REMOVING BARRIERS TO PHARMACY VACCINATION: A PATH TO BETTER HEALTH AND LOWER HEALTH CARE COSTS

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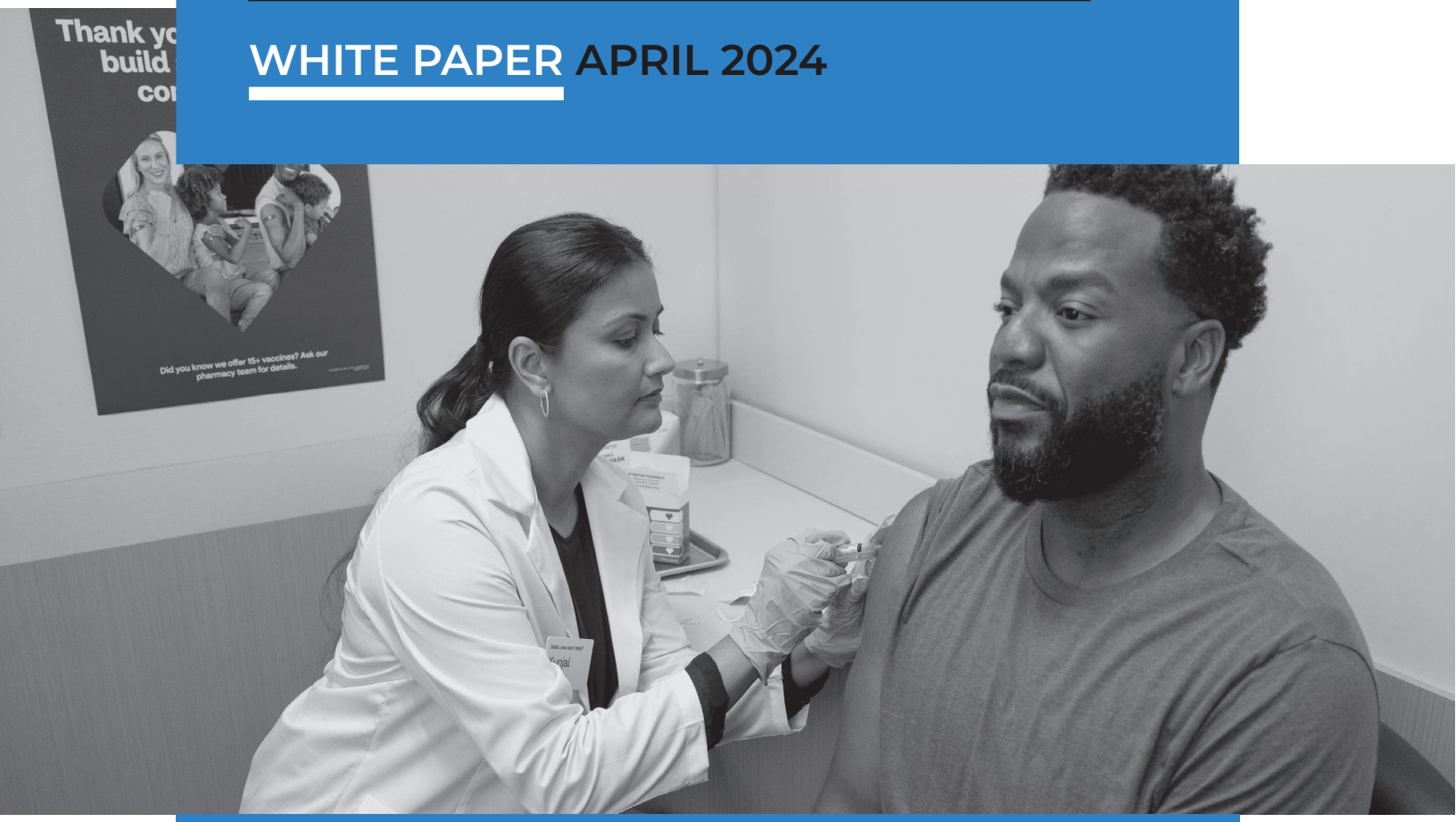

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Highlights

Cost Efficiency
Pharmacy vaccinations are less expensive than those administered in traditional medical settings, offering potential savings for the healthcare system.

Comparative Costs of Vaccination vs. Treatment
The study underscores the economic benefits of vaccination by comparing the relatively low cost of pharmacy-administered vaccines to the significantly higher costs of treating vaccine-preventable diseases. This comparison emphasizes the cost-effectiveness of vaccinations in preventing diseases like the flu and their consequential financial burden on individuals and the health care system.

Accessibility and Safety
Pharmacies offer more accessible vaccination sites, especially in low-income communities, with added safety benefits, such as reduced risk of secondary infections, compared to other healthcare facilities like hospitals.

Regulatory Hurdles
There is a wide variation in state regulatory pathways for pharmacist-administered vaccinations, which can lead to delays and increased costs for patients and the healthcare system.

Documenting Pathways and Costs
The study documents the regulatory pathways across states and the costs associated with navigating these pathways to authorize pharmacist-administered vaccines.

Economic and Health Implications
Delays in pharmacist vaccine administration due to regulatory processes can lead to higher healthcare spending, lower vaccination rates, and increased disease incidence, hospitalization, and death.

Case Study of RSV Vaccine
The paper illustrates the significant cost savings and health benefits of administering vaccines in pharmacies using the newly approved RSV vaccine as a case study.

Public Health Impact
Streamlining pharmacy vaccination processes could lead to higher vaccination rates and reduced health disparities, particularly in low-income communities.

Reducing Regulatory Barriers
Policymakers should consider reducing regulatory barriers to pharmacy vaccinations to improve health outcomes and reduce healthcare costs.

