

Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost-Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program

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Table of Contents

| Focus of this Toolkit | 4 |
|---|----|
| I. Recommended COVID-19 Vaccines and COVID-19 Vaccine Distribution | 5 |
| II. Medicaid, CHIP, and BHP Coverage and Reimbursement | 11 |
| A. The American Rescue Plan Act of 2021 (ARP) (Pub. L. 117-2) | 11 |
| B. The Families First Coronavirus Response Act (FFCRA) (Pub. L. 116-127) | 12 |
| C. Adults Covered under Traditional Medicaid | 13 |
| D. Beneficiaries Enrolled in Alternative Benefit Plans (ABPs) | 18 |
| E. Children Covered under Medicaid | 20 |
| F. Medicaid Beneficiaries Receiving Limited Benefit Packages | 22 |
| G. Separate CHIP Coverage & Reimbursement | 25 |
| H. BHP Coverage & Reimbursement | 27 |
| III. Medicaid & CHIP Managed Care | 32 |
| A. Coverage | 32 |
| B. Credentialing & Contracting | 32 |
| IV. Medicaid and CHIP SPA Templates, BHP Blueprints, and Streamlined Review Process | 34 |
| A. Medicaid | 34 |
| B. CHIP & BHP | 40 |
| V. Other Federal Requirements & Considerations | 41 |
| A. UPDATED: PREP Act | 41 |
| B. UPDATED: HHS PREP Act Authorizations Related to COVID-19 Vaccinations | 43 |
| C. UPDATED: Implications of HHS's COVID-19 PREP Act Declaration and Authorization for Medicaid and CHIP Coverage and Reimbursement of COVID-19 Vaccinations | |
| VI. Medicaid & CHIP Reporting Requirements & Implications | 53 |
| VII. Provider Enrollment in Medicaid & CHIP | 57 |
| A. Summary of Medicaid & CHIP | 57 |
| B. Data Sharing Systems & Process for Provider Enrollment | 57 |
| C. Emergency Flexibilities Available during All Public Health Emergencies | 58 |
| VIII. Education & Outreach | 59 |
| A. Coverage & Access | 60 |
| B. Payment | 60 |
| C. Engaging with Stakeholders | 60 |
| D. Immunization Reporting | 61 |



| E. Outreach & Education | 61 |
|-------------------------------------|----|
| COVID-19 Federal Resources from HHS | 62 |
| Glossary of Terms & Resources | 63 |

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Coverage and Reimbursement of Vaccines, Vaccine Administration, and Cost-Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program

Focus of this Toolkit

Updated February 11, 2022

The focus of this toolkit is to ensure that state and territorial Medicaid and Children's Health Insurance Program (CHIP) agencies have the necessary tools to respond to the COVID-19 public health emergency (PHE) and to address the needs of the nation's more than 80 million Medicaid and CHIP beneficiaries and the nearly one million Basic Health Program (BHP) enrollees. This toolkit will help state and territorial policymakers identify the issues that need to be considered and addressed in order to provide coverage and reimbursement for vaccine administration in the Medicaid program, CHIP, and BHP. Because the initial supply of COVID-19 vaccines is federally purchased, this toolkit primarily focuses on coverage of vaccine administration. The Centers for Medicare & Medicaid Services (CMS) remains available to provide technical assistance to states as they plan and prepare for COVID-19 vaccines. This toolkit will be updated as new information becomes available.

Within this toolkit, we address:

- Clinical and operational considerations of authorized COVID-19 vaccines, and the vaccination planning that should be undertaken across the three programs;
- Coverage, without cost-sharing, of COVID-19 vaccines and their administration pursuant to section 9811 of the American Rescue Plan Act of 2021 (ARP: Pub. L. 117-2). Section 9811 of the ARP established a new mandatory benefit at section 1905(a)(4)(E) of the Social Security Act (Act) for COVID-19 vaccines and their administration, and amended sections 1902(a)(10) and 1937 of the Act to ensure this benefit would be covered for nearly all Medicaid beneficiaries, including most groups with limited benefits. This section of the ARP also amended sections 1916(a)(2), 1916(b)(2), 1916A(b)(3)(B), and 1937 of the Act to require that COVID-19 vaccines and their administration be covered without cost-sharing. This coverage without cost-sharing is required from the date of enactment of the ARP (March 11, 2021) until the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act. Section 9821 of the ARP added a similar mandatory benefit for CHIP at section 2103(c)(11)(A) of the Act and amended section 2103(e)(2) of the Act; the changes require coverage of COVID-19 vaccines and their administration, without cost-sharing, for all CHIP enrollees, and apply during the same time period as the Medicaid coverage requirements under section 9811 of the ARP.
- Coverage of COVID-19 vaccines and vaccine administration under Medicaid pursuant to section 6008(b)(4) of the Families First Coronavirus Response Act (FFCRA);



- Medicaid vaccine administration coverage, reimbursement, and cost sharing policies for adults. This includes coverage under "traditional" Medicaid,¹ coverage made available by states opting to implement section 1905(a)(13)(B) of the Act (section 4106 of the Patient Protection and Affordable Care Act), and coverage under Alternative Benefit Plans (ABP). This section also provides guidance on what actions states and territories need to take, if any;
- Medicaid vaccine administration coverage, reimbursement and cost sharing policies for children, including the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit, and the Vaccines for Children (VFC) program, along with guidance on what actions states and territories need to take, if any;
- Coverage, reimbursement, and cost sharing policies for Medicaid beneficiaries receiving limited benefit packages;
- Coverage, reimbursement, and cost sharing policies under CHIP and BHP;
- Managed care considerations;
- State Plan Amendment (SPA) templates and streamlined review process;
- Reporting requirements;
- Provider enrollment;
- Information on education and outreach;
- Additional resources for states; and
- Glossary of terms and references.

I. Recommended COVID-19 Vaccines and COVID-19 Vaccine Distribution

Updated February 11, 2022

- 1. **UPDATED: Vaccine Distribution:** The following COVID-19 vaccines authorized for emergency use or FDA-approved are available for use in the United States:
 - COMIRNATY for those 16 and over (two-dose primary series)
 - Pfizer-BioNTech for those aged 5 and over
 - SPIKEVAX for those aged 18 and over (two-dose primary series)
 - Moderna for those aged 18 and over
 - Janssen (Johnson & Johnson) for those aged 18 and over
 - i. Note: On December 16, 2021, the Centers for Disease Control and Prevention (CDC) and its Advisory Committee on Immunization Practices (ACIP) updated its recommendation to express a clinical preference for

¹ Traditional Medicaid refers to the benefit packages available to adults who are eligible under a state Medicaid plan, waiver or demonstration based on pregnancy, status as a parent or caretaker, disability, or need for long-term services and supports. It does not include individuals who receive Medicaid coverage through an Alternative Benefit Plan, or individuals limited by statute or an existing 1115 demonstration to a narrow range of benefits that would not ordinarily include vaccine coverage.



individuals to receive a mRNA vaccine COVID-19 vaccine over the Janssen (Johnson & Johnson) COVID-19 Vaccine.²

The Pfizer-BioNTech COVID-19 vaccine for children ages 5-11 is a lower dose (10 micrograms) than the dose for individuals 12 years of age and older (30 micrograms).³

On August 23, 2021, FDA approved the vaccine that has been known as the Pfizer-BioNTech COVID-19 Vaccine. The approved vaccine is marketed as COMIRNATY (COVID-19 Vaccine, mRNA) for the prevention of COVID-19 in individuals 16 years of age and older. COMIRNATY is administered as a primary series of two doses, three weeks apart. The Pfizer-BioNTech COVID-19 vaccine remains under an emergency use authorization (EUA) as a two-dose primary series for individuals 5 years of age and older. In addition, as discussed further below, as a third primary series dose for individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise, and as a single booster for individuals 12 years of age and older at least five months after completing a primary series of the vaccine.⁴

On January 31, 2022, FDA approved the vaccine that has been known as the Moderna COVID-19 Vaccine. The approved vaccine is marketed as SPIKEVAX (COVID-19 Vaccine, mRNA), for the prevention of COVID-19 in individuals 18 years of age and older., The Moderna COVID-19 vaccine remains under an EUA as a two-dose primary series for individuals 18 years of age and older. In addition, and discussed further below, the Moderna COVID-19 vaccine is available under EUA as a third primary series dose for individuals 18 years of age and older who have been determined to have certain kinds of immunocompromise, and as a single booster dose for individuals 18 years and older at least five-months after completing a primary series of the vaccine.⁵

Additional Primary Dose for Moderately or Severly Immunocompromised Individuals and Booster Doses

All individuals aged 12 and over who have completed a primary COVID-19 vaccination series can receive a booster dose. For more information on current COVID-19 vaccine booster dose eligibility, see CDC's website here: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html</u>.

 ² Additional information can be found at: <u>https://www.cdc.gov/media/releases/2021/s1216-covid-19-vaccines.html</u>
 ³ Information on the FDA Pfizer-BioNTech EUA for children aged 5-11 is available here:

<u>https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age</u>. Information on the CDC/ACIP recommendation for Pfizer-BioNTech vaccine for children aged 5-11 is available here: <u>https://www.cdc.gov/media/releases/2021/s1102-PediatricCOVID-19Vaccine.html</u>

⁴ Additional information is available here: <u>https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-multiple-actions-expand-use-pfizer-biontech-covid-19-vaccine</u> and <u>https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine</u>.

⁵ Additional information is available here: <u>https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine</u>.



Additionally, some moderately or severly immunocompromised individuals age 5 and older should receive an additional primary dose after their primary series of either the Pfizer-BioNTech or Moderna COVID-19 vaccines.⁶ This additional primary dose should be administered prior to the booster dose.⁷

For additional information about dosing for immunocompromised individuals, the most up-to-date recommendations can be found here: <u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html</u>.

All COVID-19 vaccines are distributed through the CDC COVID-19 Vaccination Program.⁸ This program coordinates COVID-19 vaccine distribution and has established vaccine reporting requirements for those administering COVID-19 vaccines.

State Medicaid and CHIP agencies should continue to coordinate with their state health departments, as well as a wide range of other public and private sector partners and providers, to reach populations that are traditionally hard to reach. More information on outreach and education can be found in *Section VIII. Education and Outreach*.

2. CDC COVID-19 Vaccination Program Agreements: To receive free supplies of the COVID-19 vaccine(s), pharmacies, retail clinics, providers, and any other site of care receiving and administering COVID-19 vaccines must sign an agreement with the U.S. government (the CDC COVID-19 Vaccination Program Provider Agreement). Under this agreement, all providers must vaccinate individuals regardless of whether they have health insurance coverage or what type of coverage they have, and are prohibited from balance billing or otherwise charging vaccine recipients. This means that the agreement prohibits providers from charging cost-sharing or any other fee for a COVID-19 vaccination, even if cost-sharing would otherwise be permitted under the Medicaid or CHIP program. The agreement also prohibits providers who sign it from charging an office visit or other fee if COVID-19 vaccination is the sole medical service provided, and from requiring that patients receive additional medical services to receive COVID-19 vaccination.

Vaccine recipients must be provided with the required Fact Sheet for recipients and caregivers. In addition, a vaccination card must be provided or updated (if the vaccine administered is not the initial dose) at the time a COVID-19 vaccine is administered.⁹ Providers must also administer the vaccine in accordance with CDC and ACIP requirements, and must meet storage and recordkeeping requirements, including recording the

⁶ Additional information on the FDA Pfizer-BioNTech EUA for an additional dose for immunocompromised individuals is available here: <u>https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-multiple-actions-expand-use-pfizer-biontech-covid-19-vaccine</u>. Additional information on the FDA Moderna EUA for an additional dose for immunocompromised individuals is available here: <u>https://www.fda.gov/media/144638/download</u>

⁷ Additional information on CDC's recommendation for the additional dose for immunocompromised individuals is available at: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html</u>

⁸ Guidance on this program can be found at: <u>https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html.</u>

⁹ Additional information is available at: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccination-card.html</u>



administration of the vaccine to patients in their own systems within 24 hours, and to public health data systems (Immunization Information Systems) as soon as practical, and within 72 hours. For more information on the requirements to administer COVID-19 vaccines through the CDC COVID-19 vaccination program, see: <u>https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html</u>. Providers should also refer to the Fact Sheet for Healthcare Providers Administering Vaccine, see: <u>https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization</u>. Providers administering the vaccine to people without health insurance can request reimbursement for the administration of the COVID-19 vaccine through the Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured program (Uninsured Program). Providers can familiarize themselves with this process at <u>https://www.hrsa.gov/CovidUninsuredClaim</u>, and learn more and file claims at <u>https://coviduninsuredclaim.linkhealth.com/</u>.

