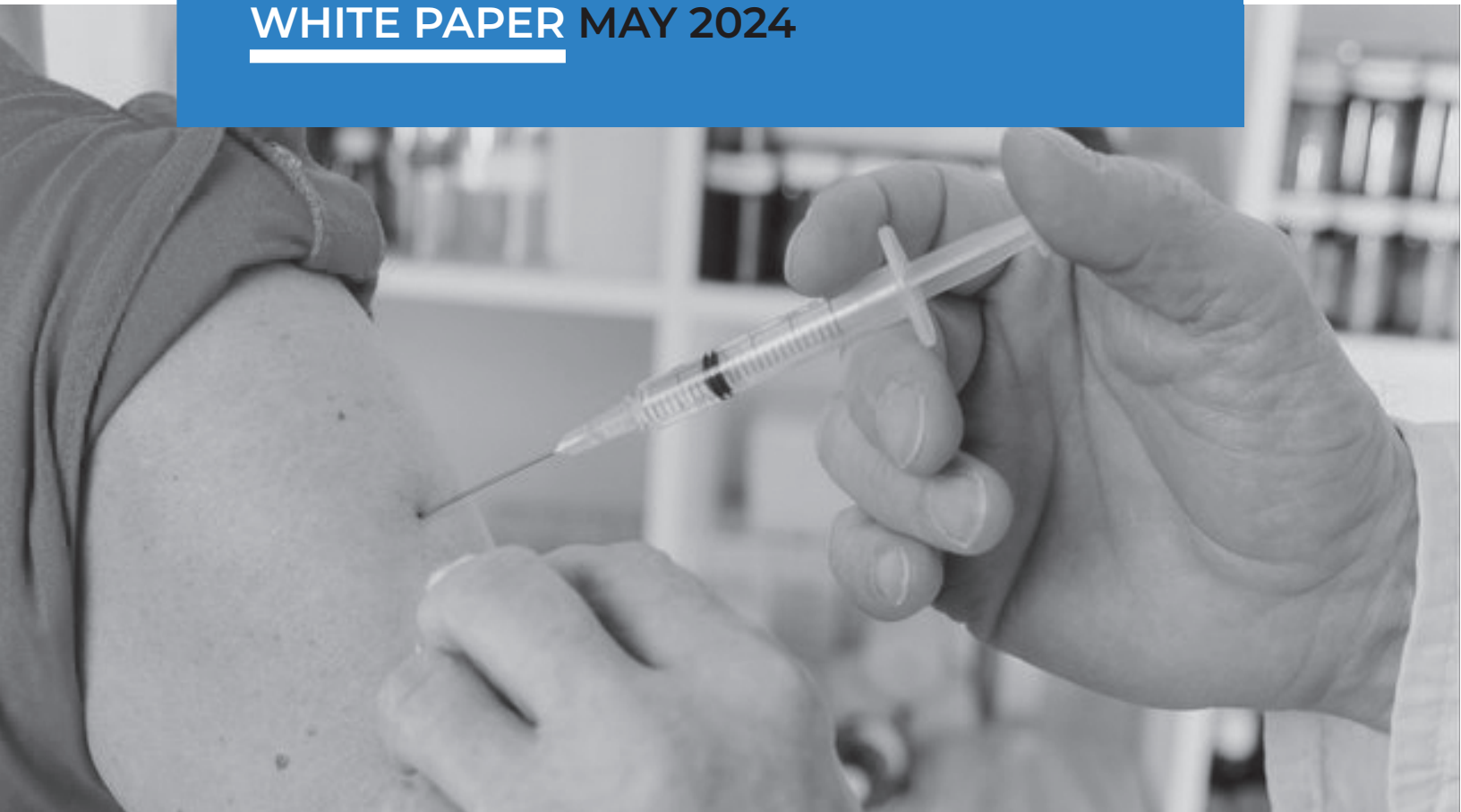


CHALLENGES IN ADULT VACCINATION: POLICY STRATEGIES FOR SUSTAINING ACCESS AND SUPPLY

WHITE PAPER MAY 2024



Robert Popovian, PharmD, MS

Chief Science Policy Officer, Global Healthy Living Foundation
Senior Health Policy Fellow, Progressive Policy Institute
Visiting Health Policy Fellow, Pioneer Institute

