NEHI Network for Excellence in Health Innovation

Medicare Vaccination Coverage After the Inflation Reduction Act:

Action Still Needed to Enable High Vaccination Rates Among Medicare Beneficiaries

A NEHI Report

May 2023

About This Report

This report was produced by NEHI following a series of key stakeholder interviews in late 2022 and early 2023, including a hybrid multi-stakeholder roundtable staged at the Kaiser Permanente Center for Total Health in Washington DC on November 29, 2022.

The views are expressed in this report are solely those of NEHI staff and not necessarily those of the project participants and sponsors. (Roundtable participants are listed in Acknowledgements.) Financial support for the project was provided by GSK, Johnson & Johnson, and Moderna.

About NEHI

NEHI is a national nonprofit, nonpartisan organization composed of stakeholders from across all key sectors of health and health care. Our mission is to solve complex problems and achieve value in health care by fostering interdisciplinary collaboration and innovation. NEHI brings together expert stakeholder perspectives with relevant research to devise policies that speed the adoption of innovations.

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Executive Summary

Medicare coverage of adult vaccinations today:

Medicare beneficiaries enjoy coverage of vaccinations recommended by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP). Influenza (flu), pneumococcal (pneumonia), Hepatitis B, and COVID-19 vaccinations are all covered under the Medicare Part B program and in medical benefits covered by standalone Medicare Advantage (MA) plans. Other ACIP-recommended vaccinations are covered under Medicare Part D prescription drug plans and by Medicare Advantage-Prescription Drug Plans (MA-PDPs)

Medicare Coverage of Adult Vaccinations*°

Part B & Medicare Advantage	Part D & Medicare Advantage Prescription Drug Plans
COVID-19 vaccine	*Haemophilus influenza* type b vaccine (Hib)
Hepatitis B vaccine (HepB)	Hepatitis A vaccine (HepA)
Influenza vaccine (inactivated)	Hepatitis A and Hepatitis B vaccine (HepA-HepB)
Influenza vaccine (live, attenuated)	Human papillomavirus vaccine (HPV)
Influenza vaccine (recombinant)	Measles, mumps, and rubella vaccine (MMR)
Pneumococcal conjugate vaccine	Meningococcal serogroups A, C, W, Y vaccine
Pneumoccocal polysaccharide vaccine	Meningococcal serogroups B vaccine
	Poliovirus vaccine
	Tetanus and diphtheria toxoid (Td)
	Tetanus and diphtheria toxoid and acellular pertussis vaccine (Tdap)
	Varicella vaccine
	Zoster (shingles) vaccine (recombinant)

* Vaccines listed in the chart are based on the CDC's Adult Immunization Schedule as recommended by the Advisory Committee on Immunization Practices (ACIP)
° Some vaccines are not recommended for adults based on age group and/or additional risk factors or other indications.

Looking ahead: is there a better way to offer vaccine coverage among Medicare beneficiaries?

The Part B-Part D split in Medicare vaccination coverage is ripe for reassessment. As Medicare Part D was launched in 2006, analysts identified the Part B-Part D split as likely to deter beneficiaries from staying up-to-date on all recommended vaccinations (due particularly to patient cost-sharing responsibilities) and likely to deter health care providers from fully promoting them.[1] The Inflation Reduction Act (IRA) of 2022 removed the cost-sharing barrier by requiring Part D plans to offer vaccinations with no out-of-pocket costs to beneficiaries.[2] However, other challenges to reaching optimal vaccination rates among Medicare beneficiaries remain, as detailed below. Moreover, Medicare vaccination coverage must also prepare for the onset of new viral threats in the years ahead, and support rapid uptake of vaccines developed to address them.

Stakeholders are open to reassessment of Medicare coverage policy.

NEHI brought together key stakeholders in Fall 2022 to discuss the future direction of Medicare coverage of adult vaccinations. NEHI did not find broad consensus on major changes in Medicare coverage, however, we did find that most stakeholders were open to a thorough reassessment of the split in Medicare vaccination coverage.

Two recommendations for short-term and long-term action:

NEHI offers two recommendations based on its consultation with stakeholders. We believe these recommendations will safeguard beneficiaries while a detailed reassessment of Medicare vaccination coverage policy takes place.

1. **Cover new, high-prevalence, infectious respiratory disease vaccinations automatically in Medicare Part B.** CMS and Congress should take action to ensure that vaccinations for infectious respiratory diseases are covered under Medicare Part B. Medicare Part B now covers vaccinations for two highly prevalent and recurring infectious respiratory diseases, influenza and COVID-19. The ACIP is likely to recommend seasonal COVID-19 vaccinations for adults by year end (2023). New vaccines for respiratory syncytial virus (RSV) are also likely to be approved in coming months and could join the ACIP list of yearly recommended vaccinations. Automatic Part B coverage of these and future respiratory disease

vaccinations will assure a unified vaccination regimen for Medicare beneficiaries, who are among adults most susceptible to illness from respiratory diseases. It will also enable the largest number of eligible vaccinators (physicians, pharmacists, and other health care professionals) to offer beneficiaries access to these vaccinations.

2. **Reassess the overall split in Medicare coverage of ACIP-recommended vaccinations.** Key policymakers (including CMS, the Medicare Payment Advisory Commission [MedPAC], and congressional committees of jurisdiction) should reassess Medicare's overall policies on vaccination coverage in light of the elimination of Part D cost-sharing, and other changing circumstances in the health care marketplace. The over-arching goal is the greatest degree of beneficiary access to all ACIP-recommended vaccinations, delivered by the most extensive network of vaccinators and vaccination sites of service.

