To: Future of Pharmacy Coalition

From: Avalere Health

Date: June 28, 2022

Re: Estimated Federal Impact of H.R. 7213 - Equitable Community Access to Pharmacist Services Act

Overview

The Future of Pharmacy Coalition commissioned Avalere Health to estimate the 10-year federal budget impact of H.R. 7213 – Equitable Community Access to Pharmacist Services Act, introduced on March 24, 2022. 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 designated by the Secretary of the Department of Health and Human Services (HHS) related to a public health emergency (PHE) or services that close health equity care gaps.[1] Avalere estimates that this legislation would increase federal spending by $2.2 billion over fiscal years 2023 – 2032. Estimates are subject to uncertainty based on a range of factors, including patient and pharmacist behavior, duration of the PHE, and other factors described in this document. Overall, the legislation's impact on federal spending is mostly driven by pharmacist testing services and related assessments, as well as by treatment services. However, Avalere outlined for a broad set of potential cost drivers in developing the analysis.

Table 1. Estimated Changes to Federal Spending Due to the Implementation of H.R. 7213, the Equitable Community Access to Pharmacist Services Act *($ in billions, by fiscal year)*

	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2023-2032
Total Change in Federal Spending	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.3	0.3	**2.2**

Note: Sums may not total due to rounding.
Source: Avalere analysis of bill text H.R. 7213 – Equitable Community Access to Pharmacist Services, introduced on March 24, 2022.

[1] H.R.7213 - Equitable Community Access to Pharmacist Services Act. Introduced March 24, 2022. Available here.

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, but only in a limited set of circumstances, and are subject to state scope of practice laws. One exception is billing for COVID-19 and flu vaccine administration as mass immunizers under Part B, a policy that has been 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 3 designated sets of services: (1) testing and related 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 or influenza. The legislation would also allow payment to pharmacists for services "that address a public health need related to a public health emergency" or services that "close gaps in health equity", as designated by the HHS Secretary.[3] 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.

Data Sources

Avalere used the following data sources to develop our estimate:

- Congressional Budget Office (CBO) – The Budget and Economic Outlook: 2022 to 2032
- Centers for Medicare & Medicaid Services
  - Medicare Trustees Report, 2022
- Center for Disease Control and Prevention (CDC)
  - Influenza (Flu): Current (2021-2022) and Past Flu Seasons (2018-2019)
  - FluView – National, Regional and State Level Outpatient Illness and Viral Surveillance
  - FluVaxView – Influenza Vaccination Coverage for Persons 6 Months and Older
- Office of the Assistant Secretary for Preparedness and Response
  - COVID Treatment – Lagevrio (molnupiravir)
  - COVID Treatment – Paxlovid
- 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
- Epic Research – RSV Rebounds Off-Season, but Influenza is Still a No-Show
- ScienceDirect – Principles and Practice of Infectious Diseases
- Clinical Infectious Diseases – Clinical Practice for the Diagnosis and Management of Group A Streptococcal Pharyngitis

[2] 2020 CMS-9912-IFC. 2020. Available here.
[3] H.R.7213 - Equitable Community Access to Pharmacist Services Act. Introduced March 24, 2022. Available here.

Assumptions and Methodology

For this analysis, Avalere leveraged internal expertise to develop a methodology and key assumptions similar to 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 will evolve to mirror endemic-like patterns seen with influenza.[4] However, if COVID-19 continues to present as a pandemic with unpredictable waves of infections, there would be deviation from the model estimates. Variability in influenza, RSV, and streptococcal pharyngitis from year-to-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 enactment in October 2022 with implementation on January 1, 2023. Under the assumption that the PHE will end in July 2023, in alignment with CBO's May 2022 baseline projections, the legislation outlines that reimbursement will be set at 100% of PFS through July of 2023, and then 85% of PFS thereafter. 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, 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 period. This approach was applied to all testing and treatment services outlined in the legislation. Epidemiologic data for influenza, RSV, and streptococcal pharyngitis were used to model utilization over the 10-year window. For all services, Avalere focused on data specific to individuals 65 and older to represent the general size and behaviors of the Medicare population. In addition, Avalere applied a proportion to ensure that estimates reflect the entire Medicare population, including non-elderly disabled individuals.

Since many pharmacists are already providing these services under authority conferred by the PHE and beneficiaries are aware they can receive these services at pharmacies,

[4] 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.