Introduction

Pharmacists and pharmacy technicians can administer vaccines more conveniently and at a lower cost.

Growing evidence shows pharmacists and pharmacy technicians, where authorized, can administer vaccines more conveniently and at a lower cost to patients and payers than traditional medical practices across the United States. An observational study by Singhal and Zhang (2014) found that:

The mean (S.D.) costs paid per enrollee per vaccine administration at physician offices, other medical settings, and pharmacies were as follows: for zoster vaccine, $208.72 (42.10), $209.51 (50.83), and $168.50 (15.66), respectively (P <0.05); for the pneumococcal vaccine, $65.69 (27.54), $72.11 (49.95), and $54.98 (9.72), respectively (P <0.05); and for influenza vaccine, $29.29 (15.29), $24.20 (13.12), and $21.57 (6.63), respectively (P <0.05).[i]

Prosser et al. (2008) conducted detailed phone interviews to evaluate the costs of administering the influenza vaccine to adults in different sites, including mass vaccination programs, pharmacies, and physician's offices.[ii] **Their results found that, in 2004 the costs were cheapest at pharmacies ($11.57) compared to $17.04 in mass vaccination programs and $28.67 at physicians' offices.**

Romero-Mancilla et al. (2023) conducted a systematic review of the literature on pharmacy-based immunization, finding that vaccination at pharmacies provided "several advantages" for patients, including accessibility, safety (particularly concerning the risk of secondary infections at other healthcare facilities like hospitals), and greater "territorial equity." [iii] Additionally, the expanded use of pharmacies as vaccination sites alleviates the workload of physicians without harming patient outcomes because pharmacies have adequate staffing levels to meet patients' needs. Regarding access, a study published in 2022 by Popovian et al. found greater access to pharmacies in low-income communities compared to physician offices. [iv]

Given these benefits, state regulations that delay patients' access to vaccinations through pharmacies impose unnecessary costs on patients and the broader healthcare system. These costs include additional healthcare expenditures, higher vaccine administration outlays, more bureaucratic burdens for pharmacists, and additional costs on patients, state governments, and companies. The specific bureaucratic processes that must be followed vary widely across the states, as do these associated costs. This wide variance creates confusion regarding the exact methods that must be followed.

The purpose of this study is two-fold: (1) to document the different regulatory pathways that must be followed across the 50 states, Washington D.C., and Puerto Rico before pharmacists are authorized to administer a newly approved vaccine, and (2) to outline the illustrative costs associated with these pathways.

Documenting the Regulatory Pathways

Research from Manatt Health provides a comprehensive assessment of the varied state regulatory pathways currently implemented as of November 2, 2023. These pathways, which can change over time, are visualized in Figure 1 (see next page). Figure 1 is a flow diagram that traces the nine different regulatory processes used across the 50 states, Washington D.C., and Puerto Rico. A roman numeral denotes each regulatory pathway.

Broadly speaking, once the Food and Drug Administration (FDA) has approved a new vaccine, there are five additional regulatory and legislative requirements that, in some combination, may need to be fulfilled before pharmacists are authorized to administer a vaccine, see Figure 1. These requirements are:

- **ACIP schedule listing:** The Center for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) "develops recommendations on the use of vaccines in the civilian population of the United States." [v] The committee meets three times yearly and votes on which vaccines should be recommended. The findings are "published in CDC's Morbidity and Mortality Weekly Report (MMWR). Upon publication, the recommendations represent the official CDC recommendations for immunizations in the United States." [vi]

- **Inclusion on the state vaccine list:** State vaccine lists denote the vaccines that pharmacists are allowed to administer in that state.