3. UPDATED: Pediatric vaccine distribution: Comirnaty is approved for those age 16 and older. The Pfizer-BioNTech COVID-19 vaccine is authorized by the FDA and recommended by CDC/ACIP for those age 5 and over and both the Moderna and Janssen (Johnson & Johnson) vaccines are authorized and recommended for those age 18 and over. Distribution of COVID-19 vaccines for those under age 19 currently occurs through the CDC COVID-19 Vaccination Program, just as it does for adults. To provide COVID-19 vaccines to this age group, a provider must be enrolled in the CDC COVID-19 Vaccination Program. Because COVID-19 vaccine distribution is outside of the VFC program at this time, a provider does not need to be enrolled in the VFC program to administer a COVID-19 vaccine to a child eligible for the VFC program.

CMS encourages states to review COVID-19 immunization messaging to ensure it encompasses any new recommendations, and consider coordinating with local and state chapters of healthcare professional organizations, faith groups, community-based groups, tribes and tribal organizations, schools, and other groups that engage with parents, caregivers, and children to share updated messaging.

4. Beneficiary incentives: Federal financial participation (FFP) is available, subject to applicable federal requirements, for state administrative costs on monetary incentives funded by states and paid to Medicaid and CHIP beneficiaries in an effort to increase vaccination uptake for COVID-19 or influenza. CMS has determined that paying beneficiaries a monetary incentive, out of state funds, to receive COVID-19 and influenza vaccinations, could be necessary for the proper and efficient operation of the Medicaid state plan and could be a reasonable cost of administering the CHIP state plan in certain circumstances. States can therefore request federal matching funds for their administrative expenditures on state-funded monetary incentives for Medicaid and CHIP beneficiaries to encourage the uptake of the COVID-19 and influenza vaccines. In Medicaid, states can request 50 percent FFP for these administrative expenditures under 42 CFR 433.15(b)(7). In CHIP, states can request federal match at the applicable Enhanced Federal Medical Assistance Percentage (EFMAP) rate for reasonable costs incurred by the state to administer the CHIP state plan under section



2105(a)(1)(D)(v) of the Act, subject to the 10 percent limit on administrative expenditures under section 2105(c)(2)(A) of the Act and 42 CFR 457.618. State payments to managed care plans for these vaccine incentive programs must be paid separately on an administrative cost basis and not included in risk-based managed care capitation rates. For more information, see State Health Official Letter #21-004, RE: Temporary increases to FMAP under sections 9811, 9814, 9815, and 9821 of the ARP and administrative claiming for vaccine incentives (Aug. 30, 2021), at https://www.medicaid.gov/federal-policy-guidance/downloads/sho-21-004.pdf.

- 5. Coding: Once the Emergency Use Authorization or approval of each COVID-19 vaccine product is received from the Food and Drug Administration (FDA), states should alert Medicaid providers to the new American Medical Association (AMA) published codes for reporting of COVID-19 immunizations. The AMA has published¹⁰ codes for all available vaccines as of the most recent publishing of this toolkit. States should continue to monitor the AMA CPT code publications to stay current on the COVID-19 PREP Act declaration added dentists to the list of qualified persons authorized to administer COVID-19 vaccines in all states. The American Dental Association (ADA) published dental codes for administration of all available COVID-19 vaccines on March 15, 2021.¹¹ States have the option to allow dentists to use these dental codes, the AMA CPT codes, or both.
- 6. Medicare Payment: On March 15, 2021, CMS updated the Medicare payment rates for COVID-19 vaccine administration. Effective for services furnished on or after March 15, 2021, the Medicare payment rate for administering a COVID-19 vaccine is approximately \$40 to administer each dose of a COVID-19 vaccine. This means that starting on March 15, 2021, for single dose COVID-19 vaccines, Medicare will pay approximately \$40 for its administration. Additionally, starting on March 15, 2021, for COVID-19 vaccines requiring multiple doses, Medicare will pay approximately \$40 to administer each dose in the series. Current Medicare payment rates include:

| Vaccine | Medicare Payment Rates | | |
|---|---|--|--|
| COVID-19 vaccines administered on or after March 15, 2021 Additional doses of the COVID-19 vaccine administered to immunocompromised individuals on or after August 12, 2021 Booster doses administered to certain individuals on or after: September 22, 2021, for the Pfizer- BioNTech vaccine | Approximately \$40 for single-dose vaccines For vaccines requiring multiple doses, approximately \$40 for each dose in the series, including any additional doses and booster doses | | |

¹⁰ For more COVID-19 CPT coding information, see <u>https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-vaccine-and-immunization-codes</u>, and https://www.ama-assn.org/find-covid-19-vaccine-codes.
 ¹¹ For more COVID-19 dental coding information, see http://www.ama-assn.org/practice-management/cpt/covid-19-cpt-vaccine-and-immunization-codes, and https://www.ama-assn.org/find-covid-19-vaccine-codes.
 ¹¹ For more COVID-19 dental coding information, see http://www.ama-assn.org/find-covid-19-vaccine-codes.
 ¹¹ Mar.pdf.



| Vaccine | Medicare Payment Rates |
|--|--|
| October 20, 2021, for the Moderna & Janssen vaccines Pediatric doses administered on or after October 29, 2021 for individuals 5-15 years old | |
| COVID-19 vaccines administered before March 15, 2021 | \$28.39 for single-dose vaccines For vaccines requiring a series of 2 or more doses: \$16.94 for the initial dose(s) in the series \$28.39 for the final dose in the series |

These rates reflect updated information about the costs involved in administering the COVID-19 vaccine for different types of providers and suppliers, and the additional resources necessary to ensure the vaccine is administered safely and appropriately. For all COVID-19 vaccine payment rates listed above, CMS also geographically adjusts the rates based on where providers or suppliers administer the vaccine. On June 8, 2021, Medicare added an additional payment amount for administering the COVID-19 vaccine in the home for certain Medicare patients of approximately \$35 per dose.¹²

CMS recognizes that Medicare's announcement of changes in the payment for COVID-19 vaccine administration, combined with authorization of a temporary 100 percent Federal Medical Assistance Percentage (FMAP) in the American Rescue Plan Act, beginning April 1, 2021, for state expenditures for medical assistance for a COVID-19 vaccine and its administration, might have implications for states with approved SPAs or pending SPAs, and for states considering payment changes related to vaccine administration. States with questions on the impact of these changes on their program should contact CMS for technical assistance. CMS provided guidance to states on implementation of the 100 percent FMAP available for payments to providers for administering the COVID-19 vaccines in August 2021.¹³

While CMS generally implements changes to Medicare payment rates for specific services through notice and comment rulemaking, the payment rate changes for COVID-19 vaccine administration services are being implemented to respond quickly to new information during the COVID-19 public health emergency.

7. Offer Direct Service Providers (DSPs) Paid Time Off to Receive a COVID-19 Vaccine: Many DSPs do not receive paid time off, and this has been identified as a barrier to DSPs receiving the COVID-19 vaccine. DSPs may be more willing to get vaccinated if they can

 ¹² For more information, please see "Additional Payment for Administering the Vaccine in the Patient's Home": <u>https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment</u>.
 ¹³ <u>https://www.medicaid.gov/federal-policy-guidance/downloads/sho-21-004.pdf</u>



take paid time off of work to do it. States can account for the extra time-off needed by DSPs to receive the COVID-19 vaccine by temporarily increasing their Medicaid payment rates. States have several options for implementing temporary rate increases for DSPs, including, for example, Medicaid State Plan Disaster Relief State Plan Amendments and the 1915(c) Appendix K. Temporary rate increases can be retroactive and/or time-limited.¹⁴ A demonstration of calculating temporary rate increases can be found in the June 29, 2021 CMS All-State Slide Deck on Medicaid.gov.¹⁵ Although the slide deck only references 1915(c) waivers, the method for calculating a rate increase described on slides 5 – 6 can be applied to HCBS fee-for-service rates in other Medicaid authorities, such as section 1905(a)(24) state plan personal care services, section 1915(k) Community First Choice programs, and section 1915(i) state plan HCBS.

II. Medicaid, CHIP, and BHP Coverage and Reimbursement¹⁶

A. The American Rescue Plan Act of 2021 (ARP) (Pub. L. 117-2)

Added May 5, 2021

Section 9811 of the ARP established a new mandatory Medicaid benefit at section 1905(a)(4)(E) of the Act and amended various other sections of the Act, including sections 1902(a)(10), 1916, 1916A, and 1937 of the Act. Under these changes to the statute, nearly all Medicaid beneficiaries must receive coverage of COVID-19 vaccines and their administration, without cost-sharing, including beneficiaries in most eligibility groups with limited benefits. The new mandatory Medicaid benefit applies to adults covered under "traditional" (i.e., non-Alternative Benefit Plan (ABP)) Medicaid, children covered under Medicaid, beneficiaries enrolled in ABPs, and most beneficiaries who receive limited benefit packages under the state plan or a section 1115 demonstration (see *Section F. Medicaid Beneficiaries Receiving Limited Benefit Packages* below for more information). This new coverage requirement generally applies during the period beginning March 11, 2021, and ending on the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act (referred to herein as the "ARP coverage period").¹⁷

Additionally, section 9811 of the ARP established a temporary FMAP of 100 percent for amounts expended by a state for medical assistance for COVID-19 vaccines and their administration. The increased FMAP will apply beginning April 1, 2021 and will end on the last

¹⁴ Note: Temporary changes authorized through an Appendix K cannot exceed sixmonths after the end of the federal PHE for COVID-19. Temporary changes authorized through a Medicaid State Plan Disaster State Plan Amendment cannot exceed the end date of the federal PHE for COVID-19.

 ¹⁵ <u>https://www.medicaid.gov/state-resource-center/downloads/cmcs-all-state-call-20210629.pdf</u>
 ¹⁶ As the vaccine is currently federally purchased, normal third party liability rules will apply for vaccine administration.

¹⁷ The optional COVID-19 group at section 1902(a)(10)(A)(ii)(XXIII) of the Act receives this coverage only through the last day of the COVID-19 PHE. No federal financial participation is available for any state expenditures on benefits for this group, including coverage of COVID-19 vaccinations, after the PHE ends.



day of the first quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act (referred to herein as the "ARP FMAP period"). On August 30, 2021, CMS released SHO Letter #21-004 regarding implementation of the ARP temporary 100 percent FMAP.¹⁸

Section 9821 of the ARP also applied the new coverage requirements and a temporary federal matching percentage of 100 percent EFMAP to all populations in CHIP through the addition of sections 2103(c)(11) and 2105(c)(12) of the Act for the same ARP coverage and ARP FMAP periods described in section 9811 of the ARP. Section 9821(c)(2) of the ARP also includes an adjustment to CHIP allotments to account for increased federal payments for coverage of COVID-19 vaccines and their administration.

The ARP requirements do not apply to the BHP.

B. The Families First Coronavirus Response Act (FFCRA) (Pub. L. 116-127)

Updated May 5, 2021

Under section 6008 of the FFCRA, state and territorial Medicaid programs may receive a temporary 6.2 percentage point increase in the FMAP. This temporary FMAP increase is available through the end of the quarter in which the COVID-19 PHE ends. To qualify for the temporary FMAP increase in a given quarter, states must meet the four conditions described in subsection (b) of section 6008 of the FFCRA during that quarter. Specifically, the state must maintain eligibility standards, methodologies, or procedures that are no more restrictive than what the state had in place as of January 1, 2020; the state may not charge premiums that exceed those that were in place as of January 1, 2020;¹⁹ and the state must maintain the enrollment of beneficiaries who were enrolled as of or after March 18, 2020.²⁰ Additionally, under section 6008(b)(4) of the FFCRA, to receive the temporary FMAP increase, a state or territory must cover COVID-19 testing services and treatments, including vaccines and their administration, specialized equipment, and therapies, for Medicaid enrollees without cost sharing. This coverage is required during any quarter for which the state or territory claims the temporary FMAP increase under section 6008 of the FFCRA.

