

CHAPTER

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**Medicare vaccine  
coverage and payment**

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## R E C O M M E N D A T I O N

- 7** The Congress should:
- cover all appropriate preventive vaccines and their administration under Part B instead of Part D without beneficiary cost sharing and
  - modify Medicare’s payment rate for Part B–covered preventive vaccines to be 103 percent of wholesale acquisition cost, and require vaccine manufacturers to report average sales price data to CMS for analysis.

**COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 0 • ABSENT 1**

# Medicare vaccine coverage and payment

## Chapter summary

Medicare covers vaccines under Part B and Part D. Part B covers vaccines for influenza, pneumococcal disease, hepatitis B (for patients at high or intermediate risk), and coronavirus disease 2019 (COVID-19), as well as other vaccines when used to treat an injury or direct exposure to a disease. (For COVID-19 vaccine doses purchased directly by the federal government, Medicare is responsible for paying for the vaccine’s administration, not the vaccine itself.) Part D covers all commercially available preventive vaccines not covered by Part B, such as vaccines for shingles and hepatitis A. For Part B–covered preventive vaccines, patients face no cost sharing for the vaccine and its administration, while beneficiaries may face out-of-pocket costs for Part D–covered vaccines depending on the cost-sharing requirements of their plan.

At Part D’s implementation in 2006, physicians had two major concerns related to Part D coverage of vaccines: (1) Most physicians had no direct way to bill Part D plans for vaccines they purchased to provide to patients, and (2) if beneficiaries had to pay the full payment rate for vaccines up front and then seek reimbursement from their plans, the out-of-pocket cost might discourage them from receiving the vaccines. Because of these concerns, in 2007, the Commission recommended that all preventive vaccine coverage be moved to Part B.

## In this chapter

- Medicare coverage of vaccines under Part B and Part D
- The CDC’s vaccine recommendations and uptake among Medicare beneficiaries
- Medicare spending for vaccines
- How Medicare pays for vaccines under Part B and Part D
- Improving Medicare coverage and payment for preventive vaccines
- Recommendation

While some initial Part D billing concerns have been alleviated, there continues to be a strong rationale for moving vaccine coverage from Part D to Part B. More Medicare beneficiaries are enrolled in Part B than in Part D. High cost sharing in some Part D plans may deter some beneficiaries from seeking recommended vaccines. A variety of health care providers bill Medicare Part B, offering more potential settings in which to vaccinate beneficiaries. Finally, beneficiaries and even some providers can find it confusing to understand which vaccines are covered by Part B versus Part D.

The Commission is concerned, however, about Medicare Part B's payment method for preventive vaccines. Medicare Part B pays for most preventive vaccines at a rate of 95 percent of the average wholesale price (AWP). (Certain types of providers, such as hospitals, are paid reasonable cost—a payment that is an estimate of the provider's vaccine costs based on Medicare cost report data.) AWP is a list price that may have little relationship to market prices. Paying for Part B-covered vaccines based on wholesale acquisition cost (WAC)—that is, the price at which the manufacturer sells the vaccine to the wholesaler—or average sales price (ASP)—the average price realized by the manufacturer for the vaccine net of rebates, discounts, and other price concessions—would improve payment accuracy. Medicare's AWP-based payment rates for Part B-covered vaccines significantly exceed WAC. Shifting the basis of payment to 103 percent of WAC would generate savings for beneficiaries and taxpayers and bring payment rates closer to market prices than the current AWP-based rates.

Although WAC is a better measure of drug prices than AWP, WAC does not incorporate any discounts or rebates that may be available. Ultimately, a payment rate based on ASP might be most appropriate because it would reflect the average market price rather than an undiscounted wholesale price. However, because ASP is an average, we do not know how much the acquisition prices for vaccines vary across purchasers such as physicians and pharmacies. In addition, it is unclear how the two-quarter lag in ASP data would affect Medicare payment rates for vaccines, especially given the seasonality of the influenza vaccine. Therefore, more study is needed before moving to an ASP-based payment rate for vaccines.

To improve coverage and payment of preventive vaccines under Part B, the Commission recommends that the Congress:

- cover all appropriate preventive vaccines and their administration under Part B instead of Part D, without cost sharing; and
- establish a payment rate of 103 percent of WAC for Part B preventive vaccines, which would moderately reduce Medicare payment rates for Part B vaccines. At

the same time, the Commission's recommendation would require manufacturers to report ASP data for vaccines so that CMS could study how payment rates would differ if they were based on ASP rather than WAC.

This recommendation would improve beneficiary access to vaccines by eliminating cost sharing and by facilitating the administration of vaccines in a variety of settings, potentially creating more opportunities for beneficiaries to be vaccinated through increased convenience (e.g., physical availability and geographical accessibility). By establishing payment rates that better reflect providers' purchase prices, the recommendation would moderately reduce Medicare payment rates for Part B vaccines while keeping vaccine payment rates at a level that should be accessible to all immunizers. At the same time, by requiring manufacturers to report ASP data for vaccines to CMS, the recommendation would provide CMS with the data to analyze the implications of moving to an ASP-based payment amount, building the knowledge base to consider ASP-based payment rates in the future. Once the study is completed, the Commission urges the Secretary to make the results of the analysis public, and seek statutory authority to adopt an ASP-based payment rate for preventives vaccines if it would improve payment accuracy. ■



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## Medicare coverage of vaccines under Part B and Part D

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Since 2020, the global coronavirus pandemic has had catastrophic consequences for many Medicare beneficiaries and affected health care delivery for all. The coronavirus pandemic has raised awareness of how developing and delivering vaccines against infectious diseases protects both population health and the economy. Developing safe and effective vaccines and deploying them widely and rapidly are critical for preserving health, reducing burden on the health care delivery system, avoiding medical expenses, and strengthening the economy. For these reasons, the Congress directed nearly \$10 billion in funding for development of vaccines and treatments for the coronavirus (referred to as coronavirus disease 2019 (COVID-19)) through the Coronavirus Aid, Relief, and Economic Security (CARES) Act and other funding.<sup>1</sup>

As of April 2021, three COVID-19 vaccines have received Emergency Use Authorization in the U.S., and additional vaccines are being tested in clinical trials and considered by the Food and Drug Administration (FDA). For the current coronavirus public health emergency, the federal government is directly purchasing hundreds of millions of vaccine doses and paying for their distribution.<sup>2</sup>

Medicare's coverage of vaccines is split across Part B and Part D. Part B covers certain preventive vaccines that are explicitly listed in statute—influenza, pneumococcal, hepatitis B (for intermediate- and high-risk populations), and COVID-19. In addition, Part B covers vaccines that are directly related to the treatment of an injury or direct exposure to a disease or a condition. Part D plans cover all commercially available preventive vaccines not otherwise covered under Part B, such as the shingles vaccine.

The focus of this chapter is on preventive vaccines. Treatment vaccines—which are immunotherapies used to treat a condition like cancer and which Medicare covers and pays for like other drugs and biologics—are outside the scope of this chapter. The use of *vaccine* in this chapter refers to “preventive vaccine” unless otherwise noted.

Before implementation of Part D in 2006, Medicare covered preventive vaccines only if they were explicitly listed in statute. The lack of comprehensive coverage for

preventive vaccines under Medicare stems from Section 1862 of the Social Security Act, which specifies that “no payment may be made under part A or part B for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” Over time, the statute has been amended to provide Medicare Part B coverage of specific preventive vaccines—for pneumococcal disease (in 1981), hepatitis B for patients at high or intermediate risk (in 1984), and seasonal influenza (in 1993). In 2020, the CARES Act added COVID-19 vaccines to that list, requiring Medicare to cover the cost of such vaccines under Part B. As with the other three Part B preventive vaccines, Medicare beneficiaries face no cost sharing for either the vaccine or its administration (Table 7-1, p. 246).<sup>3</sup> Part B also covers certain other vaccines, but only in limited circumstances when clinicians prescribe them to treat an injury or direct exposure to a disease or condition (e.g., hepatitis A; rabies; tetanus and diphtheria (Td); and tetanus, diphtheria, and pertussis (Tdap)).

After Part D was established, Medicare's coverage of preventive vaccines expanded. Part D covers all commercially available preventive vaccines (including the shingles vaccine) that Part B does not cover. Part D plans must cover both the vaccine ingredient cost and an administration fee (if any). If a Part D plan charges cost sharing, it must charge the enrollee a single amount for the vaccine and its administration. Part D plans decide where to place vaccines on their formularies, and they charge differential cost-sharing amounts depending on the applicable formulary tier. As a result, cost-sharing amounts for the same vaccine can vary across plans. Plans can also use tools such as prior authorization, but few do so. CMS encourages the use of certain recommended vaccines in Medicare Advantage (MA) plans by including the share of enrollees who obtained a vaccine in the MA quality star metrics (influenza) and display measures (pneumococcal).<sup>4</sup> CMS has also encouraged all Part D plans (both stand-alone prescription drug plans (PDPs), in which many fee-for-service (FFS) beneficiaries choose to enroll, and MA prescription drug plans (MA-PDs)) to include a vaccine tier on their formularies with zero cost sharing, but very few plans do so (Centers for Medicare & Medicaid Services 2019a). As a result, in 2020, all PDP enrollees and over 90 percent of MA-PD enrollees are required to pay cost sharing for vaccines.

**TABLE  
7-1**

**Medicare’s coverage of and payment for preventive vaccines**

	<b>Part B</b>	<b>Part D</b>
<b>Coverage</b>	Only preventive vaccines that are explicitly listed in the statute: influenza, pneumococcal, hepatitis B*, and COVID-19	All preventive vaccines not covered under Part B, primarily herpes zoster (shingles)
<b>Setting in which preventive vaccine is administered</b>	Administered in a wide range of settings, including mass immunizers (such as retail pharmacies), physician offices, hospitals, SNFs, dialysis facilities, at home during home health visits, and others	Administered primarily by retail pharmacies
<b>How program payment is set</b>	For most providers, 95 percent of AWP**	Plan-negotiated rate
<b>How beneficiary cost sharing is set</b>	No cost sharing for vaccine or administration of vaccine	Cost-sharing amounts for vaccine and administration of vaccine may vary based on plan, phase in benefit, and low-income subsidy status

Note: COVID-19 (coronavirus disease 2019), SNF (skilled nursing facilities), AWP (average wholesale price).  
 \*Under Part B, hepatitis B vaccine is covered for beneficiaries of high or intermediate risk.  
 \*\*All providers are paid 95 percent of AWP with the exception of hospitals (that are not part of the Indian Health Service), home health agencies, hospital-based dialysis facilities, rural health clinics, and Federally Qualified Health Centers, which are paid reasonable cost.

Source: MedPAC analysis of statute and CMS’s regulations.

**The CDC’s vaccine recommendations and uptake among Medicare beneficiaries**

The Centers for Disease Control and Prevention (CDC) sets recommendations and objectives for vaccine use among specific populations, including the elderly, based on input from the Advisory Committee on Immunization Practices (ACIP). ACIP consists of 15 experts in fields associated with immunization who have been selected by the Secretary of Health and Human Services to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the CDC on the most effective means to prevent vaccine-preventable diseases. ACIP advises the CDC director on population groups and circumstances for which a vaccine is recommended as well as when it is contraindicated. If the director adopts ACIP’s advice, it is published as an official CDC recommendation and included in the schedules of childhood and adult immunizations that are designed to assist states with public health (Centers for Disease Control and Prevention

2018). To make such recommendations, ACIP reviews the quality of evidence about the safety and efficacy of vaccines, the burden and epidemiology of a disease, and cost-effectiveness and other economic analyses, as well as implementation considerations.

ACIP’s recommendations are especially important for Medicare beneficiaries, who have a higher disease burden than the general population. In that sense, recommended vaccines may be more likely to improve quality of life and prevent hospitalizations and medical costs for Medicare beneficiaries than for other individuals. ACIP currently recommends that adults age 65 and older receive the following vaccines:

- An annual seasonal influenza vaccination unless contraindicated.<sup>5</sup>
- A one-time dose of 23-valent pneumococcal polysaccharide vaccine (PPSV23, also known as Pneumovax 23) for adults ages 65 and older.

