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SPECIAL EDITION

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Trump Administration Acts to Ensure Coverage of Life-Saving COVID-19 Vaccines & Therapeutics

Under President Trump's leadership, CMS is taking steps to ensure all Americans, including the nation's seniors, have access to the coronavirus disease 2019 (COVID-19) vaccine at no cost when it becomes available. On October 28, the agency released a comprehensive plan with proactive measures to remove regulatory barriers and ensure consistent coverage and payment for the administration of an eventual vaccine for millions of Americans. CMS released a set of toolkits for providers, states and insurers to help the health care system prepare to swiftly administer the vaccine once it is available. These resources are designed to increase the number of providers that can administer the vaccine, ensure adequate reimbursement for administering the vaccine in Medicare, while making it clear to private insurers and Medicaid programs their responsibility to cover the vaccine at no charge to beneficiaries. In addition, CMS is taking action to increase reimbursement for any new COVID-19 treatments that are approved or authorized by the FDA.

"Under President Trump's leadership, we have developed a comprehensive plan to support the swift and successful distribution of a safe and effective vaccine for COVID-19," said CMS Administrator Seema Verma. "As Operation Warp Speed nears its goal of delivering the vaccine in record time, CMS is acting now to remove bureaucratic barriers while ensuring that states, providers and health plans have the information and direction they need to ensure broad vaccine access and coverage for all Americans."

To ensure broad access to a vaccine for America's seniors, CMS released an Interim Final Rule with Comment Period (IFC) that establishes that any vaccine that receives Food and Drug Administration (FDA) authorization, either through an Emergency Use Authorization (EUA) or licensed under a Biologics License Application (BLA), will be covered under Medicare as a preventive vaccine at no cost to beneficiaries. The IFC also implements provisions of the CARES Act that ensure swift coverage of a COVID-19 vaccine by most private health insurance plans without cost sharing from both in and out-of-network providers during the course of the public health emergency (PHE).

In anticipation of the availability of new COVID-19 treatments, the IFC also establishes additional Medicare hospital payment to support Medicare patients' access to these potentially life-saving COVID-19 therapies. In Medicare, hospitals are generally reimbursed a fixed payment amount for the services they provide during an inpatient stay, even if their costs exceed that amount. Under current rules, hospitals may qualify for additional "outlier payments," but only when their costs for a particular patient exceed a certain threshold. Under this IFC, hospitals would qualify for additional payments when they treat patients with innovative new products approved or authorized to treat COVID-19 to mitigate any losses they may experience from making these therapies available, even if they do not reach the current outlier threshold. The IFC also makes changes to reimbursement for outpatient hospital services to ensure payment for certain innovative treatments for COVID-19 that occur outside of bundled arrangements and are paid separately. In addition, CMS released information to prepare hospitals to bill for the outpatient administration of a monoclonal antibody product in the event one is approved under an emergency use authorization (EUA).

This rule also allows states to employ a broad range of strategies - based on local needs - to appropriately manage their Medicaid program costs. The guidance and flexibility provided to states in the IFC will help them maintain Medicaid beneficiary enrollment while receiving the temporary increase in federal funding in the Families First Coronavirus Response Act (FFCRA).

CMS is also taking continued steps to ensure that price transparency extends to COVID-19 testing during the PHE. Provisions in the IFC require that any provider who performs a COVID-19 diagnostic test post their cash prices online. Providers that are non-compliant may face civil monetary penalties.

In addition to these provisions, the IFC:

- Provides an extension of Performance Year 5 for the Comprehensive Care for Joint Replacement (CJR) model; and
- Creates flexibilities in the public notice requirements and post-award public participation requirements for a State Innovation Waiver under Section 1332 of the Patient Protection and Affordable Care Act during the COVID-19 PHE.

Along with these regulatory changes, CMS is issuing three toolkits aimed at state Medicaid agencies, providers who will administer the vaccine, and health insurance plans. Together, these toolkits will help ensure the health care system is prepared to successfully administer a safe and effective vaccine by addressing issues related to access, billing and payment, and coverage.