There are some very limited circumstances in which the FFCRA section 6008(b)(4) coverage requirements do not apply. CMS does not interpret FFCRA section 6008(b)(4) to require states to provide COVID-19 testing and treatment services without cost sharing, including vaccines and

¹⁸ <u>https://www.medicaid.gov/federal-policy-guidance/downloads/sho-21-004.pdf</u>

¹⁹ Section 3720 of the CARES Act added a new subsection (d) to section 6008 of the FFCRA in order to provide states, which have increased premiums for any Medicaid beneficiaries above the amounts in effect on January 1, 2020, with a 30-day grace period to restore premiums to amounts no greater than those in effect as of January 1, 2020 without jeopardizing the state's eligibility for the temporary 6.2 percentage point FMAP increase.

 $^{^{20}}$ Additional detail on these conditions may be found in the preamble to CMS-9912-IFC, which includes rulemaking on the maintenance of enrollment condition at section 6008(b)(3) of the FFCRA. This IFC was put on display at the Federal Register on November 2, 2020.



their administration, to Medicaid eligibility groups whose coverage is limited by statute or under an existing section 1115 demonstration to a narrow range of benefits that would not ordinarily include vaccine coverage. However, beginning March 11, 2021, the ARP, as discussed above, required all states to cover COVID-19 vaccines and their administration without cost-sharing for nearly all Medicaid beneficiaries, including nearly all groups with limited benefits under the state plan or a section 1115 demonstration, and the ARP coverage period will extend beyond the period when FFCRA section 6008(b)(4) applies. Accordingly, the exceptions to FFCRA section 6008(b)(4)'s coverage requirements should generally be of only historical relevance to states' Medicaid coverage of COVID-19 vaccinations, as these exceptions will be of primary relevance (with respect to COVID-19 vaccination coverage) only to the period before the ARP's enactment on March 11, 2021. CMS is actively reviewing the ARP's coverage requirements related to testing and treatment and expects to provide further updates shortly.

The FFCRA section 6008(b)(4) requirements do not apply to separate CHIPs or the BHP. In states that use title XXI funding to expand Medicaid eligibility for children, the FFCRA section 6008(b)(4) requirements apply to these title XXI funded Medicaid beneficiaries in the same way that they do to all other Medicaid beneficiaries.

C. Adults Covered under Traditional Medicaid

Updated May 5, 2021

1. COVID Vaccines & Vaccine Administration Coverage

During the period when the initial supply of COVID-19 vaccines is federally purchased, states are not expected to provide Medicaid coverage and reimbursement for the vaccine itself. The following sections describe coverage of vaccine administration.

During the ARP Coverage Period

Coverage of COVID-19 vaccine administration is mandatory for most Medicaid beneficiaries (both adults and children), without cost sharing, during the period when section 1905(a)(4)(E) (as added by the ARP) and the corresponding ARP amendments to sections 1902(a)(10), 1916, and 1916A of the Act apply. Coverage of COVID-19 vaccine administration is also mandatory for many Medicaid beneficiaries during any quarter for which the state or territory claims the temporary FMAP increase under FFCRA section 6008. Section 1905(a)(4)(E) and the corresponding amendments to sections 1902(a)(10), 1916, and 1916A apply during the period beginning March 11, 2021, and ending on the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act (the "ARP coverage period").

As further described in Section 3 below, the ARP also authorizes a 100 percent FMAP for state expenditures for medical assistance for COVID-19 vaccines and their administration beginning April 1, 2021, through the last day of the first quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act. The FFCRA



section 6008 FMAP increase is available through the end of the quarter in which the COVID-19 PHE ends. The ARP and FFCRA coverage requirements include compensating Medicaid providers with a vaccine administration fee or reimbursement for a provider visit during which a vaccine dose is administered. Before the ARP was enacted, states claiming the FFCRA FMAP increase were not required to provide COVID-19 vaccination coverage under section FFCRA 6008(b)(4) to certain beneficiaries receiving limited benefit packages, but beginning March 11, 2021, COVID-19 vaccination coverage is required for most Medicaid beneficiaries under sections 1902(a)(10) and 1905(a)(4)(E) of the Act throughout the ARP coverage period. (See Section E. Medicaid Beneficiaries Receiving Limited Benefit Packages below for more information.)

After the ARP Coverage Period

After the ARP coverage period, coverage of ACIP-recommended vaccinations without costsharing will be mandatory for adults enrolled in an ABP (see Section D. *Beneficiaries Enrolled in Alternative Benefit Plans* below), but for other adult Medicaid beneficiaries vaccine administration is generally optional.

In general, states could cover vaccine administration for individuals whose eligibility for Medicaid, for example, is based on pregnancy, status as a parent or caretaker, disability, or need for long-term services and supports.

A state may also opt to receive a one percentage point increase in the FMAP for its expenditures on certain services under section 1905(b) of the Act for providing coverage of adult vaccines and their administration as well as certain other clinical preventive services pursuant to section 1905(a)(13)(A) and (B) of the Act.²¹ In electing such coverage, states must adhere to the following parameters:

- States claiming the one percentage point FMAP increase must cover all of the services described in section 1905(a)(13)(A) and (B), without cost-sharing. This includes: (1) any clinical preventive services that are assigned a grade of A or B by the United States Preventive Services Task Force (USPSTF) and (2) for adult beneficiaries, all ACIP-recommended approved vaccines and their administration.
- The one percentage point increase in the FMAP pursuant to section 1905(b) of the Act applies to expenditures for certain services provided through fee-for-service (FFS) or managed care, or under a benefit package under an ABP. States that seek the one percentage point FMAP increase would need to include coverage of ACIP-recommended approved COVID-19 vaccines and their administration for adults in their Medicaid programs.
- Most state Medicaid programs already cover at least some of the ACIP-recommended vaccines and the administration of those vaccines for adults. Therefore, it is possible that

²¹ https://www.medicaid.gov/federal-policy-guidance/downloads/SMD-13-002.pdf



states might cover ACIP-recommended approved COVID-19 vaccine(s) and their administration for adults pursuant to section 1905(a)(13)(B) of the Act.

After the ARP coverage period, states have flexibility to determine the benefit category under which COVID-19 vaccine administration is covered for adults. States could opt to cover vaccine administration under state plan benefits that are mandatory for many Medicaid eligibility groups, such as inpatient hospital services (42 CFR § 440.10), outpatient hospital services (42 CFR § 440.20(a)), rural health clinic services (42 CFR § 440.20(b)), Federally Qualified Health Centers (FQHCs), and physicians' services (42 CFR § 440.50), depending on how the state defines the amount, duration, and scope parameters for these benefits.

Vaccine administration could also be covered as a service under optional state plan benefits, such as preventive services (42 CFR § 440.130(c)), other licensed practitioners (OLP) (42 CFR § 440.60), or clinic services (42 CFR § 440.90).

Tribal facilities are facilities operated by Tribes and Tribal organizations under the Indian Self-Determination and Education Assistance Act, P.L. 93-638. When they participate in Medicaid, these providers are subject to the Medicaid benefit requirements under which they operate (inpatient hospital, outpatient hospital, clinic, FQHC, and nursing facility).

| Benefit | Is a SPA Required to Cover the Service "Vaccine Administration" After the ARP Coverage Period? |
|----------------------|---|
| Inpatient Hospital | No |
| Outpatient Hospital | No |
| Rural Health Clinic | No |
| Federally Qualified | No |
| Health Center | |
| Physicians' Services | No |
| Clinic | No |
| Preventive Services | Possibly, if service not already covered |
| Other Licensed | Possibly, if services of licensed practitioner not already covered |
| Practitioners | |

The following table is intended to assist states with identifying options and is meant to be a general reference tool. States should contact CMS for technical assistance about their program.

Gaps in Coverage

If funding is available after the ARP coverage period, the COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured program (Uninsured Program) administered by HRSA may be available for providers to request reimbursement for the vaccine administration costs for a COVID-19 vaccine for individuals who would not receive Medicaid coverage for a COVID-19 vaccine or its administration after the ARP coverage period ends. Providers can familiarize themselves with



this process at <u>https://www.hrsa.gov/CovidUninsuredClaim</u>, and learn more and file claims at <u>https://coviduninsuredclaim.linkhealth.com/</u>.

In addition, providers administering the vaccine to underinsured individuals, that is, individuals with health insurance that either does not include the COVID-19 vaccine administration fees as a covered benefit or covers the COVID-19 vaccination administration but with cost sharing can request reimbursement for the costs incurred for administration of the COVID-19 vaccine through the HRSA COVID-19 Coverage Assistance Fund (CAF). Providers can familiarize themselves with this process at https://www.hrsa.gov/covid19-coverage-assistance, and learn more and file claims at https://covid19coverageassistance.ssigroup.com/.

SPA/Waiver Requirements for Coverage

A SPA is not required for coverage of COVID vaccine(s) during the period when they are federally purchased.

As discussed above, during the ARP coverage period, states are required to cover COVID-19 vaccinations for most Medicaid beneficiaries under section 1905(a)(4)(E) of the Act and related ARP amendments. States will need to submit a SPA to add coverage of this mandatory benefit during the ARP coverage period. CMS plans to issue additional guidance about the requirements for SPA submission for the ARP coverage period.

After the ARP coverage period, states have flexibility to determine the benefit category under which a state will cover COVID-19 vaccine administration for adults. SPAs might need to be submitted to reflect the selected benefit category, as applicable.

For the period of the PHE, a state can elect to use the <u>Medicaid disaster relief SPA template</u> (section D. Benefits and section E. Payments) to add coverage and reimbursement for administration of the vaccine.

States should contact CMS for technical assistance to discuss their program.

2. Cost-Sharing

Coverage of COVID-19 vaccine administration is mandatory for nearly all adults, without costsharing, during the ARP coverage period.

After the ARP coverage period, coverage of ACIP-recommended vaccines and vaccine administration is mandatory and must be provided without cost-sharing to populations receiving coverage through an ABP. Coverage of ACIP-recommended approved vaccines and vaccine administration for adults, without cost-sharing, is also required in states that have opted to claim the one percentage point FMAP increase described in clause (5) of the first sentence of section 1905(b) of the Act. Otherwise, states can opt to impose cost-sharing on vaccine administration for adults in other populations, unless the beneficiary is in an eligibility group that is exempt from cost-sharing under section 1916 or section 1916A of the Act and regulations at 42 CFR § 447.56 (e.g., most children under age 18, most pregnant women, most children in foster care,



individuals receiving services in an institution that already had their medical assistance reduced by their income, individuals receiving hospice care, and American Indians who are currently receiving or have ever received an item or service furnished by an Indian health care provider or through referral under contract health services).

SPA/Waiver Requirements for Cost-Sharing

States may need to submit new cost-sharing SPAs to effectuate the cost-sharing exemptions for COVID-19 vaccines and their administration in the ARP if their state plan includes cost-sharing for such services that would become effective during the ARP coverage period (such as after the PHE ends but before the ARP coverage period ends). States may also need to submit a SPA to impose cost-sharing where permitted, after the ARP coverage period.

States should contact CMS for technical assistance to discuss their program.

3. Reimbursement of the Vaccine and Vaccine Administration

During the period when COVID-19 vaccines are federally purchased, Medicaid is not reimbursing providers for the vaccine; as such, no SPA submission would be necessary to describe reimbursement of the vaccine product.

The ARP amends section 1905 of the Act to authorize a 100 percent FMAP for state expenditures for medical assistance for COVID-19 vaccines and their administration. This increased FMAP is available beginning April 1, 2021,²² and ending on the last day of the first quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act.

States have significant discretion in determining vaccine administration reimbursement rates that are paid to qualified providers that have a provider agreement with the Medicaid agency. For vaccine administration provided by physicians and OLPs, rates are set by states. States are strongly encouraged to use a uniform billing standard for vaccine claims (e.g., the National Council for Prescription Drug Programs (NCPDP) standard for pharmacy billings). The rates for vaccine administration and associated billing procedures are typically found on the state agency published fee schedules for the applicable benefit category. States should review their payment policies for vaccine administration reimbursement to determine if the rates are sufficient and if they are accurately reflected in the Medicaid state plan, provider materials and published fee schedules.

For facility services, such as hospitals, nursing facilities, FQHCs, and Indian Health Service and tribal facilities, vaccine administration is usually included within the prospective payment system (PPS) or per diem rate applicable to services provided at the facilities. States may set higher payment rates for vaccine administration to recognize circumstances where costs exceed the established state plan rates and are encouraged to set rates at levels that incentivize access to and

²² Section 1905(hh) of the Act, as added by ARP, provides that this 100 percent FMAP will be available beginning the first day of the first quarter beginning after the enactment of the ARP, which is April 1, 2021.



availability of vaccines. For example, states could pay higher rates for the administration of a COVID-19 vaccine that requires multiple doses or based upon the qualifications of the administering practitioner or the site of service. Additionally, states may adjust or add-on to rates provided within facility settings to account for higher costs associated with COVID-19 vaccine administration that are not otherwise included within the existing state plan rates.