Previously, ACIP had also recommended a one-time dose of a second pneumococcal vaccine—13-valent pneumococcal conjugate vaccine (PCV13, also known as Prevnar 13)—for all individuals ages 65 and older. However, ACIP has modified that recommendation and now suggests the use of shared decision-making to determine whether to furnish a PCV13 vaccine to an individual age 65 or older without an immunocompromising condition (Matanock et al. 2019).<sup>6</sup>

- Two doses of recombinant zoster vaccine (Shingrix) in immunocompetent adults ages 50 or older.<sup>7</sup>
- A phased approach for the initial distribution of COVID-19 vaccines, with residents of long-term care facilities offered vaccination first (in Phase 1a of the vaccination program), followed by persons aged 75 years or older (in Phase 1b) and by persons aged 65 to 74 years and persons ages 16 to 64 with chronic medical conditions associated with higher risk for severe COVID-19 (in Phase 1c; some in this age group may be Medicare beneficiaries due to disability or end-stage renal disease (ESRD)) (Dooling et al. 2021). (This approach reflects the initial recommendation for COVID-19 vaccine distribution made by ACIP in December 2020).

For Medicare beneficiaries who are younger than age 65 or who have specific conditions, ACIP has more tailored recommendations. For example, ACIP recommends that all persons with HIV be vaccinated routinely with hepatitis A vaccine.

### **Vaccination rates among Medicare beneficiaries have increased but have not reached goals**

In 2010, the Department of Health and Human Services and other stakeholders developed the Healthy People 2020 framework to set national objectives for, among other priorities, vaccination to help avoid preventable diseases. Goals include increasing rates of influenza and pneumococcal vaccination among individuals ages 65 and older to 90 percent and increasing the rate for shingles vaccination among adults ages 60 and older to 30 percent (Office of Disease Prevention and Health Promotion 2020). While more Medicare beneficiaries have been vaccinated in recent years, some rates (influenza and pneumococcal vaccination) have not reached those objectives, and there are sizable differences in vaccination

rates by race and ethnicity. The text box (pp. 250–251) discusses factors associated with disparities in vaccination rates among Medicare beneficiaries.

### **Take-up rates of seasonal influenza vaccine among Medicare beneficiaries**

According to the CDC’s Behavioral Risk Factor Surveillance System (BRFSS) survey, influenza vaccination rates among adults ages 65 and older were about 68 percent in the 2018 to 2019 flu season and 60 percent in the 2017 to 2018 flu season (Centers for Disease Control and Prevention 2019b). Another source, the Medicare Consumer Assessment of Healthcare Providers and Systems<sup>®</sup> survey, reports an influenza vaccination rate in 2018 of 74 percent for FFS beneficiaries and 75 percent for MA beneficiaries (Centers for Medicare & Medicaid Services 2019d). By contrast, using Part B claims data for the 2018 to 2019 flu season, the Commission found that Medicare paid for influenza vaccinations for about 50 percent of FFS beneficiaries of all ages and 54 percent of beneficiaries ages 65 and older. The lower vaccination rates in the claims data compared with survey data may be the result of several factors. The claims data likely undercount influenza vaccinations received by Medicare beneficiaries because entities that offer free vaccinations are not permitted to bill Medicare and because Medicare-covered vaccines furnished by Federally Qualified Health Centers (FQHCs) and rural health clinics (RHCs) are not fully reflected in the claims data. In addition, survey data may not be fully accurate. For example, the BRFSS survey asks individuals whether they received an influenza vaccination in the last 12 months (and if so, which month), but it does not verify the responses with medical records (Centers for Disease Control and Prevention 2019a).

Based on claims data, influenza vaccination rates for FFS beneficiaries vary by age, race and ethnicity, dual-eligible (Medicare and Medicaid coverage) status, and ESRD status (Table 7-2, p. 248). In 2018 to 2019, vaccination rates increased with age, ranging from 31 percent for beneficiaries under age 65 to 60 percent for those ages 80 and older. A higher share of White beneficiaries than Black and Hispanic beneficiaries received a vaccination. Vaccination rates were lower for dually eligible beneficiaries than for other FFS beneficiaries. Beneficiaries with ESRD had a higher than average influenza vaccination rate (70 percent).

**TABLE  
7-2****FFS beneficiaries who received the influenza vaccine are more likely to be older, White or Asian American, not eligible for Medicaid, and have ESRD****Share of FFS beneficiaries who received a Part B-covered influenza vaccine in 2018-2019**

All	50%
Age	
<65	31
65-69	46
70-79	55
80+	60
Race	53
White	35
Black	30
Hispanic	49
Asian	48
Other	
Dual-eligibility status	
Dual eligible	38
Non-dual eligible	53
ESRD status	
ESRD	70
Non-ESRD	50

Note: FFS (fee-for-service), ESRD (end-stage renal disease). Analysis of 2018 to 2019 flu season, spanning July 2018 through May 2019. Data include beneficiaries who had FFS Part B coverage during that period. Beneficiaries were assigned to the dual-eligible and ESRD categories if they had that status for at least one month during this period.

Source: MedPAC analysis of Medicare claims and enrollment data.

**Take-up rates of pneumococcal vaccine among Medicare beneficiaries**

According to the BRFSS survey, in 2018, the share of adults ages 65 and older who reported ever receiving a pneumococcal vaccination was 72 percent, similar to prior years (74 percent in 2017 and 72 percent in 2016). A CDC analysis of 19 years of Medicare claims data found that about 59 percent of FFS beneficiaries ages 65 and older received at least one pneumococcal vaccine between 1999 and 2017 (Table 7-3) (Centers for Disease Control and Prevention 2019c). As with influenza vaccination rates, claims data likely understate pneumococcal vaccination rates because some vaccinations for Medicare

beneficiaries are not reflected in these data. Take-up rates of the pneumococcal vaccine vary by age, race, and ethnicity (Table 7-3). In addition to being recommended for all individuals ages 65 and older, pneumococcal vaccinations are recommended for individuals who are immunocompromised or have certain chronic conditions. CDC analysis found that nearly two-thirds of elderly beneficiaries with those conditions had received at least one pneumococcal vaccination.

ACIP's 2014 recommendation that adults ages 65 and older receive Prevnar 13 presents an opportunity to observe a newly recommended vaccine's speed of take-up. By 2017, roughly three years after ACIP's

**TABLE  
7-3**

**FFS beneficiaries who receive the pneumococcal vaccination are more likely to be older and have an immunocompromising or chronic condition**

**Share of FFS beneficiaries ages 65+ who received a Part B-covered pneumococcal vaccination in 2017 or earlier**

	<b>Any pneumococcal vaccine</b>	<b>Pneumovax 23</b>	<b>Prevnar 13</b>
All	59%	43%	40%
Age			
65–69	45	25	35
70–74	60	43	42
75–79	67	54	44
80–84	71	60	43
85+	70	59	40
Race			
White	61	45	42
Black	45	33	26
Hispanic	42	32	20
Asian	56	42	32
American Indian/Alaskan Native	54	36	33
Other	55	40	36
Immunocompromising or chronic condition			
Yes	64	47	42
No	37	22	27

Note: FFS (fee-for-service). Data reflect a Centers for Disease Control and Prevention analysis of Medicare FFS claims data, which examined pneumococcal vaccination rates among Medicare beneficiaries continuously enrolled in Medicare FFS from September 2016 to September 2017, with a retrospective review of their claims history (as far back as 1999) to identify whether they received a Medicare FFS–paid pneumococcal vaccination.

Source: Centers for Disease Control and Prevention 2019c.

recommendation, the CDC’s analysis indicates that about 40 percent of elderly FFS beneficiaries had received the vaccine. In addition, Commission analysis found that about half of the elderly beneficiaries who were continuously enrolled in the FFS program between 2014 and 2018 had received Prevnar 13 by 2018 (data not shown).

**Take-up rates of shingles vaccine among Medicare beneficiaries**

According to data from the National Health Interview Survey, 35 percent of adults ages 60 and older received the shingles vaccine by 2018 (Terlizzi and Black 2020). Our analysis of Part D data found a similar vaccination rate for

a cohort of beneficiaries who were ages 60 and older and had Part D coverage in 2010. Among the roughly 770,000 beneficiaries in the cohort, 32 percent had received either Shingrix or Zostavax by December 2018 (Figure 7-1, p. 252).

Between 2010 and 2018, shingles vaccination rates increased for all subgroups of beneficiaries that we examined.<sup>8</sup> However, some subgroups, such as beneficiaries receiving Part D’s low-income subsidy (LIS) or those belonging to a racial or ethnic minority, had lower vaccination rates (Figure 7-1, p. 252). Beneficiaries who received the LIS were less likely to have received the shingles vaccine compared with the rest

## Disparities in vaccination rates and vaccine hesitancy

The coronavirus pandemic has disproportionately affected the elderly (Freed et al. 2020). Black and Hispanic populations have also experienced higher incidences of coronavirus disease 2019 (COVID-19) cases and rates of hospitalization and death (Centers for Disease Control and Prevention 2020a). Achieving high rates of vaccination against COVID-19 will be very important for the Medicare program and the U.S. as a whole. Given the illness burden of COVID-19, increasing the uptake of influenza vaccination will also “help ameliorate the compounding of illness and health care system stress caused by the additional circulation of another potentially life-threatening viral respiratory disease” (Grohskopf et al. 2020).

However, multiple studies have found racial and ethnic disparities in vaccination rates among Medicare beneficiaries (Hall et al. 2020, Williams et al. 2017). Our own analysis found that vaccination rates for Black and Hispanic beneficiaries are consistently below those for White beneficiaries for vaccines recommended

for the Medicare population. We observed those differences even when there was no cost sharing (as for pneumococcal and influenza vaccines covered under Part B) or minimal cost sharing (as for the shingles vaccine under Part D for low-income subsidy beneficiaries). Other factors beyond cost sharing also play a role in explaining differences among vaccination rates.

Vaccine hesitancy is complex, and the reasons vary widely (Gallagher 2019, MacDonald 2015). An individual’s reluctance to get vaccinated may be rooted in misconceptions about the benefits of mass immunization, perceived health risk of a particular vaccine, or a general mistrust of the health care system (Schaffer DeRoo et al. 2020).<sup>9</sup> A recent poll suggests that as of February 2021, about 30 percent of the U.S. adult population may be unwilling to get vaccinated for COVID-19 (Funk and Tyson 2021). However, the share of adults reporting an unwillingness to get vaccinated has declined in recent months from 39 percent in November 2020. The poll also found that a greater

*(continued next page)*

of Part D beneficiaries (25 percent vs. 35 percent). Black beneficiaries had the lowest vaccination rate (18 percent), followed by Hispanic beneficiaries (23 percent).

### Medicare spending for vaccines

Medicare payments for vaccines are set very differently under Part B and Part D. In 2019, combined Part B and Part D spending for preventive vaccines (including beneficiary cost sharing for Part D vaccines) totaled nearly \$2.3 billion, and spending for their administration totaled about \$490 million. To the extent that Part D plans receive rebates from vaccine manufacturers, those rebates would not be accounted for in these spending estimates.

### Part B–covered vaccines

In 2019, Part B–covered 16.6 million doses of seasonal influenza vaccines and 3.9 million doses of pneumococcal vaccines. In addition, Part B covered the costs of roughly 300,000 doses of hepatitis B vaccine for beneficiaries who were at high or intermediate risk for the disease. In 2019, Medicare payments for influenza, pneumococcal, and hepatitis B vaccines totaled nearly \$1.4 billion (Table 7-4, p. 253). In addition to the three vaccines shown in Table 7-4, Part B also covers certain vaccines when used to treat an injury or direct exposure to a disease (e.g., hepatitis A, rabies, and tetanus), with 2019 Part B spending on these vaccines totaling about \$13 million. Total spending on administration fees for Part B vaccines totaled about \$365 million (with nearly all of this sum for administration of influenza, pneumococcal, and hepatitis B vaccines) (data

## Disparities in vaccination rates and vaccine hesitancy (cont.)

share of Black adults than other racial and ethnic groups reported an unwillingness to get vaccinated, but the share of Black adults unwilling to get vaccinated decreased from 58 percent in November 2020 to 39 percent in February 2021. Hesitancy to get the COVID-19 vaccine varies demographically and by an individual's place of residence (Funk and Tyson 2021). Intent to get vaccinated remains higher among those ages 65 and older than among younger adults (Funk and Tyson 2021). By place of residence, individuals residing in suburban (73 percent) areas and urban (70 percent) areas are more likely than those in rural areas (60 percent) to say they have been, or plan to get, vaccinated for COVID-19 (Funk and Tyson 2021).

