

United States Senate
WASHINGTON, DC 20510

May 2, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Administrator Brooks-LaSure:

We appreciate the steps the Centers for Medicare and Medicaid Services (CMS) took throughout the COVID-19 pandemic to ensure access to COVID-19 testing and vaccination services, especially in rural and urban underserved areas. In particular, we support CMS's efforts to empower pharmacists to serve as Medicare providers to increase access to testing and get shots in arms. While we recognize that current statute limits the capacity of licensed pharmacists to provide and bill Medicare directly for professional services, we appreciate efforts by CMS to facilitate pharmacists as providers in the Medicare program through existing authorities and we are encouraged by the potential for pharmacists to continue to serve their communities as Medicare providers following the end of the COVID-19 public health emergency (PHE) designation. As the Department of Health and Human Services (HHS) and CMS consider ending the COVID-19 PHE, we urge you to take steps to ensure a smooth transition that ensures Medicare beneficiaries can continue to access essential COVID-19 services to Medicare beneficiaries, vaccination, and other medical services from their local pharmacist.

We are committed to improving health care access in rural and urban underserved areas.¹ We have introduced legislation² that encourages pharmacists to serve older Americans in communities lacking easy access to doctors by offering certain medical services, such as COVID-19 testing, immunizations, health and wellness screenings, and diabetes management. Approximately 93% of Americans live within five miles of a pharmacy and can utilize certain medical services performed by a pharmacist.³ While many states allow pharmacists to provide certain medical services,⁴ there is currently no way for a pharmacist to receive Medicare Part B reimbursement for providing these services. We remain committed to passing bipartisan legislation to improve access to these services. We also recognize pharmacists have been granted regulatory flexibilities during the COVID-19 pandemic and we want to ensure those flexibilities are clarified under current statute once the PHE declaration ends.

¹ Underserved areas define as: Medically Underserved Areas (MUAs), Medically Underserved Populations (MUPs), or Health Professional Shortage Areas (HPSAs).

² Pharmacy and Medically Underserved Areas Enhancement Act, S. 1362, 117th Cong. (2021).

³ Casserlie, L. M., & Mager, N. A. (2016). Pharmacists' perceptions of advancing public health priorities through medication therapy management. *Pharmacy practice*, 14(3), 792. <https://doi.org/10.18549/PharmPract.2016.03.792>

⁴ Pharmacy and Medically Underserved Areas Enhancement Act, S. 1362, 117th Cong. (2021).

As a result of the federal government’s COVID-19 response, pharmacists have served the Medicare population through COVID-19 testing,⁵ vaccine administration,⁶ and certain medical services⁷ authorized under the PHE declaration. For example, through the Federal Pharmacy Retail Program, pharmacists opened more than 10,000 free testing sites and administered nearly 230 million vaccine doses.^{8, 9} Research suggests pharmacies are practical locations for testing¹⁰ and many independent pharmacies serve our most vulnerable and underserved communities.¹¹

As HHS and CMS prepare to end the PHE, we want to ensure a smooth transition ensuring maximum regulatory flexibility under the statute. We request clarification about the flexibilities granted to pharmacists once the PHE ends regarding testing, vaccination, and other medical services. We respectfully ask you to address the following questions:

1. Following the end of the PHE, do pharmacists have the ability to bill for lab tests and vaccine administration under Medicare Part B?
2. Following the end of the PHE, will pharmacists employed by pharmacies without a Clinical Laboratory Improvement Amendments (CLIA) Certificate or Certificate of Waiver receive direct Medicare Part B reimbursement for COVID-19, influenza, respiratory syncytial virus, and/or streptococcal pharyngitis testing services including specimen collection? If not, please clarify how CMS, in partnership with state regulatory agencies, has streamlined the process.
3. Following the end of the PHE, can pharmacists receive Medicare Part B reimbursement for administering vaccinations without mass-immunizer enrollment?
4. Following the end of the PHE, can pharmacists receive Medicare Part B reimbursement for certain medical services (e.g., health and wellness screenings and diabetes management)?

We also request CMS publish guidance about what flexibilities and clarified roles pharmacists will be able to maintain under Medicare once the PHE ends. We ask that this information be easy

⁵ CMS, “COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing,” February 28, 2022. <https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf>.

⁶ 85 Fed. Reg. 52,138 (cols. b.-c.); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, available at www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf.

⁷ CMS, “COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing,” February 28, 2022. <https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf>.

⁸ Centers for Disease Control & Prevention, “The Federal Retail Pharmacy Program for COVID-19 Vaccination,” March 2022. <https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html>.

⁹ Department of Health & Human Services, “Community-Based Testing Sites for COVID-19,” January 2022. <https://www.hhs.gov/coronavirus/community-based-testing-sites/index.html>.

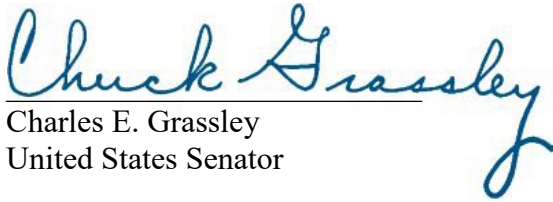
¹⁰ Doucette, J. & Lavino, J. (2021). Ability of community pharmacists to independently perform CLIA-waived testing – A multistate legal review, Vol. 2, 100024. <https://doi.org/10.1016/j.rcsop.2021.100024>.

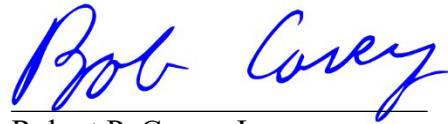
¹¹ National Community Pharmacists Association, “Independent Pharmacy is the Safety Net Against COVID-19 for Millions of Americans, New Data Shows,” April 7, 2020. <https://ncpa.org/newsroom/news-releases/2020/04/07/independent-pharmacy-safety-net-against-covid-19-millions>.


to understand for pharmacies of all sizes. While some of this guidance has been provided, we believe it is important this information is clarified in one location online.

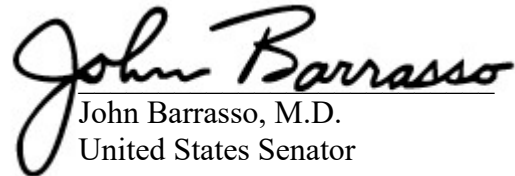
The pandemic has confirmed the importance of ensuring continued access local pharmacists and we have long supported improving patient access to pharmacy services. This includes changing Medicare policy so pharmacists can receive reimbursement for additional health care services authorized under state law. We appreciate your attention to this matter as we seek to ensure pharmacists can continue to provide important medical services that keep their communities healthy.

Sincerely,


Charles E. Grassley
United States Senator


Robert P. Casey, Jr.
United States Senator


Sherrod Brown
United States Senator


John Barrasso, M.D.
United States Senator


Ben Ray Luján
United States Senator