescription drug rebates” within H.R. 3684, the Infrastructure Investment and Jobs Act.

Navitus has previously commented on why the so-called “Rebate Reform Rule” is ill-advised. On April 5, 2019, Navitus submitted comments to the U.S. Department of Health & Human Services (HHS) on the then-

¹ 85 Fed. Reg. 76666 (Nov. 30, 2020).

proposed rule.² Additionally, on May 9, 2019, I testified before the U.S. House Energy & Commerce Subcommittee on Health at a hearing on "Lowering Prescription Drug Prices: Deconstructing The Drug Supply Chain."³ Our concerns regarding the rule pertain to the following topics outlined in those documents:

- **The Rule Will Result in Increased Costs for Part D Beneficiaries, Plans, and CMS**
- **Safe Harbors for Any Amounts Retained by PBMs from Drug Manufacturers Creates a Conflict of Interest**
- **The Rule Ignores Existing Transparent Model PBMs**
- **The Actuarial and Economic Analyses Yield Uncertain Outcomes from the Rule**
- **"Chargeback" Definition and Implementation of Price Reductions at the Point of Sale are Unclear**
- **The Rule Potentially Violates Federal Law**
- **The Timeframe for Compliance is Unreasonable**
- **The Rule Ignores the Role of Drug Manufacturers in Setting Drug Prices**
- **The Safe Harbor Should Include Claims with 100% Cost Sharing**

For the reasons outlined in the Congressional testimony and the regulatory comment letter, we urge Congress to pass Section 90006 of H.R. 3684 and delay the implementation date of the Rebate Reform Rule to January 1, 2026.

Thank you for the opportunity to provide feedback on this matter. If we can provide any additional information or answer additional questions, please let us know. Please also let us know if you would like to meet with us at any of our facilities in Madison or Appleton in Wisconsin; Austin, Texas; Phoenix, Arizona; Gaithersburg, Maryland; Irvine, California; or Brentwood, Tennessee.

Sincerely,



Brent J. Eberle, RPh, MBA
Senior Vice President & Chief Pharmacy Officer

CC: Members, Committee on Energy and Commerce, U.S. House of Representatives

Enclosed:

Navitus Regulatory Comment Letter to the U.S. Department of Health & Human Services (April 5, 2019).

Navitus Testimony Submitted to the U.S. House of Representatives, Energy & Commerce Committee, Subcommittee on Health (May 9, 2019).

² Available at <https://www.regulations.gov/comment/HHSIG-2019-0001-19509>.

³ Available at <https://bit.ly/3jjNDyQ>.