Avalere assumed a faster ramp-up period for service utilization—75% of estimated utilization in year 1 and 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 of their 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.[5] Avalere also assumed that the convenience of receiving services from pharmacists would result in a demand increase of 35% for testing and treatment services. Inducement rate was informed by recent CDC data on the share of influenza vaccines administered by pharmacists.[6]

Pharmacist Testing Services

Avalere used current testing data to determine the volume that would be provided by pharmacists as outlined in the legislation. 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).[7] To account for pharmacies engaged in CLIA-waived testing, Avalere attributed the proportion of pharmacies that are CLIA-waived labs (approximately 45%) to the baseline number of tests administered by pharmacists. CLIA-waived tests are generally simple tests with a low risk for error.[8] Another way pharmacies can conduct testing is by engaging in specimen collection under contract with a laboratory. Under these arrangements, payment flows through the laboratory which is the billing provider. 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. 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 2023-2032 window. Testing estimates were adjusted to account for 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, including writing and filling a prescription, would be rendered. Avalere applied the share of Medicare beneficiaries living in the 10 states that allow pharmacist prescribing capabilities (~16 million or 28%) to an estimated percentage of positive tests.[9] Positivity rate was based on COVID-19 data from Johns

[5] CDC. FluVaxView – Place of Vaccination. Available here. CDC. FluVaxView – Place of Flu Vaccinations by Age Group, Adults, United State, 2020-21 Season. Available here.
[6] CDC. FluVaxView – Place of Flu Vaccinations by Age Group, Adults, United State, 2020-21 Season. Available here.
[7] CDC. Laboratory Quality: Waived Tests. Available here.
[8] 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 U.S as reported by IQVIA.
[9] States with expanded pharmacist prescribing authority include AR, CA, CO, FL, ID, ND, NM, OR, UT, VA

Hopkins University Coronavirus Resource Center 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 current pandemic. For each condition, Avalere estimated that an annual average of approximately 120,000 beneficiaries would receive treatment from pharmacists, under the legislation. Avalere assumed pharmacist-administered treatment for streptococcal pharyngitis and influenza would occur in 2023, and COVID-19 in 2024 following the assumed date for full FDA authorization of these treatments. Avalere assumed that the same 10 states with expanded pharmacist prescribing authorities would continue such expansions to allow the prescription of COVID-19 treatment when flexibilities under the Public Readiness and Emergency Preparedness (PREP) Act expire, which is currently set at October 1, 2024.[10]

Pharmacist-Administered Vaccinations

Under current law[11], pharmacists would continue to bill Part B for COVID-19 and influenza vaccine administration post-PHE as mass immunizers. As a result, Avalere assumed no additional budgetary impact under this legislation for direct billing provisions.

Additional Services Related to Public Health Emergencies

Avalere examined the number of relevant PHEs over the last several decades and determined that approximately 7 occurred over the last 2 decades. The public emergencies of international concern (PHEIC) considered were H1N1, Middle East respiratory syndrome (MERS), polio, Ebola (2 incidences), Zika virus, and COVID-19.[12] Avalere applied a probability of 35% (7 PHEs / 20 years) for future PHEs. During a PHE, reimbursement to pharmacists will increase to 100% of PFS rates. The cost of this section of the legislation is negligible.

Services to Address Gaps in Health Equity

Avalere does not anticipate that CBO will score provisions granting the HHS Secretary authority to allow pharmacists to bill for services that close gaps in health equity, as it is difficult to predict actions the HHS Secretary may take under the broad flexibilities granted in the proposed legislation.

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. For assessment and testing, Avalere utilized 2022 second quarter clinical laboratory fee schedule (CLFS) rates for COVID-

[10] 2022 Department of Health and Human Services (HHS) 87 FR 982. 2022. Available here.
[11] 2020 CMS-9912-IFC. 2020. Available here.
[12] Council on Foreign Relations. 2022. Available here. Roychoudhury et al. 2022. Available here.

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 assumed that payment would comprise 2 parts: (1) reimbursement under Part B for evaluating a patient presenting at the pharmacy and initiating the drug regimen, and (2) reimbursement under Part D for the product dispensed. For pharmacy patients, Avalere assumed that a new code would be developed specific to this service whose value would be a blend of non-facility level 1 and 2 evaluation and management (E/M) services, 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. Part D payment was estimated based on the cost of a treatment regimen for relevant products. These included either Lagevrio or Paxlovid for treating COVID-19, Tamiflu for treating influenza, and amoxicillin for treating strep. Avalere assumed average costs for the COVID-19 treatments are about $600 per treatment in 2022. The prices of these drugs were grown at the average Part D per capita growth rate over the budget window. Because limited data exists on product utilization for monoclonal antibodies (mAbs) to treat COVID-19, Avalere assumed that both products would be prescribed with equal frequency, each comprising 50% of prescription volume.