States may also want to consider using Medicare's policies and rates for vaccine administration, outlined earlier in this toolkit. States should also consider whether their billing manuals appropriately reflect policies to streamline and facilitate vaccine administration (e.g., through roster billing) and explain that, in accordance with regulations at 42 CFR § 447.15, providers may not balance bill Medicaid beneficiaries amounts additional to the amount paid by the state agency plus any deductible, coinsurance or copayment required by the state plan to be paid by the beneficiary.²³

SPA/Waiver Requirements for Reimbursement

States will need to submit SPAs to describe payment for the vaccine administration if the state wants to establish a new payment methodology for the new mandatory COVID-19 vaccine administration benefit at section 1905(a)(4)(E) or if the state wants to implement a payment methodology for administering a COVID-19 vaccine that is different from the vaccine administration payment methodology that is otherwise approved under the state plan. For example, a state may choose to pay higher rates for COVID-19 vaccine administration than what is already approved in the state plan for influenza vaccination due to additional complexity associated with COVID-19 vaccine administration.

States may submit payment SPAs through the Disaster Relief Medicaid SPA template, which (if approved) would be effective through the expiration of the PHE (section E. Payments of the template) or through a non-disaster relief SPA submission (as applicable, attachments 4.19-A, 4.19-B and 4.19-D). CMS remains available for technical assistance on these issues. For additional guidance and samples of state plan payment language, see Section IV.A *Medicaid and CHIP SPA Templates, BHP Blueprints, and Streamlined Review Process*.

D. Beneficiaries Enrolled in Alternative Benefit Plans (ABPs)

Updated May 5, 2021

All Medicaid beneficiaries enrolled in the Medicaid expansion group described at section 1902(a)(10)(A)(i)(VIII) of the Act must receive their benefits through an ABP authorized under section 1937 of the Act. States may also choose to provide benefits to other eligibility groups through an ABP. Depending on the eligibility group, the state may optionally or mandatorily enroll them in the ABP. ABPs provide states the flexibility to design a benefit package for

²³ Under the amendments made by section 9811 of the ARP, coverage of COVID-19 vaccine administration is mandatory for nearly all Medicaid beneficiaries, without cost-sharing, during the ARP coverage period.



specific populations that is based on commercial market benefits, the state's approved Medicaid state plan or a combination of both. The EPSDT benefit applies to children under age 21 enrolled in ABPs, including 19 and 20 year olds covered as part of the expansion group.

1. COVID-19 Vaccine and Vaccine Administration Coverage

During the period when COVID-19 vaccines are federally purchased, states are not expected to provide Medicaid coverage and reimbursement for the vaccine itself. The following sections describe coverage of vaccine administration. Prior to the enactment of the ARP, ABPs were, and still are, required to cover all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) without cost-sharing, as a preventive service.

During the ARP Coverage Period

As mentioned earlier, coverage of COVID-19 vaccine administration without cost-sharing is mandatory for nearly all Medicaid beneficiaries, including all children and adults enrolled in ABPs, during the ARP coverage period. The ARP amended section 1937 of the Act to require states to include, in any ABP, coverage of COVID-19 vaccines and their administration, without imposition of any deduction, cost-sharing or similar charge, during the ARP coverage period. In addition, due to updates made to 45 CFR §147.130 in the Interim Final Rule (CMS-9912-IFC) that appeared in the Federal Register on November 6, 2020, Medicaid ABPs must provide coverage for and must not impose any cost-sharing for "qualifying coronavirus preventive services," including a COVID vaccine delivered through fee-for-service or in-network or out-of-network in managed care.

After the ARP Coverage Period

Regardless of the benefit design, all ABPs must include the ten essential health benefit (EHB) categories. One of the ten categories of EHB is "preventive and wellness services and chronic disease management". Under this category, current law and regulations require specific vaccines (including administration) to be covered as an EHB without cost-sharing, when ACIP recommends them.

Gaps in Coverage

There are no gaps in coverage when a beneficiary is covered under an ABP.

SPA/Waiver Requirements for Coverage

During the period when COVID-19 vaccines are federally purchased, a SPA to cover COVID-19 vaccines is not necessary. However an ABP coverage SPA is required to add coverage for the administration of COVID-19 vaccines, as required under ARP's amendments to section 1937. If a state provided for coverage or payment for COVID-19 vaccine administration through an ABP under a Disaster Relief Medicaid SPA, the state would need to prepare to have an ABP SPA in place under the traditional SPA submission process after its Disaster Relief Medicaid SPA



expires at the end of the PHE, to effectuate coverage and payment for COVID-19 vaccinations under an ABP throughout the entire ARP coverage period.

States should contact CMS for technical assistance to discuss their program.

2. Cost-Sharing

Both during the ARP coverage period, and after it ends, there is generally no cost-sharing for ACIP-recommended COVID-19 vaccinations covered through an ABP.

3. Reimbursement

During the period when COVID-19 vaccines are federally purchased, Medicaid would not reimburse providers for the vaccine, so no SPA submission would be necessary to describe reimbursement of the vaccine product.

For populations enrolled in ABPs, including the Medicaid expansion population, states may rely on the same reimbursement policy options as are discussed above under *Section C. Adults Covered under Traditional Medicaid*.

SPA/Waiver Requirements for Reimbursement

A state will need to amend its reimbursement page if the state needs to establish a new payment methodology for COVID-19 vaccine administration, or wants to establish a vaccine administration reimbursement methodology that is different from the currently approved methodology.

States should contact CMS for technical assistance to discuss their program.

E. Children Covered under Medicaid

Updated February 11, 2022

Coverage of COVID-19 vaccine administration is mandatory for most Medicaid beneficiaries (both adults and children), without cost-sharing, during the period when section 1905(a)(4)(E) (added by the ARP) and the corresponding amendments to sections 1902(a)(10), 1916, and 1916A of the Act apply. See Section II.A. *The American Rescue Plan Act* above for a more fulsome description of the coverage for both adults and children.



1. UPDATED: COVID-19 Vaccine and Vaccine Administration Coverage

The Pfizer-BioNTech vaccine is recommended for those age 5 and over and the Moderna and Janssen (Johnson & Johnson) vaccines are recommended for those age 18 and over. Just as for adults, COVID-19 vaccines for this age group are federally purchased; therefore, states are not expected to provide Medicaid coverage and reimbursement for the vaccine itself.²⁴

During the ARP Coverage Period

Most children enrolled in Medicaid have coverage of COVID-19 vaccines and their administration without cost-sharing under section 1905(a)(4)(E) (and other provisions added or amended by section 9811 of the ARP) throughout the ARP coverage period.

After the ARP Coverage Period

Coverage of administration for all ACIP-recommended vaccines is mandatory for Medicaidenrolled children under age 21 who are eligible for the EPSDT benefit, including children enrolled in the Medicaid-expansion portion of CHIP (funded through title XXI). While in general, ACIP-recommended vaccines are provided through the VFC program for Medicaideligible children through age 18, at this time, all COVID-19 vaccines are provided through the CDC COVID-19 Vaccination Program, and therefore, outside of the VFC program.

Gaps in Coverage

There are no gaps in coverage for administration of a COVID-19 vaccine recommended by ACIP for Medicaid-enrolled children through age 20 who are eligible for the EPSDT benefit, either during or after the ARP coverage period.

SPA/Waiver Requirements for Coverage

No state action is required to cover any newly ACIP-recommended vaccine added to the pediatric vaccine schedule. However, a state may choose to submit a SPA to explicitly detail coverage provisions.

States should contact CMS for technical assistance to discuss their program.

²⁴ CDC information for states, providers, and stakeholders for vaccinating children age 5-11 is available at: https://www.cdc.gov/vaccines/covid-19/planning/children.html#covid19-vax-recommendations. In addition. COVID-19 vaccine specific information for children is available at: https://www.cdc.gov/coronavirus/2019ncov/vaccines/recommendations/children-teens.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-

ncov%2Fvaccines%2Frecommendations%2Fadolescents.html



2. Cost-Sharing

Cost-sharing may not be imposed for COVID-19 vaccines and their administration during the ARP coverage period.

After the ARP coverage period, states may impose cost-sharing on 19 and 20 year olds who are not enrolled in an ABP. However, cost-sharing may generally not be imposed for vaccines and their administration provided to beneficiaries under age 18.

SPA/Waiver Requirements for Cost-Sharing

A SPA would be required if a state opts to change state policy to exempt 19 and 20 year olds not enrolled in ABPs from cost-sharing requirements for vaccine administration after the ARP coverage period.

States should contact CMS for technical assistance to discuss their program.

3. Reimbursement of the Vaccine and Vaccine Administration

During the period when COVID-19 vaccines are federally purchased, Medicaid would not reimburse providers for the vaccine, so no SPA submission would be necessary to describe reimbursement of the vaccine product.

Because COVID-19 vaccines are currently being distributed outside of the VFC program, the VFC regional maximum administration fees do not apply. Therefore, states should consider changing the vaccine administration fee for those under age 19 to match that of adults, including (for example) to align with Medicare payment rates for COVID-19 vaccine administration. Section I.8 of this document identifies Medicare COVID-19 vaccine payment rates.²⁵

SPA/Waiver Requirements for Reimbursement

No SPA is required, unless the state needs to establish a new payment methodology for COVID-19 vaccine administration, or adds or amends a vaccine administration payment methodology or administration fee rate.

States should contact CMS for technical assistance to discuss their program.

F. Medicaid Beneficiaries Receiving Limited Benefit Packages

Updated May 5, 2021

²⁵ For more information on Medicare payment, see <u>https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment</u>.



1. COVID-19 Vaccine & Vaccine Administration Coverage

During the period when COVID-19 vaccines are federally purchased, states are not expected to provide Medicaid coverage and reimbursement for the vaccine itself. The following sections describe coverage of vaccine administration.

Medicaid includes several eligibility groups that receive limited benefit packages under statutory authority or existing section 1115 demonstration authority.

During the PHE and ARP Coverage Period

Starting March 11, 2021, section 1905(a)(4)(E) of the Act (as added by section 9811 of the ARP), and corresponding amendments to sections 1902(a)(10), 1916, 1916A, and 1937 of the Act, require states to cover COVID-19 vaccines and their administration, without cost-sharing, for nearly all Medicaid beneficiaries, including most groups receiving limited benefit packages under the state plan or a section 1115 demonstration. Generally, this coverage is required from March 11, 2021, until the last day of the first calendar quarter that begins one year after the last day of the emergency period.

As a result, individuals in the following limited-benefit eligibility groups are eligible for COVID-19 vaccine and vaccine administration coverage beginning March 11, 2021.

- Individuals eligible only for family planning benefits;
- Individuals eligible for tuberculosis-related benefits;
- Individuals eligible for the optional COVID-19 group (previously referred to as the optional COVID-19 testing group);²⁶
- Individuals eligible for medically needy coverage; and
- Section 1115(a)(2) expenditure authority limited-benefit group(s): Several states have section 1115(a)(2) demonstration authority to provide a limited benefit package to select beneficiaries not otherwise eligible for Medicaid.

States will likely need to submit SPAs to add coverage for the section 1905(a)(4)(E) benefit during the ARP coverage period, including for limited-benefit state plan eligibility groups, and may need to submit cost-sharing and reimbursement SPAs related to that new coverage. CMS is available to provide technical assistance on this topic. Additionally, CMS will provide separate technical assistance to states with section 1115(a)(2) limited benefit demonstration populations, as described above. States will need to provide coverage for COVID-19 vaccine administration

²⁶ Under section 1902(a)(10)(A)(ii)(XXIII) of the Act and the matter following section 1902(a)(10)(G) of the Act (as amended by the ARP), states can provide coverage to the optional COVID-19 group only through the last day of the COVID-19 PHE. No federal financial participation is available for any state expenditures on benefits for this group, including coverage of COVID-19 vaccinations, after the PHE ends.



for these section 1115(a)(2) limited-benefit demonstration populations under the approved demonstration project during the ARP coverage period.