There is no modern-day policy mechanism, such as school-entry requirements, to drive routine adult immunizations (Hughes et al. 2019). Additionally, tracking vaccine administration for adults is difficult because they may see many providers over their lifetime as they change jobs, switch health plans, or move to new locales (Hughes et al. 2019).

There are limited data on how to effectively address vaccine hesitancy or increase vaccination rates among undervaccinated populations (Flowers et al. 2008, Jarrett et al. 2015). Multiple strategies would likely be needed to increase vaccination rates for Medicare beneficiaries. Policymakers would need to implement educational campaigns to increase awareness and acceptance of COVID-19 vaccines, aimed at both beneficiaries and health care providers (Flowers et al. 2008, Schaffer DeRoo et al. 2020). Buy-in from clinicians in minority communities can have positive influence on vaccine acceptance (Hall et al. 2020). One review of studies found that the most effective interventions were tailored to the target population and their reasons for hesitancy (Jarrett et al. 2015). For Medicare beneficiaries, policymakers may want to consider strategies at both the federal and state levels to increase immunization rates, such as the use of patient and provider reminders and making providers accountable for vaccination rates (Flowers et al. 2008).<sup>10</sup> ■

not shown). The average administration payment per Part B vaccine was about \$18 in 2019.

Part B–covered vaccines are administered in a variety of settings (Figure 7-2, p. 253). For influenza vaccines, mass immunizers such as pharmacies play a large role, accounting for 48 percent of all vaccinations in 2019. For pneumococcal vaccines, just over half of vaccinations occur in the physician office setting (53 percent), while mass immunizers and hospitals also play a significant role. Because Part B coverage of the hepatitis B vaccine is limited to beneficiaries at medium and high risk, most hepatitis B vaccines are furnished by ESRD facilities since the ESRD population is one of the groups designated as at risk for hepatitis B. While less common, other facilities such as skilled nursing facilities, public health clinics, and other providers (e.g., home health agencies) also play a role in furnishing Part B vaccines.

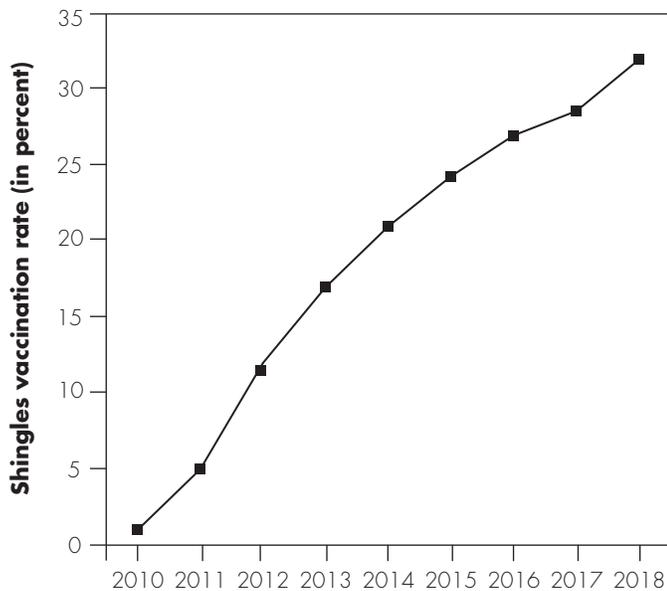
### Part D–covered vaccines

In 2019, 7 million vaccine doses were administered and paid through Part D at a total cost of about \$925 million including beneficiary cost sharing (Table 7-5, p. 254). Beneficiaries were liable for about 40 percent (\$370 million) of Part D vaccine costs in 2019, and the Medicare program covered an additional \$70 million in cost sharing for beneficiaries receiving the low-income subsidy (data not shown). Shingles (herpes zoster) vaccines (Shingrix and Zostavax) made up over 80 percent of claims and over 90 percent of all Part D spending on vaccinations. Part D also covered vaccines for tetanus and diphtheria, hepatitis A, and hepatitis B (for individuals who do not meet the Part B coverage criteria). Vaccine administration fees totaled about \$120 million, and the average administration payment per vaccination was about \$18 in 2019 (data not shown).

**FIGURE  
7-1**

**Between 2010 and 2018, shingles vaccination rate increased among the cohort of Part D enrollees newly joining the program in 2010**

**All beneficiaries in the cohort**



**By plan type and beneficiary characteristics**

	Percent ever vaccinated	Percent of beneficiaries
All beneficiaries in the cohort	32%	100%
By plan type during 2010–2018		
PDP	32	43
MA–PD	33	36
PDP and MA–PD	30	21
By LIS status during 2010–2018		
LIS	25	22
Non LIS	35	78
By gender		
Male	31	39
Female	33	61
By race		
White, non-Hispanic	34	74
Black	18	8
Hispanic	23	11
Other	39	6

Note: PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), LIS (low-income [drug] subsidy). The analysis includes all beneficiaries who were age 60 or older and were enrolled in Part D in 2010. Components in the “Percent of beneficiaries” column may not sum to 100 percent due to rounding.

Source: MedPAC analysis of Part D prescription drug event data and Medicare enrollment files from CMS.

Between 2018 and 2019, utilization and spending for the shingles vaccine grew substantially, with the number of Part D–covered doses of shingles vaccine increasing from 3.1 million to 5.8 million, and Part D gross spending rising from \$450 million to \$857 million (Table 7-5, p. 254; 2018 data not shown). Growth in use of the shingles vaccine in 2019 in part likely reflects an easing of a shortage of the Shingrix vaccine. After Shingrix was launched in late 2017, demand for the product was reported to initially exceed supply (Castia Rx 2019).

The vast majority of vaccines covered under Part D are administered in retail or community pharmacies. In 2019, more than 95 percent of vaccines were furnished in those settings. Most vaccine claims are submitted electronically by pharmacies or providers through clearinghouse platforms. In 2019, only a small share of claims were for vaccines administered out of network, for example, at physician offices (less than 3 percent of the claims

by providers and less than 1 percent of the claims by beneficiaries).

**Cost sharing for vaccines covered by Part D plans**

We analyzed data for the shingles vaccine to assess cost sharing for Part D vaccines since that vaccine accounted for over 80 percent of Part D–covered vaccine doses in 2019. That year, nearly all of the claims for shingles vaccines were for Shingrix.<sup>11</sup> Formulary tier placement information reported on the claims indicates that Shingrix was most frequently placed on a brand or preferred brand tier (about 53 percent), followed by a nonpreferred brand tier (about 30 percent). Less than 1 percent of the claims were for prescriptions in which the plan placed the vaccine on a \$0 copay vaccine tier.

Many plan sponsors use fixed copayments for generic and preferred brand-tier drugs filled during the initial coverage phase (ICP) of Part D’s benefit (Medicare

**TABLE  
7-4**

**Part B spending for influenza, pneumococcal, and hepatitis B vaccines, 2019**

	Part B FFS spending		Doses	
	Millions of dollars	Percent	Millions of doses	Percent
Influenza	\$729	54%	16.6	80%
Pneumococcal	593	44	3.9	19
Hepatitis B	39	3	0.3	2
Total	1,361	100	20.9	100

Note: FFS (fee-for-service). Included in the payment totals are roughly \$111 million in payments to providers paid reasonable cost based on the payment amounts reported on claims. Any adjustment to these payments that occurred at cost report settlement are not included in these totals. Data exclude vaccines furnished by Federally Qualified Health Centers (FQHCs) and rural health clinics (RHCs), which are paid for influenza and pneumococcal vaccinations only through the cost report and not through claims. In cost report year 2019, we estimate FQHCs and RHCs furnished approximately 630,000 influenza vaccines and 200,000 pneumococcal vaccines to Medicare beneficiaries based on cost report data currently available; RHC and FQHC vaccine numbers may be understated due to delayed cost reporting by a small share of providers. Components may not sum to totals due to rounding.

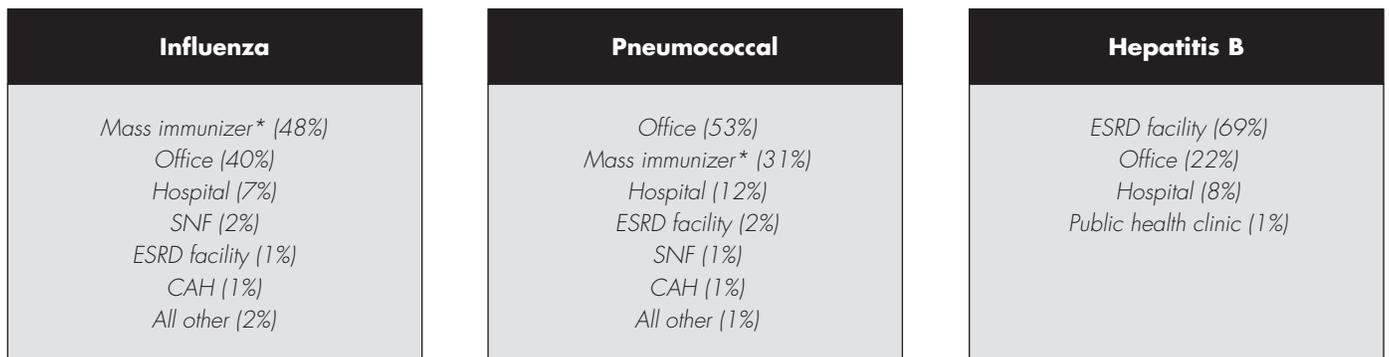
Source: MedPAC analysis of Medicare FFS claims.

Payment Advisory Commission 2019). For Shingrix, a two-dose vaccine, the median copayment per dose filled by Part D enrollees without the LIS during the ICP was \$60 for PDPs and \$45 for MA-PDs in 2019. However, cost-sharing amounts varied considerably, from \$0 at the

10th percentile to \$167 at the 90th percentile, reflecting differences in benefit design across plan sponsors and across benefit phases (Table 7-6, p. 255). For example, an enrollee in a plan with a deductible may have had to pay the full retail cost of the vaccine (about \$146 per dose in 2019), in addition to any cost sharing they may have owed

**FIGURE  
7-2**

**In 2019, most Part B preventive vaccines were administered by mass immunizers and in physician offices**



Note: SNF (skilled nursing facility), ESRD (end-stage renal disease), CAH (critical access hospital). Analysis of Medicare carrier and institutional claims. Examples of place of service from carrier-billed claims include office, mass immunizer, and public health clinic. Examples of type of bill from institutional claims include hospital (inpatient or outpatient), SNF, ESRD facility, and CAH. Components may not sum to totals due to rounding.

\*"Mass immunizer" refers to nontraditional Medicare providers (e.g., pharmacists) that enroll in Medicare for the purposes of administering influenza and pneumococcal vaccinations. Mass immunizers can also include traditional Medicare providers who enroll as mass immunizers to utilize the simplified vaccine roster billing permitted for mass immunizers.

Source: MedPAC analysis of Medicare claims data.

**TABLE  
7-5**

**Vaccines administered and paid through Part D, 2019**

	Gross spending		Doses	
	Millions of dollars	Percent	Millions of doses	Percent
Herpes zoster (shingles)	\$857	93%	5.8	83%
Tetanus/diphtheria*	36	4	0.8	12
Hepatitis A/B	21	2	0.3	4
Other**	11	1	0.1	2
Total	925	100	7.0	100

Note: Gross spending includes all payments to pharmacies for ingredient costs, dispensing fees, and sales tax and includes beneficiary cost sharing. Gross spending does not include vaccine administration costs, which totaled \$123 million. Percentages may not sum to 100 percent due to rounding.

\*Includes vaccines that also provide protection against pertussis.

\*\*Examples of other vaccines covered under Part D include vaccines against measles, mumps, and rubella; meningitis B; meningococcal meningitis; and haemophilus B influenzae.

Source: MedPAC analysis of Part D prescription drug event data and Medicare enrollment files from CMS.

for vaccine administration. Most Part D plans also use a percentage coinsurance in the coverage gap rather than fixed-dollar copayments.