Executive Summary

- ▶ Vaccines are one of the most clinically meaningful and cost-beneficial interventions in healthcare.
- ▶ Every vaccine is unique due to molecular variation, differing indications, and side-effect profiles.
- ▶ Private and public insurers are required to provide coverage and reimbursement for all recommended vaccines without any out-of-pocket requirement for all eligible individuals.
- ▶ The current payment and coverage model for adult vaccines has led to robust access for all patients with minimal impact on healthcare spending in the U.S.
- ▶ PBM contractual involvement does not benefit patients financially and harms patient access.
- ▶ Pharmacists are the most accessible healthcare professionals in the U.S.
- ▶ The majority of all adult immunizations today are provided by pharmacists in the U.S.
- ▶ Pharmacies are far more accessible in low-income neighborhoods where ethnic and racial minority adults are overrepresented.
- ▶ Any contracting interference by PBMs concerning pharmacy reimbursement in the current model will inevitably negatively affect underserved patients.
- ▶ Vaccine manufacturing is a complex proposition requiring significant and ongoing investment by biopharmaceutical companies in the upkeep of facilities.
- ▶ Impeding in the current reimbursement and payment model will negatively impact the competitive market, leading to potential vaccine supply challenges.
- ▶ Policymakers should:
 - Champion a competitive vaccine market to maintain a strong supply by prohibiting artificial manipulation by for-profit PBMs and insurers.
 - Make sure private and public insurers cover all adult vaccines.
 - Maintain the current payment and reimbursement model instituted by pharmacists and pharmacies, providing consumers with unhindered access.
 - Continue ensuring patients have access to all eligible vaccines without any out-of-pocket requirements.
 - Ensure that patients continue receiving vaccines at their favored immunization location – at the community pharmacy.

Adult Vaccination in the U.S.

■ Vaccination is considered among the most cost-beneficial public health interventions.¹



According to Plotkin and Mortimer, “the impact of vaccination on the health of the world’s peoples is hard to exaggerate. With the exception of safe water, no other modality has had such a major effect on mortality reduction and population growth.”²

Unfortunately, there have been challenges concerning adult vaccination rates for the past few years due to various factors, including vaccine hesitancy and lack of education.³ The latest immunization data confirms that we are well below the adult vaccination rates recommended by the Centers for Disease Control and Prevention (CDC).^{4,5,6} This also parallels historical data that adult immunization rates have been below recommended Healthy 2020 levels.⁴ For example, the Healthy 2020 objective for pneumococcal vaccination of adults aged 65 or older was 90 percent, while the latest CDC data shows that only 70 percent of people in this age group received this vaccine.^{7,8} The outcome of this behavior is demonstrated by deaths and hospitalizations among adults due to vaccine-preventable diseases.⁹ For example, CDC estimates that since 2010, there have been upwards of 710,000 flu-related hospitalizations and 56,000 flu-related deaths in the United States.⁹ Unfortunately, the reduced vaccination rate is more pronounced in the underserved

communities that are overrepresented by ethnic and racial minorities, as Medicaid-enrolled adults have lower vaccination rates than those with private insurance for nearly all Advisory Committee on Immunization Practices (ACIP) recommended vaccines.¹⁰ Specifically, the vaccination rates among pregnant women are distinctly lower in the Medicaid population.¹⁰

A study published in 2016 by Ozawa et al. estimated that due to low adult vaccination rates the U.S. spends approximately \$9 billion annually treating vaccine-preventable diseases.¹¹ The authors estimated that unvaccinated individuals accounted for almost 80 percent of that spending. More recently, a study published by the Progressive Policy Institute (PPI) estimated that the development of the COVID-19 vaccination and booster saved an estimated 2.9 million lives and prevented 12.5 million hospitalizations.¹² Considering these findings, every policy and educational intervention must focus on increasing immunization rates in the U.S.

Adult Immunization Access in The U.S.

■ Zero out-of-pocket costs for vaccines for which individuals are eligible for in the U.S.

Unlike medications, where high out-of-pocket costs burden patients, all insured individuals, irrespective of age or insurance coverage, have zero out-of-pocket costs for the vaccines they are eligible for in the U.S. This arrangement has been codified into law through the Affordable Care Act (ACA), and most recently, through the Inflation Reduction Act (IRA). Thus, all vaccines recommended by ACIP or the Food and Drug Administration (FDA) and approved for adults must be covered through Medicare, Medicaid, and private insurance without any out-of-pocket cost for adults. Administrative burdens such as prior authorization, tiering, and formulary exclusions are prohibited or unnecessary.