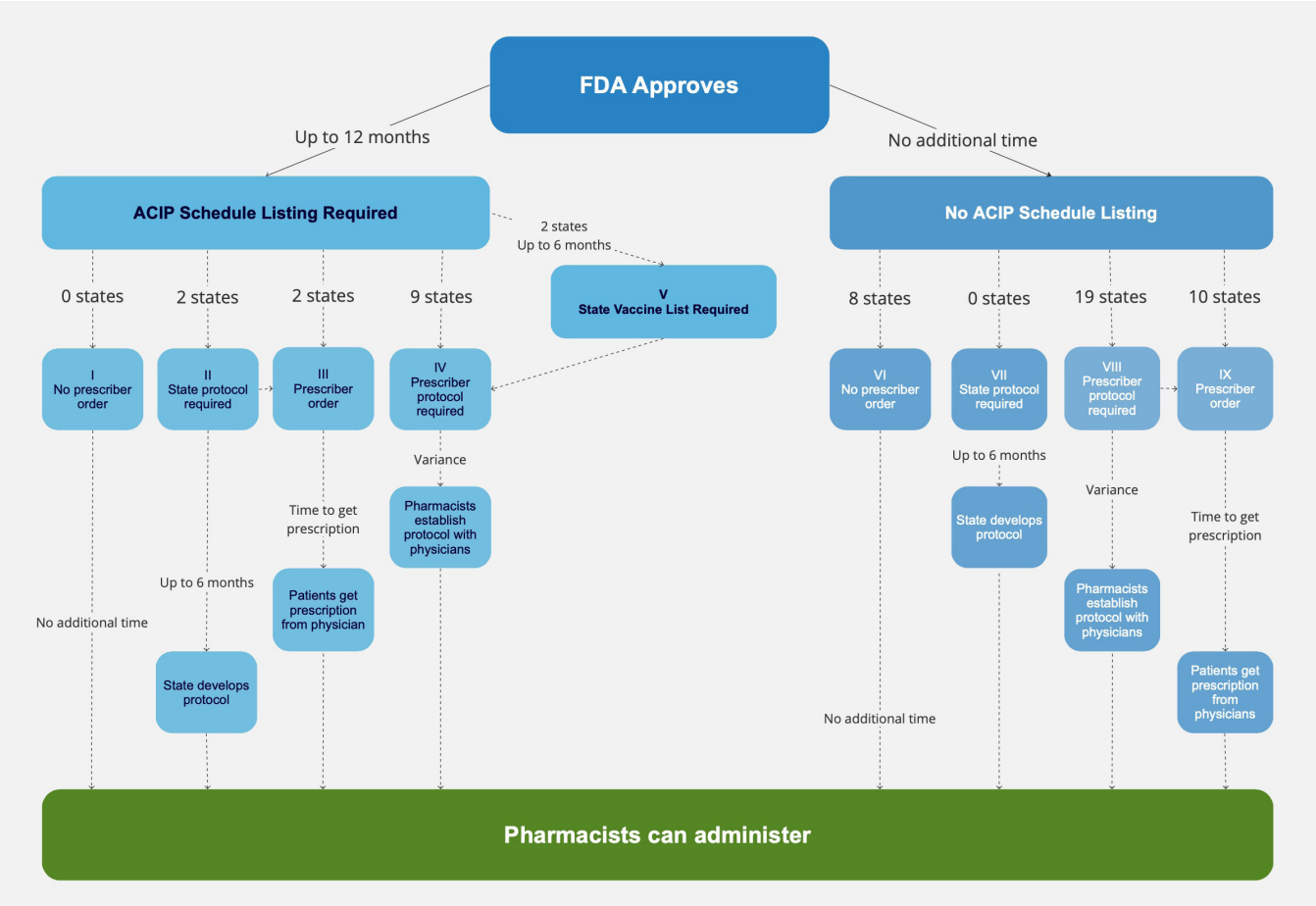
- **Creation of a vaccine protocol with providers:** A vaccine protocol requires pharmacies to establish standing orders with specific providers prior to administering the vaccine. The content and requirements of the protocols vary by state, and a protocol with patients' particular physicians must be in effect before the pharmacist can administer vaccines to those patients.

- **Creation of a state vaccine protocol or standing order:** A state vaccine protocol establishes the criteria for administering the vaccine within the state. When these criteria are met, qualified pharmacists can administer the specific vaccine under consideration. Protocols can vary in complexity.

- **Obtain a provider prescription:** Where required, a patient must obtain a prescription from their healthcare provider authorizing the pharmacist to administer the prescribed vaccine.

Figure 1

Various Regulatory Pathways to Authorize Pharmacist Vaccination for New Vaccinations



Source: Authors' interpretation of Manatt Health data, available upon request.

As Figure 1 details, the 50 states, Washington D.C. and Puerto Rico, employ different combinations of these requirements. A minority of states **(15)** require that ACIP recommends the vaccine before pharmacists are authorized to administer it (denoted as pathways I, II, III, IV, and V in Figure 1).

The remaining states **(37)** do not require an ACIP listing as a prerequisite (pathways VI, VII, VIII, and IX). It is important to note that even though most states do not require an ACIP listing before authorizing pharmacists to administer the vaccine, many healthcare professionals may refrain from advising patients to take the vaccine without the listing. The distinction will be viewed as material for estimating the cost differentials for the different regulatory pathways because the option for earlier authorization exists.

Of the 15 states requiring an ACIP listing, 2 states (New York and New Hampshire) have an added step of establishing a state vaccine list, while the other 13 states do not. Of the states that do not require ACIP listing, none require adding the vaccine to a state vaccine list.

With the question of the ACIP recommendation lists considered, authorizing pharmacists to administer the vaccine in question will then follow one of five pathways:

1. No prescriber order or protocol is required, enabling pharmacists to administer all allowable vaccines (pathways I and VI).

2. The creation of a state vaccination protocol or standing order is required before pharmacists can administer all allowable vaccines (pathways II and VII).

3. A prescriber order for each patient is necessary before a pharmacist can administer each vaccine (pathways III and VIII).

4. A prescriber protocol is needed with each physician before pharmacists can administer a vaccine (pathways IV and IX).

5. A vaccine must be added to the state vaccine list, followed by the prescriber protocol requirement (pathway V).

These regulatory steps impose potential costs on patients and the broader healthcare system. These potential costs will fall into four broad categories:

Time delays

Each step delays vaccines' availability at pharmacies. This delayed access imposes two types of potential costs. First, patients may receive their vaccines at costlier physician offices rather than pharmacies, unnecessarily raising total healthcare spending. Second, patients who would have obtained the vaccine if it had been available at the pharmacy may never receive it. The reduced vaccination rates would increase total disease incidence, hospitalization, and death because the potential benefits of the vaccine are lost. The precise combination of these costs will vary depending on patients' choices in light of the lost access.

Government administrative outlays

Adding the latest vaccines to state lists or updating state protocols requires state

legislatures and other regulatory officials to devote valuable time to duplicate the findings of the FDA and, in most instances, the CDC. Due to this duplication, unnecessary government costs are expended to create the latest vaccine protocol or add the vaccine to a state vaccine list. Moreover, this listing process adds months of delays before the vaccines are available at the pharmacy, thereby potentially increasing disease incidence and the risk of hospitalization and death.

Private sector outlays

Requirements to create a duplicative protocol for the latest vaccine or separately add the latest vaccine to the state list elicit private expenditures. These expenditures are typically used to raise awareness among legislators regarding the FDA's and CDC's latest decisions and the potential benefits of the vaccine under consideration.