As discussed in the preamble of CMS-9912-IFC (which appeared in the Federal Register on November 6, 2020), CMS does not interpret FFCRA section 6008(b)(4) to require states or territories to provide coverage for COVID-19 vaccines to eligibility groups whose coverage is limited by statute or under an existing section 1115 demonstration to a narrow range of benefits that would not ordinarily include vaccine coverage. Accordingly, for periods prior to enactment of the ARP on March 11, 2021, COVID-19 vaccination coverage was not available to such groups, even in states claiming the FFCRA section 6008 temporary FMAP increase.

Prior to March 11, 2021, a state would generally lack authority to cover COVID-19 vaccinations for many limited-benefit groups, unless it obtains section 1115 demonstration authority to provide this coverage. States can submit section 1115 requests to add this section 1115 demonstration authority effective retroactively to periods prior to March 11, 2021. The HRSA COVID-19 Claims Reimbursement Program may also be available for reimbursement of COVID-19 vaccine administration costs prior to March 11, 2021, for individuals whose Medicaid coverage does not include COVID-19 vaccine administration.

After the ARP Coverage Period

After the ARP coverage period ends, the state would generally lack authority to cover COVID-19 vaccinations for limited benefit groups, unless it obtains section 1115 demonstration authority to provide this coverage. Consequently, the following groups of individuals are likely to have gaps in vaccine administration coverage after the ARP coverage period ends.

- Individuals eligible only for family planning benefits: After the ARP coverage period, benefits and services for these individuals are limited to family planning and family planning-related services. Although states may furnish vaccinations to such individuals after the ARP coverage period ends, typically coverage of vaccinations for this group would be limited to vaccinations associated with an individual's reproductive health (e.g., human papilloma virus (HPV) vaccine) and not their general health, such as a flu vaccine or a COVID-19 vaccine;
- Individuals eligible for tuberculosis-related benefits: Benefits and services for these individuals are limited to services relating to the treatment of tuberculosis and do not include vaccines; and
- Section 1115(a)(2) expenditure authority limited benefit group(s): Several states have section 1115(a)(2) demonstration authority to provide a limited benefit package to select beneficiaries not otherwise eligible for Medicaid.

States wishing to address gaps in vaccination coverage following the ARP coverage period could choose to submit section 1115 requests to use section 1115(a)(2) expenditure authority to add coverage for COVID-19 vaccines and their administration to the benefits provided to limited-



benefit demonstration populations. If funding is available after the ARP coverage period, the COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured program (Uninsured Program) administered by HRSA may be available for providers to request reimbursement for the vaccine administration costs for a COVID-19 vaccine for individuals who would not receive Medicaid coverage for a COVID-19 vaccine or its administration.

In addition, providers administering the vaccine to underinsured individuals, that is, individuals with health insurance that either does not include the COVID-19 vaccine administration fees as a covered benefit or covers the COVID-19 vaccination administration but with cost sharing can request reimbursement for the costs incurred for administration of the COVID-19 vaccine through the HRSA COVID-19 Coverage Assistance Fund (CAF). Providers can familiarize themselves with this process at https://www.hrsa.gov/covid19-coverage-assistance, and learn more and file claims at https://covid19coverageassistance.ssigroup.com/.

CMS is available to provide technical assistance, as needed, and states should reach out to either their CMS State Demonstrations Group project officer or their CMCS state lead for such assistance.

G. Separate CHIP Coverage & Reimbursement

Updated February 11, 2022

1. UPDATED: COVID-19 Vaccine & Vaccine Administration Coverage

During the period when COVID-19 vaccines are federally purchased, states are not expected to provide CHIP coverage and reimbursement for the vaccine itself. The following sections describe coverage of vaccine administration. As noted earlier, the Pfizer-BioNTech vaccine is recommended by the ACIP for those age 5 and over and the Moderna and Janssen (Johnson & Johnson) vaccines are recommended for those age 18 and over.

During and After the ARP Coverage Period

Pursuant to section 9821(a) of the ARP, beginning on March 11, 2021, and ending on the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act, states must cover a COVID-19 vaccine and its administration without any cost-sharing requirements for all CHIP populations. After the expiration of the ARP requirement, an ACIP-recommended COVID-19 vaccine would be treated in the same manner as other ACIP-recommended vaccines. States must provide ACIP-recommended vaccines for children enrolled in a separate CHIP, with no cost-sharing, under 42 CFR §§ 457.410(b)(2) and 457.520(b)(4). As noted earlier, the ACIP has recommended the Pfizer-BioNTech vaccine for those age 5 and over and Moderna and Janssen (Johnson & Johnson) vaccines for those age 18 and over. Therefore, the administration fee for those vaccines is a mandatory benefit for children in applicable age groups who are enrolled in a separate CHIP.



Gaps in Coverage Addressed

Under section 9821 of the ARP, COVID-19 vaccines now are also required to be covered for optional pregnant women populations covered through a separate CHIP pursuant to section 2112 of the Act, without cost-sharing, beginning March 11, 2021, and ending on the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act. As of this publication, all states that cover pregnant women through a separate CHIP under section 2112 of the Act already cover vaccines and their administration without cost-sharing.

SPA/Waiver Requirements for Coverage

States will need to submit a CHIP SPA to demonstrate compliance with the new benefit at section 2103(c)(11)(A) of the Act during the ARP coverage period. CMS expects to issue additional guidance about SPA submission.

2. Cost-Sharing

Cost-sharing may not be imposed on vaccines or vaccine administration for children enrolled in CHIP. Under section 9821 of the ARP, states may not charge cost-sharing for COVID-19 vaccines for pregnant women covered through a separate CHIP, beginning March 11, 2021, and ending on the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act.

SPA/Waiver Requirements for Coverage

States will need to submit a CHIP SPA to demonstrate compliance with the new cost-sharing exemption at section 2103(e)(2) of the Act during the ARP coverage period. CMS expects to issue additional guidance about SPA submission.

3. Reimbursement

The ARP also amends section 1905 of the Act to authorize a 100 percent FMAP for state expenditures for medical assistance for COVID-19 vaccines and their administration. This increased FMAP is available beginning April 1, 2021,²⁷ and ending on the last day of the first quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act. Section 9821 of the ARP also applied the new coverage requirements and a temporary federal matching percentage of 100 percent EFMAP to all populations in CHIP through the addition of sections 2103(c)(11) and 2105(c)(12) of the Act for

²⁷ Section 1905(hh) of the Act, as added by ARP, provides that this 100 percent FMAP will be available beginning the first day of the first quarter beginning after the enactment of the ARP, which is April 1, 2021.



the same ARP coverage and ARP FMAP periods described in section 9811 of the ARP. Section 9821(c)(2) of the ARP also includes an adjustment to CHIP allotments to account for increased federal payments for coverage of COVID-19 vaccines and their administration.

Separate CHIP programs determine the rate and manner of reimbursement of the administration fees. States can claim FFP against their CHIP allotment for the administration of the vaccine.

States determine the vaccine administration rates paid to providers. States may want to consider using the same policies and rates for vaccine administration that have been established by Medicare, which are identified earlier in this toolkit.

SPA/Waiver Requirements for Reimbursement

No SPA is required for reimbursement for any newly recommended vaccines.

States should contact CMS for technical assistance to discuss their program.

H. BHP Coverage & Reimbursement

BHP is an optional health benefits coverage program that states can elect to operate for certain low-income residents who would otherwise be eligible to purchase coverage through Health Insurance Exchanges. Currently, only Minnesota and New York operate a BHP.

1. COVID-19 Vaccine and Vaccine Administration Coverage

During the period when the COVID-19 vaccines are federally purchased, coverage and reimbursement is not applicable for the vaccine itself. The following sections describe coverage of vaccine administration.

During the PHE

FFCRA section 6008(b)(4) and sections 9811 and 9821 of the ARP do not apply to BHPs. In BHP, vaccine coverage is largely the same during and outside of the PHE.

BHP benefits include at least the ten EHBs, which include all ACIP-recommended vaccines without cost-sharing under 42 CFR §§ 600.405(a) and 600.510(b). Therefore, an ACIP-recommended COVID-19 vaccine and the administration fee would be covered for individuals enrolled in BHP.

In addition, during the COVID-19 PHE, plans must provide coverage for and must not impose any cost-sharing for "qualifying coronavirus preventive services," including a COVID-19



vaccine, regardless of whether the vaccine is delivered by an in-network or out-of-network provider.

Outside the PHE

After the COVID-19 PHE ends, states must continue to cover an ACIP-recommended COVID-19 vaccine and the administration fee without cost-sharing. However, plans will no longer be required to cover vaccines provided by out-of-network providers.

Blueprint Requirements for Coverage

No state action is required to cover any newly recommended vaccine.

States should contact CMS for technical assistance to discuss their program.

2. Cost-Sharing

Cost-sharing may not be imposed on vaccines or vaccine administration for individuals enrolled in a BHP. During the COVID-19 PHE, plans must not impose any cost-sharing for "qualifying coronavirus preventive services," including a COVID-19 vaccine, regardless of whether the vaccine is delivered by an in-network or out-of-network provider.

3. Reimbursement

Federal funding for a BHP is on a per enrollee basis. States receive federal funding equal to 95 percent of the amount of premium tax credits and cost-sharing reductions that would have otherwise been provided to eligible, enrolled individuals, if those individuals were instead enrolled in Qualified Health Plans through the Marketplace. Therefore, states that operate a BHP would not receive specific federal funding for administration of COVID-19 vaccines. There are no federal BHP guidelines regarding the reimbursement of the administration of vaccines through a BHP. States determine the BHP vaccine administration rates paid to providers. More information on the Medicare payment rates (which states may want to consider adopting) is provided in the *Medicare Payment* section on page 10.

Blueprint Requirements for Reimbursement

No state action is required for reimbursement for any newly recommended COVID-19 vaccines.

States should contact CMS for technical assistance to discuss their program.

The following table summarizes the provisions for coverage, cost-sharing and reimbursement described above. The table is meant to be a general reference tool for states.



MEDICAID, CHIP AND BHP PROVISIONS FOR COVID-19 VACCINE ADMINISTRATION During the ARP Coverage Period ²⁸ and Beyond

| Population | Coverage During the ARP Coverage Period | Cost- Sharing During the ARP Coverage Period | Provider Reimbursement During the ARP Coverage Period | Coverage After the ARP Coverage Period | Cost-Sharing After the ARP Coverage Period | Provider Reimbursement After the ARP Coverage Period |
|--|---|---|--|--|---|---|
| Adults Covered Under Traditional Medicaid | Mandatory | None | State-established reimbursement rates | Mandatory in states receiving extra 1 percentage point FMAP for preventive services as described in section 1905(b); optional for others | None in states receiving extra 1 percentage point FMAP for preventive services as described in section 1905(b); otherwise at state option for certain populations ^{29*} | State-established reimbursement rates |
| Medicaid Beneficiaries Enrolled in ABPs (Including Expansion Adults) | Mandatory | None | State-established reimbursement rates | Mandatory | None | State-established reimbursement rates |
| Children Covered Under Medicaid | Mandatory | None | State-established reimbursement rates | Mandatory | None for individuals under age 18; at state option for individuals ages 19 and 20 | State-established reimbursement rates |

²⁸ The "ARP Coverage Period" is the period for mandatory coverage for COVID-19 vaccines and their administration (without cost-sharing) in Medicaid and CHIP that is described in sections 9811 and 9821 of the ARP: beginning on the date of enactment of the ARP (March 11, 2021) and ending on the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act.

²⁹ State has the option to apply cost-sharing unless the beneficiary is in an eligibility group that is exempt from cost-sharing under section 1916 or section 1916A of the Act and regulations at 42 CFR § 447.56.



| Population | Coverage During the ARP Coverage Period | Cost- Sharing During the ARP Coverage Period | Provider Reimbursement During the ARP Coverage Period | Coverage After the ARP Coverage Period | Cost-Sharing After the ARP Coverage Period | Provider Reimbursement After the ARP Coverage Period |
|--|---|--|--|---|---|---|
| Medicaid Limited Benefit Group Enrollees | Mandatory, with certain limited exceptions | None | State-established reimbursement rates | N/A, other than under section 1115(a)(2) authority | N/A | N/A |
| CHIP Enrollees | Mandatory (including for pregnant women group) | None | State-established reimbursement rates | Mandatory for ACIP- recommended vaccines (excepting pregnant women group) | None | State-established reimbursement rates |
| BHP Enrollees | ARP does not apply to BHP, but coverage is mandatory during this period. | ARP does not apply to BHP, but no cost- sharing is permitted during this period | State-established reimbursement rates | Mandatory | None | State-established reimbursement rates |



The following table summarizes Medicaid and CHIP SPA, and BHP Blueprint submission requirements for COVID-19 Vaccine Administration. The table is meant to be a general reference tool for states.

