

To: Future of Pharmacy Coalition

From: Avalere Health

Date: July 30, 2023

Re: Estimated Federal Impact of H.R. 1770 – Equitable Community Access to

Pharmacist Services Act

Overview

The Future of Pharmacy Coalition commissioned Avalere to estimate the 10-year federal budget impact of H.R. 1770 – Equitable Community Access to Pharmacist Services Act, introduced on March 23, 2023. This legislation would allow Medicare to reimburse pharmacists for certain services under Part B, such as testing, treatment, and vaccination for certain conditions. In addition, the bill would allow payment to pharmacists for services related to a public health emergency (PHE).¹

Avalere estimates that this legislation would increase federal spending by \$1.5 billion over fiscal years 2024 – 2033, after accounting for an estimated \$221 million in federal savings due to improved health outcomes (Table 1).

Table 1. Estimated Federal Spending and Savings Due to the Implementation of H.R. 1770, the Equitable Community Access to Pharmacist Services Act (\$ in billions, by fiscal year)

	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2024- 2033
Total Federal Spending	0.05	0.14	0.15	0.16	0.16	0.16	0.17	0.17	0.18	0.19	1.54
Estimated Savings from Improved Health Outcomes	(0.01)	(0.02)	(0.02)	(0.02)	(0.02)	(0.02)	(0.02)	(0.02)	(0.02)	(0.02)	(0.22)

Note: Sums may not total due to rounding.

Source: Avalere analysis of revised bill text for H.R. 1710 – Equitable Community Access to Pharmacist Services Act, as introduced on March 23, 2023.

©2023. Avalere Health LLC. All Rights Reserved

The projected estimates are subject to uncertainty based on a range of factors, including patient behavior, pharmacist behavior, and other factors described in this document. The primary driver

¹ H.R.1770 – Equitable Community Access to Pharmacist Services Act. Introduced March 23, 2023. Available here.



for the increase in federal spending is the cost for additional pharmacist treatment services. However, Avalere considered a broad set of potential cost drivers in developing the analysis.

Description of Key Provisions

Under current law, pharmacists are not able to bill Medicare directly for most services under Part B. They can bill incident-to-physician services in a limited set of circumstances and are subject to state scope of practice laws. One exception is billing for COVID-19 and influenza vaccine administration as mass immunizers under Part B, a policy established through regulatory authority.² Under the proposed Equitable Community Access to Pharmacist Services Act, Medicare would allow pharmacists to bill and be reimbursed for three designated sets of services:

- (1) Testing and related evaluation and management services for COVID-19, influenza, respiratory syncytial virus (RSV), or streptococcal pharyngitis;
- (2) Initiation of a drug regimen for COVID-19, influenza, or streptococcal pharyngitis; and
- (3) Administration of a vaccine and related services for COVID-19, influenza, pneumococcal, or hepatitis B.

The legislation would also allow payment to pharmacists for services "that address a public health need related to a public health emergency." Reimbursement would be set at 85% of the physician fee schedule (PFS) unless services are provided in the context of a federal emergency, during which pharmacists would be reimbursed at 100% of the PFS payment rates.

Literature Search Results

Avalere conducted a PubMed literature search on US-based, English language research studies published between 2020-2023. The search strategy focused on Medicare patients and the impact of COVID-19, RSV, and influenza testing, treatment, and vaccine administration on hospitalization and mortality rates. Furthermore, Avalere supplemented its PubMed search with ancillary articles that focused on general access to pharmacies, pharmacists' willingness/ability to adopt additional services, and whether patients use healthcare services earlier or more because of pharmacy availability.

A review of key findings included in abstracts of articles identified highlight the role that pharmacists play in promoting and delivering preventive care, primarily as mass immunizers. The article abstracts suggest pharmacists could be well positioned to expand testing and administration services, especially for patients with high needs (i.e., Medicare enrollees).4 The literature review highlights that pharmacies are often more accessible in both rural and urban

⁴ Bartsch, S. M., Taitel, M. S., DePasse, J. V., Cox, S. N., Smith-Ray, R. L., Wedlock, P., Singh, T. G., Carr, S., Siegmund, S. S., & Lee, B. Y. (2018). Epidemiologic and economic impact of pharmacies as vaccination locations during an influenza epidemic. Vaccine, 36(46), 7054–7063. https://doi.org/10.1016/j.vaccine.2018.09.040



² 2020 CMS-9912-IFC. 2020. Available <u>here</u>.