Because Shingrix has a median out-of-pocket cost of about \$50 per dose and requires two doses given a few months apart, the cost may pose a barrier to vaccination for Part D enrollees who do not receive the LIS (Galewitz 2020, Yan et al. 2018). In 2018, the vaccination rate for Shingrix averaged about 4 percent across all Part D enrollees. The vaccination rate, however, did not appear to be related in a systematic manner to the typical cost-sharing amounts charged by plans. Instead, we found greater disparities in vaccination rates by LIS status and by race and ethnicity, with Black beneficiaries least likely to receive a Shingrix vaccination in 2018 (1.7 percent) followed by Hispanic beneficiaries (2.3 percent) compared with nearly 4.5 percent among the White, non-Hispanic beneficiaries.

**How Medicare pays for vaccines under Part B and Part D**

As shown in Table 7-1 (p. 246), most preventive vaccines covered under Part B are paid based on the product’s average wholesale price (AWP). Under Part D, payment is

based on each plan’s negotiated payment. While there is no beneficiary cost sharing for preventive vaccines under Part B, cost sharing under Part D varies across plans and benefit phases (see text box, pp. 258–259, for a summary of the differences between the processes that immunizers follow to bill under Part B and Part D).

**Part B-covered vaccines**

Medicare pays for most doses of Part B vaccines, such as those furnished in physician offices and mass immunizer settings, at a rate of 95 percent of AWP (while certain settings such as hospitals are paid reasonable cost).<sup>12</sup> AWP is a list price, often compared with a “sticker price,” that does not represent actual market prices. The use of AWP is a departure from the payment method for other Part B drugs and biologics, which is based on the average sales price (reflecting the average price realized by the manufacturer for sales to all purchasers net of rebates, discounts, and price concessions, with certain exceptions). Because AWP is a list price, Medicare’s payment rate at 95 percent of AWP has little relationship to providers’ costs to acquire the vaccine.

How Part B vaccines are assigned to billing codes affects Medicare’s payment rates and price competition among similar products.<sup>13</sup> When a billing code contains only one manufacturer’s vaccine, Medicare pays 95 percent of the

**TABLE  
7-6**

**Cost-sharing amounts for Shingrix ranged from \$0 to over \$160 per dose, 2019**

	Percentile of the distribution					
	Mean	Median	10th	25th	75th	90th
All Shingrix claims	\$68	\$47	\$0	\$30	\$84	\$167
Shingrix claims for PDP enrollees						
LIS	90	79	9	47	161	171
Without LIS	74	60	0	30	128	168
Shingrix claims for MA-PD enrollees						
LIS	82	47	9	41	160	172
Without LIS	51	45	0	30	47	144

Note: PDP (prescription drug plan), LIS (low-income subsidy), MA-PD (Medicare Advantage-Prescription Drug [plan]). Cost-sharing amounts for LIS enrollees include amounts covered by the LIS. LIS enrollees paid between \$0 and \$8.50 (maximum LIS copay amount set by law for 2019).

Source: MedPAC analysis of Part D prescription drug event data and Medicare enrollment files from CMS.

AWP established by that manufacturer for the product.<sup>14</sup> For billing codes that contain multiple manufacturers’ vaccines, Medicare pays 95 percent of the lowest AWP across the different manufacturers’ products. In general, for Part B vaccines that have their own billing code, there is little constraint on manufacturers’ ability to increase AWP and Medicare’s payment rate over time. When vaccines from multiple manufacturers share a billing code, the use of the lowest AWP across the products may provide some constraint on price increases. As shown in Table 7-7 (p. 256), AWP inflation has been greatest for vaccines where a single manufacturer’s product has its own billing code, while AWP inflation has been modest for vaccines where multiple manufacturers’ products share a billing code. For example, among the top six influenza vaccines in 2019, four that have their own billing codes (Fluzone High Dose, Fludac, Flublok, and Flucelvax) have experienced substantial price growth, while the quadrivalent vaccines that are offered by multiple manufacturers and grouped together in a combined billing code have experienced very limited price growth.

When a Part B-covered vaccine is furnished by a hospital, skilled nursing facility, home health agency, hospital-based dialysis facility, RHC, or FQHC, Medicare’s payment for the vaccine is based on reasonable cost instead of 95 percent of AWP. It is difficult to know how much Medicare

pays for vaccines based on reasonable cost. For most of these provider types, we can observe the amount paid for vaccines on claims, but the actual amount may be adjusted at cost report settlement.<sup>15</sup> The cost reports include some data on vaccines, but the data combine all vaccines together and are not granular enough to determine what Medicare paid for each vaccine. In 2019, providers paid based on reasonable cost accounted for approximately 9 percent to 14 percent of influenza, pneumococcal, and hepatitis B vaccine doses covered by Part B.<sup>16</sup>

In certain circumstances, Part B covers vaccines as treatment for an injury or direct exposure to an illness. For example, Part B covers hepatitis A vaccine, rabies vaccine, and Td and Tdap vaccines in such circumstances. In those cases, Part B covers and pays for these products like other drugs and biologics used to treat illness or injury at a rate of 106 percent of the average sales price (ASP), with the beneficiary liable for 20 percent cost sharing.<sup>17</sup>

Besides paying for the vaccine itself, Medicare makes a separate payment under Part B to immunizers for administering the vaccine. In 2019, Medicare’s payment for administering Part B vaccines totaled approximately \$365 million. In 2019, across all settings, the vaccine administration fee averaged about \$18 per injection. Providers are paid under the physician fee schedule or outpatient prospective payment system (with a few

**TABLE  
7-7**

**Growth in payment rates for Part B vaccines**

CPT code	Description	Medicare payment rate 1st quarter 2020	Average annual price growth	Years over which growth is calculated	Number of manufacturers
<b>Top 6 influenza vaccines with highest total Medicare spending (2019)</b>					
90662	IIV increased antigen (Fluzone High Dose)	\$56.01	7.5%	2011–2020	1
90653	IIV adjuvanted (Fluad)	\$59.53	16.8	2017–2020	1
90682	RIV quadrivalent (Flublok)	\$56.01	10.0	2018–2020	1
90686	IIV quadrivalent, PF (multiple products)	\$19.03	–0.3	2014–2020	3
90674	Cell culture–based IIV quadrivalent (Flucelvax)	\$28.13	7.0	2017–2020	1
90688	IIV quadrivalent (multiple products)	\$17.84	1.1	2015–2020	3
<b>Pneumococcal vaccines</b>					
90670	Pevnar 13	\$214.62	6.3	2011–2020	1
90732	Pneumovax 23	\$114.21	11.2	2005–2020	1
<b>Top 3 hepatitis B vaccines</b>					
90740	Hepatitis B 3-dose immunosuppressed (multiple products)	\$134.12	1.1	2005–2020	2
90747	Hepatitis B 4-dose immunosuppressed (multiple products)	\$134.12	1.1	2005–2020	2
90746	Hepatitis B 3-dose adult (multiple products)	\$67.06	1.1	2005–2020	2

Note: CPT (Current Procedural Terminology), IIV (inactivated influenza vaccine), RIV (recombinant influenza vaccine), PF (preservative free). Average annual price growth is calculated based on the CMS-published payment for the first quarter of each year. For each type of vaccine, products are listed in order of highest total Medicare spending.

Source: MedPAC analysis of CMS-published payment rates and crosswalk.

exceptions for providers such as hospital-based dialysis facilities and critical access hospitals).

**Part D–covered vaccines**

Under Part D’s market-based approach, manufacturers’ pricing incentives for vaccines would be expected to vary, depending on factors such as the manufacturer’s Medicare market share and the degree of competition. Most Part D plans require their enrollees to pay cost sharing for vaccines, which may discourage some

beneficiaries from accessing preventive vaccines.

Depending on the plan’s benefit design and the benefit phase, beneficiaries may pay coinsurance based on list prices or the full retail prices at the pharmacy. As a result, manufacturers’ incentives to increase drug prices may be more restrained relative to having no beneficiary cost sharing, as under the Part B program. It is worth noting that Medicare pays most of the enrollee’s cost sharing for beneficiaries who receive LIS.

For vaccines with competing alternatives, plan sponsors can use differential cost sharing to encourage the use of lower cost products. That, in turn, may allow plan sponsors to gain more leverage in negotiating rebates with manufacturers, potentially lowering Medicare's spending for Part D. However, because many vaccines are typically administered once (or infrequently) and account for a lower share of Part D overall spending, Part D plans may have limited incentive to negotiate rebates or discounts.

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## **Improving Medicare coverage and payment for preventive vaccines**

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Currently, as new preventive vaccines enter the market, Part B will cover only those that prevent diseases specified in law. By 2010, Part B already covered influenza and pneumococcal vaccines with no beneficiary cost sharing, but patients who needed immunization for hepatitis B were responsible for 20 percent cost sharing. A subsequent provision of the Affordable Care Act of 2010 (ACA) removed cost sharing for hepatitis B vaccines.<sup>18</sup> In 2020, the Congress provided coverage under Part B for COVID-19 vaccines without beneficiary cost sharing. Any other new vaccines that the Food and Drug Administration approves would fall under Part D, in which private plans can manage benefits and set enrollee cost-sharing requirements.

Although Medicare's vaccine coverage today is broader than it was at the start of the program, the coverage of vaccines by some commercial health plans is even broader. In 2010, the ACA required nongrandfathered commercial health policies to cover, at no cost sharing on ingredient costs, all age-appropriate vaccinations recommended by the CDC's Advisory Committee on Immunization Practices (ACIP) (Center for Value-Based Insurance Design 2017).<sup>19</sup> One should note, however, that some commercial health plans charge cost sharing on vaccine administration fees. The ACA made no changes related to Part D's coverage of ACIP-recommended vaccines, and thus most Part D plans can and do continue to require cost sharing for these vaccines.

To improve beneficiary access to preventive vaccines, the Commission recommends a policy that covers all appropriate preventive vaccines under Part B. The Commission also recommends improving payment accuracy for preventive vaccines under Part B by changing payment from 95 percent of AWP, a list price that may

have little relationship to market prices, to 103 percent of wholesale acquisition cost (WAC), which is a better measure of market prices than AWP. We also recommend vaccine manufacturers be required to report ASP data to CMS so that the Secretary can study the appropriateness of basing payment for preventive vaccines on ASP, a payment mechanism that is more reflective of market prices than either AWP or WAC. In addition to recommending coverage and payment changes to preventive vaccines, the text box (pp. 265–267) summarizes Medicare's efforts to measure and report on rates of vaccination that some researchers assert can help identify vaccine disparities among population groups.

## **Covering all preventive vaccines under Part B**

In 2007, the Commission recommended that all vaccine coverage be moved to Part B. At the time, the Part D program was just getting underway, and physicians had at least two major concerns related to coverage of vaccines through Part D plans. Physicians purchased vaccines in the same way as other Part B drugs and administered them in their offices, but at the time, most had no direct way of billing Part D plans. A second concern was that if beneficiaries had to pay the full payment rate for vaccines up front and then seek reimbursement from their plans, the out-of-pocket cost would discourage them from seeking appropriate preventive care.

For those reasons, in 2007, the Commission recommended that the Congress permit coverage for appropriate preventive vaccines under Part B instead of Part D (Medicare Payment Advisory Commission 2007). Under Part B, physicians would be able to administer new vaccines in their offices as they do other covered vaccines, giving beneficiaries more access to preventive care.

The CARES Act placed Medicare coverage of COVID-19 vaccines under Part B. While the issue of Medicare coverage for COVID-19 vaccines has been settled, there remains the broader issue of whether Medicare coverage for all vaccines should be moved to Part B. Because it has been more than 10 years since the Commission recommended covering all vaccines under Part B, the current public health environment suggests it is timely for the Commission to revisit its reasoning.

Today, some of the Commission's original rationale for its recommendation no longer applies. Physicians and other immunizers (including pharmacists) can generally bill Part D plans through clearinghouse platforms.

## Immunizers and their billing approaches

Physicians, nurses, and other licensed medical professionals have long administered vaccines. Historically, pharmacists have partnered with other immunizers to vaccinate, but over the past two decades their role has grown, and most states have expanded pharmacists' scope of practice to play a more independent role. A 2018 survey of independent pharmacists found that 90 percent provided flu vaccinations and 76 percent documented vaccinations through state-based immunization information systems (registries) (National Community Pharmacists Association 2019). Nearly 90 percent of Americans live within five miles of a pharmacy (National Association of Chain Drug Stores 2020). As a result, including pharmacists among eligible immunizers can expand access to vaccinations, likely at lower cost than administering them at physician offices or hospital clinics.