MEDICAID AND CHIP SPA SUBMISSION AND BHP BLUEPRINT REQUIREMENTS FOR COVID-19 VACCINE ADMINISTRATION ³⁰ During and After the ARP Coverage Period

| Population | Is a SPA/Blueprint needed for | Is a SPA/Blueprint needed for |
|--|---|---|
| | coverage purposes? | reimbursement purposes? |
| Adults Covered Under Traditional Medicaid | Yes for new mandatory benefit at 1905(a)(4)(E) for ARP Coverage Period. No for mandatory benefits and clinic benefit. Yes for optional benefits if not otherwise covered. | Yes, if the state needs to establish a new payment methodology for COVID-19 vaccine administration or amends an approved vaccine administration payment methodology or administration fee rates. |
| Medicaid Beneficiaries Enrolled in ABPs (Including Expansion Adults) | Yes for new mandatory benefit at 1905(a)(4)(E) for ARP Coverage Period. Otherwise, no SPA required. ³¹ | Yes, if the state needs to establish a new payment methodology for COVID-19 vaccine administration or amends an approved vaccine administration payment methodology or administration fee rates. |
| Children Covered Under Medicaid | State option to submit a SPA to explicitly detail coverage provisions. | Yes, if the state needs to establish a new payment methodology for COVID-19 vaccine administration or amends an approved vaccine administration payment methodology or administration fee rates. |
| Beneficiaries Receiving Limited Medicaid Benefit Pack ages | Yes for new mandatory benefit at 1905(a)(4)(E) for ARP Coverage Period. Otherwise, not applicable. | Yes, for the ARP coverage period, if the state needs to establish a new payment methodology for COVID-19 vaccine administration or updates approved vaccine administration rates. Otherwise, not applicable. |
| СНІР ВНР | Yes for new mandatory benefit at 2103(c)(11)(A) for ARP Coverage Period. Otherwise, no SPA required No | No |
| ЫП | | NU |

³⁰ The initial supply of COVID-19 vaccines is federally purchased.

³¹ Assumes ACIP recommendation of COVID-19 vaccine(s).



III. Medicaid & CHIP Managed Care

Last updated May 5, 2021

A. Coverage

States must ensure that all services covered under the Medicaid and CHIP state plans are available and accessible to enrollees of managed care plans in a timely manner, including the administration of covered vaccines in accordance with sections 9811 and 9821 of the ARP (see 42 CFR §§ 438.206, 438.210 and 457.1230(a)). This means, as noted above, that coverage of COVID-19 vaccine administration is mandatory for most Medicaid and CHIP beneficiaries, without cost-sharing, during the ARP coverage period, regardless of the delivery system in which the beneficiary is served (fee-for-service or managed care). Therefore, states that utilize a managed care delivery system may elect to include vaccine administration coverage in their managed care plan contracts and capitation rates. Alternatively, states may also elect to provide vaccine administration coverage and payment under their Medicaid and CHIP fee-for-service programs, and carve the vaccine benefit out of the managed care program and contracts.

If states utilize a managed care delivery system, as with all covered benefits in a managed care plan contract, Medicaid capitation rates must be developed to include all reasonable, appropriate, and attainable costs that are required under the terms of the contract, as specified in 42 CFR § 438.4(a). For CHIP, in accordance with section 9821 of the ARP to cover COVID-19 vaccines and their administration, a state must use payment rates based on public or private payment rates for comparable services for comparable populations, consistent with actuarially sound principles, as specified in 42 CFR § 457.1203(a).

B. Credentialing & Contracting

Managed care plan network requirements for credentialing and contracting, including compliance with 42 CFR §§ 438.214, 438.608(b), 457.1233(a), and 457.1285, apply to providers administering vaccines. To ensure that beneficiaries enrolled in managed care plans have easy and prompt access to a COVID-19 vaccine, states are strongly encouraged to consider whether any requirements under § 438.214(b)(1) or 457.1233(a) on their managed care plans for credentialing and network contracting should be amended. In addition, states are strongly encouraged to amend their managed care contracts to suspend limits on out-of-network coverage for managed care enrollees to specifically improve access to COVID-19 vaccines.

In accordance with 42 CFR § 438.206(b) and § 457.1230(a), each managed care plan must maintain and monitor a network of appropriate providers that is supported by written agreements and that is sufficient to provide adequate access to all services covered under the managed care contract for all enrollees. Specifically, under 42 CFR §§ 438.68 and 457.1218, states are required to develop network adequacy standards for specific provider types, including pharmacy providers. As states consider the development of these network adequacy standards, states could consider setting specific network adequacy standards for pharmacy providers who furnish COVID-19 vaccines. Further, managed care plans could consider offering additional network



provider agreements to pharmacy providers who furnish COVID-19 vaccines in order to ensure adequate and timely access to COVID-19 vaccines.

Access to a COVID-19 vaccine is critical and should be maximized to the fullest extent possible regardless of the delivery system through which a beneficiary receives their Medicaid benefits. Reimbursement for vaccines and associated administration may be specified by the state in a managed care plan's contract, subject to the approval requirements for state directed payments in 42 CFR § 438.6(c), or may be determined by the managed care plan. There are multiple approaches under which states can permit payment for COVID-19 vaccine administration in Medicaid managed care programs:

- To the extent that Medicaid managed care plans are contractually responsible for providing COVID-19 vaccines for their Medicaid managed care enrollees, they must cover administration of the COVID-19 vaccine. In the event the approved capitation rates are not sufficient to cover the cost of the vaccine administration, states may wish to pursue actuarially sound rate adjustments. States could amend their capitation rates to include an adjustment for these costs, if such an adjustment is actuarially sound and complies with 42 CFR §§ 438.4 through 438.7 regarding rate development and amendment of capitation rates.
- States could also pay for the administration of the COVID-19 vaccine outside of the managed care capitation rates as a non-risk payment arrangement, subject to the requirements specified under 42 CFR § 438.2 and the upper payment limits outlined in 42 CFR § 447.362 consistent with the requirements for non-risk contracts.
- States always have the option to pay for the administration of the COVID-19 vaccine under their Medicaid fee-for-service (FFS) programs, and carve this benefit out of the managed care program and contracts. States should carefully analyze and assess whether this approach will necessitate any SPA submissions to CMS. This approach is similar to how coverage for COVID-19 vaccinations administered during calendar years 2020 and 2021 for Medicare beneficiaries enrolled in Medicare Advantage plans will be provided by the Medicare FFS program.³²

As states consider these various approaches related to reimbursement of the COVID-19 vaccine, we strongly urge states to analyze and assess their current managed care contracts and capitation rates for any necessary revisions or amendments due to the COVID-19 vaccine. States should also consult with their actuaries as appropriate for any potential impacts to managed care plans' capitation rates. As always, we will work with states to prioritize and expedite CMS' review and approval of any necessary changes to managed care contracts or rate certifications due to the COVID-19 public health emergency.

³² See Medicare's memo regarding the COVID-19 vaccine: <u>https://www.cms.gov/files/document/hpms-memo-covid-19-vaccine-significant-cost-determination.pdf</u>. Additional detail on this may be found in the preamble to CMS-9912-IFC. This IFC appeared in the Federal Register on November 6, 2020. *See* 85 FR 71142, 71148, at <u>https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency</u>.



IV. Medicaid and CHIP SPA Templates, BHP Blueprints, and Streamlined Review Process

Updated February 11, 2022

A. Medicaid

This section is a guide to assist states with assessing the need for SPAs to effectuate coverage and/or payment for COVID-19 vaccinations. Because each state's Medicaid state plan is different, CMS recommends that states contact CMS for technical assistance about their program. Importantly, states must provide coverage and payment for COVID-19 vaccines and their administration throughout the ARP coverage period.

In March 2020, CMS created a Disaster Relief <u>Medicaid SPA template</u> to help states respond to the COVID-19 PHE. This streamlined SPA template combines multiple, time-limited state plan options into one single template for submission to CMS, eliminating the need for a state to submit multiple SPA proposals. Coverage and payment for COVID-19 vaccine administration can be executed through a Disaster Relief Medicaid SPA. However, coverage and payment changes under a Disaster Relief Medicaid SPA can be effective only for the duration of the COVID-19 PHE (and any extensions thereof), and may be effective for a shorter timeframe within the COVID-19 PHE.

The state's Disaster Relief Medicaid SPAs cannot extend beyond the date that the COVID-19 PHE ends. Accordingly, if a state provides for COVID-19 vaccine administration coverage and/or payment under a Disaster Relief Medicaid SPA, it would likely need to have a non-disaster SPA in place to effectuate coverage and payment for COVID-19 vaccinations at least through the end of the ARP coverage period. CMS created streamlined ARP Medicaid SPA templates to aid states in their response to the COVID-19 PHE through non-disaster SPAs. One template allows states to combine multiple, time-limited state plan options for coverage and/or payment for COVID-19 vaccine administration, testing, treatment and prevention into one submission to CMS. The other template allows for states to elect a section 1135 waiver of SPA requirements for submission to CMS. These streamlined templates are limited to the ARP coverage period and include an area to note vaccine counseling coverage in compliance with section 9811 of the ARP. CMS encourages states that avail themselves of the Disaster Relief Medicaid SPA process to also consider providing more permanent coverage and payment for COVID-19 vaccine administration through a subsequent submission of a non-disaster SPA.

A SPA governing reimbursement for COVID-19 vaccine administration is necessary if the state needs to establish a new payment methodology for COVID-19 vaccine administration or wants to implement a payment methodology for COVID-19 vaccine administration that differs from what is already approved under the state's Medicaid plan. For example, a state may want to set a new methodology for COVID-19 vaccine administration that describes administration in multiple doses or at alternative sites of service, or to mirror Medicare reimbursement. States should review their existing state plan language to determine if it authorizes payments for administering COVID-19 vaccine boosters and additional doses beyond initial and second doses.



Also, the earliest effective date available for non-disaster Medicaid reimbursement state plan amendments is the later of the first day of the quarter in which the state plan amendment was submitted and the first day after public notice.

However, if a state uses the Disaster Relief Medicaid SPA template for coverage and reimbursement of vaccine administration, CMS may also approve certain SPA process flexibilities under section 1135 of the Social Security Act, including a modification of the submission date requirements so that the SPA can have a retroactive effective date earlier than the first day of the quarter in which the SPA was submitted, a modification of applicable public notice timelines, and a modification of tribal consultation timelines. Again, payment provisions submitted and approved through Disaster Relief Medicaid SPAs are temporary, but may provide states with an earlier effective date than would be available without using the Disaster Relief Medicaid SPA process. Also, if payment for vaccine administration is carved out of the state's contracts with managed care plans, payment for vaccine administration will be governed by the approved state plan authority for fee-for-service reimbursement, including any timeframes for which that reimbursement methodology is approved under a Disaster Relief Medicaid SPA.

1. Considerations for States to Cover and Pay for Vaccine Administration

As states make decisions about payment for administration of the COVID-19 vaccine, they may consider the options below to either amend existing state plan authority and/or create a new payment methodology under the Medicaid state plan.

• During the ARP coverage period, states will need to cover vaccination administration under the new benefit category at 1905(a)(4)(E). At such time as the federal government stops paying for the COVID-19 vaccine, the vaccine itself would be covered under this benefit. CMS expects to issue additional guidance about SPA submissions related to the new section 1905(a)(4)(E) benefit.

Additionally, section 9811 of the ARP established a temporary FMAP of 100 percent for amounts expended by a state for medical assistance for COVID-19 vaccines and their administration. The increased FMAP applies beginning April 1, 2021, and will end on the last day of the first quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act (referred to herein as the "ARP FMAP period"). On August 30, 2021, CMS released guidance to states regarding implementation of the ARP temporary 100 percent FMAP.³³ Section 9821 of the ARP also applied the new coverage requirements and a temporary federal matching percentage of 100 percent Enhanced FMAP (EFMAP) to all populations in CHIP through the addition of sections 2103(c)(11) and 2105(c)(12) of the Act for the same ARP coverage and ARP FMAP periods described in section 9811 of the ARP. Section 9821(c)(2) of the ARP also includes an adjustment to CHIP allotments to account for increased federal payments for coverage of COVID-19 vaccines and their administration.