From a patient outcome standpoint, not all vaccines are created equal just because they are intended to prevent a similar disease. Molecular variation and differing data concerning efficacy, effectiveness, safety, and FDA indications make it clinically untenable to institute utilization management tactics of restricting access to a single vaccine in a therapeutic class. Due to the unique personal health factors and healthcare provider recommendations,

individuals may need a specific vaccine. Thus, it is vital that pharmacies and all institutions engaged in immunization practice stock and administer all vaccines and that insurers engage in reimbursement mechanisms that will not favor a specific vaccine. Further, the Centers for Medicare & Medicaid Services (CMS) should rigorously apply its existing regulations that require insurers to reimburse all qualifying vaccines. Utilization of each medicine or vaccine leads to a unique patient outcome, and generalizing such endpoints to gain price concessions that don't translate to direct patient savings should be questioned.

CDC generally does not favor one vaccine over another in the same class unless there is a discernable clinical benefit for patients. For example, although several formulations of the flu vaccine are available in the marketplace, the CDC does not recommend one vaccine manufacturer over another (i.e., preferential treatment) but recommends that all patients be vaccinated against the flu. CDC's policy allows healthcare providers to act as true immunization advocates and determine which flu vaccine is the most appropriate for the specific patient.

The Role of Pharmacists in Adult Immunization

■ Pharmacists are the most accessible healthcare professionals in the U.S.

Pharmacists and pharmacies play a crucial role in adult vaccine access.

Pharmacists are the most accessible healthcare professionals in the U.S.,

where 88.9 percent of individuals live within 5 miles, and 96.5 percent live within 10 miles of a community pharmacy.¹³ For Medicare-eligible beneficiaries (i.e., primarily individuals 65 years and older), pharmacies are a critical access point. A study published in 2018 in the *Journal of American Medical Association* concluded that the median number of visits to community pharmacies was significantly higher than encounters with primary care physicians for Medicare patients.¹⁴

Overall, adult patients prefer going to a pharmacy for their vaccination(s). **A report published in 2023 by IQVIA Human Data Sciences and Global Healthy Living Foundation found that post COVID-19 pandemic, almost 90 percent of adult vaccinations occur at a pharmacy.**¹⁵ This preference was most recently underscored as over 80 percent of respiratory syncytial virus (RSV) vaccines were administered at a pharmacy in the U.S.¹⁶ The report further captures the preference of minorities in utilizing a pharmacy as an immunization site compared to white patients. This

finding further illustrates pharmacists' value in addressing access to medicines in diverse and underserved communities and why pharmacies must be reimbursed for all eligible vaccines.⁹

The role of pharmacists in underserved communities has expanded beyond traditional dispensing functions. A study published in 2021 in the *Journal of American Pharmacists Association* found that **pharmacies and pharmacists are far more accessible in low-income communities than physician practices,** especially when hours of operation are considered.¹⁷ Such access is vital for patients who cannot easily receive vaccinations during typical work hours, lack flexible work schedules, and cannot take time off work during regular work hours when most physician offices are open. Most importantly, racial and ethnic minorities are overrepresented in low-income communities, which makes immunization access through a pharmacist an essential objective in addressing health disparities. A 2018 study found that most African-American patients preferred to receive their vaccination at a pharmacy instead of their physician's office because they could more easily access a pharmacy from their residence.¹⁸

Insurance and Pharmacy Benefit Management Tactics Limit Access to Vaccinations and Affect Pharmacists' Quality of Care

- The negotiation approach has created robust vaccine access for patients.

Pharmaceutical companies engage in price negotiations with retail pharmacies, health systems, and other providers and primarily follow the principles of a competitive private sector marketplace where the engaged parties set prices based on value. This tried-and-true approach has led to significant fiscal benefits, with vaccine spending in the U.S. accounting for only 1.2 percent of total biopharmaceutical spending.¹⁹ Furthermore, the negotiation approach has created robust vaccine access for patients. Finally, such methodology has led to unprecedented investment by the biopharmaceutical industry in the development of innovative vaccines for the prevention of infectious diseases and other dreaded illnesses such as cancers.²⁰

