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# Vaccine Coverage Requirements in the U.S.

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# Introduction

The Affordable Care Act established new standards for preventive service coverage beginning in 2014. This paper describes the current insurance coverage requirements for vaccines and the laws that govern those requirements for the following markets:

1. Commercial (group and individual)
2. Medicaid
3. Medicare (Parts B and D)

**Table 1 — Vaccine Coverage and Cost Sharing by Market**

Market	Covered Vaccines	Cost Sharing
Commercial	All ACIP-recommended	Prohibited
Medicaid Expansion	All ACIP-recommended	Prohibited
Traditional Medicaid	Determined by state	Determined by state
Medicare Part B	Pneumococcal, influenza, hepatitis B, <sup>1</sup> vaccines needed as the result of an injury or direct exposure to a disease	Prohibited
Medicare Part D	All ACIP-recommended, except those covered under Part B	Allowed

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<sup>1</sup> The hepatitis B vaccine is only covered for beneficiaries at intermediate to high risk of contracting the disease.

## Background

The requirements for insurance coverage of vaccines vary across the commercial, Medicaid, and Medicare markets, including whether plans must cover vaccines and whether patient cost sharing is permitted. These requirements have changed significantly over time, with the most recent standards implemented through the Affordable Care Act (ACA).

Historically, issuers in the commercial insurance market could choose whether or not to cover vaccines in their plans. A 2001 National Survey of Employer-Sponsored Health Plans found that health maintenance organizations (HMOs) frequently included vaccines as a basic benefit, covering 66% of adult vaccines, while preferred provider organizations (PPOs) did not cover vaccines as commonly, with 57% of adult vaccines covered.<sup>2</sup> Issuers that chose to cover vaccines could control utilization through formulary placement and cost sharing. The Centers for Disease Control and Prevention's (CDC) 2002 National Immunization Survey found that 79% of privately insured children faced out-of-pocket costs for their most recent vaccination visit.<sup>3</sup>

Recognizing the public health value of vaccines as a preventive service and the negative relationship between cost sharing and vaccine uptake,<sup>4</sup> Congress and the Centers for Medicare and Medicaid Services (CMS) eventually implemented vaccine coverage and cost sharing requirements in commercial, Medicaid, and Medicare plans; however, these standards vary significantly by market.

## Commercial

The Affordable Care Act requires coverage for all ACIP-recommended vaccines with no cost sharing and federal regulations clarify that cost sharing does not apply as long as vaccination is not billed separately from an office visit and vaccination is the main purpose of the office visit.

Vaccine coverage and cost sharing in the commercial insurance market are governed by two separate, but related, provisions in the ACA. First, the ACA added Section 2713 to the Public Health Service Act (PHSA), which requires non-grandfathered group health plans and issuers in the individual market to provide coverage for specified preventive services without any cost sharing. The preventive services include:

- Services with an A or B rating from the United States Preventive Services Task Force (USPSTF);
- Immunizations with a recommendation from the Advisory Committee on Immunization Practices (ACIP) in effect; and

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<sup>2</sup> Institute of Medicine (US) Committee on the Evaluation of Vaccine Purchase Financing in the United States, *Financing Vaccines in the 21st Century*, Washington, DC: National Academies Press (US), 2003, available at: <https://www.ncbi.nlm.nih.gov/books/NBK221817/>

<sup>3</sup> Ibid.

<sup>4</sup> Stoecker, Charles, Stewart, Alexandra M., and Megan C. Lindley, *The Cost of Cost-Sharing: The Impact of Medicaid Benefit Design on Influenza Vaccination Uptake*, *Vaccines* 5, no. 1 (March 6, 2017): 8, available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5371744/>.

- Preventive care and screenings for women, infants, children, and adolescents supported by Health Resources and Services Administration (HRSA) guidelines.