Patient burdens

States requiring patients to acquire a prescription from their healthcare provider before a pharmacist can administer a vaccine impose a not negligible burden on patients who wish to have a pharmacist administer it. They must now make an appointment with their primary care provider, which can take weeks, obtain the prescription, and then head to the pharmacy to get their vaccine. Beyond the costs associated with the time delays, there are direct outlay costs that patients must spend. Further, the rule will likely increase the healthcare costs spent on administering the vaccine. Even though the vaccine costs are higher at the physician's office than at the pharmacy, it will likely be more convenient to receive their vaccine at the physician's office once there — assuming the physician carries the vaccine.

Since the different pathways create a diverse combination of steps, the potential costs for the nine tracks defined in Figure 1 will vary. The analysis leverages a range of cost estimates from various studies to provide perspective on the different burdens associated with each regulatory pathway. The recently approved vaccine for RSV for older adults is used as a case study to demonstrate these costs.

CDC / ACIP Schedule Listing Required

The need to obtain ACIP approval creates delays.

ACIP typically meets three times annually to make vaccine recommendations. The need to obtain ACIP approval creates delays. Due to these delays, patients cannot access pharmacist-administered vaccines in the 15 states that require an ACIP listing until the approval is passed — and in some states, not until the results are officially published in the MMWR or until the updated annual CDC immunization schedules are published, which is even later. The requirement that the results be published in the MMWR or CDC immunization schedules before pharmacists can administer the vaccine further lengthens the delay. Typically, the time between FDA approval and ACIP recommendation is six months, but it has been as long as 12 months or longer.

These delays will, by definition, impose actual costs for regulatory pathways I through V. While the costs can legally be avoided for regulatory pathways VI through IX, many physicians and other health professionals may be hesitant to offer the vaccine without the CDC's recommendation even in those states that do not require an ACIP listing. Due to this hesitancy, the costs associated with ACIP MMWR/immunization schedule listing may also apply to these different states. Therefore, vaccine uptake will likely be severely reduced across all regulatory pathways until the CDC recommends the vaccine, and the costs of delayed access estimated below will potentially apply to the entire population.

The costs from delayed access to efficacious vaccines at pharmacy locations manifested through higher vaccination expenditures for patients. They reduced vaccination rates, which will cause higher rates of infection, severe illness, hospitalization, and mortality. How the costs are divided between these outcomes depends on how people respond to the unavailability of vaccines at pharmacies and the type of vaccine impacted.

Since there is no reliable data to estimate how the costs will be divided between these two possible outcomes, the below analysis benchmarks the costs by assuming that 100 percent of the costs are

due to all patients switching from receiving the vaccine at pharmacies to obtaining the immunization at the physicians' offices or 100 percent of the costs are expected to all patients who would have acquired their vaccine at the pharmacy forgoing the vaccination for the year. These estimates provide the maximum potential costs for each category, with the likely impacts being a combined fraction of these costs.

A perspective on the potential costs can be gathered by benchmarking the costs from delaying access to the RSV vaccines at pharmacies based on the assumption that the ACIP delays prevent access to the vaccine at the pharmacy for an entire respiratory infection season. It is further assumed that access to the vaccine is still available at physicians' offices. Should physicians be reticent to administer a vaccine not recommended on the ACIP list, which is a likely possibility, then all the costs will be borne through higher infection rates rather than higher costs of administering vaccines in physicians' offices. Further, while not considered here, the costs would include those patients who would have received their vaccination at the physician's office.

To estimate the impact on the administration costs, it is necessary to define how much more expensive it is to administer a vaccine at physicians' offices than at pharmacies. Based on the results in Singhal and Zhang (2014), reproduced in Table 1, i the average premium across the three vaccines examined was 26 percent. Based on this cost premium, coupled with the cost estimate methodology presented in Table 2, the total costs from delaying access to RSV vaccines at pharmacies would be between $1.3 billion and $2.1 billion, based on the assumption that all people who would presumably receive their vaccines at pharmacies would receive their vaccines at physicians' offices instead.

Table 1 Vaccine Costs at Pharmacies versus Physicians' Offices

	Physician Offices	Other Medical Settings	Pharmacies	Physician Premium
Zoster (shingles)	$208.72	$209.51	$168.50	24%
Pneumococcal	$65.69	$72.11	$54.98	19%
Influenza	$29.29	$24.30	$21.57	36%
Average				**26%**

Source: Singhal and Zhang (2014)

Table 2

Total Potential Cost Premium from Delaying RSV Older Adult Vaccination at Pharmacies for 1 RSV Season

Row No		Low	High	Source
1	RSV	$180.00	$295.00	*
2	Physician Practice	$180.00	$295.00	(1)
3	Pharmacy	$142.43	$233.42	(2) / 1.26^
4	**Physician Practice Cost Premium**	**$37.57**	**$61.58**	**(3) - (2)**
Population (000s)				
5	60 to 64 years	21,174	21,174	**
6	65 to 74 years	33,704	33,704	**
7	75 years and over	22,489	22,489	**
8	**60 years and over**	**77,367**	**77,367**	**(5) + (6) + (7)**
Vaccination Rates				
9	60 to 64 years	62%	62%	***
10	65 to 74 years	77%	77%	***
11	75 years and over	76%	76%	***
Total Vaccinated				
12	60 to 64 years	13,128	13,128	(5) * (9)
13	65 to 74 years	25,952	25,952	(6) * (10)
14	75 years and over	17,092	17,092	(7) * (11)
15	**60 years and over**	**56,172**	**56,172**	**(12) + (13) + (14)**
16	Percentage of flu vaccines administered in pharmacy (through 5/27/2023)	59.7%	59.7%	^^

Row No		Low	High	Source
Total Vaccinated at Pharmacies				
17	60 to 64 years	7,840	7,840	(5) * (9)
18	65 to 74 years	15,499	15,499	(6) * (10)
19	75 years and over	10,207	10,207	(7) * (11)
20	**60 years and over**	**33,546**	**33,546**	**(12) + (13) + (14)**
21	**Total Potential Cost Premium (in billions)**	**$1.26**	**$2.07**	**(4) * (20)**

* https://kffhealthnews.org/news/article/timing-cost-vaccines-insurance-flu-covid-rsv/#:~:text=Similar%20rules%20apply%20to%20the,private%20insurance%20without%20a%20copay.