³ H.R.1770 – Equitable Community Access to Pharmacist Services Act. Introduced March 23, 2023. Available <u>here</u>.

settings and experienced an increase in healthcare visibility throughout the COVID-19 pandemic.

Most literature that Avalere identified focuses on the reduction in hospitalization rates after vaccination.⁵ Avalere also found studies outlining the burden of infectious diseases such as influenza and RSV on the US healthcare system.⁶ Finally, Avalere reviewed studies on testing and treatment for infectious diseases. Most studies focused on testing and treatment related to COVID-19, specifically use of nirmatrelvir-ritonavir (Paxlovid).⁷

Shah et al. highlighted reduced hospitalization from early COVID-19 treatment with Paxlovid. The findings suggest that early COVID-19 treatment (i.e., administering Paxlovid to a patient within five days of a COVID-19 diagnosis) resulted in a 47% decrease in hospitalization rates among patients over age 65, compared with similar patients who had not received Paxlovid.⁸ Avalere incorporated this reduction of hospitalizations as an assumption in the calculation of cost savings resulting from H.R. 1770.

Data Sources

Avalere used the following data sources to develop our estimate:

- Congressional Budget Office (CBO) An Update to the Budget Outlook: 2023 to 2033
- Centers for Medicare & Medicaid Services Medicare Trustees Report, 2023
- Center for Disease Control and Prevention (CDC)
 - o Influenza (Flu): Current (2022-2023) and Past Flu Seasons (2018-2019)
 - FluView <u>National</u>, <u>Regional and State Level Outpatient Illness and Viral</u> <u>Surveillance</u>
 - FluVaxView Influenza Vaccination Coverage for Persons 6 Months and Older
 - Morbidity and Mortality Weekly Report <u>Seasonality of Respiratory Syncytial</u>
 Virus United States, 2017-2023
- Office of the Assistant Secretary for Preparedness and Response
 - COVID Treatment Lagevrio (molnupiravir)
 - COVID Treatment Paxlovid (nirmatrelvir-ritonavir)

⁸ Shah, M. M., Joyce, B., Plumb, I. D., Sahakian, S., Feldstein, L. R., Barkley, E., Paccione, M., Deckert, J., Sandmann, D., Gerhart, J. L., & Hagen, M. B. (2022). Paxlovid Associated with Decreased Hospitalization Rate Among Adults with COVID-19 - United States, April-September 2022. MMWR. Morbidity and mortality weekly report, 71(48), 1531–1537. https://doi.org/10.15585/mmwr.mm7148e2



Moline, H. L., Whitaker, M., Deng, L., Rhodes, J. C., Milucky, J., Pham, H., Patel, K., Anglin, O., Reingold, A., Chai, S. J., Alden, N. B., Kawasaki, B., Meek, J., Yousey-Hindes, K., Anderson, E. J., Farley, M. M., Ryan, P. A., Kim, S., Nunez, V. T., Como-Sabetti, K., ... Havers, F. P. (2021). Effectiveness of COVID-19 Vaccines in Preventing Hospitalization Among Adults Aged ≥65 Years - COVID-NET, 13 States, February-April 2021. MMWR. Morbidity and mortality weekly report, 70(32), 1088–1093. https://doi.org/10.15585/mmwr.mm7032e3

⁶ Zheng, Z., Warren, J.L., Shapiro, E.D. et al. Estimated incidence of respiratory hospitalizations attributable to RSV infections across age and socioeconomic groups. Pneumonia 14, 6 (2022). https://doi.org/10.1186/s41479-022-00098-x