Despite the success of the patient-centered model, there are indications that pharmacy

benefit managers (PBMs) and their allies, the insurance companies, are trying to insert themselves into the established price negotiation paradigm. The vaccine market is one of the few biopharmaceuticals or medical interventions for which PBM or insurer contracting tactics have not penetrated. Hence, PBMs are eager to engage as they see the vaccine market as an untapped profit center. As always, the PBM excuse is that they can negotiate lower prices, but the question everyone should ask is, lower prices for whom? It is well established that any time an insurer or PBM gets involved in drug price contracting, three things happen. **One**, drug list prices increase while net prices remain flat, where the difference is captured as profit by the PBMs.^{21,22} **Two**, when PBMs negotiate and enter the reimbursement model with retail and independent pharmacies, pharmacies end up forgoing reimbursement, which

helps enrich the PBM's bottom line. Beyond undermining the pharmacy business model, this methodology also leads to PBMs and insurance companies pocketing the so-called savings.^{23,24} **Three**, whenever a PBM becomes involved in access management, patient access diminishes. For example, formulary exclusions have expanded so much that most omissions do not benefit patients financially or clinically.²⁵ Regarding vaccines, CMS has stated that they will review Part D formularies to ensure all vaccines are covered.²⁶ However, CMS allows Part D sponsors to place ACIP-recommended adult vaccines on any formulary tier.²⁷

Beyond forgoing the ability to negotiate and benefit from concessions directly, pharmacists and pharmacies should be concerned about the differential payment for administering a particular vaccine. Depending on the price, pharmacies may be reimbursed for different medicines or vaccines at different rates. However, paying pharmacists a different administration fee to entice them to provide a particular vaccine is, at best, undermining clinical decision-making by a healthcare professional and, at worst, illegal. While pharmacists receiving higher administration fees for a specific brand of vaccine may seem economically advantageous, ensuring that such arrangements comply with legal and ethical standards, including anti-kickback laws, transparency requirements, and professional guidelines, is vital. In addition, CMS has weighed in on this topic:

“Part D sponsors will have the discretion to implement either a single vaccine administration fee for all vaccines or multiple administration fees based on the type of vaccine, variance in provider type, and product administration complexity. CMS plans to retrospectively review vaccine administration fees to look for outliers and potentially discriminatory practices that would impact beneficiary access to Part D vaccines”.²⁶

Additionally, pharmacists should always prioritize patient-centered care and ensure their decisions are based on the patient's best interests and public health, which involves administering the right vaccine to the right patient at the right time.

There is legal precedence that payment to entice a healthcare provider to administer a specific medicine or vaccine may be illegal. For example, in the late 2000s, insurers paid physicians to switch patients from one prescribed medicine to another. The insurer initiative paid physicians \$100 to switch a patient from a brand-name medicine to a less expensive generic with a different active ingredient. The American Medical Association (AMA) affirmed that accepting payment for moving a patient from a brand-name medicine to a generic medicine not FDA-approved for substitution could be considered an anti-kickback statute violation.²⁸

CMS has also voiced concerns about PBM and health plan payment practices. CMS, in its guidance, has stated the following in a December 2023 letter to Plans and Pharmacy Benefit Managers:

“CMS is very concerned about payment practices that may impede access to recommended vaccinations, and it is imperative that plans and PBMs take immediate steps to ensure adequate payment for and access to vaccine.”²⁹

Potential Impact of Contracting Tactics on Long-term Viability of Vaccine Market

■ Make vaccines less profitable than repeat-purchase treatments

Preferential contracting practices that require payment for a specific vaccine or promote an individual manufacturer's vaccine over another may have short-term positive bearings, such as lower prices. However, the lack of competition will negatively impact access, choice of vaccines, and potential liability for vaccine supply in the case of any manufacturing disruption. Therefore, any entity utilizing its bargaining power to achieve substantial discounts that will not be shared with patients directly undervalues vaccines while reducing the biopharmaceutical industry's incentive for research and

development and short-run production capacity.³⁰

PBMs commonly use exclusive contracts in the U.S. market to restrict medication access. The scheme is used mainly as a profit-maximizing tactic without any consideration of how such a decision may impact patient access to life-saving medicines. The Federal Trade Commission (FTC) is investigating exclusionary contracts' impact on patient access and affordability.³¹ Insurers and PBMs have not yet applied this methodology to vaccines.