Key considerations in reassessing Medicare vaccination coverage include:

- Extending coverage to the approximately 6 million beneficiaries who do not have Part D coverage
- Increasing Part D vaccination offerings from physician practices and other under-utilized vaccinators, including independent pharmacies
- Protecting Medicare beneficiaries in nursing homes
- Recognizing Medicare Advantage's role as an increasingly dominant source of coverage, and optimizing MA benefits and quality improvement goals to raise beneficiaries' vaccination rates
- Linking vaccination coverage to Medicare quality improvement goals, including goals for equitable access and uptake

Why is Medicare Vaccination Coverage Split Between Part B Medical Benefits and Part D Prescription Drug Benefits?

The split in Medicare vaccination coverage has its roots in the original Medicare statute, enacted in 1965. Medicare was authorized to cover services deemed medically necessary, a standard that remains today. This standard was defined as excluding preventive health measures, including vaccinations for the prevention of disease. The original Medicare program also did not extend coverage to prescription drugs, coverage which might have included vaccinations otherwise. The Medicare Part D prescription drug program would not be enacted until 2003 and launched in 2006. Vaccinations approved by the Food and Drug Administration (FDA) and recommended by the Advisory Committee on Immunization Practices (ACIP) for administration to adults since 2006 are now covered by Medicare Part D, with the exception of COVID-19 vaccinations.

In the thirty-eight years between the launch of the original Medicare program and the launch of Part D, Congress acted three times to extend Part B coverage to ACIP-recommended vaccinations for three specific diseases. A fourth vaccination, COVID-19, was added in 2020.

- Pneumococcal vaccination: The first vaccine to prevent pneumonia was licensed for use in the U.S. in 1977. In 1980 Congress approved Part B coverage of pneumococcal vaccinations starting July 1, 1981. Approval was attributed in part to analyses from the Congressional Budget Office and the Office of Technology Assessment that found coverage of pneumococcal vaccinations would avert costs of treatment for pneumonia and related complications and become cost-saving to the Medicare program by Year 4.[3]
- Hepatitis B vaccination: Vaccination for Hepatitis B was added to Part B coverage in the Deficit Reduction Act of 1984. Coverage was approved for Medicare beneficiaries identified as at high-risk for exposure to Hepatitis B due to pre-existing conditions, including beneficiaries on dialysis for end-stage renal disease.[4]
- Influenza vaccination: The 1987 Budget Reconciliation Act authorized the Secretary of Health and Human Services to cover influenza vaccination in Part B if coverage was found to be cost-effective, based on the results of a specified demonstration project. The Medicare Influenza Vaccination Demonstration (1988-1992), was staged in ten states. An evaluation of the demonstration project found that patients enjoyed positive health benefits and coverage of influenza vaccination averted Medicare costs thanks to the prevention of influenza and related illnesses. Influenza vaccination became a Part B covered benefit as of May 1, 1993.[5]
- COVID-19 vaccination: COVID-19 vaccinations were added to Part B coverage by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) in March 2020, with the aim of expediting the uptake of COVID-19 vaccines by Medicare beneficiaries. The CARES Act stipulated that Part B coverage would begin the day the FDA approved a COVID-19 vaccine; the first COVID-19 vaccine would not be approved until December 11, 2020.[6]

Medicare and Adult Vaccinations: What's Next?

Context

Historically, older Americans with Medicare coverage persistently achieve the highest rates of vaccination among all American adults. Nevertheless, many Medicare vaccination rates typically fall below national public health goals. Then again, while Medicare beneficiaries often reach the national goal (the U.S. Department of Health and Human Services [HHS] Healthy People goals) of about 70 percent for influenza (flu) vaccinations[7], the goal itself leaves room for substantial improvement. Improving immunization rates among older Americans, always a high priority for public health, is now needed more urgently as Medicare beneficiaries face new risks to their health and health resilience in the aftermath of the COVID-19 pandemic.

Medicare's vaccination coverage is ripe for reassessment, given the split between Part B medical benefits and Part D prescription drug benefits, as well as the corresponding split in coverage between standalone Medicare Advantage (MA) plans and Medicare Advantage-Prescription Drug plans (MA-PDP). The over-arching goal for reassessment should be improvement in vaccination rates for all immunizations recommended for older adults by the Center for Disease Control and Prevention's (CDC) Advisory Committee on Immunizations Practices (ACIP), regardless of which Medicare program covers them.[8]

NEHI solicited the views of a broad cross section of stakeholder groups through expert interviews and a multi-stakeholder roundtable held in November 2022. We did not find universal consensus on major changes in Medicare vaccination coverage. However, we did find a new openness to reconsideration of Medicare coverage policy from the standpoint of improving beneficiary vaccination rates for all ACIP-recommended vaccinations, and preparing for new vaccinations that will address as-yet unknown future threats of infectious disease.