⁷ Dryden-Peterson, S., Kim, A., Kim, A. Y., Caniglia, E. C., Lennes, I. T., Patel, R., Gainer, L., Dutton, L., Donahue, E., Gandhi, R. T., Baden, L. R., & Woolley, A. E. (2023). Nirmatrelvir Plus Ritonavir for Early COVID-19 in a Large U.S. Health System: A Population-Based Cohort Study. Annals of internal medicine, 176(1), 77–84. https://doi.org/10.7326/M22-2141

- Johns Hopkins University Coronavirus Resource Center Daily State-By-State Testing **Trends**
- Kaiser Family Foundation (KFF) COVID-19 Vaccine Monitor
- Mayo Clinic U.S. COVID-19 Vaccine Tracker
- ScienceDirect Principles and Practice of Infectious Diseases
- Clinical Infectious Diseases Clinical Practice for the Diagnosis and Management of Group A Streptococcal Pharyngitis

Assumptions and Methodology

For this analysis, Avalere leveraged internal expertise to develop a methodology and key assumptions like those that would be used by CBO. This estimate, however, is subject to uncertainty given the range in assumptions and reliance on patient and pharmacist behavior, as well as availability of services.

Specifically, this estimate assumes the disease trajectory of COVID-19 has evolved to mirror endemic-like patterns seen with influenza.9 However, if COVID-19 continues to experience the emergence of new variants with unpredictable waves of infections, there would be deviation from the model estimates. Variability in influenza, RSV, and streptococcal pharyngitis from yearto-year also creates uncertainty for estimates around testing, treatment, and vaccination rates for these conditions. Finally, this model leverages assumptions that are subject to uncertainty about the frequency of future PHEs. In developing assumptions around COVID-19 services, Avalere assumed that the term COVID-19 refers to disease caused by current and future variants of the SARS-CoV-2 virus.

Avalere assumed legislation enacted in January 2024 would be implemented in March 2024. In alignment with CBO's May 2023 baseline projections and the termination of the PHE on May 11, 2023, Avalere assumed reimbursement will be set at 85% of PFS except during future PHEs. Detailed information on the methodology and assumptions used to develop this estimate are outlined below.

Uptake by Beneficiaries and Service Utilization

Avalere estimated the total volume of services that patients would receive from pharmacists under the bill by determining the number of applicable services Medicare beneficiaries may receive for each year of the budget window and the share they would obtain from pharmacists. Epidemiologic data for influenza, COVID-19, RSV, and streptococcal pharyngitis were used to model utilization over the 10-year window. For services where historical data are limited or future projections are uncertain/unavailable, Avalere relied on analogues to estimate volumes. For instance, estimates related to COVID-19 activities were informed by baseline COVID-19 data and projected using relevant influenza data to model endemic behavior over a 10-year

⁹ On average, in the 2018-2019 influenza season, the 65+ population had approximately 2.2 million influenza cases. CDC. Influenza (Flu): 2018-2019 Flu Season. Available here.



period. This approach was applied to all testing and treatment services outlined in the legislation. For all services, Avalere focused on data specific to individuals 65 and older to represent the general size and behaviors of the Medicare population. Avalere then scaled its estimates to ensure they reflect the entire Medicare population, including non-elderly disabled individuals.

Since many pharmacists are already providing COVID-19 vaccination, testing, and treatment services under authority conferred under the Public Readiness and Emergency Preparedness (PREP) Act during the PHE and beneficiaries are aware they can receive these services at pharmacies, Avalere assumed a faster ramp-up period for service utilization—75% of estimated utilization in year 1 then 100% of estimated utilization for years 2 through 10 of the budget window. Avalere also assumed that while beneficiaries will continue to receive most primary care through physician offices, 10% would seek care at pharmacies, instead of physician offices, for testing and treatment services outlined in the legislation based on historical data for site of flu vaccinations.¹⁰ Avalere also assumed that the convenience of receiving services from pharmacists would result in a demand increase of 35% for testing and treatment services. Utilization of services provided by pharmacist was informed by recent CDC data on the share of influenza vaccines administered by pharmacists.11

Pharmacist Testing Services

Facilities in the US that perform laboratory testing for health assessment or the diagnosis, prevention, or treatment of disease are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Facilities that do not typically function as labs, such as pharmacies, can pursue CLIA certificates of waiver to examine patients using tests that are approved for home use or that have a low risk of erroneous results (CLIA-waived tests).12 To account for pharmacies engaged in CLIA-waived testing, Avalere attributed the proportion of pharmacies that are CLIA-waived labs (approximately 41%) to the baseline number of tests administered by pharmacists.¹³ CLIA-waived tests are generally simple tests with a low risk for error. Another way pharmacies can conduct testing is by engaging in specimen collection under contract with a laboratory. Under these arrangements, payment flows through the billing laboratory. Avalere accounted for these arrangements and found that they would have a negligible impact on spending, as pharmacists do not directly bill Medicare for this service.