Increasing Access to Vaccines for Medicare & Medicaid Beneficiaries

The toolkits issued today give health care providers not currently enrolled in Medicare the information needed to administer and bill vaccines to Medicare patients. CMS is working to increase the number of providers that will administer a COVID-19 vaccine to Medicare beneficiaries when it becomes available, to make it as convenient as possible for America's seniors. New providers are now able to enroll as a "Medicare mass immunizers" through an expedited 24-hour process. The ability to easily enroll as a mass immunizer is important for some pharmacies, schools, and other entities that may be non-traditional providers or otherwise not eligible for Medicare enrollment. To further increase the number of providers who can administer the COVID-19 vaccine, CMS will continue to share approved Medicare provider information with states to assist with Medicaid provider enrollment efforts. CMS is also making it easier for newly enrolled Medicare providers to also enroll in state Medicaid programs to support state administration of vaccines for Medicaid recipients.

Coverage

As a condition of receiving free COVID-19 vaccines from the federal government, providers will be prohibited from charging consumers for administration of the vaccine. To ensure broad and consistent coverage across programs and payers, the toolkits have specific information for several programs, including:

Medicare: Beneficiaries with Medicare pay nothing for COVID-19 vaccines and their copayment/coinsurance and deductible are waived.

Medicare Advantage (MA): For calendar years 2020 and 2021, Medicare will pay directly for the COVID-19 vaccine and its administration for beneficiaries enrolled in MA plans. MA plans would not be responsible for reimbursing providers to administer the vaccine during this time. Medicare Advantage beneficiaries also pay nothing for COVID-19 vaccines and their copayment/coinsurance and deductible are waived.

Medicaid: State Medicaid and CHIP agencies must provide vaccine administration with no cost sharing for most beneficiaries during the public health emergency. Following the public health emergency, depending on the population, states may have to evaluate cost sharing policies and may have to submit state plan amendments if updates are needed.

Private Plans: CMS, along with the Departments of Labor and the Treasury, is requiring that most private health plans and issuers cover a recommended COVID-19 vaccine and its administration, both in-network and out-of-network, with no cost sharing. The rule also provides that out-of-network rates cannot be unreasonably low, and references CMS's reimbursement rates as a potential guideline for insurance companies.

Uninsured: For individuals who are uninsured, providers will be able to be reimbursed for administering the COVID-19 vaccine to individuals without insurance through the Provider Relief Fund, administered by the Health Resources and Services Administration (HRSA).

Billing and Payment

The toolkits also address issues related to billing and payment. After the FDA either approves or authorizes a vaccine for COVID-19, CMS will identify the specific vaccine codes, by dose if necessary, and specific vaccine administration codes for each dose for Medicare payment. CMS and the American Medical Association (AMA) are working collaboratively on finalizing a new approach to report use of COVID-19 vaccines, which include separate vaccine-specific codes. Providers and insurance companies will be able to use these to bill for and track vaccinations for the different vaccines that are provided to their enrollees.

Medicare Payment

CMS also released new Medicare payment rates for COVID-19 vaccine administration. The Medicare payment rates will be \$28.39 to administer single-dose vaccines. For a COVID-19 vaccine requiring a series of two or more doses, the initial dose(s) administration payment rate will be \$16.94, and \$28.39 for the administration of the final dose in the series. These rates will be geographically adjusted and recognize the costs involved in administering the vaccine, including the additional resources involved with required public health reporting, conducting important outreach and patient education, and spending additional time with patients answering any questions they may have about the vaccine. Medicare beneficiaries, those in Original Medicare or enrolled in Medicare Advantage, will be able to get the vaccine at no cost.

CMS is encouraging state policymakers and other private insurance agencies 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. Using the Medicare strategy as a model would allow states to match federal efforts in successfully administering the full vaccine to the most vulnerable populations.

The IFC ([CMS-9912-IFC](#)) is scheduled to display at the Federal Register as soon as possible with an immediate effective date and a 30-day comment period.

For More Information:

- [Fact Sheet](#)
- [COVID-19 vaccine resources](#) for providers, health plans and State Medicaid programs
- [FAQs](#) on billing for therapeutics

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