Adult Vaccines Recommended by the Advisory Committee on Immunization Practices (ACIP)

	Vaccination Rates by Age Group							
Medicare Part B & Medicare Advantage Vaccines	Ages 18-64	Ages 19-49	Ages 18-49	Ages 50-64	Ages 60-64 Years	Ages ≥50	Ages ≥65	Year(s)
COVID-19 vaccine [1]								
- Completed primary series	-	-	78.0%	88.5%	-	-	96.2%	2021-Present
- Received first booster dose (among adults who completed primary series)	-	-	56.9%	70.2%	-	-	82.5%	2021-2022
- Received updated bivalent booster dose (among adults who completed primary series)	-	-	26.2%	37.4%	-	-	49.6%	2022-Present
Influenza vaccine (inactivated), influenza vaccine (live, attenuated), or influenza vaccine (recombinant) [2]	42.0%	-	-	-	-	-	73.9%	2021-2022
Pneumococcal conjugate vaccine or pneumococcal polysaccharide vaccine [3]	29.7%*	-	-	-	-	-	70.1%	2021
Hepatitis B vaccine (HepB) (at least 3 doses) [4]	-	40.3%	-	-	-	19.1%	-	2018
Medicare Part D & Medicare Advantage Prescription Drug Plan Vaccines	**Ages 18-64**	**Ages 19-49**	**Ages 18-49**	**Ages 50-64**	**Ages 60-64 Years**	**Ages ≥50**	**Ages ≥65**	**Year(s)**
Hepatitis A vaccine (HepA) (at least 2 doses) [5]	-	-	-	-	-	6.1%	-	2017
Tetanus and diphtheria toxoids (Td) or Tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap) [6]	-	-	73.1%	69.8%	-	-	65.1%	2019
Zoster vaccine (recombinant) [7]	-	-	-	-	27.1%	-	45.7%	2020
*Haemophilus influenzae type b vaccine (Hib)***	-	-	-	-	-	-	-	-
Hepatitis A and hepatitis B vaccine (HepA-HepB)**	-	-	-	-	-	-	-	-
Human papillomavirus vaccine (HPV)***	-	-	-	-	-	-	-	-
Measles, mumps, and rubella vaccine (MMR)***	-	-	-	-	-	-	-	-
Meningococcal serogroups A, C, W, Y vaccine***	-	-	-	-	-	-	-	-
Meningococcal serogroup B vaccine***	-	-	-	-	-	-	-	-
Poliovirus vaccine***	-	-	-	-	-	-	-	-
Varicella vaccine***	-	-	-	-	-	-	-	-

Notes:

*Vaccination rate among Adults Ages 18-64 at Increased Risk

**Typically administered to individuals at increased risk. Vaccination rates across adult age groups are not available

*** Typically administered prior to adulthood

Sources:

1. https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adults.html
2. https://www.cdc.gov/flu/fluvaxview/interactive-general-population.htm
3. https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/data-reports/general-population/index.html
4. https://www.cdc.gov/mmwr/volumes/71/wr/mm7113a1.htm#:~:text=HepB%20vaccination%20coverage%20(%E2%89%A53%20doses)%20was%2040.3%25%20for,adults%20aged%20%E2%89%A550%20years.
5. https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2017.html#:~:text=In%202017%2C%20reported%20hepatitis%20A,points%20increase%20compared%20with%202016
6. https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/data-reports/general-population/index.html
7. https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/data-reports/general-population/index.html

We found broad support, in principle, for the "immunization neighborhood;" that is, support (through reimbursement, quality improvement incentives, and the like) for the most extensive and active network of qualified vaccinators available to offer all ACIP-recommended vaccinations, throughout the country. The federal government's support for the "immunization neighborhood" reached a high point with measures taken under the COVID-19 Public Health Emergency (PHE), which invoked emergency powers to promote local COVID-19 vaccination by physician practices, pharmacies, and community-based organizations, including a temporary override of state pharmacist scope-of-practice laws that allowed pharmacists and pharmacist technicians in all 50 states to administer COVID-19 vaccines. This "all hands on deck" approach supported rapid vaccination of more than 90 percent of Medicare beneficiaries with the primary doses of COVID-19 vaccines in 2020 and 2021. However, pharmacist scope-of-practice laws and regulations are coming back into force now with the May 11, 2023 termination of the COVI-19 PHE.

Scope-of-practice laws and regulations in nearly every state allow pharmacists to administer vaccines for the two most highly prevalent and recurring infectious respiratory diseases, influenza and COVID-19, and COVID-19 vaccinations will likely be recommended by the CDC for annual administration to older adults at least once every year. Both influenza and COVID-19 vaccinations are covered by Medicare in Part B; as such, physicians bill Part B as eligible medical providers. Pharmacists, however, are not accorded provider status under Part B but are eligible to bill under Part B for vaccinations as qualified mass immunizers. Consequently, Medicare beneficiaries have access to flu and COVID-19 vaccinations in widespread networks of physician practices and pharmacies.

On the other hand, Medicare beneficiaries' vaccination rates for vaccinations covered by Part D were significantly lower than flu vaccination rates before the onset of COVID-19 and declined during the COVID-19 pandemic. Patient co-pays and other cost sharing imposed in many Part D prescription drug plans were seen as a major deterrent to patient uptake of these vaccinations, a deterrent now eliminated by the 2022 Inflation Reduction Act (IRA). Medicare reimbursement levels for administering vaccinations were also flat for several years up to and including the COVID-19 pandemic. CMS raised reimbursement rates for 2023 and plans to revise rates on an annual basis.[9]

* Pharmacist-administered influenza vaccinations are allowed in all 50 states while COVID-19 vaccinations are allowed in 49 states. Certain restrictions apply in most states.