** U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplement, 2022.

*** https://grady.uga.edu/more-adults-likely-to-get-a-flu-vaccination-than-receive-an-updated-covid-19-vaccine/#:~:text=Adults%20aged%2055%20and%20older,intend%20to%20receive%20a%20vaccine.

^ The 26% cost premium at physician practices is the average of the cost premium for zoster, pneumococcal, and influenza vaccines; see: Puneet K Singhal, Dongmu Zhang.

^^ Centers for Disease Control and Prevention, https://www.cdc.gov/flu/fluvaxview/dashboard/vaccination-administered.html.

The total costs from delaying pharmacist authority to administer the RSV vaccine are based on the cost to administer each vaccine as estimated by the Kaiser Family Foundation, which was between $180 and $295 (Row 1, Table 2).[vii] For conservative purposes, we assume these estimates provide a low-cost to high-cost range for administering the vaccines at physicians' offices (Row 2, Table 2). Since it is 26 percent cheaper to administer the vaccines at pharmacies, these values are divided by 1.26, resulting in an estimated cost estimate of $142.43 and $233.42 to administer the RSV vaccines at pharmacies (Row 3, Table 2). These figures imply that it is between $37.57 and $61.58 cheaper per RSV vaccine to administer at a pharmacy than at a physician's office (Row 4, Table 2).

Based on the U.S. Census estimate for the number of people over age 60 (Rows 5 – 8, Table 2) and the estimated flu vaccination rates by age category for the 2022-23 flu season (Rows 9 – 11, Table 2), the total number of people over age 60 who received a flu vaccine can be estimated, which was 56.2 million people (Rows 12 – 15, Table 2). Assuming the flu vaccination rate is a good proxy for the RSV vaccination rate, the estimated population of people who will receive the RSV vaccine is approximately 56.2 million.

According to the CDC, of the total flu vaccines administered during the 2022-23 flu season, 59.7 percent were administered in a pharmacy (Row 16, Table 2). Applying this percentage to the total number of people, the estimated number to obtain the RSV vaccine at pharmacies is 33.5 million (Rows 17 – 20, Table 2). Applying the $37.57 and $61.58 per vaccine cost premium at physicians' offices compared to pharmacies indicates that removing the option to receive the RSV vaccine at pharmacies would increase total administration costs by between $1.3 billion and $2.1 billion, assuming all people who would have obtained their RSV vaccine at pharmacies receive those vaccines at physicians' offices.

The other boundary possibility is that all people 60 and over who would be expected to receive their vaccines at pharmacies will not obtain the vaccine until it is available at pharmacies. Applying the assumption that the RSV vaccine is unavailable in the pharmacy setting for the whole RSV season, a potential reduction of 21,489 and 57,304 hospitalizations and 2,149 and 3,581 mortalities will not be realized. Due to the increased hospitalizations, total potential healthcare savings of between $0.537 billion and $1.433 billion will be lost. Additionally, based on the average statistical value of life, the possible reduction of $15.5 billion and $25.8 billion in mortality costs is lost. Table 3 demonstrates these calculations.

Table 3

Total Potential Lost Healthcare Savings from Delaying RSV Vaccination at Pharmacies for 1 RSV Season

		Low	High	Source
1	Hospitalizations	60,000	160,000	*
2	Mortality	6,000	10,000	*
3	RSV Vaccine Efficacy	82.6%	82.6%	**
Population (000s)				
4	60 to 64 years	21,174	21,174	Table2
5	65 years to 74 years	33,704	33,704	Table2
6	75 years and over	22,489	22,489	Table2
7	**60 years and over**	**77,367**	**77,367**	**Table2**
Total Vaccinated at Pharmacies (000s)				
8	60 to 64 years	7,840	7,840	Table2
9	65 years to 74 years	15,499	15,499	Table2
10	75 years and over	10,207	10,207	Table2
11	**60 years and over**	**33,546**	**33,546**	**Table2**
12	Total Vaccinated at Pharmacies % Over 60	43.4%	43.4%	(11) / (7)
Patient Impacts No Pharmacy Vaccination				
13	Hospitalizations	26,016	69,375	(1) * (12)
14	Mortality	2,602	4,336	(2) * (12)
Patient Impacts No Pharmacy Vaccination				
15	Hospitalizations	4,527	12,071	(13) * [1-(3)]
16	Mortality	453	754	(14) * [1-(3)]
Impact Reduction Due to Pharmacy Vaccination				
17	Hospitalizations	21,489	57,304	(13) - (15)
18	Mortality	2,149	3,581	(14) - (16)

		Low	High	Source
19	Average RSV Hospitalization Costs	$25,000	$25,000	***
20	**Lost Hospitalization Savings (billions)**	**$0.537**	**$0.537**	**(19) * (17)**
21	Statistical Value of Life	$7,200,000	$7,200,000	^
22	**Economic Value of Additional Lives Lost**	**$15.5**	**$15.5**	**(18) * (21)**

* CDC MMWR: https://www.cdc.gov/mmwr/volumes/72/wr/mm7240a2.htm#:~:text=Respiratory%20syncytial%20virus%20(RSV)%20is,%E2%89%A565%20years%20(1).