International organizations have also weighed in on the topic of exclusionary contracts. World Health Organization notes:

“Exclusive contracts should be conducted to purchase high-quality, consistent, and effective products; therefore, deciding which supplier(s) is awarded the contract should not be based solely on price.”³²

In 2020, the European Parliament noted:

“Prioritizing the lowest-cost offers over those most economically advantageous can weaken innovation and global competitiveness.”¹⁷

Artificially manipulating drug prices through contracting tactics may make it financially challenging for manufacturers to maintain or expand production capacity, especially for medications with low-profit margins or complex molecules, such as vaccines. As a result, some manufacturers may choose to discontinue production or prioritize other, more profitable products, leading to shortages of such products.

It is also important to note that vaccines prevent rather than treat disease and provide long-term effects in contrast to products that are administered repeatedly.

These dynamics make vaccines less profitable than repeat-purchase treatments, even given comparable intellectual property protection. Therefore, contracting tactics that promote exclusivity, leading to lower prices and profit margins on vaccines, will force manufacturers to consolidate. Consolidation in the long term will advance to possible shortages if the dominant supplier encounters manufacturing issues, quality concerns, or regulatory actions. More

importantly, lack of competition will eventually entice the dominant player to raise prices or provide fewer concessions.

Additionally, we need to consider the complexity of manufacturing a vaccine.³³

Unlike small molecule pharmaceuticals, vaccines utilize an infinite combination of biological variability among individuals, mutations related to the microorganism, and steps involved in purification in their manufacturing processes.

Failure to effectively handle these complexities may lead to expensive product recalls and inability to meet manufacturer obligations, disrupting regular immunization efforts and detrimentally affecting public health. Moreover, vaccine shelf-life and storage issues pose challenges, potentially affecting accessibility if a manufacturer fails to meet market demands. As such, the duration required to manufacture a batch of vaccines varies from several months to several years.

The vaccine manufacturing facility constitutes substantial challenges, such as fixed and continual maintenance expenses for the manufacturer.³⁴ Usually, biopharmaceutical firms establish manufacturing capacity according to market requirements and demand. Consequently, the fixed cost burden could become unsustainable if the capacity exceeds requirements. Conversely, if the capacity falls short, it may fail to adequately

address market needs, particularly during shifts such as heightened demand stemming from a pandemic.

Price setting in vaccines, unless there is a guaranteed market, which in the case of adult immunization is non-existent, may also hamper future investment in research and development due to a lack of return on investment.

Case Study: The 2004 Flu Vaccine Shortage in the U.S.

In October of 2004, at the beginning of the flu vaccine season, Chiron Corporation announced that it was withdrawing its entire flu vaccine supply due to concerns about the sterility of its manufacturing facility. At that time, the U.S. relied primarily on two suppliers for the flu vaccine — Chiron and Sanofi Pasteur. The decision by Chiron significantly reduced the flu vaccine supply in the U.S., which led to widespread concerns about the potential impact on public health, especially among vulnerable populations. Due to this vulnerability in the supply chain, policymakers were prompted to address the flu vaccine supply and the need to develop a more diversified and resilient vaccine supply.

However, Chiron's withdrawal of the flu vaccine supply due to a safety concern was not the only reason the market lacked an adequate number of manufacturers to ensure appropriate supply. The absence of demand in previous years had created an environment of overproduction and subsequent loss of manufacturers, where only 83 million flu vaccine doses were available in 2004. In contrast, an estimated 185 million doses were needed.³⁵ Consequently, lack of competition led to a disastrous outcome where patients were put in a perilous situation.

Policy Considerations

CHAMPION A COMPETITIVE MARKET FOR VACCINES TO FORCE LOWER PRICES.

As declared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) within the U.S. Department of Health and Human Services, competition is the cornerstone of a well-operating market.³⁶ By encouraging competition, it becomes feasible to stimulate innovation and enhance market stability, thereby improving the accessibility and affordability of products. ASPE notes that biopharmaceuticals with only one or a limited number of manufacturers tend to have higher prices than drugs with multiple manufacturers.

MAINTAIN THE CURRENT MODEL OF PRICE NEGOTIATION BETWEEN RETAIL PHARMACIES AND MANUFACTURERS.

Currently, in the U.S., retail pharmacies directly negotiate with biopharmaceutical companies to gain concessions and favorable vaccine pricing. The current model has served patients with robust access to vaccines and has also been favorable to taxpayers, as vaccines consume only 1.2 percent of pharmaceutical spending in the U.S. Finally, the current model ensures that the PBM business model does not financially undermine retail pharmacies' business viability.

CONTINUE THE CURRENT VACCINE ACCESS MODEL AS IT HELPS PATIENTS.