³³ https://www.medicaid.gov/federal-policy-guidance/downloads/sho-21-004.pdf



- For long term care facilities, including nursing facilities (NF), states may cover and pay for vaccine administration through the Medicaid NF benefit either as part of the per diem rate or as a carve-out service. In the instance of a carve-out service, the NF would make arrangements for beneficiaries to be vaccinated and would be paid directly for the vaccine administration as a NF service, separately from and in addition to the NF per diem rate. States also have the option to cover and pay for the administration of the vaccine under other Medicaid benefit categories, such as: the new section 1905(a)(4)(E), physician, other licensed practitioners (OLP), and the preventive services benefit categories. Under that option, states would pay for the service provided by practitioners under those benefit categories directly for administering vaccines to NF residents. States would need to ensure that their payment policies are aligned so that payments are not duplicated and in line with their Medicaid state plan, waiver, or demonstration authority, as applicable.
- For FQHCs and RHCs, vaccine administration may be included within the prospective payment system (PPS) rate. States should review their current definitions of FQHC/RHC encounters to ensure appropriate guidance is provided to FQHC/RHC providers and generally apply the same policy for COVID-19 vaccinations as is applied for other vaccine products.
- Regarding alternative sites, vaccine administration may be provided at drive-through sites when delivered by qualified Medicaid practitioners (such as physicians and OLPs) otherwise authorized to administer vaccines under the state plan, as long as applicable federal Medicaid regulations governing coverage and reimbursement for the applicable benefit are met. An add-on payment may be applied to account for overhead costs associated with the drive-through site.
- For vaccination products that require cold storage, the state could adjust the rate to apply an add-on payment to account for overhead costs assumed by the administering provider and any geographical wage adjustment for the provider. States should also consider a payment structure that accounts for the administration of both single dose and multiple dose vaccines mirroring the Medicare payment methodology. On March 15, 2021, CMS updated the Medicare payment rates for COVID-19 vaccine administration. Effective for services furnished on or after March 15, 2021, the new Medicare payment rate for administering a COVID-19 vaccine will be approximately \$40 to administer each dose of a COVID-19 vaccines, Medicare will pay approximately \$40 for its administration. Starting on March 15, 2021, for COVID-19 vaccines requiring multiple doses, Medicare will pay approximately \$40 for each dose in the series. The rate will be geographically adjusted based on where the service is furnished. Please see *Medicare Payment* on page 10 for more information. States with questions on the impact of this Medicare payment change on their program should contact CMS for technical assistance.
- Coverage or payment for COVID-19 vaccinations administered by pharmacists, pharmacy interns, or pharmacy technicians as authorized by the HHS COVID-19 PREP Act declaration and related authorizations (see *Section V* below), including any applicable payment



methodologies, should be clearly described in the state plan, which means that the state may need to submit a SPA.

- The Seventh Amendment to the HHS COVID-19 PREP Act declaration added dentists to the list of qualified persons authorized to administer COVID-19 vaccines in all states. The American Dental Association (ADA) published dental codes for the administration of all available COVID-19 vaccines on March 15, 2021.³⁴ States have the option to allow dentists to use these dental codes, the AMA CPT codes, or both. Please see Medicaid & CHIP Reporting Requirements & Implications on page 53 for more information.
- Additional doses of the Moderna and Pfizer-BioNTech vaccines, booster doses of the Moderna and Pfizer-BioNTech vaccine beyond the original two-dose regimen, or booster doses of the Janssen (Johnson&Johnson) vaccine beyond the original single-dose regimen. If a state has an approved plan that indicates payment for first dose and "additional dose," it is likely a SPA is not needed as long as reimbursement is the same for all additional doses. States with proposed or approved state plan pages that include specific payment rates for specific dose numbers, or states that wish to deviate from their existing "additional dose" rate or the Medicare per dose rate (which is \$40 for each dose, including additional or booster doses), might need to update their approved or pending SPA(s).

As mentioned above, several states currently authorize payment for administration of vaccines; therefore, a SPA submission is necessary only if the state intends to revise the existing payment methodology. If appropriate, a state may choose to use the same rates of pay for COVID-19 vaccine administration currently utilized for other vaccination products. This is true even if a state establishes a new billing code specific to COVID-19 vaccine administration. States may add the new billing code to established fee schedules without submitting a SPA as long as the state does not change the rates approved for vaccine administration. States should notify providers of the new billing code through provider bulletins or updates to provider manuals. During the ARP coverage period, some states may need to submit a payment SPA to ensure their payment methodology is comprehensive and reflects the new 1905(a)(4)(E) mandatory benefit.

2. Sample Approaches to State Plan Payment Language

Another approach that may limit the time necessary for CMS to review the SPA submission is to create a stand-alone SPA page that describes payment methods for mandatory and optional benefits through which states will pay for COVID-19 vaccine administration. The amendment would list the Medicaid benefit(s) and the associated payment methodology the state will use to pay for COVID-19 vaccine administration. The new state plan page would be located at the front of each applicable Medicaid state plan attachment (i.e., 4.19-A, 4.19-B, 4.19-D) that includes a benefit under which the state would authorize payment for COVID-19 vaccine

³⁴ For more COVID-19 dental coding information, see <u>http://www.ada.org/~/media/ADA/Publications/Files/CDT_COVID_19_VaccinationProcedureCodeGuidance_2021</u> Mar.pdf.



administration. CMS recommends this approach as it would significantly reduce CMS SPA processing time, in addition to eliminating the requirement for a same page review.

A similar approach that would also limit the time necessary for CMS review is to submit a standalone page that describes the payment rate for multiple eligible providers covered by the state plan Attachment. An Attachment 4.19-B submission, for example, could describe the initial and additional or final dose administration rate paid under the new 1905(a)(4)(E) benefit category to eligible providers, while also including add-on rates that cover alternate site and cold storage costs. The rates and associated add-ons must be consistent with section 1902(a)(30)(A) of the Act.

Attachment 4.19-B Example 1:

Rates of pay for administration of COVID-19 immunizations are as follows for the benefit categories that are otherwise described within attachment 4.19-B:

• Physician Services - Fee for initial vaccine administration of \$XX.XX (stand-alone vaccination). A \$XX.XX vaccine administration rate is paid when administered in conjunction with a comprehensive office visit.

- Second and additional doses A differential administration fee equal to \$XX.XX for second and additional doses of the vaccination, recognizing a potential need for additional practitioner care due to increased incidence of adverse reaction to the vaccine.
- Alternate or drive-through vaccinations An additional \$XX.XX per administered vaccine to cover any overhead costs related to alternate site delivery, e.g. site location costs, mobile record technology, etc.
- Cold-storage vaccine An additional \$XX.XX per administered vaccine to cover costs of cold storage of vaccines.

• Other Licensed Practitioners - Fee for initial vaccine administration of \$XX.XX (stand-alone vaccination). A \$XX.XX vaccine administration rate is paid when administered in conjunction with a comprehensive office visit.

- Second and additional doses A differential administration fee equal to \$XX.XX for second and additional doses of the vaccination, recognizing a potential need for additional practitioner care due to increased incidence of adverse reaction to the vaccine.
- Alternate or drive-through vaccinations An additional \$XX.XX per administered vaccine to cover any overhead costs related to alternate site delivery, e.g. site location costs, mobile record technology, etc.
- Cold-storage vaccine An additional \$XX.XX per administered vaccine to cover costs of cold storage of vaccines.



3. Use of Medicare Payment Rates

States also have the option of paying established Medicare rates for administration of vaccines. CMS recognizes that Medicare's March 15, 2021, announcement of certain changes in Medicare Part B payment for COVID-19 vaccine administration might have implications for states with approved SPAs or pending SPAs, and for states considering payment changes related to vaccine administration. Accordingly, states with proposed or approved state plan pages that include specific or hard-coded payment rates, or states with more general references to Medicare payment rates, might need to update their approved or pending state plan amendment(s) to reflect any change(s) to Medicare payment if they intend to continue paying rates that align with Medicare. Medicare's most up to date list of billing codes, payment allowances, and effective dates are available on Medicare's website.

For Medicare, the rate is geographically adjusted based on where the service is furnished. Each state that elects to pay the Medicare payment amount for administration of a COVID-19 vaccine should clearly describe whether the national average (\$40) or the geographically adjusted amount applies. Please see *Medicare Payment* on page 9 for more information.

Attachment 4.19-B Example 2:

Payment for administration of COVID-19 immunizations is made at the rates established by Medicare. Effective for services furnished on or after March 15, 2021, the new Medicare payment rate for administering a COVID-19 vaccine is \$40 to administer each dose of a COVID-19 vaccine. For COVID-19 vaccine administration services furnished before March 15, 2021, the Medicare payment rate for a single-dose vaccine or for the final dose in a series is \$28.39. For COVID-19 vaccine administration services requiring a series of two or more doses, the payment rate is \$16.94 for the initial dose(s) in the series and \$28.39 for the final dose in the series. These rates will also be geographically adjusted based on where the service is furnished.

4. Use of State Developed Fee Schedule Rates

States may also describe their own rate setting methodology and provide a link to the resulting fee schedule in the state plan with the applicable effective date. The partial fee schedule below provides an example of the calculation. States are not required to display all components of the calculated fee schedule, e.g., the cold storage or alternate site add-ons, but should provide a comprehensive description of the calculation in narrative format along with the final fee schedule amounts.



Attachment 4.19-B Example 3:

Payment for administration of COVID-19 immunizations equals the Medicaid fee schedule amount, plus add-ons to account for the costs of overhead related to cold storage and administration of the vaccine at an alternate site.

| Code | Description | Medicaid Fee | Cold-Storage Add-on | Alternate-Site Add-on |
|-------|--|-----------------|------------------------|--------------------------|
| 90471 | Initial Administration of vaccination/immunization – Child | \$ XX.XX | \$XX.XX | \$XX.XX |
| 90472 | Second and additional Administration of vaccination/immunization – Child | \$ XX.XX | \$XX.XX | \$XX.XX |
| 90473 | Initial Administration of vaccination/immunization – Adult | \$ XX.XX | \$XX.XX | \$XX.XX |
| 90474 | Second and additional Administration of vaccination/immunization – Adult | \$ XX.XX | \$XX.XX | \$XX.XX |

"Hyperlink to state Medicaid agency fee schedule for physician, OLP, etc."

(For illustration purposes only – not a live link.)

If a state submits a traditional SPA (i.e., not a Disaster Relief Medicaid SPA) in response to the COVID-19 public health emergency for coverage or payment of vaccine administration, it should identify that SPA as a COVID-19 response SPA, and CMS will expedite its review and adjudication. Unless CMS has approved a section 1135 waiver related to a Disaster Relief Medicaid SPA submission, the state will need to comply with all applicable federal SPA submission requirements, including public notice, tribal consultation, and effective date requirements.

B. CHIP & BHP

States will need to submit a CHIP SPA to demonstrate compliance with the new ARP provision at section 2103(c)(11)(A) of the Act during the ARP coverage period. CMS has provided states with a streamlined process for these SPA submissions. States should reach out to their CHIP Project Officer with any questions.

A BHP Blueprint is not necessary for coverage and payment for a COVID-19 vaccine and administration.



V. Other Federal Requirements & Considerations

Updated February 11, 2022

UPDATE: CMS is updating the toolkit to reflect various amendments to the HHS COVID-19 PREP Act declaration. Specifically, CMS is combining prior sections V.B. and V.C and updating them to reflect that HHS has authorized several additional types of practitioners to administer COVID-19 vaccinations, and has also redesignated former section V.D. as V.C and updated it to reflect these additional authorizations. We encourage states to remain up-to-date regarding future HHS COVID-19 PREP Act authorizations and updates by reviewing information at https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.

A. UPDATED: PREP Act

The Public Readiness and Emergency Preparedness (PREP) Act authorizes the Secretary of Health and Human Services (Secretary) to issue a declaration (PREP Act declaration) that provides immunity from suit and liability (except for willful misconduct) for claims of loss caused by, arising out of, relating to, or resulting from administration or use of covered countermeasures to diseases, health conditions, or other threats to health determined by the Secretary to constitute a present, or credible risk of a future public health emergency. Immunity extends to entities and individuals involved in the development, manufacturing, testing, distribution, administration, and use of such countermeasures.³⁵ A PREP Act declaration is not dependent on other emergency declarations.