** Papi et al. (2023) https://pubmed.ncbi.nlm.nih.gov/36791160/.

*** Grace et al. (2023) estimated the total costs between $1.5 and $4.0 billion divided by total low/high estimated patients over 60 hospitalized due to RSV

^ Sweis (2022); https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9017085/

The potential lost reductions in hospitalizations and mortality are based on the estimated number of RSV hospitalizations, the total mortality for adults aged 60 and above, and the RSV vaccine efficacy. According to the CDC, there are between 60,000 and 160,000 annual RSV hospitalizations for adults aged 60 and above (Row 1, Table 3) and a total number of mortalities between 6,000 and 10,000 (Row 2, Table 3). [viii] Papi et al. (2023) found a statistically significant efficacy of 82.6 percent for the RSV vaccine.[ix]

Using the over-60 population data (Rows 4 – 7, Table 3) and the estimated total number of people aged 60 and above who would receive a vaccine at pharmacies (Rows 8 – 11, Table 4), the total percentage of people aged 60 and over who would be vaccinated at a pharmacy can be estimated – 43.4 percent (Row 12, Table 3). Without a vaccine, and assuming the risks of contracting RSV are unrelated to where a person would choose to be vaccinated (at the pharmacy or physician's office), the over-60 population that would receive their vaccines at pharmacies would account for between 26,016 and 69,375 hospitalizations (Row 13, Table 3) and between 2,602 and 4,336 deaths (Row 14, Table 3).

If the RSV vaccine were administered to this population, then, at the current efficacy rate, the total hospitalizations of this population would fall to between 4,527 and 12,071 (Row 15, Table 3), a decrease of between 21,489 and 57,304 (Row 17, Table 3). Similarly, the number of deaths would decline to between 453 and 753 (Row 16, Table 3), a decrease of 2,149 and 3,581 (Row 18, Table 3).

Grace et al. (2023) reviewed the literature estimating the total RSV hospitalization costs, finding "the national direct cost burden of RSV hospitalizations was $1.3 billion for all adults and $1.5 - $4.0 billion for adults aged >60 years. [x] Applying the lower range cost estimate to the lower range estimate for the number of hospitalizations and the upper range cost estimate to the upper range estimate for the number of hospitalizations yields an average hospitalization cost of $25,000 (Row 19, Table 3). Multiplying the average hospitalization cost by the potential hospitalization reduction estimates the total lost potential hospital savings, ranging between $0.537 billion and $1.433 billion (Row 20, Table 3).

Valuing the lost potential mortality reductions at $7.2 million per life (Row 21, Table 3), see Sweiss (2022), the lost mortality benefits are between $15.5 billion and $25.8 billion.[xi]

These calculations indicate that long delays between FDA approval of a vaccine and its inclusion on the ACIP list of recommended vaccines could impose high costs on patients and the healthcare system. While the manner and extent of these costs will manifest depending on the reaction of providers and patients, the analysis suggests the longer the delay between FDA approval and ACIP recommendation, the more likely costs will increase.

In addition to administrative and human costs, the regulatory pathways for authorizing pharmacists to administer a newly approved vaccine will potentially impose other costs. Importantly, because the FDA has approved the vaccine and the ACIP has recommended the vaccine, the benefits gained by these additional costs are likely to be small to nonexistent from a patient and healthcare system perspective. Consequently, these regulatory costs impose unnecessary burdens.

Protocols, Prescriber Orders, and State Vaccine Lists

Once the costs of requiring an ACIP listing have been considered, there are five potential regulatory pathways that each state can follow. For some states, the regulatory path can vary depending on the vaccine.

NO PRESCRIBER ORDER

Regulatory pathways I and VI impose no additional costs, making these pathways the least costly regulatory environments. According to Manatt, no states currently follow regulatory pathway I – the 15 states that require an ACIP listing also impose additional costs before pharmacists have the authority to administer vaccines. Of the 37 states that do not require an ACIP listing, 8 states do not impose any other additional requirements beyond FDA approval before a pharmacist is authorized to administer a vaccine.

All remaining regulatory pathways impose costs on patients, pharmacists, and/or providers depending on the mandates that must be followed. Costs will include administrative burdens, time delays, and direct outlays, which are highly dependent on the mandated pathway and state cost particulars.

STATE PROTOCOL REQUIREMENTS

Starting with the need to add a new vaccine to the state protocol – regulatory pathways II (2 states implement) and VII (0 states implement) – the additional costs include the time and resources required for the state legislature to add the new vaccine to the protocol and administratively implement the necessary procedures. These costs will vary across time and states. Table 4 details the additional expenses associated with these pathways based on estimates for state legislatures' legislative, administrative, and lobbying costs. A 2019 analysis in Time estimates that enacting a new state law costs $272,500 once all the salaries and administrative expenditures are considered. Even if the costs for adding a vaccine to the protocol are one-half of these estimates, for conservative purposes, the need to add a vaccine to the state protocol still adds $136,250 in legislative costs.