Nevertheless, other factors may still be at play that deter uptake of vaccinations covered in Part D. Medicare Part D covers all other commercially available vaccinations not covered under Part B, such as series vaccinations (e.g., zoster [shingles] and Hepatitis A) that are administered at intervals over a period of years and/or to beneficiaries at special risk of disease. They are not the objects of mass immunization campaigns, unlike influenza and COVID-19. For vaccinators with limited resources, such as smaller physician practices and independent pharmacies, there are limited economies of scale for undertaking the job of procuring, managing, and billing for Part D vaccinations on their own. Moreover, physicians typically bill few services of any kind to Medicare Part D, so billing for vaccinations provides an added layer of complexity to their daily practice (as detailed further below in our recommendations).

Vaccines for respiratory syncytial virus (RSV) could be an exception. Multiple novel vaccines for RSV are expected to receive approval in the next two years. Like influenza and COVID-19, RSV is a seasonally recurring respiratory disease. Unlike influenza and COVID-19 vaccinations, however, Medicare coverage of RSV vaccinations will automatically default to Medicare Part D (and MA-PDP plans), unless action is taken to cover RSV vaccinations explicitly in Part B alongside influenza and COVID-19. This potential misalignment of respiratory disease coverage is a major primary reason for our first recommendation, below.

Recommendation One

Cover new, high-prevalence infectious respiratory disease vaccinations automatically in Medicare Part B through new congressional action or through rule-making by CMS.

The approval of novel RSV vaccines is an opportunity to consolidate coverage of seasonally administered respiratory disease vaccinations in Medicare Part B. Part B already covers influenza and COVID-19 vaccinations for prevention of these two, high-prevalence respiratory diseases. Medicare's coverage of RSV vaccines will default to Medicare Part D unless action is taken to extend coverage to Part B from Part D, or to assign coverage exclusively to Part B. A split in respiratory disease coverage (influenza and COVID-19 in Part B; RSV in Part D) will weaken the ability to address flu-COVID-RSV "tripledemics."[10]

Prompt action to provide Part B coverage of RSV vaccinations will also facilitate uptake of combination vaccines (e.g., flu, COVID-19, RSV) that may be introduced in the near future and enable vaccination against three diseases through one vaccine product.[11]

Equally important, prospective coverage of infectious respiratory disease vaccinations will be a pandemic preparedness measure. Prospective coverage of ACIP-recommended, infectious respiratory disease vaccinations in Medicare Part B will strengthen preparedness against future outbreaks of novel respiratory disease viruses--events that are now widely predicted by the scientific community.[12]

Consolidation of coverage might be achieved through a National Coverage Determination.[13] Existing, if rarely used authority exists to extend coverage under Part B to "additional preventive services" through a National Coverage Determination (NCD). An NCD could be used to cover additional specific vaccine products not currently covered under the Part B statute. CMS is currently considering coverage of long-acting injectable PrEP for HIV, which may offer some precedent for this approach. CMS could also consider using this discretionary authority to add categorical coverage of ACIP-recommended vaccines to Part B through rulemaking.

Congress should act in parallel to extend prospective coverage of infectious respiratory disease vaccinations to Part B as a pandemic preparedness measure. Given the uncertain prospects for CMS both proposing and successfully promulgating an NCD, Congress should consider taking action in statute to guarantee coverage of ACIP-recommended infectious respiratory disease vaccinations in Part B. Prospective coverage of respiratory disease vaccinations in Part B will be consistent with the precedent set by the 2020 CARES Act in assigning COVID-19 vaccines to Part B coverage in advance of their FDA approval and ACIP recommendations.[14] Reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) could serve as a vehicle. PAHPA is due for reauthorization by September 30, 2023.

Recommendation Two

Policymakers, including CMS, the Medicare Payment Advisory Commission (MedPAC), and congressional committees of jurisdiction should reconsider the continuing split in Medicare's vaccination coverage in light of conditions that have changed since the onset of the COVID-19 pandemic, including the elimination of patient cost-sharing for vaccinations covered under Part D, and Part B's now-

strengthened status as the source of coverage for seasonally administered vaccinations for high-prevalence, infectious respiratory diseases.

As noted earlier, elimination of Part D cost-sharing was the primary rationale for repeated recommendations by MedPAC for consolidation of all vaccinations covered by Medicare within Part B.[15] The Biden Administration endorsed consolidation of Medicare vaccinations into Part B in its Fiscal Year 2023 budget.[16]

Despite the elimination of patient cost-sharing, stakeholders still perceive barriers to beneficiary uptake of the entire list of ACIP-recommended vaccinations. While inclusion of COVID-19 vaccinations in Part B coverage has further solidified Part B as the coverage vehicle for seasonally administered, infectious respiratory disease vaccinations, the majority of other ACIP-recommended vaccinations fall under Medicare Part D coverage as pharmacy benefits. Pharmacy claims, for drugs and vaccinations alike, are routinely processed by pharmacists and pharmacies, but are far less routinely filed as claims by physicians and physician practices who typically bill for services covered as medical benefits under Part B. The necessity for physician practices to bill for shingles, Hepatitis A, and other Part D-covered vaccinations as pharmacy claims, was flagged as a potential roadblock to physician-administered vaccinations from the launch of the Part D program in 2006.

While CMS has encouraged the growth of new services to facilitate vaccination claims processing by physician practices to Medicare Part D insurance plans, including the TransactRx processing clearinghouse,[17] physician organizations and physician stakeholders consulted by NEHI still perceive these services as under-adopted, leaving physician administration of Part D vaccinations under-adopted as well. Conversely, pharmacists do not enjoy health care provider status under Medicare Part B, and are thus ineligible to administer and bill for vaccinations (such as Hepatitis B vaccinations) that are otherwise covered under Part B.

