



January 4, 2021

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Centers for Medicare & Medicaid Services (CMS)  
Department of Health and Human Services (HHS)  
Attention: CMS-9912-IFC  
P.O. Box 8016  
Baltimore, MD 21244-8016

**RE: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (RIN 0938-AU35)**

To Whom It May Concern:

The American Pharmacists Association (APhA) is pleased to submit these comments in response to the fourth interim final rule with request for comments (IFC) on CMS' implementation of section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which established Medicare Part B coverage and payment for Coronavirus Disease 2019 (COVID-19) vaccine and its administration.

APhA is the largest association of pharmacists in the United States and the only organization advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community (independent and chain) pharmacies, hospitals and hospital systems, long-term care facilities, physician offices, clinics, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

Specifically, APhA recommends:

- CMS clearly communicate instructions to Medicare providers and suppliers regarding vaccine administration in order to ensure timely beneficiary access to and coverage for COVID-19 vaccines.
- CMS use existing emergency authority under the public health emergency (PHE) to immediately increase the vaccine administration values of HCPCS codes G0008, G0009, and G0010.
- CMS value CPT codes for administration that reflect the actual value of the additional practice expenses specific to COVID-19 vaccine administration.
- CMS issue a letter to state Medicaid Directors and Commercial Payors and an HHS Secretary letter to the state Governors to reference the appropriately determined Medicare vaccine administration payment rates, as a first option, to ensure equitable implementation of COVID-19 vaccine administration coverage for all patients across the country, regardless of health care coverage.

- Additionally, guidance should be issued to reference the Medicare administration rates, as a first option, from the Center for Consumer Information and Insurance Oversight (CCIIO) for the Health Insurance Marketplace plans and the Labor and Treasury Departments for private plans, ERISA plans (self-funded, fully-insured), etc.
- CMS clarify to all payors the agency’s view that the payment pathway for administration of the COVID-19 vaccine(s) be through Part B (medical side) and not through Part D (pharmacy benefit), unless reasonable barriers exist to the timely onboarding of providers, in which case, payment to providers should be equitable to all providers whether paid through Part B or Part D.
- CMS provide clear guidance that states must cover COVID-19 vaccines without cost sharing for all Medicaid beneficiaries, regardless of their benefit or waiver category.

### **A. Medicare Coding and Payment for COVID–19 Vaccine**

APhA strongly supports CMS’ interpretation of the CARES Act to permit a payment pathway for administration of the COVID-19 vaccine by immunizers and urges CMS to clearly communicate instructions to Medicare providers and suppliers in order to ensure timely beneficiary access to COVID–19 vaccines.

Specifically, the IFC states that:

*“[g]iven the high risk nature of the Medicare population, the circumstances of this nationwide pandemic, and FDA’s guidance that an EUA may be appropriate for a COVID-19 vaccine prior to its licensure if there is a demonstration of safety and efficacy in a clear and compelling manner from at least one Phase 3 clinical trial, we believe it is appropriate for Medicare to consider any EUA under section 564 of the FD&C Act issued for a COVID-19 vaccine during the PHE to be tantamount to a license under section 351 of the PHS Act for the sole purpose of considering such a vaccine to be described in section 1861(s)(10)(A) of the Act.”*

CMS also notes “that section 3713(e) of the CARES Act permits CMS to implement the changes made by that section through “program instruction or otherwise,” and we intend to issue any necessary instructions for Medicare providers and suppliers expediently in order to ensure beneficiary access to COVID-19 vaccines as quickly as possible.”

### **4. Implementation and Methods of Coding and Payment for COVID–19 Vaccine and Administration**

In the IFC, CMS addresses provider reimbursement rates for the cost of a COVID-19 vaccine and its administration during the PHE. However, APhA requests clarity both during and beyond the PHE. Despite HHS’ recent authorization for pharmacists<sup>1</sup> and other providers to administer

<sup>1</sup> See, e.g., Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/authorizinglicensed-pharmacists-to-order-and-administer-covid-19-tests.pdf> (last visited Dec. 1, 2020); Guidance for PREP Act Coverage for COVID-19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, OASH, Aug. 31, 2020, available at

vaccinations, CMS failed to modernize payment rates for immunization administration services in the 2021 physician fee schedule final rule and instead is maintaining the current 2019 rates, which represent a 44% cut from rates in 2017.<sup>2</sup> It is unclear why CMS is cutting immunization payment rates for providers in the middle of a pandemic, and the importance for patients to be up-to-date on all Centers for Disease Control and Prevention (CDC)-Advisory Committee on Immunization Practices (ACIP) recommended vaccinations. This action reverses a previous indication by CMS to correct a former incorrectly applied reduction and requires immediate attention by CMS. Therefore, APhA strongly urges CMS to use existing emergency authority under the PHE to immediately increase the vaccine administration values of HCPCS codes G0008, G0009, and G0010. The pandemic has placed a significant financial burden on many immunizing providers and we cannot afford to undermine their ability to offer access to immunization services, especially the COVID-19 vaccines.

In addition, APhA urges CMS to value CPT codes for administration that reflect the actual cost of the additional practice expenses specific to COVID-19 vaccine administration. The new COVID-19 vaccines have varying storage, handling, documentation, patient education, and administration requirements that make them more expensive than routine immunizations, such as flu and pneumococcal. COVID-19 vaccines also require pharmacists and other providers to dedicate more time and resources to patient and caregiver counseling and education. Adequate reimbursement that reflects these additional costs is essential to ensuring widespread access and provider sustainability to COVID-19 vaccines across the immunization neighborhood. It is likely that current Medicare rates for vaccine administration will not sufficiently account for the resources required to successfully implement COVID-19 vaccination efforts in all provider settings—such as pharmacies.