Table 4 Additional Costs Associated with Adding a Vaccine to the State Protocol

Costs to Establish State Protocol	Low	High
Expenditures to pass laws	$136,250	$272,500
Cost to biopharma companies, patient and provider groups, other advocacy and lobbying efforts	$62,674	$125,348
Total Administrative Costs	**$198,924**	**$397,848**

In addition to the legislative costs, expenditures by the private sector are required to present the efficacy and safety data to legislators and advocate for adding the vaccine to the state protocol. While these costs will vary tremendously by state, the Total Lobbying Expenditure report for Wisconsin in 2023 provides perspective.[xiii] During the 2023 legislative session, organizations spent approximately $20.4 million and nearly 104,000 hours, roughly $196 per hour, lobbying the state legislature. Assuming that, on average, four different organizations typically spend between 2 to 4 weeks working with the legislature, these lobbying and education efforts add between $62,674 and $125,348 in additional costs. These figures suggest that the requirement to add the vaccine to a state protocol adds $200,000 to $400,000 in expenses.

Since it takes time to pass the bill, additional delay costs could occur depending on the legislature's timing. Should the disease, such as RSV, be seasonal and the timing cost another season, then some combination of the costs detailed in Tables 2 and 3 would again be incurred.

PRESCRIPTION REQUIREMENTS

Regulatory pathways III (2 states implement) and VIII (10 states implement) require that patients obtain a prescription from a provider before a pharmacist can administer a vaccine. This requirement creates three types of costs.

First, the extra burden of obtaining a prescription from a physician before going to the pharmacist to have the vaccine administered may encourage more people to decline getting the vaccine. To the extent the requirements discourage people from obtaining the vaccine, the more significant healthcare and mortality consequences described in Table 3 are also applicable.

At the extreme that all people who would be vaccinated at the pharmacy forgo their RSV vaccines due to the higher burdens, then the state's portion of the total potential healthcare savings of between $0.537 billion and $1.433 billion due to fewer hospitalizations and severe illness would be lost. Additionally, based on the average statistical value of life, the state's share of the potential reduction of $15.5 billion and $25.8 billion in mortality benefits would also be lost.

It is important to emphasize that, unlike the ACIP regulations, where pharmacy pharmacy-administered vaccines are delayed for one year, the prescription requirement burden is ongoing. Consequently, the lost savings would be a recurring burden with illnesses, hospitalizations, and higher mortality rates because the prescription requirements have discouraged greater vaccination rates.

Second, getting a prescription before being eligible to receive the vaccine at a pharmacy incentivizes patients to acquire their vaccines at the provider's office, which is a more expensive option than the pharmacy. If patients respond to these burdens by having their vaccines administered in a physician's office rather than by a pharmacist, then the costs would increase between $37.57 and $61.58 for every patient who chooses to have their vaccine administered at a physician's office rather than the pharmacy.

It is unlikely that either of these extreme outcomes will result. It logically follows that these incentives will encourage some adults to receive their vaccine at the provider's office rather than the pharmacy and discourage some adults from getting it. Therefore, it is likely that some unknown portion of the estimated costs presented in Tables 2 and 3 will be incurred annually in every state that requires a physician's prescription before a patient receives a vaccine in a pharmacy.

The other possible outcome is that patients obtain the vaccine prescription and have a pharmacist administer it. This outcome imposes two types of additional costs. First, an appointment with the provider must be scheduled, which increases the burden on physicians who are already struggling to see patients in a timely manner.[xiv] Second, patients must incur the costs of two separate appointments to receive the vaccine – the physician's appointment and then the vaccine appointment. This increases the time commitment and dollar outlays for patients.

PRESCRIBER PROTOCOL REQUIREMENTS AND STATE VACCINE LISTS

Pathways IV, V, and IX require pharmacists to obtain a protocol with the patients' provider before that pharmacist/pharmacy location can administer a vaccine. Pathway V requires the vaccine to be included on the state vaccine list before the pharmacist can establish prescriber protocols.

Starting with the two states that mandate state vaccine lists (New Hampshire and New York), these states combine the costs associated with establishing a state protocol with the costs associated with establishing prescriber protocols. Consequently, these two states are incurring $200,000 to $400,000 in costs to add a newly CDC-approved vaccine to the state vaccine list (see Table 4) before the costs that pharmacists must bear in all states that require separate prescriber protocols.

Pharmacists directly bear the costs of establishing prescriber protocol because they must reach out to all relevant physicians and manage the protocol process, including all necessary updates. Therefore, the prescriber protocol requirements increase the administrative burdens and time commitments pharmacies must incur to provide vaccination services to patients. These higher regulatory expenses will be passed along to patients (in whole or part), reducing the cost savings that pharmacy vaccination offers.

The prescriber protocols also alter the competitive landscape in the pharmacy industry because the higher administrative costs are less burdensome on larger national pharmacy chains. As a result, it is less likely that community pharmacies will offer vaccination services. Compounding the lost vaccination opportunities, community pharmacies lose the potential foot traffic and tie-in sales when patients seek out other, likely larger chain stores that provide the vaccination services. Consequently, prescriber protocol requirements create a competitive disadvantage for smaller, family-owned pharmacies.

Conclusion

Administer vaccines to adults efficaciously, more conveniently, and for less cost.

Pharmacists have a proven track record of administering vaccines to adults efficaciously, more conveniently, and for less cost. Consequently, pharmacists and pharmacy technicians, where authorized, can help reduce the barriers that may inhibit adults from receiving vaccines, subsequently improving health outcomes, particularly for older adults or patients in low-income communities. Higher vaccination rates also improve broader public health outcomes by helping to diminish the spread of communicable diseases such as the annual flu or RSV. Ultimately, this may lead to reduced health disparities since racial and ethnic minorities are over-represented in low-income communities.

Policymakers should recognize these benefits when considering which regulatory environment should be implemented to oversee the administration of vaccines at pharmacies. Overly burdensome regulatory environments impose unnecessary costs on patients and the broader healthcare system, including additional healthcare expenditures, higher vaccine administration outlays, and more bureaucratic burdens on state governments and companies.