As described above, in the Fall of 2022, NEHI conducted expert interviews and convened a broad cross-section of stakeholder groups to canvass their views on the Medicare vaccination coverage split. While we did not find universal consensus on major changes in Medicare vaccination coverage, we did find a new openness to reconsideration of Medicare coverage, from three standpoints:

- Improving beneficiary vaccination rates, across all ACIP-recommended vaccinations;
- Improving vaccination administration by drawing on a wide network of vaccinators and vaccination sites (an extensive "immunization neighborhood"); and
- Improving the preparedness of the Medicare program to protect beneficiaries from future infectious disease outbreaks.

A reassessment is needed to identify the most realistic and feasible pathway to operationalizing four goals in particular.

1. **Extending vaccination coverage to Medicare beneficiaries who have no Part D prescription drug coverage**
   Changes in Part D benefits† mandated by the IRA may induce greater uptake of coverage by the approximately 6 million beneficiaries who are now estimated to have Part B coverage but have elected no Part D coverage.[18]

   Still, little is publicly known about the characteristics of this "no Part D" group. Analysis released by HHS in 2022 suggest that, as a whole, the group is somewhat healthier than other Medicare beneficiaries, with fewer diagnosed conditions and disabilities, and thus might feel less of a need, in the moment, for prescription drug coverage.[19] Thus these beneficiaries enjoy no coverage for vaccinations for shingles, Hepatitis A, and other vaccinations covered under Part D. These beneficiaries would receive coverage automatically if all Medicare vaccination coverage is assigned to Part B, as recommended by MedPAC. Improving vaccination rates among this cohort–through Part B consolidation or other means–should be a key consideration for Medicare coverage policy from the standpoint of averting vaccine-preventable diseases in the long term.

2. **Increasing uptake of Part D vaccinations offered by physician practices**
   Innovative private sector solutions have appeared to ease physician-led administration of Part D vaccinations (e.g., the VaxCare service[20]). Nevertheless, as vaccine policy expert Richard Hughes points out in a recent Health Affairs article,

† Benefit changes include a cap of $35 per month on out-of-pocket spending for insulin as of 2023, and a cap on annual out-of-pocket spending at $2,000 by 2025.

CMS has not identified or adopted rules allowing for a seamless cross-over of physician claims filed under Part B to Part D plans, a goal the agency set when the Medicare Part D program was first launched.[21] Reassessment of Medicare vaccination coverage should focus on a better understanding of the potential for further utilization of private sector solutions, and what may be a continued need for supportive Medicare rule-making.

At the same time, other challenges may be deterring physician practices from offering the full range of ACIP-recommended vaccinations. As noted earlier, vaccinations administered in high volumes (influenza, and now COVID-19) are administered under Part B, while vaccinations covered under Part D are typically indicated for administration to patients over intervals of years, and thus administered by physician practices in smaller and less predictable volumes. Recent data suggests that pharmacies are playing an increasing role in administering Part D vaccinations, a sign that the "immunization neighborhood" for Part D vaccinations is growing, but also a sign that physician practices may be diverting Medicare beneficiaries to pharmacies for these immunizations.[22]

CMS has increased 2023 reimbursement rates to physicians for administration of Part B vaccinations, recognizing declines in vaccination rates that occurred with the onset of the COVID-19 pandemic.[23] CMS plans to update reimbursement rates annually and adjust for differing costs of administration by geographic region.[24] Nevertheless, a thoroughgoing reassessment of Medicare coverage of all vaccinations should consider the overall profitability and administrative burden on physician practices that may deter them from offering all Part D vaccinations. Overcoming these barriers will be essential to achieving the goal of improved vaccination rates, across all ACIP-recommended vaccinations, whether overall coverage is assigned to Part B or Part D or continues to be split between the two programs.

3. **Supporting other under-utilized vaccination sites of service**
   Barriers to physician-administered vaccinations are felt most acutely by smaller physician practices that have fewer resources to finance procurement, management, administration, and billing of vaccinations. Similar barriers face other vaccinators who may be under-utilized, including independent pharmacies. While the COVID-19 mass immunization campaign was highly successful in

reaching up to 90 percent of Medicare beneficiaries with the primary course of COVID-19 vaccines, both smaller physician practices and independent pharmacies asserted that implementation plans designed by the 50 states did not fully engage them.[25] Smaller practices and pharmacies play an important role in medically underserved areas, both rural and urban, and barriers they faced during the COVID-19 emergency likely inhibit their initiative in offering non-COVID vaccines as well.[26] Here again an overall strategy to maximize all qualified vaccinators in the "immunization neighborhood" should be a key consideration for a reassessment of overall Medicare coverage of vaccinations.

4. **Protecting Medicare beneficiaries in long-term care**

   Nursing home residents represent only about two (2) percent of all Medicare beneficiaries, but they are among the beneficiaries most highly vulnerable to infectious disease, as was seen in the early months of the COVID-19 pandemic before COVID-19 vaccines were available.[27] A reassessment of Medicare's overall vaccination coverage (consolidation in Part B , Part D, or coverage in both) should include consideration of how coverage might better support nursing home residents' access to vaccinations, and initiatives by nursing home operators and others to keep residents' vaccinations up-to-date and prepared to rapidly vaccinate when new infectious disease outbreaks occur.