Unlike biopharmaceuticals, patients in the U.S. are not burdened by outrageous out-of-pocket costs for vaccines. Policymakers have ensured that private or public insurers cover all recommended vaccines and that patients will have zero out-of-pocket expenditures when acquiring the vaccines.

LIMIT MIDDLEMAN INFLUENCE ON VACCINE PRICING.

PBM negotiation tactics often lead to higher prices, less patient access, and undermining of the retail pharmacy business model. PBMs currently have no role in setting vaccine reimbursement. As a society, we need to realize that PBMs are interested in inserting themselves into this process because they see it as a revenue model that enriches their coffers.

PRIORITIZE PATIENT-CENTERED CARE THROUGH PHARMACISTS.

Pharmacists are, first and foremost, healthcare professionals and patient advocates. Any financial incentive by a third party to prefer one medicine/vaccine versus another, whether by a biopharmaceutical company or a PBM, should be frowned upon. Moreover, adult patients unequivocally prefer receiving their immunization at pharmacies by a pharmacist or pharmacy technician.

RECOGNIZE THE DISTINCTION IN THE VACCINE MARKET.

Vaccines are complex molecules that require sophisticated manufacturing capabilities. Manufacturing a single batch of vaccines requires years of intricate processes. Due to these complexities, the vaccine market is far more susceptible to schemes such as exclusive contracts and price controls, potentially hindering the long-term availability of these life-saving products.

PRIORITIZE PAYMENT MODELS THAT DON'T UNDERMINE THE COMPETITIVE MARKETPLACE

Payment for vaccines through medical benefits ensures that the middleman stays out of the negotiation, and the government sets competitive prices concerning reimbursement. This payment model has done wonders for the flu vaccine market, where prices are stable, and the vaccine choice is based on the optimal outcome for the patient.

Bibliography

- ¹ Maciosek, Michael V., et al. "Influenza Vaccination." *American Journal of Preventive Medicine*, vol. 31, no. 1, July 2006, pp. 72–79, <https://doi.org/10.1016/j.amepre.2006.03.008>. Accessed 16 Dec. 2020.
- ² Plotkin S. A., Mortimer E. A. (1988). *Vaccines*. Philadelphia, PA: Saunders.
- ³ <https://www.vaccinetrack.com/>
- ⁴ "Healthy People 2020 Progress Table." www.cdc.gov, 31 Mar. 2021, www.cdc.gov/nchs/healthy_people/hp2020/progress-tables.htm.
- ⁵ "Vaccination Coverage among Adults in the United States, National Health Interview Survey, 2021 | CDC." www.cdc.gov, 21 July 2023, www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/vaccination-coverage-adults-2021.html.
- ⁶ "Flu Vaccination Coverage, United States, 2022–23 Influenza Season | *FluVaxView* | Seasonal Influenza (Flu) | CDC." www.cdc.gov, 21 Sept. 2023, www.cdc.gov/flu/fluview/coverage-2223estimates.htm.
- ⁷ Immunization and Infectious Diseases (IID) *Lead Agency Centers for Disease Control and Prevention*. <https://www.cdc.gov/nchs/data/hpdata2020/hp2020mcr-c23-iid.pdf>
- ⁸ "*AdultVaxView* | General Population Reports | Vaccination Coverage | CDC." www.cdc.gov, 20 May 2021, www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/data-reports/general-population/index.html. <https://www.cdc.gov/vaccines/adults/vpd.html>
- ⁹ Vaccine Preventable Adult Diseases. 2019, www.cdc.gov/vaccines/adults/vpd.html.
- ¹⁰ Vaccine Access for Adults Enrolled in Medicaid. <https://www.macpac.gov/wp-content/uploads/2022/03/Chapter-2-Vaccine-Access-for-Adults-Enrolled-in-Medicaid.pdf>
- ¹¹ Ozawa, Sachiko, et al. "Modeling the Economic Burden of Adult Vaccine-Preventable Diseases in the United States." *Health Affairs*, vol. 35, no. 11, Nov. 2016, pp. 2124–2132, <https://doi.org/10.1377/hlthaff.2016.0462>.
- ¹² Mandel, Michael, et al. "Quantifying the Economic and Health Benefits from COVID-19 Vaccines and Boosters." *Progressive Policy Institute*, www.progressivepolicy.org/pressrelease/quantifying-the-economic-and-health-benefits-from-covid-19-vaccines-and-boosters/.
- ¹³ Berenbrok, Lucas A., et al. "Access to Community Pharmacies: A Nationwide Geographic Information Systems Cross-Sectional Analysis." *Journal of the American Pharmacists Association*, vol. 62, no. 6, July 2022, [www.japha.org/article/S1544-3191\(22\)00233-3/pdf](http://www.japha.org/article/S1544-3191(22)00233-3/pdf), <https://doi.org/10.1016/j.japh.2022.07.003>.
- ¹⁴ Berenbrok, Lucas A., et al. "Evaluation of Frequency of Encounters with Primary Care Physicians vs Visits to Community Pharmacies among Medicare Beneficiaries." *JAMA Network Open*, vol. 3, no. 7, 15 July 2020, p. e209132, <https://doi.org/10.1001/jamanetworkopen.2020.9132>.
- ¹⁵ Aitken, Murray, et al. "Trends in Vaccine Administration in the United States." www.iqvia.com, Jan. 2023, www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/trends-in-vaccine-administration-in-the-united-states.