Avalere used current testing data to estimate the volume that would be provided by pharmacists as outlined in the legislation. For COVID-19, influenza, RSV, and streptococcal pharyngitis, testing estimates were projected using existing testing, incidence, and prevalence data. Avalere estimated that on average about 1.5 million tests would be provided for each disease by pharmacists each year, under the legislation, in the 2024-2033 window. Testing estimates were

¹³ To calculate the share of retail pharmacies that operate as CLIA-waived labs, Avalere divided the number of pharmacies with a CLIA certificate of waiver according to CMS' Quality Certification & Oversight Reports as of June 2022 by the number of pharmacies in the US as reported by IQVIA.



¹⁰ CDC. FluVaxView - Place of Vaccination. Available here and Place of Flu Vaccinations by Age Group, Adults, United States, 2020-21 Season. Available here.

¹¹ CDC. FluVaxView – Place of Flu Vaccinations by Age Group, Adults, United States, 2020-21 Season. Available here.

¹² CDC. Laboratory Quality: Waived Tests. Available <u>here</u>.

adjusted to account for surges due to new variants and increased availability and utilization of at-home COVID-19 tests.

Pharmacist Treatment Services

After identifying the number of beneficiaries who would utilize testing services, Avalere estimated the number of encounters anticipated per year where treatment would be rendered, including prescribing and dispensing treatment. Avalere applied the share of Medicare beneficiaries living in the ten states that allow pharmacist prescribing capabilities (~16 million or 28%) to an estimated percentage of positive tests. 14 Positivity rate was based on COVID-19 data from Johns Hopkins University Coronavirus Resource Center¹⁵ and was used as proxy for streptococcal pharyngitis and influenza. For COVID-19, estimates for treatment services utilized COVID-19 testing data and applied a similar treatment pattern based on seasonal influenza to determine the number of beneficiaries that will receive treatment. Treatment estimates for influenza and streptococcal pharyngitis were based on epidemiologic data for 2019, prior to the COVID-19 pandemic.

For each condition, Avalere estimated that an annual average of approximately 108,000 beneficiaries would receive treatment from pharmacists under the legislation. Avalere assumed pharmacist-administered treatment for streptococcal pharyngitis, influenza, and COVID-19 would occur in 2024. Avalere assumed that the same 10 states with expanded pharmacist prescribing authorities would continue to allow the prescription of COVID-19 treatment when flexibilities under the PREP Act expire, currently December 31, 2024.16

Pharmacist-Administered Vaccines

In addition to pharmacist testing and treatment services, Avalere examined uptake and utilization of pharmacist-administered vaccinations. Under current law, pharmacists would continue to bill Part B for COVID-19, pneumococcal, and influenza vaccine administration as mass immunizers.¹⁷ As a result, Avalere assumed no additional budgetary impact under this legislation for direct billing provisions. For hepatitis B, Avalere estimated that an annual average of 33,000 beneficiaries would receive the vaccine from pharmacists over the 10-year budget window. This was calculated based on hepatitis B vaccine use among Medicare Part D enrollees as reported by the Department of Health and Human Services.¹⁸

Additional Services Related to Public Health Emergencies

Avalere examined the number of relevant PHEs over the last two decades and determined that approximately seven occurred during that time. The public health emergencies of international concern (PHEIC) considered were H1N1, Middle East respiratory syndrome (MERS), polio, Ebola (2 incidences), Zika virus, and COVID-19.19 Avalere applied a probability of 35% (7 PHEs / 20 years) of future PHEs occurring during the 10-year budget window. During a PHE,



¹⁴ States with expanded pharmacist prescribing authority include AR, CA, CO, FL, ID, ND, NM, OR, UT, and VA.