   To be sure, protection of beneficiaries in long-term care will require actions that are otherwise unrelated to Medicare coverage. Notwithstanding some recent success with the administration of COVID-19 bivalent boosters, only about half of nursing home residents are up-to-date with COVID-19 vaccination as of the publishing of this report.[28] The CDC has recognized the importance of developing standards of care for maintaining routine immunizations (COVID-19 and other vaccinations) among nursing home residents, an effort that could place greater priority on maintaining vaccinations as a quality improvement goal for nursing home care in the future.[29] A major challenge that may be beyond the reach of Medicare policy is the challenge of risks created by unvaccinated staff and outside visitors in nursing homes. For the most part, prior mandates for maintaining updated vaccinations among staff are no longer in place or enforced.

Finally, in reassessing Medicare vaccination coverage, two key factors should be weighed:

A. Recognizing Medicare Advantage's role as an increasingly dominant source of coverage.

MA plans will cover over 50 percent of all beneficiaries as early as this year (2023), and the Congressional Budget Office estimates that 60 percent of beneficiaries will choose MA plans by 2030. Over 70 percent of MA beneficiaries choose plans with prescription drug coverage (MA-PDPs), and enrollment in standalone MA-PDPs has been steadily declining.[30] If these trends persist, 40 percent or more of all beneficiaries will enjoy what will amount to consolidated (Part B and Part D) coverage of all ACIP-recommended vaccinations within the decade.

Major national insurers active in the MA program are also moving rapidly into ownership of primary care practices, as are major pharmacy and retail chains, which will expand sites of service capable of offering both Part B and Part D vaccinations.[31] MA-PDPs may be the best positioned of all sources of Medicare coverage to demonstrate improved vaccination rates, across all ACIP-recommended vaccinations, given the financial incentives they enjoy to coordinate management of both medical (Part B) and prescription drug (Part D) benefits. MA plans also enjoy financial and enrollment incentives linked to achievement of yearly Star Ratings quality improvement metrics, and reassessment of Medicare vaccination coverage should consider ways to assure consistency between vaccination coverage and Medicare's quality improvement initiatives, as detailed below.

B. Linking vaccination coverage to Medicare quality improvement goals, including goals for equitable access and uptake.

Physicians participating in the 2023 Merit-based Incentive Payment System (MIPS), the quality improvement program in traditional, fee-for-service Medicare, can elect to demonstrate performance on the Adult Immunization Status (AIS) measure in seeking performance-based payments.[32] The AIS measure has also been incorporated within Healthcare Effectiveness Data and Information Set (HEDIS) measures for reporting by health plans to the National Committee on Quality Assurance (NCQA) to determine annual HEDIS health plan quality ratings.[33] HEDIS plan ratings are incorporated into Medicare's Star Ratings of MA and MA-PDPs. CMS's over-arching strategy for quality improvement in Medicare

has identified the AIS measure as part of a "Universal Foundation" for quality improvement.[34]

The current AIS metric is a composite of vaccination rates across several vaccines for which Medicare coverage is split between Part B medical benefits and Part D prescription drug benefits, (influenza and pneumococcal in Part B, shingles, tetanus and diphtheria [Td], and tetanus-diphtheria-pertussis [Tdap] in Part D.) Providers may be reluctant to pursue performance on the AIS measure (or their performance may be less than optimal) to the extent that they must seek reimbursement from two disparate processes (Part B and Part D claims processes), as detailed above. The consolidated vaccination coverage offered in MA-PDPs may give MA-PDPs an advantage in promoting updated coverage with all ACIP-recommended vaccines, but as of now Star Ratings for MA plans do not include the AIS measure.

A reassessment of overall Medicare vaccination coverage should include a review for consistency with Medicare's larger quality improvement goals. Alignment with Medicare's quality improvement strategy is particularly important for addressing longstanding racial-ethnic disparities in vaccination rates. NCQA will stratify health plans' results on the AIS measure by race and ethnicity.[35] CMS intends to apply equity-related analysis to all quality improvement metrics that are part of its "Universal Foundation" for quality improvement in both Medicare and Medicaid.

Conclusion

Expectations are high that the elimination of patient cost-sharing for vaccinations covered in Medicare Part D will prompt Part D beneficiaries to seek out vaccinations they may have avoided in the past. It may be some months or a few years before the impact of zero cost-sharing is clearly seen. As new data emerges, a reassessment can and should take place of the remaining barriers and challenges that inhibit Medicare beneficiaries from seeking their recommended Part D vaccinations and deter providers from offering them.

In the interim, policymakers should not hesitate to take action to ensure that Medicare and its beneficiaries are fully prepared to seek appropriate vaccination in the event that respiratory disease endemic or pandemic breaks out as COVID-19 did in 2020. There is strong consensus in the scientific community that future outbreaks are not a matter of if, but when. The impending arrival of novel vaccines for RSV will be a test case for policymakers, as Medicare coverage of RSV vaccinations will default to Part D unless Congress mandates coverage in Part B or CMS successfully uses existing authority to incorporate RSV vaccinations into Part B. Split coverage of infectious respiratory disease vaccinations (influenza and COVID-19 in Part B, RSV in Part D) will dilute the ability of public health and health care providers to mount a unified campaign against all three respiratory diseases, and set a poor precedent for pandemic preparedness against future respiratory disease threats. A unified approach to respiratory disease is more urgent than before given the vulnerability of older and disabled Medicare beneficiaries to illness, now made more vulnerable for many due to the lingering effects of COVID-19.