As of 2019, about 360,000 pharmacists were trained to provide immunizations, and all 50 states permitted pharmacists to do so in some capacity (Levy 2020). State regulations vary considerably depending on the type of vaccine, age, and condition of the patient. For certain types of vaccines, some states require a physician's prescription before a pharmacist may administer the immunization. States may use a vaccination protocol developed by physicians or a state health department that stipulates which vaccines, and under which conditions, a pharmacist may provide. For certain vaccines such as for influenza, most states permit pharmacists to immunize independently (Xavier and Goad 2017).

Under Part B, immunizers' billing methods depend on whether the patient is in traditional fee-for-service (FFS) Medicare or enrolled in a Medicare Advantage (MA) plan. For Part B vaccines administered to FFS patients, immunizers submit claims to their

*(continued next page)*

Relatively few Medicare beneficiaries (1 percent) pay the full cost of the vaccine upfront and then seek retroactive reimbursement from their plan. While some initial Part D vaccine billing concerns have been alleviated, the Commission believes that there continue to be good reasons to move all preventive vaccine coverage to Part B.

- As of 2020, more Medicare beneficiaries are enrolled in Part B (57.3 million) than in Part D (48.8 million) (Boards of Trustees 2020). Thus, coverage of vaccines under Part B has the potential to reach a larger group of beneficiaries.
- High cost sharing in some Part D plans may prevent some beneficiaries from seeking recommended preventive vaccines.
- A wide variety of health care providers (e.g., hospitals, physician clinics, dialysis facilities) bill Medicare under Part B, offering more settings where beneficiaries can receive vaccines than under Part D.

- Beneficiaries and even some providers may find it confusing to understand which vaccines are covered by Part B versus Part D.

For these reasons, the Commission believes a policy similar to the 2007 recommendation, under which Medicare would cover appropriate preventive vaccines and their administration under Part B instead of Part D without cost sharing, would improve beneficiary access to preventive vaccines. Cost sharing is the key difference between the policy the Commission articulates in this chapter and the 2007 recommendation. Our previous recommendation did not discuss cost sharing, whereas the policy we are recommending now would explicitly eliminate beneficiary cost sharing for Part B–covered preventive vaccines and their administration. Currently, beneficiaries face no cost sharing for the four Part B–covered vaccines (flu, pneumococcal, hepatitis B, and COVID-19) or for their administration. Similarly, this policy would ensure that beneficiaries face no cost

## Immunizers and their billing approaches (cont.)

regional Medicare administrative contractor for the vaccine itself as well as for a separate payment for vaccine administration. Although pharmacists are not considered Medicare providers, they can register with CMS as “mass immunizers” and thereby bill Part B for influenza, pneumococcal, and COVID-19 vaccinations.<sup>20</sup> For patients enrolled in MA, in-network providers bill the patient’s plan for reimbursement.

Physicians and office-based immunizers may not bill Part B for administering Part D vaccines. When Part D began in 2006, its plans had to develop methods to pay physicians to administer Part D vaccines. Subsequently, companies created clearinghouse platforms that allow medical providers to look up the patient’s coverage, cost sharing, and the payer’s reimbursement amount to the provider before a patient receives a vaccine (Yan et al. 2018). If the provider administers the vaccine, they can also adjudicate the claim with the Part D plan’s pharmacy benefit manager (PBM) through the clearinghouse. Nevertheless, patients’ access to

vaccines under Part D may be affected because some plans may not participate in a clearinghouse or because some providers may not find the platforms easy to use. Instead, the patient may have to pay the immunizer up front for the vaccine and then submit a claim to their Part D plan themselves for reimbursement (Centers for Medicare & Medicaid Services 2019b). If an immunizer’s charge is higher than a plan’s allowable charge, the patient must pay the difference.

Most pharmacies enter into contracts with all or nearly all Part D plans to be included in the plans’ pharmacy networks. When a provider transmits a prescription for a vaccine to a pharmacy, or if the vaccine is one that pharmacists can administer without a prescription, an in-network pharmacy collects the plan’s cost-sharing amount from the patient and adjudicates the claim with the plan’s PBM for reimbursement. In most cases, Part D plans do not reimburse out-of-network pharmacies, so beneficiaries have a financial disincentive to receive immunizations at out-of-network pharmacies. ■

sharing for any additional vaccines that become covered by Part B (i.e., for vaccines that are moved from Part D to Part B coverage and for future vaccines). While some beneficiaries have coverage of Part B cost sharing through Medigap or Medicaid, not all beneficiaries have supplemental coverage; the policy would ensure that these beneficiaries do not face cost sharing for future Part B–covered preventive vaccines.

The elimination of cost sharing under Part B would lead to additional Medicare spending (because under Part D, beneficiaries who do not receive the low-income subsidy may be liable for cost sharing on the shingles vaccine, whereas under the Commission’s recommended policy they would not, if coverage were moved to Part B). In addition, some Medicare beneficiaries receive drug coverage from sources other than Part D (e.g., related to past employment such as the Federal Employees Health Benefits Program, TRICARE, and other employers that sponsor retiree drug coverage outside of the Part D

program). For a subset of beneficiaries with Part B, the coverage of vaccines would shift from plans offered by their former employers to Part B. This shift would result in higher Part B spending on vaccines. In addition, if the policy increases the share of beneficiaries who receive the shingles vaccine, it would also increase Medicare spending on the vaccine.

At the same time, Medicare spending on Part A and Part B services might be reduced to the extent that cases of shingles are prevented by increased shingles vaccination. The CDC estimates that, for every 11 to 17 immunocompetent individuals age 50 and older who are vaccinated with Shingrix, one case of shingles is prevented (Dooling et al. 2018).<sup>21</sup> The agency also estimates that it would require vaccinating between 70 and 187 individuals to prevent one case of shingles with postherpetic neuralgia (PHN), a complication of shingles associated with longer-term nerve pain (Dooling et al. 2018). Researchers have attributed increased health care utilization—particularly

office visits, hospital outpatient visits, and outpatient medications—to the treatment of shingles (Johnson et al. 2016, Meyers et al. 2017).<sup>22</sup> Health care use attributable to shingles increased due to the presence of PHN and generally increased with increasing age (Johnson et al. 2016, Meyers et al. 2017, Yawn et al. 2009).<sup>23</sup> Prevention of shingles cases thus would be expected to reduce utilization of health care services associated with shingles treatment. However, any reduction to Part A and Part B spending on shingles treatment would likely be spread over a long time horizon. In addition, the increase in spending due to increased shingles vaccination would likely be greater than the reduction in spending associated with reduced incidence of shingles.

### **Changing Medicare’s payment for Part B preventive vaccines**

Medicare Part B’s payment method for preventive vaccines causes some concern. Medicare pays for most doses of Part B–covered vaccines at a rate of 95 percent of AWP, a list price that does not reflect market prices. Other pricing metrics, such as WAC and ASP, would better reflect purchasers’ acquisition costs than AWP does.

Aside from preventive vaccines, Medicare generally pays for Part B–covered drugs and biologics based on ASP but uses WAC in certain circumstances. For most Part B–covered drugs and biologics, Medicare pays 106 percent of ASP. The ASP for a drug is the average price realized by the manufacturer for sales to all purchasers net of most rebates, discounts, and price concessions, with certain exceptions. For new products that initially lack ASP data, Medicare pays 103 percent of WAC. The WAC for a drug is the price at which the manufacturer sells the product to the wholesaler; the price does not reflect discounts or rebates if available.

To gauge the effect of changing the payment rate for Part B–covered preventive vaccines, we analyzed the available pricing data on vaccines.

- For three Part B–covered vaccines paid at 95 percent of AWP (flu, pneumococcal, and hepatitis B), we have data on AWP and WAC, but not on ASP.
- For a few vaccines that are covered under Part B when used as treatment for an injury or direct exposure and covered under Part D when used for preventive reasons, we have data on ASP, Part D plan payment rates to the pharmacy (i.e., before any rebates), and WAC.

- For vaccines that are covered only under Part D, such as the shingles vaccine, we have data on Part D plan payment rates and WAC.

For the three Part B–covered preventive vaccines, Medicare’s current payment rate of 95 percent of AWP exceeds WAC by a significant amount. Based on an analysis of 15 billing codes for these vaccines as of July 2020, the payment rate of 95 percent of AWP was equivalent to between 85 percent and 138 percent of WAC for the individual products (i.e., national drug codes (NDCs) assigned to these billing codes) (Table 7-8). For the influenza vaccine, the payment rate ranged from 108 percent to 138 percent of WAC, with a median of 117 percent. For the pneumococcal vaccine, the payment rate ranged from 111 percent to 117 percent of WAC, with a median of 114 percent. Among hepatitis B vaccines, one product was paid less than WAC (85 percent), while the remaining products were paid between 114 percent and 122 percent of WAC. Thus, except for the one hepatitis B vaccine that was paid less than WAC, Medicare paid between 8 percent and 38 percent more than the gross price the manufacturer charges the wholesalers for the three Part B–covered preventive vaccines. (Note that WAC is a gross price charged to the wholesaler and does not reflect discounts and rebates, so the actual price a provider pays for the vaccine may be lower.)

For four vaccines (hepatitis A, rabies, Td, and Tdap) covered by both Part B and Part D, the Part B’s 106 percent of ASP payment rate ranged from 73 percent of WAC to 94 percent of WAC. Discounts or rebates likely account for the difference between ASP and WAC for these four vaccines. WAC is the undiscounted price from the manufacturer to the wholesaler, whereas ASP incorporates most discounts and rebates received by purchasers to the extent they are available. The four vaccines all have at least two competing manufacturers, which might provide leverage for pharmacies, physicians, and hospitals to secure discounts or rebates.

Median Part D plan payment rates for the ingredient cost of these four vaccines were higher, ranging from 98 percent to 106 percent of WAC.<sup>24</sup> The median Part D plan payment rate for Shingrix, the shingles vaccine that accounted for over 90 percent of Part D gross drug spending on vaccines in 2019, was 101 percent of WAC. Thus, based on the data for these five vaccines, Part D plan payment rates for the ingredient cost of vaccines are generally near or slightly above WAC. However, Part D

**TABLE  
7-8**

**Comparison of Medicare’s vaccine payment rates to wholesale acquisition cost**

	Part B		Part D
	95% of AWP payment rate as a share of WAC, 2020	106% of ASP payment rate as a share of WAC, 2020	Median payment rate as a share of WAC, 2019
	Range across NDCs (median NDC)	Range across NDCs (median NDC)	Range across NDCs (median NDC)
<b>Part B–covered preventive vaccines</b>			
Influenza	108%–138% (117%)	N/A	N/A
Pneumococcal	111%–117% (114%)	N/A	N/A
Hepatitis B	85%–122% (115%)	N/A	N/A
<b>Vaccines covered by Part B and Part D</b>			
Hepatitis A	N/A	87%–88% (87%)	102%–105% (104%)
Rabies	N/A	83%–87% (85%)	98%–104% (101%)
Td	N/A	73%–94% (73%)	99%–105% (103%)
Tdap	N/A	76%–84% (77%)	105%–106% (105%)
<b>Vaccine covered by Part D</b>			
Shingles (Shingrix)	N/A	N/A	101%*

Note: AWP (average wholesale price), ASP (average sales price), WAC (wholesale acquisition cost), NDC (national drug code), N/A (not applicable), Td (tetanus and diphtheria), Tdap (tetanus, diphtheria, and pertussis). Estimates reflect the median NDC when there are multiple NDCs for a particular type of vaccine. The Part D payment rate reflects the median total payment to pharmacies for ingredient cost, including cost sharing, and does not reflect any manufacturer rebates if available. WAC prices and Part B payment rates are for July of a given year. Data exclude Part B and Part D payments for vaccine administration and any Part D dispensing fee. We compared Part B payment rates (95% of AWP or 106% of ASP) to WAC by comparing the billing code–level payment rates with the individual WAC for each NDC in the billing code. We compared median Part D payment rates with WAC by comparing both payment rates and WAC at the NDC level.  
\*We provide a single figure for Shingrix because it has just one NDC.

Source: MedPAC analysis of Part D prescription drug event data, public ASP payment rate files from CMS, and data from First Databank.

plan payment amounts do not reflect any rebates that the vaccine manufacturer may have paid to the Part D plan. We do not know whether Part D plans collect any rebates for vaccines. For vaccines where there are competing products from multiple manufacturers, Part D plans may have leverage to negotiate rebates. But if a vaccine

accounts for a small share of Part D plan spending or lacks competitor products, Part D plans may lack the incentive or leverage to negotiate rebates.