Regulations from the Department of the Treasury, Department of Labor (DOL), and Department of Health and Human Services (HHS) further clarify the vaccine coverage requirements under Section 2713, stating “...a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for all . . . immunizations for routine use . . . that have in effect a recommendation from the [ACIP].”<sup>5</sup> The regulations clarify that “a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention.”<sup>6</sup> Unlike contraception, for which HRSA issues “binding comprehensive health plan coverage guidelines,” issuers must in effect cover all vaccine products recommended by ACIP.<sup>7</sup>

Regulations also specify circumstances under which issuers may and may not apply cost sharing to vaccines. If a vaccination is billed separately from an office visit, issuers may apply cost sharing. If a vaccination is not billed separately from an office visit, issuers must consider the primary purpose of the office visit when determining whether or not they may apply cost sharing: if vaccination is not the main purpose of the visit, issuers may apply cost sharing; if vaccination is the main purpose of the visit, issuers may not apply cost sharing.<sup>8</sup>

The ACA also created the Essential Health Benefits (EHB) requirement, which requires non-grandfathered plans in the individual and small group markets to cover benefits under 10 specified categories. One of these categories is “preventive and wellness services and chronic disease management,” which the Department of Treasury, DOL, and HHS interpreted in regulations to include all ACIP-recommended vaccines.

## Medicaid

### Medicaid Expansion

Medicaid expansion enrollees receive first dollar coverage of all ACIP-recommended vaccines as a result of the ACA and subsequent CMS rulemaking. When the ACA effectively expanded Medicaid eligibility up to 138% of the Federal Poverty Level (FPL), the law applied EHB requirements, which provide for coverage of preventive services, to the new expansion population. While this requirement established coverage of vaccines for expansion enrollees, it did not address cost sharing. In its interpretation through EHB-implementing rules, CMS

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<sup>5</sup> 45 CFR § 147.130(a)(1).

<sup>6</sup> 45 CFR § 147.130(a)(1)(ii).

<sup>7</sup> 45 CFR § 147.130(a)(1).

<sup>8</sup> 45 CFR § 147.130(a)(2).

determined that states must cover all ACIP-recommended vaccines without cost sharing for the Medicaid expansion population consistent with Section 2713 of the ACA.<sup>9</sup>

## Traditional Medicaid

Federal law does not require that states cover vaccines or eliminate cost sharing for vaccines for their traditional Medicaid populations. The decisions as to which vaccines to cover for adults and whether to apply cost sharing to those vaccines lay with individual states. Medicaid-eligible children ages 0 to 18 years old (including those enrolled in Medicaid) receive vaccines free of cost through the Vaccines for Children program.

However, the ACA created an incentive for states to cover vaccines and eliminate cost sharing for preventive services, including vaccines.<sup>10</sup> Specifically, the ACA included a 1% Federal Medical Assistance Percentage (FMAP) increase for states that choose to cover preventive services without cost sharing. State coverage and cost sharing of vaccines in traditional Medicaid continue to vary widely by vaccine and beneficiary age.

## Medicare

### Part B

Vaccines in Medicare are covered under either the physician benefit (Part B) or the pharmacy benefit (Part D). Specifically, the pneumococcal, influenza, and hepatitis B vaccines are the only vaccines covered under Part B, per SSA Section 1861(s)(10)(A),(B). The hepatitis B vaccine is only covered for beneficiaries at intermediate to high risk of contracting the disease. Part B also covers vaccines needed as the result of an injury or direct exposure to a disease.

The pneumococcal and influenza vaccines were required to be covered with no cost sharing prior to the ACA through SSA Section 1833(a)(1)(B). The ACA later established a first dollar coverage requirement for the hepatitis B vaccine in Medicare.<sup>11</sup> Medicare Advantage (MA) and Medicare Advantage Prescription Drug (MA-PD) plans must also cover all Part B vaccines without cost sharing.

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<sup>9</sup> CMS, Medicaid and Children's Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment. 78 FR 42159; 42224-42226. <https://www.federalregister.gov/documents/2013/07/15/2013-16271/medicaid-and-childrens-health-insurance-programs-essential-health-benefits-in-alternative-benefit>.

<sup>10</sup> Affordable Care Act § 4106.

<sup>11</sup> The ACA added a Medicare requirement for first dollar coverage for the Initial Preventive Physical Exam (IPPE), Annual Wellness Visit, and for those preventive services recommended by the United State Preventive Services Task Force with a grade A or B for any indication or population and that are appropriate for the individual. See Social Security Act § 1833(a)(1), as amended by Affordable Care Act § 4101(b)(4). The Centers for Medicare & Medicaid Services has interpreted this to include, among others, first dollar coverage for the hepatitis B vaccine, which is included in the IPPE; CMS Claims Processing Manual Chapter 18: - Preventive and Screening Services, Medicare Claims Processing Manual 1.3, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c18.pdf>.