¹⁶ Centers for Disease Control and Prevention National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention National Center for Immunization and Respiratory Diseases RSV Vaccination Implementation Update Advisory Committee on Immunization Practices. 2024. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2024-02-28-29/04-RSV-Adults-Black-508.pdf>

¹⁷ Popovian, Robert, et al. "Accessibility of Adult Immunizations in Pharmacies Compared to Physician Offices in Low-Income Communities." *JAPHA*, vol. 62, no. 5, 1 Sept. 2022, pp. 1644–1647, <https://doi.org/10.1016/j.japh.2022.03.021>.

¹⁸ Pattin, Anthony J., and Leduc Sherman. "Experiences among African American Community Members with Pharmacy-Based Immunization Services in Detroit, Michigan." *Journal of Pharmacy Technology*, vol. 34, no. 6, 19 Sept. 2018, pp. 259–265, <https://doi.org/10.1177/8755122518801288>.

¹⁹ "Trends in Global Adult Vaccination: Impact of COVID-19 ." www.iqvia.com, July 2023, www.iqvia.com/-/media/iqvia/pdfs/institute-reports/trends-in-global-adult-vaccination/iqvia-institute-trends-in-global-vaccination---covid-07-23-forweb-260723.pdf.

²⁰ Fan, Ting, et al. "Therapeutic Cancer Vaccines: Advancements, Challenges, and Prospects." *Signal Transduction and Targeted Therapy*, vol. 8, no. 1, 13 Dec. 2023, <https://doi.org/10.1038/s41392-023-01674-3>.

²¹ Senate Finance Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug, 2019. [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL).pdf)

²² Dickson, Sean, et al. "Assessment of Commercial and Mandatory Discounts in the Cross-To-Net Bubble for the Top Insulin Products from 2012 to 2019." *JAMA Network Open*, vol. 6, no. 6, 14 June 2023, pp. e2318145–e2318145, <https://doi.org/10.1001/jamanetworkopen.2023.18145>.

²³ Fein, Adam J. "Cross-To-Net Bubble Update: 2022 Pricing Realities at 10 Top Drugmakers." *Drug Channels*, Jan. 2023, www.drugchannels.net/2023/06/gross-to-net-bubble-update-2022-pricing.html.

²⁴ Texas Department of Insurance, 2022, <https://www.tdi.texas.gov/reports/life/pharmacy-benefit-managers-2022.html>

²⁵ Chea, Sara, et al. "Analysis of Drug Formulary Exclusions from the Patient's Perspective: 2023 Update." *Health Science Journal*, vol. 0, no. 0, 3 Jan. 2024, pp. 1–5, www.itmedicalteam.pl/articles/analysis-of-drug-formulary-exclusions-from-the-patients-perspective-update-2023-125203.html, <https://doi.org/10.36648/1791-809X.16.S8.002>.

²⁶ Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements, <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf>

²⁷ Final Contract Year (CY) 2024 Part D Bidding Instructions, 2024 <https://www.cms.gov/files/document/final-cy-2024-part-d-bidding-instructions.pdf>

²⁸ Fuhrmans, Vanessa. "Doctors Paid to Prescribe Generic Pills." *WSJ*, 24 Jan. 2008, www.wsj.com/articles/SB120114138064112219.