¹⁵ Johns Hopkins University Coronavirus Resource Center. Available <u>here</u>.

¹⁶ 2023 HHS 88 FR 30768. Available <u>here</u>.

^{17 2020} CMS-9912-IFC. 2020. Available here; Medicare coverage determination for the recently FDA-approved RSV vaccine is currently underway. It is assumed that administration of the RSV vaccine, once approved, would fall under the mass immunizer program.

¹⁸ ASPE. Medicare Part D Enrollee Savings from Elimination of Vaccine Cost-Sharing. Avalere <u>here</u>.

¹⁹ Council on Foreign Relations. 2022. Available <u>here</u>. Roychoudhury et al. 2022. Available <u>here</u>.

reimbursement to pharmacists will increase to 100% of PFS rates. The cost of this section of the legislation is negligible.

Medicare Payment for Pharmacist Services

To develop cost estimates, Avalere identified the specific items and services that would be reimbursed under each set of newly billable pharmacist services. Avalere assumed that payment would comprise 2 parts: (1) reimbursement under Part B for evaluating a patient presenting at the pharmacy, testing, and initiating the drug regimen, and (2) reimbursement under Part D for the product dispensed.

Avalere assumed that a new Current Procedural Terminology (CPT) code would be developed specific to pharmacist patient assessment evaluation and management (E/M) services. The CPT would be a blend of non-facility level 1 and 2, valued at approximately \$30. This blend reflects a higher proportion of the patients testing negative and receiving level 1 E/M service, while the remaining test positive and receive level 2 E/M service.

For testing, Avalere utilized 2023 second guarter clinical laboratory fee schedule (CLFS) rates for COVID-19, influenza, RSV, and streptococcal pharyngitis tests. Testing costs ranged from \$14 for RSV to \$25 for COVID-19.

For treatment of patients who test positive for COVID-19, influenza, and streptococcal pharyngitis, Avalere estimated Part D payment based on the cost of a treatment regimen for relevant products. These included either Lagevrio or Paxlovid for treating COVID-19, oseltamivir (Tamiflu) for treating influenza, and amoxicillin or azithromycin for treating streptococcal pharyngitis. Avalere assumed average costs per treatment in 2022 of \$600 for COVID-19 treatments, \$75 for influenza, and \$5 for streptococcal pharyngitis. The prices of these drugs were grown at the average Part D per capita growth rate over the budget window. Avalere assumed that Paxlovid and Lagevrio would account for 87% and 13% of COVID-19 prescription volume, respectively.20

Downstream Impact of Pharmacist Services

Considering the convenience of pharmacist services and the literature findings, Avalere estimated the downstream impact on health outcomes and federal budgetary savings that could occur under this legislation. To estimate potential savings from pharmacist testing for and treatment of COVID-19, Avalere used COVID-19 hospitalization rates and cost data for the age 65 and older population.²¹ Differential hospitalization rates (0.88% for individuals that received treatment and 2.03% for those not receiving treatment) were applied to the additional volume of treatment that would occur under the legislation to calculate the volume of avoided hospitalizations. The average COVID-19 inpatient hospitalization cost for Medicare FFS beneficiaries (\$22,000) was grown by annual rate increases for Part A payments and later

²¹ Shah, Melisa M., et al. "Paxlovid Associated with Decreased Hospitalization Rate Among Adults with COVID-19 — United States, April–September 2022." Morbidity and Mortality Weekly Report 71, no. 48 (December 2022): 1531-1537. Available here.



²⁰ ASPR. COVID-19 Therapeutics Thresholds, Orders, and Replenishment. Available <u>here</u>.

applied to the number of avoided hospitalizations to derive the estimated savings between 2024-2033.22

²² Tsai, Yuping, Tara M. Vogt, and Fangjun Zhou. "Patient Characteristics and Costs Associated With COVID-19–Related Medical Care Among Medicare Fee-for-Service Beneficiaries." Annals of Internal Medicine (August 2021). Available here.