References

1 Medicare Payment Advisory Commission, "Promoting Greater Efficiency in Medicare," June, 2007, accessed at https://www.medpac.gov/wp-content/uploads/2022/08/Jun07_EntireReport_SEC.pdf

2 Inflation Reduction Act of 2022, Public Law 117-169, Title 1, Subtitle B, Part 5, Section 11401, accessed at https://www.congress.gov/117/plaws/publ169/PLAW-117publ169.pdf

3 Public Law 96-611, accessed at https://www.congress.gov/96/statute/STATUTE-94/STATUTE-94-Pg3566.pdf; see also Office of Technology Assessment, "A Review of Selected Federal Vaccine and Immunization Policies, Based on Case Studies of Pneumococcal Vaccine," September 1979, accessed at https://www.princeton.edu/~ota/disk3/1979/7915/7915.PDF; Congressional Budget Office Staff Working Paper, "An Analysis of President Reagan's Budget Revisions," March 1981, (conclusions based on a prior report, "Proposed Pneumococcal Vaccination Benefits: Their Impact on Medicare Outlays," August 1980) accessed at https://www.cbo.gov/sites/default/files/97th-congress-1981-1982/reports/81doc11b.pdf; see also Chambers JD, Cangelosi MJ, Neumann PJ. Medicare's use of cost-effectiveness analysis for prevention (but not for treatment). Health Policy. 2015 Feb;119(2):156-63

4 Public Law 98-369, Title III, Part 1, Section 2323, accessed at https://www.congress.gov/98/statute/STATUTE-98/STATUTE-98-Pg494.pdf

5 Public Law 100-203 (Omnibus Budget Reconciliation Act of 1987), Section 4071, as excerpted by the Social Security Administration, accessed at https://www.ssa.gov/OP_Home/comp2/F100-203.html; see also Center for Disease Control and Prevention, " Perspectives in Disease Prevention and Health Promotion- Final Results: Medicare Influenza Vaccine Demonstration—Selected State, 1988-1992", August 19, 1993, accessed at https://www.cdc.gov/mmwr/PDF/wk/mm4231.pdf

6 Public Law 166-136, Section 3713, accessed at https://www.congress.gov/116/plaws/publ136/PLAW-116publ136.pdf; see also Katie Keith, "Senate Passes COVID-19 Package #3: The Coverage Provisions," Health Affairs Forefront, March 26, 2020, accessed at https://www.healthaffairs.org/do/10.1377/forefront.20200326.765600/

7 See Centers for Disease Control and Prevention, Healthy People 2030 goals at https://health.gov/healthypeople/objectives-and-data/browse-objectives/vaccination/increase-proportion-people-who-get-flu-vaccine-every-year-iid-09

8 Complete ACIP schedule of vaccinations recommended for adults at https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html

9 Avalere Health, " Vaccine Incentives for Providers Would Change Due to 2 MPFS Proposals," August 4, 2022, accessed at https://avalere.com/insights/vaccine-incentives-for-providers-would-change-due-to-2-mpfs-proposals

10 Ciara Linnane, " Americans are facing years of 'tripledemic' winters that may put patients with other ailments at risk, Jha says," MarketWatch, January 17, 2023, accessd at https://www.marketwatch.com/story/americans-are-facing-years-of-tripledemic-winters-that-may-put-patients-with-other-ailments-at-risk-jha-says-11673636418

11 Andrew Dunn, "Pfizer RSV data set up $10B showdown with GSK and Moderna for the next big vaccine market," Endpoints News, April 5, 2023, accessed at https://endpts.com/pfizer-rsv-data-sets-up-10b-showdown-with-gsk-and-moderna-for-the-next-big-vaccine-market/; see also Keren Landman, "New RSV vaccines are coming. This is very, very good news," Vox, November 1, 2022, accessed at https://www.vox.com/science-and-health/23424379/rsv-cold-virus-vaccines-monoclonal-antibodies-flu-covid-maternal-babies-infants-older-adults

12 Kai Kupperschmidt," SARS-like viruses may jump from animals to people hundreds of thousands of times a year," Science, September 15, 2021, accessed at https://www.science.org/content/article/sars-viruses-may-jump-animals-people-hundreds-thousands-times-year

13 Richard Hughes IV, "CMS can fix Medicare vaccine coverage to protect seniors from RSV," Health Affairs Forefront, March 30, 2023 accessed at https://www.healthaffairs.org/content/forefront/cms-can-fix-medicare-vaccine-coverage-protect-seniors-rsv

14 Public Law 116-136, Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Section 3713, accessed at https://www.congress.gov/116/plaws/publ136/PLAW-116publ136.pdf

15 Medicare Payment Advisory Commission, June 2021 Report to the Congress: Medicare and the Health Care Delivery System, Jun 15, 2021, accessed at https://www.medpac.gov/document/june-2021-report-to-the-congress-medicare-and-the-health-care-delivery-system/#:~:text=The%20Commission%20recommends%20that%20the,further%20improvements%20in%20the%20future.