This analysis is instructive because it suggests the magnitude of the difference between list prices (AWP)

and the prices paid by wholesalers before discounts and rebates are applied (WAC) and the price net of discounts and rebates (ASP). Medicare's payment rate of 95 percent of AWP for Part B preventive vaccines substantially exceeds WAC, which indicates that it is higher than needed to cover immunizers' cost of acquiring the vaccine. Shifting the basis of payment from AWP to WAC—for example, to a rate of 103 percent of WAC, similar to the rate Part B pays for new drugs and biologics that lack ASP data—would generate savings for taxpayers. This change would also reduce payments for vaccines to immunizers, but we expect that immunizers would continue to be able to obtain vaccines at prices within the Medicare's payment amount.

Although WAC is a better measure of drug prices than AWP (as it reflects the price at which the manufacturer sells its pharmaceutical product to wholesalers or directly to customers), WAC does not incorporate any discounts or rebates that may be available, so it likely overstates market prices. For the small number of vaccines for which we have data, WAC is substantially higher than ASP. The vaccines for which we have WAC and ASP data all have at least two competing products from different manufacturers. We do not know how WAC and ASP relate for other vaccines. ASP and WAC may be closer for vaccines that lack competitors or that are viewed as having differential benefits for certain populations than alternative manufacturers' vaccines. Nonetheless, the substantial difference between WAC and ASP we observe for the vaccines for which we have data suggest that ultimately a payment rate based on ASP might be most appropriate, as it would reflect actual market prices rather than undiscounted wholesale prices.

For a number of reasons, it would be helpful to have more data before considering an ASP-based payment amount for vaccines that are currently paid 95 percent of AWP. Because ASP is an average, we do not know how much the acquisition prices for vaccines vary across purchasers, such as physicians and pharmacies. Understanding that price variation would help policymakers determine whether 106 percent of ASP or an alternate add-on to ASP is an appropriate payment rate.

It is not clear how the two-quarter lag in ASP data reporting would affect Medicare payment rates for preventive vaccines, given the seasonality of the influenza vaccine and potential supply and demand dynamics that can affect vaccines more generally.<sup>25</sup> The influenza vaccine is modified slightly each year. Most influenza

vaccinations among Medicare beneficiaries occur in the third and fourth quarter of the calendar year. Due to the two-quarter lag in ASP data, an ASP-based payment rate for the influenza vaccine for the third quarter of the year would be based on the ASP for influenza vaccine sold during the first quarter of the year (the prior version of the influenza vaccine). Similarly, ASP-based payment rates for the fourth quarter of the year would be based on the ASP for sales in the second quarter of the year (the prior version of the influenza vaccine during a quarter when very few influenza vaccinations occur). We do not know whether there is much variation in the ASP for the influenza vaccine across these time periods due to seasonality. More generally, vaccine supply can vary over time, with either a larger or smaller number of doses available than expected during some periods (Centers for Disease Control and Prevention 2021). How frequently these supply and demand gaps occur and what effect, if any, they would have on Medicare payment rates given the two-quarter lag is unknown. Having data on the ASP for vaccines would help address these questions and make it easier to develop an ASP-based payment policy that accounts for any such issues.

A two-part approach to modifying Medicare Part B's payment for preventive vaccines could improve the accuracy of Medicare payment for vaccines while promoting beneficiary access. A policy that immediately modifies Medicare Part B's payment for vaccines to 103 percent of WAC and that requires vaccine manufacturers to report ASP data to CMS for study would improve Medicare's current payment rate for vaccines and build the knowledge base that could facilitate the development of an ASP-based payment rate in the future. First, by setting Medicare's payment rate at 103 percent of WAC, this policy would moderately reduce payment rates by moving away from inefficient AWP-based payment while maintaining vaccine payment rates at a level that should keep vaccines accessible to all immunizers. In addition, for vaccines currently covered under Part D that the Commission recommended be moved to Part B in 2007, a payment rate of 103 percent of WAC would be similar to the payment rates Part D plans have been paying for vaccines. Second, by requiring manufacturers to report ASP data for vaccines to CMS, the policy would enable the agency to study how payment rates would be different if they were based on ASP rather than WAC. As part of this assessment, the Secretary should, potentially through the Office of Inspector General (OIG), gather data on immunizers' acquisition costs for vaccines to study how

vaccine prices vary across immunizers and how those prices relate to ASP and WAC. OIG has experience conducting studies of acquisition costs for other drugs and biologics (such as for drugs furnished by dialysis facilities and for immune globulin furnished by hospital outpatient departments and physician offices) (Office of Inspector General 2010, Office of Inspector General 2007, Office of Inspector General 2006). The collection of ASP data by CMS and acquisition price information by the Secretary would build the knowledge base to consider and develop an ASP-based payment rate for Part B vaccines in the future.

The same payment policy for Part B preventive vaccines should apply across settings, including those settings in which providers are currently paid reasonable cost. Inpatient and outpatient hospitals (except Indian Health Service hospitals), skilled nursing facilities, home health agencies, hospital-based dialysis facilities, RHCs, and FQHCs are currently paid for vaccines based on reasonable cost. Cost-based reimbursement can result in wide variation in payment rates across providers for the same vaccine. Cost-based reimbursement also makes it difficult to know how much Medicare is spending on each vaccine because payments can be revised at cost report settlement. In general, the Commission has held that Medicare should pay similar rates for similar care. If a WAC-based payment is appropriate for settings that are currently paid 95 percent of AWP (such as physician offices, mass immunizers, Indian Health Service hospitals, freestanding dialysis facilities, and hospices), then the principle of paying similar rates for similar care would suggest the same WAC-based rate is appropriate for hospitals and other settings that are currently paid reasonable cost for Part B–covered vaccines. Medicare’s current approach to paying for nonvaccine Part B–covered drugs and biologics provides a precedent for paying the same rate across settings, with Medicare generally paying the same rate (106 percent of ASP) across a number of settings—physician offices, hospital outpatient departments, pharmacies, and durable medical equipment suppliers.<sup>26</sup> Thus, hospital outpatient departments are already paid under the ASP-based payment system for most drugs that they furnish. With respect to RHCs and FQHCs, we also note that moving to WAC-based payment might have positive cash flow benefits for these entities because WAC-based payment would be made through claims submission, whereas currently these entities are paid for influenza and pneumococcal vaccines only at the end of the cost report year.<sup>27</sup>

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## Recommendation

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### RECOMMENDATION 7

#### The Congress should:

- **cover all appropriate preventive vaccines and their administration under Part B instead of Part D without beneficiary cost sharing and**
- **modify Medicare’s payment rate for Part B–covered preventive vaccines to be 103 percent of wholesale acquisition cost, and require vaccine manufacturers to report average sales price data to CMS for analysis.**

### RATIONALE 7

The recommendation to cover all appropriate preventive vaccines under Part B without cost sharing would improve beneficiary access to vaccines because more beneficiaries have coverage under Part B than Part D and because beneficiaries would face no cost sharing for vaccines under Part B. It would also facilitate the administration of vaccines in a variety of settings, potentially creating more opportunities to reach beneficiaries for preventive vaccinations. Under this policy, the Secretary should consider expanding the set of vaccines (now limited to influenza, pneumococcal, and COVID-19) that mass immunizers can furnish.

The recommendation would also improve Medicare Part B payment for preventive vaccines by moving away from payment based on 95 percent of AWP or reasonable cost. By establishing a payment rate of 103 percent of WAC, the recommendation would moderately reduce Medicare payment rates for Part B vaccines while keeping vaccine payment rates at a level that should be accessible to all immunizers. At the same time, the recommendation would require manufacturers to report ASP data for vaccines to CMS so that the agency could study how payment rates would differ if they were based on ASP rather than WAC. As part of this assessment, the Secretary could, potentially through OIG, gather data on immunizers’ acquisition costs for vaccines to study how vaccine prices vary across immunizers and how those prices relate to ASP and WAC. This approach would build the knowledge base to consider development of ASP-based payment rates in the future. Once the study is completed, the Commission urges the Secretary to make the results of the analysis public and seek statutory authority to adopt an ASP-based payment rate for preventive vaccines if it would improve payment accuracy.

**Spending**

- The Congressional Budget Office estimates that this recommendation would increase Medicare program spending by \$250 million to \$750 million over one year and \$1 billion to \$5 billion over five years.

Several dynamics underlie this estimate of the recommendation’s net effect. The movement of vaccines from Part D to Part B is expected to increase Medicare program spending because more beneficiaries are enrolled in Part B than Part D and because the recommendation would eliminate beneficiary cost sharing under Part B for vaccines and their administration that would have, in the absence of the recommendation, been subject to beneficiary cost sharing under Part D. The second part of the recommendation, improving Medicare’s payment for Part B–covered vaccines, would reduce Medicare program spending due to savings from paying 103 percent of WAC instead of a higher AWP-based rate.

To the extent that increased shingles vaccination prevents cases of shingles, it would be expected to reduce FFS utilization and spending associated with shingles treatment. At the same time, increased uptake of shingles vaccine would increase Medicare spending for the vaccine and its administration. The increase in spending due to increased shingles vaccination would likely be greater than the reduction in spending associated with reduced incidence of shingles. The CDC estimates that one case of shingles is prevented for every 11 to 17 immunocompetent individuals age 50 and older who is vaccinated with Shingrix (Dooling et al. 2018).

**Beneficiary and provider**

- We expect the recommendation would increase beneficiary access to preventive vaccines and would result in vaccines being furnished in a wider range of provider settings. This recommendation is not expected to affect providers’ willingness or ability to care for Medicare beneficiaries.

**Implementation issues**

To execute this vaccine coverage policy, CMS would need to define “appropriate preventive vaccines,” which could be defined as vaccines recommended by the CDC’s ACIP, the entity in the U.S. that makes recommendations on appropriate use of vaccines (e.g., who should receive

the vaccines, at what ages they should be given, how many doses are needed, how multi-dose vaccinations are spaced, and precautions or contraindications). This approach would be similar to the standard set by the ACA for vaccine coverage by nongrandfathered commercial plans and for adult vaccine coverage by state Medicaid programs.

The process Medicare uses to cover preventive services could also serve as a model for this vaccine policy. For preventive services (e.g., screening for certain types of cancer), the Secretary has authority to cover those services that are (1) reasonable and necessary for the prevention or detection of an illness or disability, (2) recommended with a grade of A or B by the U.S. Preventive Services Task Force (USPSTF), and (3) appropriate for individuals with Part A or Part B coverage. The statute gives the Secretary the authority to determine whether a preventive service meets these criteria under the national coverage determination (NCD) process.<sup>28</sup> Because the USPSTF does not make recommendations on vaccines, this process does not apply to vaccines. But a similar process could be developed for preventive vaccines, under which the Secretary could be permitted to cover preventive vaccines if recommended by an expert panel (such as ACIP) and the Secretary determines the vaccine meets the other criteria in the NCD process.<sup>29</sup>

For the small number of vaccines currently used to prevent disease as well as to treat an injury or a direct exposure to a disease (e.g., hepatitis A, rabies, Td, and Tdap), an implementation issue arises in that the vaccines would potentially be paid at two different rates under Medicare Part B. Currently, these Part B–covered vaccines that are furnished for the treatment of an injury or direct exposure are paid at a rate of 106 percent of ASP if provided in a physician office or separately paid under the outpatient prospective payment system. The Commission’s recommendation is that appropriate preventive vaccines be paid 103 percent of WAC. Thus, doses of these vaccines not used in response to injury or direct exposure could be paid based on WAC. However, given that some doses of these vaccines are currently paid based on ASP under Part B, the policy could grandfather these vaccines and maintain their payment rate at 106 percent of ASP, regardless of how they are used. Unlike the high-volume preventive vaccines like influenza, pneumococcal, and hepatitis B, Medicare already has ASP data for the hepatitis, rabies, Td, and Tdap vaccines and has some experience paying for them based on ASP. Thus, the rationale for WAC-based payment as an interim policy

## Medicare's reporting of vaccination rates and efforts to improve uptake are uneven

Medicare's tracking of vaccination rates and efforts to improve uptake are uneven. While more Medicare beneficiaries have been vaccinated in recent years, some rates have not reached objectives established by the Centers for Disease Control and Prevention (CDC), and sizable differences in vaccination rates exist by race and ethnicity. Researchers maintain that measuring and reporting on rates of vaccination can help identify disparities among population groups. Researchers have also suggested that tying payment to quality measurement can be a promising lever to increase adult vaccination rates and achieve national population health targets (Hughes et al. 2019). In 2013, the Department of Health and Human Services contracted the National Quality Forum (NQF) to identify, analyze, prioritize, and make recommendations to fill gaps in adult immunizations. The NQF recommended increasing vaccination rates through the use of (1) reporting programs, (2) financial and other incentives, and (3) technology and infrastructure support. The NQF also identified the development of two quality measures that would be applicable for the Medicare population: (1) a composite performance measure that includes immunization with other preventive care services, as recommended by age and sex, and (2) a composite measure of all vaccines recommended by the Advisory Committee

on Immunization Practices (National Quality Forum 2014).