## Part D

The Medicare Part D program requires coverage of all commercially available vaccines except those covered under Part B.<sup>12</sup> According to the Medicare Prescription Drug Benefit Manual, CMS will review all Part D formularies “to ensure they contain all commercially available vaccines.”<sup>13</sup> Sponsors may only apply utilization management to less commonly recommended vaccines (e.g. anthrax and yellow fever), to ensure vaccination consistent with the ACIP recommendations, or to evaluate potential for alternative reimbursement under Part B.<sup>14</sup> Otherwise, according to CMS, sponsors should provide coverage consistent with ACIP recommendations.<sup>15</sup> Medicare Advantage Prescription Drug (MA-PD) plans also must cover all vaccines covered under Part D.

Vaccines covered under Part D are still subject to cost sharing; the ACA’s first dollar coverage requirement does not apply to Part D. CMS has encouraged plans to offer vaccines without cost sharing, but has not acted to require it. For example, since 2012, CMS has allowed Part D plans to use a 6<sup>th</sup> formulary tier as “a \$0 vaccine-only tier.”<sup>16</sup> Additionally, in its 2015 and 2016 Medicare Advantage and Part D Final Call Letters, CMS encouraged Part D plans to offer vaccines with zero or low cost sharing, explaining that “Despite ACIP recommendations and Healthy People 2020 targets, adult immunization rates, while increasing, still remain quite low.”<sup>17</sup>

However, without binding requirements from CMS, cost sharing for vaccines has continued under Part D. MA-PD and stand-alone Part D plans (PDPs) frequently place vaccines in tiers with cost sharing. A previous Avalere analysis found that, in 2015, approximately 3% of MA-PD plans, covering approximately 7% of MA-PD enrollees, used the optional 0% cost sharing vaccine tier for any of the 10 vaccines examined in the analysis.<sup>18</sup> As of 2015, no PDPs had ever placed any of the 10 products examined on the vaccine tier.<sup>19</sup> MA-PD plan tier placement was similar for all 10 vaccines in 2016, with plans most frequently placing each vaccine on the Preferred Brand drug tier.<sup>20</sup>

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<sup>12</sup> 42 U.S.C. § 1395w-102(e)(1)(B); 42 CFR § 423.100.

<sup>13</sup> CMS, Medicare Prescription Drug Benefit Manual Chapter 6: – Part D Drugs and Formulary Requirements 30.2.7, available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

<sup>14</sup> *Ibid.*

<sup>15</sup> CMS, CMS Medicare Prescription Drug Benefit Manual Chapter 6: – Part D Drugs and Formulary Requirements 10.14.3, available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

<sup>16</sup> CMS, Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (April 4, 2011), available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/CY2012-Hospice-Rates-FinalCallLetter.pdf>.

<sup>17</sup> CMS, Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (April 6, 2015), available at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvSpecRateStats/Downloads/Announcement2016.pdf>; CMS, Advance Notice of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter (February 19, 2016), available at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvSpecRateStats/Downloads/Advance2017.pdf>.

<sup>18</sup> Avalere Health, Adult Vaccine Coverage In Medicare Part D Plans (February 2016), available at: [http://go.avalere.com/acton/attachment/12909/f-0297/1/-/-/-/20160217\\_Medicare%20Vaccines%20Coverage%20Paper.pdf](http://go.avalere.com/acton/attachment/12909/f-0297/1/-/-/-/20160217_Medicare%20Vaccines%20Coverage%20Paper.pdf).

<sup>19</sup> *Ibid.*

<sup>20</sup> *Ibid.*

## Conclusion

Coverage requirements for vaccines continue to vary across markets. Standards are strongest in the commercial and Medicaid expansion markets, where issuers must cover all ACIP-recommended vaccines without cost sharing. Coverage requirements lag in traditional Medicaid, where states may choose which vaccines to cover and whether or not to apply cost sharing. In Medicare, Parts B and D work in conjunction to cover all ACIP-recommended vaccines; while cost sharing is prohibited in Part B, the majority of MA-PD and PDP beneficiaries continue to bear out-of-pocket costs for Part D vaccines.<sup>21</sup> In general, federal laws and regulations in recent years have moved toward increased coverage requirements and the elimination of cost sharing for vaccines.

*Merck & Co., Inc. provided funding for this analysis. Avalere maintained full editorial control of the paper.*

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<sup>21</sup> Ibid.

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