## **B. COVID-19 Vaccine Coverage for Medicaid, CHIP, and BHP Beneficiaries**

APhA members are generally pleased with CMS' new Medicare payment rates for COVID-19 vaccine(s) administration, including \$28.39 to administer single-dose vaccines and for multi-dose vaccines at \$16.94 for an initial dose(s) administration payment rate, and \$28.39 for the administration of the final dose in the series.<sup>3</sup> CMS is also “encouraging state policymakers and other private insurance entities to utilize the information on the Medicare reimbursement strategy to develop their vaccine administration payment plan in the Medicaid program, CHIP, the Basic Health Program (BHP), and private plans.” CMS states that “using the Medicare strategy as a

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<https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-coverage-for-screening-incongregate-settings.pdf> (last visited Dec. 1, 2020); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Dec. 1, 2020); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, Oct. 20, 2020, available at <https://www.hhs.gov/sites/default/files/prepact-guidance.pdf> (last visited Dec. 1, 2020); PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, Oct. 29, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf> (last visited Dec. 1, 2020).”

<sup>2</sup> CMS. Final Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2021. December 1, 2020, available at: <https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-1>

<sup>3</sup> HHS. Trump Administration Acts to Ensure Coverage of Life-Saving COVID-19 Vaccines & Therapeutics. October 28, 2020, available at: <https://www.cms.gov/newsroom/press-releases/trump-administration-acts-ensure-coverage-life-saving-covid-19-vaccines-therapeutics>

model would allow states to *match federal efforts* [emphasis added] in successfully administering the full vaccine to the most vulnerable populations.”<sup>4</sup>

As CMS understands, all states received additional Medicaid funding and are supposed to pay vaccine administration rates out of that funding. However, states may defer, particularly in managed care states, to pharmacy benefit managers (PBMs), which could lower these rates below costs. Some states pay lower Medicaid rates for the influenza vaccine that do not cover administration costs and would likely do the same for COVID-19. While CMS does not have direct oversight of payment rates for states and commercial plans, CMS and HHS is in a strong position to work closely with the states and should issue a letter to state Medicaid Directors and Commercial Payors and state Governors to reference the appropriately determined Medicare vaccine administration rates and the importance of paying reasonable reimbursement rates to providers. The letter should stress that this is important to ensure equitable and seamless implementation of COVID-19 vaccine administration coverage for all patients across the country, regardless of health care coverage. Additionally, guidance should be issued to reference the Medicare administration rates, as a first option, from the Center for Consumer Information and Insurance Oversight (CCIIO) for the Health Insurance Marketplace plans and the Labor and Treasury Departments for private plans, ERISA plans (self-funded, fully-insured), etc.

- As CMS states in the IFC, section 3713 of the CARES Act established Medicare Part B coverage and payment (on the medical side) for the COVID-19 vaccine and its administration. We are aware there have been different conversations between CMS and a few pharmacy organizations and chain pharmacies for payment under the pharmacy benefit, which is direct contrast to the CARES Act. Permitting states and other payers to create a payment pathway under the pharmacy benefit that relies on pharmaceutical benefit managers (PBMs) opens the door for decreased payment, unfair recoupments, and payment to intermediaries taken on the backs of providers. As mentioned above, PBMs arbitrarily decrease payment for other vaccine administration. Unfortunately, we expect PBMs to continue with their unfair and harmful practices for the COVID-19 vaccine(s). Therefore, we believe it is important for CMS to clarify to all payors the agency’s view that the payment pathway for administration of the COVID-19 vaccine(s) be through Part B (medical side) and not through Part D (pharmacy benefit), unless reasonable barriers exist to the timely onboarding of providers, in which case, payment to providers should be equitable to all providers whether paid through Part B or Part D.

APhA is also concerned the IFC does not apply to all Medicaid beneficiaries. The IFC states “CMS has not interpreted section 6008(b)(4) of the FFCRA [Families First Coronavirus Response Act or FFCRA] to require that state Medicaid programs cover the services described in that provision for individuals whose Medicaid eligibility is limited by statute to only a narrow range of benefits that would not otherwise include these services. FFCRA section 6008(b)(4) did not amend the varying benefits packages that are required for different Medicaid eligibility groups under section 1902(a)(10) of the Act.” Accordingly, APhA strongly urges CMS to provide clear guidance that states must cover COVID-19 vaccines without cost sharing for all Medicaid beneficiaries, regardless of their benefit or waiver category to guarantee that all Medicaid beneficiaries have access to COVID-19 vaccines.

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<sup>4</sup> Ibid.

APhA also appreciates that Provider Relief Funds have been made available to compensate providers for COVID-19 vaccine administration costs for uninsured populations. However, our members have concerns regarding reimbursement under the Health Resources and Services Administration's (HRSA) through the COVID-19 Uninsured Program Portal. Therefore, we urge CMS to work with HRSA to streamline and expedite this program with clear, step-by-step instructions for pharmacists and other providers to receive reimbursement and ensure uninsured populations have timely and equitable access to the COVID-19 vaccine(s).

Thank you for the opportunity to provide comments on the fourth IFC. We support CMS' ongoing efforts to ensure appropriate reimbursement for vaccine administration in order to maximize the use of pharmacists and other health care practitioners to meet the public health needs of our nation during this pandemic. If you have any questions or require additional information, please contact Michael Baxter, Senior Director of Regulatory Policy, at [mbaxter@aphanet.org](mailto:mbaxter@aphanet.org).

Sincerely,

A handwritten signature in cursive script that reads "Ilisa BG Bernstein".

Ilisa BG Bernstein, PharmD, JD, FAPhA  
Senior Vice President, Pharmacy Practice and Government Affairs