Medicare measures vaccination rates among some health care personnel since vaccinating this group has been associated with substantial reductions in the rate of influenza-like illness and all-cause mortality among both staff members and patients in various health care settings. For example, health care personnel risk passing on influenza to their patients as well as their colleagues. Health care personnel who are vaccinated also positively influence vaccine uptake among their clients, compared with health care personnel who are not vaccinated (Centers for Disease Control and Prevention 2006).

Table 7-9 (p. 267) compares the availability of publicly reported vaccine rates and the use of vaccine measures in pay-for-reporting programs (i.e., quality reporting programs) and in pay-for-performance programs (value-based purchasing) across settings. Several vaccine-related measures are publicly reported on the Medicare.gov website, and the specific measures vary across fee-for-service (FFS) providers. For example, several types of institutional providers—such as hospitals paid under the inpatient prospective payment system (PPS), PPS-exempt

*(continued next page)*

to permit time to collect ASP data and study the potential effects of ASP-based payment rates is not as relevant for these four vaccines. However, should data collected by the Secretary on the distribution of acquisition costs for higher volume preventive vaccines suggest that a different add-on to ASP is warranted, such a change should be considered for vaccines currently paid at 106 percent of ASP also.

CMS should take steps to ensure that the payment rate for drug administration of Part B-covered vaccines is appropriate and accurately incorporates the various costs associated with vaccine administration. For example, CMS should reevaluate and update the work and practice expense components of the relative value units associated

with the vaccine administration codes (Current Procedural Terminology (CPT) codes 90460–90474 and Healthcare Common Procedure Coding System codes G0008–G0010) under the physician fee schedule. CMS has valued these codes based on a direct crosswalk to another service (CPT code 96372, which is for “therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular”). For 2021, the agency has maintained the 2019 payment amounts for vaccine administration services instead of pursuing other options, such as crosswalking the value to an alternative service (CPT code 36000, which is for “introduction of needle or intracatheter, vein”) or using the 2009 recommendation

## Medicare's reporting of vaccination rates and efforts to improve uptake are uneven (cont.)

cancer hospitals, long-term care hospitals, and inpatient rehabilitation facilities—report the influenza vaccination rate for their health care personnel in their quality reporting programs; this measure is publicly available on Medicare.gov. For nursing homes and home health providers, information on both influenza and pneumococcal vaccination rates for patients is publicly reported on Medicare.gov. Across all FFS providers listed in Table 7-9, the measure results are calculated using some combination of providers' own administrative data, clinical data (e.g., electronic health records), and assessment data, which are then reported to CMS (or in some cases to the CDC). Although not finalized, CMS is considering adding a COVID-19 vaccination rate for health care personnel to the quality reporting programs for most institutional settings (Centers for Medicare & Medicaid Services 2020a).

For individual clinicians, influenza and pneumococcal vaccination rates of beneficiaries are not publicly reported on Medicare.gov, but clinicians can report them as one of their six measures scored in the quality category of the Merit-based Incentive Payment System (MIPS).<sup>30</sup> CMS has included vaccination rates in the suggested measure sets for the following specialties: allergy/immunology, cardiology, endocrinology, family medicine, geriatrics, infectious disease, internal medicine, nephrology, obstetrics/gynecology, oncology/hematology, otolaryngology, preventive medicine, pulmonology, and rheumatology. In 2021, the MIPS quality category also includes the shingles vaccination rate for selected specialties.<sup>31</sup>

With the exception of clinicians, none of the FFS providers listed in Table 7-9 include a requirement for either health care personnel or patient vaccination measures to be scored in a value-based payment program (or the setting does not have a value-based payment program). Given the CDC's position that vaccination is particularly critical for individuals with end-stage renal disease (ESRD), the lack of vaccination-related measures that are either publicly reported or used in the value-based payment program for dialysis facilities for 2021 is notable (Centers for Disease Control and Prevention 2020b). For ambulatory surgical centers and hospice providers, no vaccine-

related measures are publicly reported on Medicare.gov or included in their quality reporting program.

Accountable care organizations (ACOs), including those participating in the Medicare Shared Savings Program, have to report and may be scored on their performance on an influenza vaccination measure. ACOs report their results to CMS based on their own administrative and clinical data (e.g., electronic health records). In 2019, ACOs reported an average beneficiary influenza vaccination rate of 76 percent. Although ACOs have the option to report and be scored on beneficiaries' vaccination for influenza in payment year 2021, they will not be scored on this measure starting in payment year 2022. The Comprehensive ESRD Care (CEC) Model, a specialized ACO-like model which began in 2015 and ended in March 2021, measured the share of beneficiaries receiving the influenza vaccine, but did not measure performance for other types of vaccinations, including pneumococcal and hepatitis B that the CDC recommends for ESRD patients. An analysis of the first three years of the CEC Model found that influenza vaccination rates were significantly higher for beneficiaries treated by participating providers compared with a matched control population (Marrufo et al. 2020).

The Medicare Advantage (MA) star rating system used for public reporting and the quality bonus program includes a measure of the share of MA plan members who report receiving an influenza vaccination based on data from the MA Consumer Assessment of Healthcare Providers and Systems® (CAHPS®) survey. The MA CAHPS survey results are collected from a sample of plan enrollees. According to CMS, the national average of MA plan enrollees who reported in CAHPS that they received an annual flu vaccine was 75 percent in both 2017 and 2018 (latest year available) (Centers for Medicare & Medicaid Services 2019d, Centers for Medicare & Medicaid Services 2018). MA plans must also report to CMS pneumococcal vaccine rates collected through the CAHPS survey as a display measure; however, these results are not currently used for public reporting or in the quality bonus program. ■

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## Medicare's reporting of vaccination rates and efforts to improve uptake are uneven (cont.)

**TABLE  
7-9**

**Vaccination measures used in Medicare's public reporting and value-based payment programs vary across fee-for-service provider types**

	<b>Publicly available on Care Compare on Medicare.gov</b>	<b>Included in quality reporting program<sup>a</sup></b>	<b>Included in value-based payment program<sup>b</sup></b>
Physicians and other health care professionals	None	None	Option to be scored on the influenza and pneumococcal vaccination of beneficiaries for selected clinician specialties (MIPS) <sup>c</sup>
Inpatient PPS hospitals	NHSN influenza vaccination coverage among health care personnel	NHSN influenza vaccination coverage among health care personnel	None
PPS-exempt cancer hospitals	NHSN influenza vaccination coverage among health care personnel	NHSN influenza vaccination coverage among health care personnel	N/A
Inpatient psychiatric facilities	Influenza immunization of patients	Influenza immunization of patients	N/A
Inpatient rehabilitation facilities	NHSN influenza vaccination coverage among health care personnel	NHSN influenza vaccination coverage among health care personnel	N/A
Long-term care hospitals	NHSN influenza vaccination coverage among health care personnel	NHSN influenza vaccination coverage among health care personnel	N/A
Ambulatory surgical centers	None	None	N/A
Dialysis facilities	None	N/A	None <sup>d</sup>
Nursing homes	Share of long-stay residents given the seasonal influenza vaccine and the pneumococcal vaccine	N/A	N/A
Skilled nursing facilities	Share of short-stay residents given the seasonal influenza vaccine and the pneumococcal vaccine	None	None
Home health agencies	Rate at which home health team determined whether beneficiary received influenza vaccine during current influenza season and pneumococcal vaccine	Rate at which home health team determined whether beneficiary received influenza vaccine during current influenza season and pneumococcal vaccine	None <sup>e</sup>
Hospice	None	None	N/A

Note: MIPS (Merit-based Incentive Payment System), PPS (prospective payment system), NHSN (National Healthcare Safety Network), N/A (not applicable). "None" means one or more vaccine measures are not used in a given program (i.e., Care Compare on Medicare.gov, quality reporting program, or value-based payment program). "N/A" means that Medicare has not established the program for a given provider type. The CDC's NHSN is a widely used health care-associated infection tracking system.

<sup>a</sup>By "quality reporting program," we mean a program that links providers' payment to reporting of quality measures.

<sup>b</sup>By "value-based payment program," we mean a program that links providers' payment to the quality of care they furnish.

<sup>c</sup>For payment years 2022 and 2023, vaccine measures in MIPS assess (1) share of patients ages 6 months and older seen for a visit between October 1 and March 31 who received an influenza vaccine or who reported previous receipt of an influenza vaccine and (2) share of patients 65 years of age and older who have ever received a pneumococcal vaccine. In 2023, these measures were included for the following specialties: allergy/immunology, cardiology, endocrinology, family medicine, geriatrics, infectious disease, internal medicine, nephrology, obstetrics/gynecology, oncology/hematology, otolaryngology, preventive medicine, pulmonology, rheumatology, and skilled nursing facility. Only the influenza measure applies for pediatrics. In payment year 2021, a measure assessing vaccination for shingles is also used.

<sup>d</sup>Beginning in 2021, CMS eliminated the ESRD [End-Stage Renal Disease] Quality Incentive Program's measure on whether facilities reported the Healthcare Personnel Influenza Vaccination Summary to the NHSN.

<sup>e</sup>The Home Health Value-based Purchasing Program, in its fourth year, removed the scoring of two measures: Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received. The Home Health Value-based Purchasing Program applies to only agencies in nine states, but CMS has expressed an intent to expand the model nationally.

Source: MedPAC analysis of CMS websites.

on the value of the codes from the American Medical Association/Specialty Society Relative Value Scale Update Committee (which would result in a lower payment rate across all codes). CMS recognized the importance of accurately determining the resource costs for these codes and stated that it would “welcome the results of an updated formal review of these services as well as any additional information that may be helpful for valuation in the immediate future” (Centers for Medicare & Medicaid Services 2020b).

We note CMS has established a special approach for payment for COVID-19 vaccine administration.<sup>32</sup> For COVID-19 vaccines administered on or after March 15, 2021, the national average payment rate for physicians, hospitals, pharmacies, and many other immunizers will be \$40 to administer each dose of a COVID-19 vaccine. This rate represents an increase from approximately \$28 to \$40 for the administration of single-dose vaccines, and an increase from approximately \$45 to \$80 for the administration of COVID-19 vaccines requiring two doses. The exact payment rate for administration of each dose of a COVID-19 vaccine will depend on the type of entity that furnishes the service and will be geographically adjusted based on where the service is furnished.

The payment policy change we outline would represent an important move away from inefficient AWP-based payment and reasonable cost-based payment for vaccines, but the policy would have only a limited effect on incentives for manufacturers to reduce prices or to slow price increases. In the future, other policies to promote price competition and value for Part B products, including vaccines, could be explored. In June 2017, the Commission recommended that manufacturers of Part B drugs pay Medicare a rebate when their prices increase faster than an inflation benchmark. One benefit of an inflation rebate structured this way is that manufacturers, rather than providers, are at risk for price increases. The Commission’s rebate recommendation applied to Part B drugs and biologics paid based on ASP, so it did not include vaccines, which are currently paid based on 95 percent of AWP. However, a manufacturer inflation rebate policy could be explored for vaccines as well.