16 Budget of the United States Government, Fiscal Year 2023, accessed at https://www.whitehouse.gov/wp-content/uploads/2022/03/budget_fy2023.pdf

17 See https://www.transactrx.com/

18 Richard Hughes, op cit

19 Tarazi, op cit

20 See https://www.vaxcare.com/

21 Richard Hughes, op cit

22 IQVIA Institute for Human Data Science, "Trends in Vaccine Administration in the United States," January 13, 2023, accessed at https://www.iqvia.com/insights/the-iqvia-institute/reports/trends-in-vaccine-administration-in-the-united-states

23 American Medical Association, "CY 2023 Physician Fee Schedule and Quality Payment Program Final Rule Summary," November 1, 2022, accessed at https://www.ama-assn.org/system/files/2023-mpfs-final-rule-summary.pdf

24 Avalere Health, op cit

25 Reed Abelson, " Primary Care Doctors Are Left Out of the Vaccine Rollout," The New York Times, February 10, 2021, accessed at https://www.nytimes.com/2021/02/10/health/covid-doctors-vaccine.html#:~:text=Despite%20their%20eagerness%20to%20participate,Primary%20Care%20Collaborative%2C%20a%20nonprofit' ; Markian Hawryluk, "Covid Shot in the Arm Not Enough to Keep Pharmacies in Business," Kaiser Health News, May 5, 2021, accessed at https://khn.org/news/article/covid-shot-in-the-arm-not-enough-to-keep-pharmacies-in-business/

26 Markian Hawryluk, “Rural Americans in Pharmacy Deserts Hurting for Covid Vaccines,” Kaiser Health News, March 3, 2021, accessed at https://khn.org/news/article/rural-america-pharmacy-deserts-hurting-for-covid-vaccine-access/ ; Jennifer A. Kingson, “The growth of “pharmacy deserts,” Axios, January 7, 2021, accessed at https://www.axios.com/2021/01/07/pharmacy-deserts-cities-prescriptions

27 Centers for Medicare and Medicaid Services, “The Impact of COVID-19 on Medicare Beneficiaries in Nursing Homes,” undated analysis of data received by CMS as of March 19, 2021, accessed at https://www.cms.gov/files/document/medicare-covid-19-nursing-home-analysis.pdf ; U.S. Department of Health and Human Services, Office of the Inspector General, “COVID-19 Had a Devastating Impact on Medicare Beneficiaries in Nursing Homes During 2020,” June 2021, accessed at https://oig.hhs.gov/oei/reports/OEI-02-20-00490.pdf

28 Press release: LeadingAge (association of nursing homes), “65.8% LeadingAge Nursing Homes Residents Have Bivalent Booster,” February 4, 2023, accessed at https://leadingage.org/65-8-leadingage-nursing-homes-residents-have-bivalent-booster/

29 Alicia Lasek, “AMDA launches ‘Moving Needles’ vaccination initiative across 3 LTC organizations,” McKnights Long Term Care News, July 28,2022, accessed at https://www.mcknights.com/news/clinical-news/amda-launches-moving-needles-vaccination-initiative-across-3-ltc-organizations/

30 Meredith Freed, et al, “Medicare Advantage in 2022: Enrollment Update and Key Trends,” Kaiser Family Foundation, August 25,2022, accessed at https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/ ; Juliet Cubanski, Tricia Neuman, “What to Know about Medicare Spending and Financing,” January 19, 2023, accessed at https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing/

31 Advisory Board, “Daily Briefing: Inside the ‘wave’ of health care acquisitions,” updated March 18, 2023, accessed at https://www.advisory.com/daily-briefing/2022/09/13/healthcare-acquisition

32 Centers for Medicare and Medicaid Services, 2023 Quality Measures - Quality ID #493 (NQF 3620): Adult Immunization Status, December 16, 2022, accessed at https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2023_Measure_493_MIPSCQM.pdf

33 Amy Salls, SS&C Blog, “NCQA Adds ECDS Measures to Public Reporting for MY2022 and MY2023,” August 2, 2022, accessed at https://www.ssctech.com/blog/ncqa-adds-ecds-measures-to-public-reporting-for-my2022-and-my2023 ; also see National Committee for Quality Assurance(NCQA) HEDIS Measures and Technical Resources, “Adult Immunization Status,” https://www.ncqa.org/hedis/measures/adult-immunization-status/

34 Douglas B. Jacobs, et al, “Aligning Quality Measures across CMS — The Universal Foundation,” New England Journal of Medicine, March 2, 2023, accessed at https://www.nejm.org/doi/full/10.1056/NEJMp2215539

35 Tony Walsh, “Stratified Measures: How HEDIS Can Enhance Health Equity,” National Committee for Quality Assurance (NCQA), October 18, 2022, accessed at https://www.ncqa.org/blog/stratified-measures-how-hedis-can-enhance-health-equity/#:~:text=One%20of%20the%20first%N,racial%20or%20ethnic%20care%20gaps.

Acknowledgments

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Organizations represented at the roundtable (and listed here for identification purposes only) included:

- AARP Public Policy Institute
- Alliance of Community Health Plans
- Adult Vaccine Access Coalition
- AHIP- America's Health Insurance Plans
- American Academy of Family Practice
- Better Medicare Alliance
- CVS Health
- Epstein Becker & Green
- Gerontological Society of America
- GSK
- HealthNexus
- Johnson & Johnson
- Kaiser Permanente
- LeadingAge
- Moderna
- National Association of Chain Drug Stores
- National Community Pharmacists Association
- National Council of Prescription Drug Plans
- STCHealth
- TransactRX
- VaxCare
- Walgreens

Our thanks as well to Jewel Mullen, M.D., MPH, of the University of Texas Dell Medical School for her participation and counsel.

Layout and Design

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