²⁹ "CMS Letter to Plans and Pharmacy Benefit Managers." www.cms.gov, 14 Dec. 2023, www.cms.gov/newsroom/fact-sheets/cms-letter-plans-and-pharmacy-benefit-managers#:~:text=Particularly%20as%20we%20encourage%20people,for%20and%20access%20to%20vaccines.

³⁰ Institute of Medicine (US) Committee on the Evaluation of Vaccine Purchase Financing in the United States. "Financing Vaccines in the 21st Century: Assuring Access and Availability." www.ncbi.nlm.nih.gov, National Academies Press (US), 2003, www.ncbi.nlm.nih.gov/books/NBK221811/.

³¹ “FTC to Ramp up Enforcement against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman That Block Cheaper Drugs.” Federal Trade Commission, 16 June 2022, www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes.

³² Dranitsaris, George, et al. “Drug Tendering: Drug Supply and Shortage Implications for the Uptake of Biosimilars.” *ClinicoEconomics and Outcomes Research*, vol. Volume 9, Sept. 2017, pp. 573–584, <https://doi.org/10.2147/ceor.s140063>.

³³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5518734/>

³⁴ Plotkin, Stanley. “The Complexity and Cost of Vaccine Manufacturing – an Overview.” *Vaccine*, vol. 35, no. 33, July 2017, pp. 4064–4071, www.sciencedirect.com/science/article/pii/S0264410X17307703, <https://doi.org/10.1016/j.vaccine.2017.06.003>.

³⁵ Charatan, Fred. “Widespread Flu in United States Exposes Shortage of Vaccine.” *BMJ*, vol. 328, no. 7430, 3 Jan. 2004, pp. 8-a-8, <https://doi.org/10.1136/bmj.328.7430.8-a>.

³⁶ Competition in Prescription Drug Markets, 2017-2022 ASPE REPORT. Assistant Secretary for Planning and Evaluation, Dec. 2023. <https://aspe.hhs.gov/sites/default/files/documents/1aa9c46b849246ea53f2d69825a32ac8/competition-prescription-drug-markets.pdf>

GHLF's Patient-Focused Economic and Policy Research Division

At the Global Healthy Living Foundation, the Patient-Centered Economic and Policy Research Division conducts original research focused on health policy economics and outcomes research to better understand how current and proposed health policies, regulations, and legislation affect patients' financial, healthcare, quality-of-life, and other outcomes. We aim to increase transparency and understanding of the public health policies, regulations, and legislation impacting chronic disease patient communities by sharing our research via publication, our website, social media platforms, and conventional media. Our researchers also address these important topics through opinion editorials, speaking engagements, and our world-class podcast series – Healthcare Matters. Our experts have published extensively on the impact of biopharmaceutical and health policies on costs and clinical outcomes in the most prominent medical sources and media publications. They are sought-after speakers, providing briefings and expert reviews for the U.S. Congress, dozens of state legislatures, and at conferences and medical symposiums around the world. Learn more at <https://ghlf.org/our-work/economic-policy-research/>.



515 N Midland Ave
Upper Nyack, NY
10960



Telephone
845 348 0400



E-mail:
info@ghlf.org



Find us online

CreakyJoints: [CreakyJoints.org](https://www.creakyjoints.org)

CreakyJoints Español: www.CreakyJoints.org.es

CreakyJoints Canada: [CreakyJoints.ca](https://www.creakyjoints.ca)

CreakyJoints Australia: [CreakyJoints.org.au](https://www.creakyjoints.org.au)

Global Healthy Living Foundation: ghlf.org

Facebook: [facebook.com/CreakyJoints](https://www.facebook.com/CreakyJoints) & [facebook.com/GlobalHealthyLivingFoundation](https://www.facebook.com/GlobalHealthyLivingFoundation)

Twitter: [@GHLFmg](https://twitter.com/GHLFmg), [@CreakyJoints](https://twitter.com/CreakyJoints), [#CreakyChats](https://twitter.com/CreakyChats)

Instagram: [@creaky_joints](https://www.instagram.com/creaky_joints), [@creakyjoints_australia](https://www.instagram.com/creakyjoints_australia), [@creakyjoints_esp](https://www.instagram.com/creakyjoints_esp)

TikTok: [globalhealthylivingfnd](https://www.tiktok.com/globalhealthylivingfnd)

LinkedIn: [linkedin.com/company/ghlf](https://www.linkedin.com/company/ghlf)



Scan the QR code to access GHLF's vaccine resources or go to <https://ghlf.org/vaccine-resources/>