The Commission’s work on consolidated billing codes and reference pricing for Part B drugs and biologics also has relevance to vaccines. The Commission has found that the structure of the ASP payment system—where single-source drugs and biologics receive their own billing code and are

paid 106 percent of their own ASP—does not promote price competition among some groups of drugs with similar health effects. To address this issue, in our June 2017 report to the Congress the Commission recommended that biosimilars and their reference biologics be paid under a consolidated billing code (i.e., a common billing code), with all products assigned to the code paid at the same rate. In the June 2019 report, the Commission explored the use of reference pricing or consolidated billing codes to spur price competition among single-source drugs and biologics with similar health effects that are assigned to separate billing codes. As the Commission continues to explore reference pricing policies in the future, our work could consider vaccines in addition to other Part B single-source drugs and biologics. Currently, some vaccines are already subject to a form of reference pricing in that products from multiple manufacturers are included in the same billing code and paid 95 percent of the lowest AWP among the NDCs assigned to the code. However, the Part B vaccines with the highest spending generally have their own billing codes, and the growth in payment rates has been most rapid among these products (Table 7-7, p. 256). Even if payment rates for Part B vaccines were modified to 103 percent of WAC or to an ASP-based payment rate, price competition would be limited for products in their own billing codes. Thus, to the extent that there are vaccines with similar health effects that have distinct billing codes, it may be worth considering these products in our broader work on reference pricing and consolidated billing policies. (See our June 2019 report to the Congress for more information on the Commission’s work on reference pricing, including examples of groups of products that are competitors and are each paid under separate billing codes based on their separate ASPs, located at [http://www.medpac.gov/docs/default-source/reports/jun19\\_ch3\\_medpac\\_reporttocongress\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/reports/jun19_ch3_medpac_reporttocongress_sec.pdf?sfvrsn=0).)

In the future, alternative approaches to paying for vaccines may also merit exploration. For example, under current policy, the federal government is directly purchasing COVID-19 vaccines for distribution, and Medicare is paying only an administration fee to immunizers, rather than providers purchasing the vaccines and subsequently seeking payment from Medicare to cover the cost of the vaccine. This type of bulk purchasing approach could provide a model for the Medicare program to explore bulk purchasing for other vaccines or other drugs and biological products. ■

## Endnotes

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- 1 In addition, other funds have been made available for vaccine-related efforts. For example, in fiscal year 2020, up to roughly \$30 billion was made available to the National Institutes of Health, the Department of Defense, and the Public Health and Social Services Emergency Fund for vaccine development, manufacturing, and purchase until September 30, 2024. In fiscal year 2021, nearly \$20 billion is available for the costs associated with manufacturing, producing, and purchasing vaccines, therapeutics, and ancillary supplies (Congressional Research Service 2021).
- 2 Under Section 319 of the Public Health Services Act, the Secretary of Health and Human Services may determine that a disease or disorder presents a public health emergency (PHE) or that a PHE, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists. The Secretary first determined the existence of a coronavirus PHE, based on confirmed cases of COVID-19 in the U.S., on January 31, 2020. At the time of publication of this report, the coronavirus PHE had been renewed several times for 90-day periods, most recently on April 21, 2021.
- 3 Medicare beneficiaries enrolled in Medicare Advantage (MA) HMOs and preferred provider organizations (PPOs) face no cost sharing for Part B preventive vaccines furnished at in-network providers. If an MA HMO enrollee uses a non-network provider, the beneficiary could have to pay the full cost of the vaccine; an MA PPO enrollee using a non-network provider would be subject to the PPO's cost-sharing rules for non-network care. (However, for the duration of the coronavirus public health emergency, MA plans must cover vaccines received out-of-plan, and the care is to be considered in-network for purposes of determining cost sharing, which in the case of Part B vaccines means there is zero cost sharing).
- 4 CMS reports a plan-level pneumococcal vaccine measure (referred to as "pneumonia vaccine") in a zipped file on the agency's website. However, this measure is not included in CMS's online MA Plan Finder that enables beneficiaries to compare plans in a given area. The National Committee on Quality Assurance has been evaluating a composite measure for the Healthcare Effectiveness Data and Information Set that would incorporate rates of immunization for four routine adult vaccines: influenza; tetanus, diphtheria, and pertussis (Tdap) or tetanus and diphtheria booster vaccine (Td); herpes zoster; and pneumococcal.
- 5 The effectiveness of various types of influenza vaccines in the elderly is an active area of research. Accumulated research suggests that a high dose of trivalent inactivated influenza vaccine is more effective than a standard dose of inactivated influenza vaccine in this population. However, data are still limited (Grohskopf et al. 2019). For the 2020 to 2021 flu season, two new vaccines are available for individuals ages 65 or older: a high-dose quadrivalent version of Fluzone, which replaces the high-dose trivalent version, and Flud quadrivalent (Splete 2020).
- 6 ACIP decided to no longer recommend that all healthy elderly persons receive a one-time Prevnar 13 (PCV13) vaccination because the "incidence of PCV13-type disease has been reduced to historically low levels among adults ages ≥65 years through indirect effects from pediatric PCV13 use. Implementation of a PCV13 recommendation for all adults ages ≥65 years in 2014 has had minimal impact on PCV13-type disease at the population in this age group" (Matanock et al. 2019).
- 7 As of November 2020, Zostavax, which was approved by the FDA in 2006 for the prevention of shingles, is no longer available for use in the U.S. (Centers for Disease Control and Prevention 2020c). In 2017, ACIP recommended Shingrix preferentially over Zostavax based on information about their relative efficacy (Dooling et al. 2018).
- 8 Shingles vaccination rates in 2018 may have been affected by the shortage of Shingrix vaccine that year (Castia Rx 2019). When we examined the preliminary claims data for 2019, we found that shingles vaccination rates for this cohort of beneficiaries may have been about 37 percent by the end of 2019.
- 9 Research has found that the Tuskegee Syphilis Study resulted in African Americans' skepticism about vaccines and a general mistrust of the health care system (Carroll 2016, Quinn et al. 2017, Schaffer DeRoo et al. 2020).
- 10 In 2005, CMS issued a final rule requiring Medicare and Medicaid long-term care facilities to offer flu and pneumococcal vaccines to their residents and document instances in which the resident or his or her legal representative received appropriate education but refused to take a vaccine (<https://www.federalregister.gov/documents/2005/10/07/05-19987/medicare-and-medicaid-programs-condition-of-participation-immunization-standard-for-long-term-care>).
- 11 In 2019, Part D claims for Shingrix accounted for 99.9 percent of all shingles vaccines administered to Part D enrollees.
- 12 Immunizers paid 95 percent of AWP include physician offices, mass immunizers, freestanding dialysis facilities, hospices, comprehensive outpatient rehabilitation facilities, and Indian Health Service hospitals. Immunizers paid reasonable cost

- include hospitals (other than Indian Health Service hospitals), skilled nursing facilities, home health agencies, hospital-based dialysis facilities, RHCs, and FQHCs. “Reasonable cost” is a payment methodology in which the provider’s final payment is determined at cost report settlement based on an estimate of the provider’s cost for vaccines using the provider’s charges for the vaccines and a cost-to-charge ratio.
- 13 CMS has generally relied on the vaccine Current Procedural Terminology codes developed by the American Medical Association, although CMS could use other billing codes if the agency determined there was reason to do so.
  - 14 If a billing code contains only one manufacturer’s vaccine and several national drug codes (NDCs) exist for that vaccine (e.g., because the manufacturer offers the vaccine in several package sizes), Medicare sets the payment rate at 95 percent of the lowest AWP per unit across the manufacturer’s NDCs.
  - 15 RHCs and FQHCs are not paid for influenza or pneumococcal vaccines through claims submission and are instead paid for these services retroactively at cost report settlement. The hepatitis B vaccine is included in the all-inclusive rate paid for visits to these providers and they do not receive separate payment for this vaccination.
  - 16 These data are based on Medicare claims and do not include vaccines administered by RHCs and FQHCs that are paid under the cost report (and not claims).
  - 17 These four vaccines are paid at a rate of 106 percent of average sales price (ASP) in the physician office setting. Under the hospital outpatient prospective payment system (OPPS), Medicare packages payment for low-cost drugs and biologics into the payment for associated services. Consequently, the OPPS pays separately for the rabies vaccine at a rate of 106 percent of ASP and packages payment for the other three vaccines (hepatitis A, Td, and Tdap).
  - 18 Beneficiaries who receive a Part B–covered vaccine to address injury or direct exposure (e.g., rabies vaccine) are subject to 20 percent cost sharing, the same cost-sharing requirement as for Part B–covered drugs and biologics.
  - 19 “Grandfathered” refers to individual health insurance policies purchased before the ACA’s date of enactment, March 23, 2010. The same section of the ACA also required coverage without cost sharing of all A- and B-rated evidence-based items or services recommended by the U.S. Preventive Services Task Force.
  - 20 For influenza, pneumococcal, and COVID-19 immunizations, Medicare permits nontraditional providers that normally are not eligible to bill Medicare—such as pharmacists, supermarkets, senior centers, and public health clinics—to enroll as mass immunizers for the purpose of providing vaccinations to large numbers of individuals. Mass immunizers are required to be properly licensed in the state where they operate. Mass immunizers are permitted to use roster billing, a simplified process for submitting claims to Medicare for multiple enrollees. Medicare permits traditional Medicare providers also to register as mass immunizers for the purpose of using roster billing if they wish.
  - 21 According to the CDC, a person cannot get shingles from someone who has shingles. Therefore, increasing rates of shingles vaccination would be expected to reduce the incidence of shingles among vaccinated individuals, but would not be expected to affect the number of unvaccinated beneficiaries who acquire shingles.
  - 22 For example, compared with matched controls, a greater percentage of patients 50 years or older diagnosed with shingles (between 2008 and 2013) had, in the 12 months following diagnosis, at least one inpatient visit (8 percent versus 11 percent), emergency department visit (13 percent versus 21 percent), outpatient hospital visit (53 percent versus 64 percent), office visit (85 percent versus 98 percent), and pharmacy claims (69 percent versus 80 percent) (Meyers et al. 2017). The authors also reported that compared with matched controls, the incremental health care utilization attributable to shingles was 5.8 office visit claims, 2.7 outpatient hospital visit claims, 2.0 other outpatient visit claims, 0.3 emergency department visits, 0.05 inpatient visit claims, and 4.4 pharmacy claims.
  - 23 These three studies each received some funding from manufacturers of the shingles vaccines.
  - 24 In addition to paying for the ingredient cost, Part D plans also pay immunizers a small dispensing fee and an administration fee. For Shingrix, the median dispensing fee is \$0.50 and the administration fee is \$20.
  - 25 A two-quarter lag in ASP payment rates for drugs and biologics exists due to the time needed for the manufacturer to report ASP data to CMS and for CMS to establish a new payment rate. For example, a manufacturer reporting ASP data for the first quarter of the year is required to submit that data by 30 days after the close of the quarter. Once CMS receives the ASP data 30 days into second quarter, CMS has the remainder of the second quarter to process the data and establish a payment rate that will become effective for the next calendar quarter, that is, the third quarter of the year.
  - 26 The 340B Drug Pricing Program permits participating hospitals that meet certain criteria to obtain outpatient drugs at substantially discounted prices. Under the outpatient prospective payment system, Medicare pays a lower rate of ASP – 22.5 percent to 340B hospitals for nonvaccine drugs and biologics in recognition of the statutory discounts those providers receive through the 340B program. Vaccines are

- not considered “covered outpatient drugs” for purposes of the 340B program, so 340B providers do not receive statutory discounts on vaccines.
- 27 Some FQHC stakeholders have raised concern about the cash flow lags resulting from payment of vaccines at cost report settlement (Centers for Medicare & Medicaid Services 2014).
  - 28 As part of this NCD process, the statute states that the Secretary may conduct an assessment of the relationship between predicted outcomes and the expenditures for such service and may take into account the results of such assessment in making such determination.
  - 29 Such a process should give the Secretary the discretion to temporarily bypass the coverage determination process if the Secretary determines there is substantial and significant evidence that public health would be harmed due to a delay in coverage, such as in the case of a public health emergency.
  - 30 The 2020 MIPS quality measure list included over 200 measures from which clinicians could choose.
  - 31 CMS removed the shingles measure, effective payment year 2022 (Centers for Medicare & Medicaid Services 2019c).
  - 32 MA plans are not liable for the cost of administering COVID-19 vaccines in plan years 2020 and 2021 (because these costs for new coverage were not included in the MA benchmarks), and providers administering COVID-19 vaccines during this time period bill FFS Medicare to receive payment for vaccine administration. Beginning in plan year 2022, MA plans will be responsible for the cost of COVID-19 vaccine administration.

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