The first question states must address is whether the CDC advises the vaccine is necessary once the FDA has authorized a vaccine as safe and efficacious. Fifteen states require that a vaccine appear on the CDC's ACIP list or CDC immunization schedule before granting pharmacists the authority to administer a vaccine. While most states do not need the CDC recommendation before pharmacists are granted the authority to administer a vaccine, many providers and patients will not recommend/seek a vaccine that the CDC does not recommend. In addition, most insurers will not pay for the immunization unless ACIP recommendation is captured.

An ACIP listing is not the only prerequisite many states require before pharmacists are authorized to administer specific vaccines. This paper documents that there are, broadly speaking, **five pathways** that states follow before granting this authorization. These are (including Washington D.C. and Puerto Rico):

8 states
that do not require any additional prescriber orders or protocols, which means that pharmacists can administer all FDA-approved vaccines (noted as pathways I and VI in Figure 1)

2 states
that require a state vaccination protocol before pharmacists can administer all allowable vaccines (noted as pathways II and VII)

12 states
that mandate a prescription before pharmacists can administer a vaccine (pathways IV and IX)

28 states
that require pharmacists to establish a protocol with each prescriber before they can administer a vaccine (pathways III and VIII), and

2 states
that direct the state to add vaccines to a state vaccine list before establishing a prescriber protocol.

The costs from these different regulatory pathways, which can vary significantly, include time delays for patients, additional costs on state legislatures, higher expenses on pharmacies, more burdens on physicians, and higher overall healthcare costs. As these costs can be quite significant, the potential benefits from these regulations must be judged against these burdens. As such, states must attempt to streamline and/or eliminate these regulatory burdens to maximize the health and cost benefits the pharmacist vaccination authority enables. These changes will best serve patients and our healthcare system.

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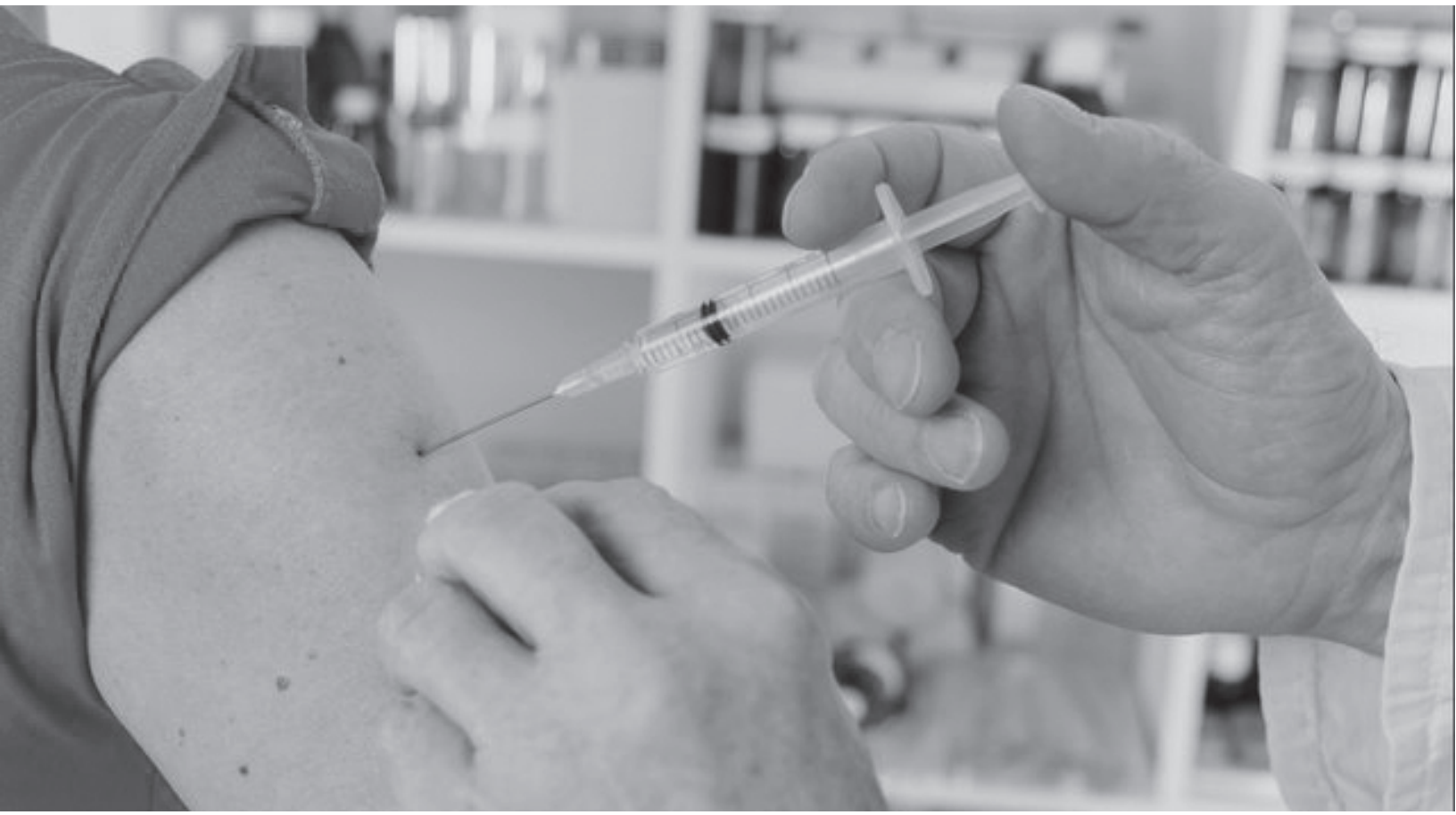

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