On March 10, 2020, the Secretary issued a PREP Act declaration, effective February 4, 2020, to provide liability protections for activities related to medical countermeasures against COVID-19 (HHS COVID-19 PREP Act declaration).³⁶ As discussed below, pharmacists, pharmacy interns, and pharmacy technicians are covered persons under the PREP Act when they administer certain covered countermeasures, including certain COVID-19 tests, routine childhood vaccinations, and COVID-19 vaccinations, provided that the conditions in the PREP Act and the HHS COVID-19 PREP Act declaration and authorizations have been satisfied.³⁷

³⁷ See, e.g., Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act, OASH, (Apr. 8, 2020), <u>https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf;</u> Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, (Sept. 3, 2020),

https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacyinterns-regarding-covid-19-vaccines-immunity.pdf; 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), <u>https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf.</u>

³⁵ <u>https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx</u>

³⁶ See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198 (Mar. 17, 2020); 85 Fed. Reg. 21,012 (Apr. 15, 2020); 85 Fed. Reg. 35,100 (June 8, 2020); 85 Fed. Reg. 52,136 (Aug. 24, 2020); see also Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e.



There have been a number of amendments and corrections to the HHS COVID-19 PREP Act declaration, including:

- The Fifth Amendment, effective February 2, 2021, added categories of qualified persons authorized to administer COVID-19 vaccines.
- The Sixth Amendment, effective February 16, 2021, added another category of qualified persons (i.e., certain federal workers) authorized to administer COVID-19 vaccines.
- On February 22, 2021, HHS issued technical corrections to the Fifth and Sixth Amendments (effective retroactively to the effective dates of the Fifth and Sixth Amendments, as applicable), including to clarify that members of a uniformed service are included in the list of federal workers authorized to administer COVID-19 vaccines.
- The Seventh Amendment, effective March 11, 2021, added several categories of qualified persons authorized to administer COVID-19 vaccines.
- The Eighth Amendment, effective August 4, 2021, clarified that qualified pharmacy technicians are "qualified persons" covered by the declaration, including by adding language to the declaration that aligns with their authorization to administer COVID-19 vaccines under the Office of the Assistant Secretary for Health (OASH) guidance described below.³⁸
- On October 4, 2021, a correction to the declaration and related guidance and opinions appeared in the Federal Register.³⁹ This correction clarifies that what are commonly referred to as "ACIP recommendations" and "ACIP standard immunization schedules" are in fact recommendations and schedules made by the CDC after consultation with ACIP. These corrections and clarifications are also intended to recognize coverage of recommendations issued directly by the CDC.

https://www.federalregister.gov/documents/2021/08/04/2021-16681/eighth-amendment-to-declaration-under-thepublic-readiness-and-emergency-preparedness-act-for. The Ninth Amendment to the HHS COVID-19 PREP Act declaration, effective September 14, 2021, authorized certain pharmacists to order and administer, and certain pharmacy interns and pharmacy technicians to administer, beginning September 9, 2021, certain types of COVID-19 therapeutics, such as monoclonal antibodies, and does not affect authorizations for administering COVID-19 vaccines, Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 51,160 (Sept. 14, 2021), at https://www.federalregister.gov/documents/2021/09/14/2021-19790/ninth-amendment-to-declaration-under-thepublic-readiness-and-emergency-preparedness-act-for-medical. The Tenth Amendment to the HHS COVID-19 PREP Act declaration expanded the scope of authority under the declaration, beginning December 30, 2021, for licensed pharmacists to order and administer and qualified pharmacy interns to administer seasonal influenza vaccines, and also does not affect authorizations for administering COVID-19 vaccines. Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 87 Fed. Reg. 982 (Jan. 7, 2022), at https://www.federalregister.gov/documents/2022/01/07/2022-00151/tenth-amendment-to-declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical. ³⁹ Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19; Correction, 86 Fed. Reg. 54,696 (Oct. 4, 2021),

³⁸ Eighth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 41,977 (Aug. 4, 2021),

https://www.federalregister.gov/documents/2021/10/04/2021-21652/declaration-under-the-public-readiness-andemergency-preparedness-act-for-medical-countermeasures.



We discuss the aspects of these amendments that are relevant to Medicaid and CHIP coverage in more detail below.

The HHS Office of the General Counsel issued an advisory opinion on May 19, 2020, explaining that the PREP Act and the HHS COVID-19 PREP Act declaration preempt state laws that would otherwise prohibit or effectively prohibit licensed pharmacists from ordering and administering covered countermeasures described in the HHS COVID-19 PREP Act declaration.⁴⁰ Based on the reasoning set forth in the May 19, 2020 advisory opinion, any state law that would prohibit "qualified persons" identified in the HHS COVID-19 PREP Act declaration and related authorizations from administering a covered countermeasure (such as prescribing, dispensing, or administering COVID-19 vaccines) is also preempted. This means that states cannot rely on state law to prevent these persons from providing COVID-19 vaccinations (or other covered countermeasures) if they are authorized to do so under the HHS COVID-19 PREP Act declaration and related authorizations. In accordance with section 319F–3(i)(8)(A) of the Public Health Service Act, a state remains free to expand the universe of individuals authorized to administer covered countermeasures within its jurisdiction under state law.

B. UPDATED: HHS PREP Act Authorizations Related to COVID-19 Vaccinations

1. Pharmacists, Pharmacy Technicians, and Pharmacy Interns

As an "Authority Having Jurisdiction" under the HHS COVID-19 PREP Act declaration, OASH issued an authorization for certain pharmacists and pharmacy interns, effective September 3, 2020, specific to COVID-19 vaccine administration. This was done to expand the scope of qualified persons available to administer the COVID-19 vaccine.⁴¹

On October 20, 2020, HHS authorized qualified pharmacy technicians and state-authorized pharmacy interns acting under the supervision of a qualified pharmacist to administer FDA-authorized or FDA-licensed COVID-19 vaccinations to persons aged 3 or older.⁴²

The September 3, 2020 and October 20, 2020 authorizations provide that, in order to be covered by the PREP Act liability immunity for ordering or administering COVID-19 vaccinations,

⁴² 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) https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf.

⁴⁰ Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, <u>https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf</u>. *See also* Department of Justice Office of Legal Counsel Advisory Opinion for Robert P. Charrow, General Counsel of the Department of Health and Human Services, January 19, 2021, available at: <u>https://www.justice.gov/sites/default/files/opinions/attachments/2021/01/19/2021-01-19-prep-act-preemption.pdf</u>.

⁴¹ Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, (Sept. 3, 2020), <u>https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf.</u>



qualified state-licensed pharmacists, state-authorized pharmacy interns, and qualified pharmacy technicians⁴³ must satisfy certain requirements.

The Third Amendment to the HHS COVID-19 PREP Act declaration added pharmacists and pharmacy interns to the declaration, and the Fourth Amendment incorporated the OASH guidance by reference. The Eighth Amendment also clarified that qualified pharmacy technicians are "qualified persons" covered by the declaration, including by adding language to the declaration that aligns with their authorization to administer COVID-19 vaccines under the OASH guidance described above. Accordingly, the authorizations and requirements described above are now generally incorporated into the HHS COVID-19 PREP Act declaration.

The HHS COVID-19 PREP Act declaration provides that "qualified persons" under the declaration include a state-licensed pharmacist who orders and administers, and pharmacy interns and qualified pharmacy technicians who administer, FDA-authorized or FDA-licensed COVID-19 vaccines to persons ages three or older. The pharmacy intern or technician must act under the supervision of the qualified pharmacist and the pharmacy intern or technician must be licensed or registered by his or her state board of pharmacy. Such state-licensed pharmacists and the state-licensed or registered interns or technicians under their supervision are qualified persons with respect to COVID-19 vaccinations only if the following requirements are met:

- The vaccine must be authorized, approved, or licensed by the FDA.
- The vaccination must be ordered and administered according to CDC's/ACIP's⁴⁴ COVID-19 vaccine recommendation(s).
- If the vaccine is administered by a qualified pharmacy technician, the supervising qualified pharmacist must be readily and immediately available to the immunizing qualified pharmacy technician.
- The licensed pharmacist must have completed the immunization training that the licensing state requires for pharmacists to order and administer vaccines. If the state does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. This training program must include hands-on

⁴³ To be a qualified pharmacy technician, pharmacy technicians working in states with licensure and/or registration requirements must be licensed and/or registered in accordance with state requirements; pharmacy technicians working in states without licensure and/or registration requirements must have a Certified Pharmacy Technician certification from either the Pharmacy Technician Certification Board or National Healthcareer Association. *Id.*⁴⁴ As explained in the October 4, 2021 correction notice, where the termCDC/ACIP recommendations or similar

Insurgers used in the HHS COVID-19 PREP Act declaration and related guidance and opinions, this includes both direct CDC recommendations as well as recommendations adopted by the CDC Director after recommendation by ACIP, which are commonly referred to as ACIP recommendations. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19; Correction, 86 Fed. Reg. 54,696, 54,696 n.2 (Oct. 4, 2021), https://www.federalregister.gov/documents/2021/10/04/2021-21652/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures.



injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

- The qualified pharmacy technician or licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed pharmacist, qualified pharmacy technician, or licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each state licensing period.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the state or local immunization information system (vaccine registry), complying with requirements related to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.
- The licensed pharmacist, the licensed or registered pharmacy intern, and the qualified pharmacy technician must comply with any applicable requirements (or conditions of use) as set forth in the CDC COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

The HHS COVID-19 PREP Act declaration, and the September 3, 2020 and October 20, 2020 authorizations, preempt any state and local law that prohibits or effectively prohibits qualified pharmacists from ordering and administering—and qualified state-authorized pharmacy interns or pharmacy technicians from administering—COVID-19 vaccines as set forth above. However, these authorizations do not preempt state and local laws that permit additional individuals to administer COVID-19 vaccines to additional persons.

2. Pharmacies

OASH issued an authorization under the HHS COVID-19 PREP Act declaration on October 29, 2020,⁴⁵ clarifying that:

[P]harmacies are also qualified persons under 42 U.S.C. 247d-6d(i)(8)(B) when their staff pharmacists order and administer, or their pharmacy interns and pharmacy technicians administer, these covered countermeasures consistent with the terms and

⁴⁵ PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, OASH, (Oct. 29, 2020), <u>https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf</u>.



conditions of the Secretary's Declaration and guidance, as of the date that these staff pharmacists, pharmacy interns, and pharmacy technicians were authorized to order or administer these covered countermeasures. Such pharmacies qualify as "covered persons" under the PREP Act,⁴⁶ subject to other applicable requirements of the PREP Act and the Declaration. Such pharmacies are therefore immune from suit and liability under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of "covered countermeasures" as described in the Secretary's Declaration and guidance, including the administration or use of COVID-19 tests authorized, approved, or cleared by the FDA and the administration or use of FDA-authorized or FDA-licensed COVID-19 vaccines or ACIPrecommended childhood vaccinations. 42 U.S.C. § 247d-6d(a)(1).

The October 29, 2020 authorization further stated:

Any state or local law that prohibits or effectively prohibits those pharmacies that satisfy these requirements from distributing or administering COVID-19 vaccines, ACIPrecommended routine childhood vaccines, or COVID-19 tests as set forth above, is preempted. State and local laws that permit additional individuals to order or administer COVID-19 vaccines, ACIP-recommended routine childhood vaccines, or COVID-19 tests to additional persons are not preempted.

The October 29, 2020 authorization from OASH clarifies that pharmacies are authorized to administer certain covered countermeasures (including COVID-19 vaccinations) under the PREP Act and HHS COVID-19 PREP Act declaration and authorizations when their staff pharmacists order and administer, or their staff pharmacy interns and pharmacy technicians administer, these countermeasures consistent with the HHS COVID-19 PREP Act declaration and authorizations.

3. Other Qualified Persons Authorized to Administer COVID-19 Vaccinations Under Various Amendments to the HHS COVID-19 PREP Act Declaration

The Fifth, Sixth, and Seventh Amendments⁴⁷ to the HHS COVID-19 PREP Act declaration authorized an additional array of persons qualified to prescribe, dispense, or administer COVID-19 vaccines. In particular, the Seventh Amendment added a range of provider types that fall into the following 3 general categories: (1) licensed or certified healthcare professionals who may not

⁴⁶ See 42 U.S.C. 247d-6d(i)(3), (6), (8)(B).

⁴⁷ Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures against COVID-19, 86 Fed. Reg. 7872, (Feb. 2, 2021), <u>https://www.govinfo.gov/content/pkg/FR-2021-02-02/pdf/2021-02174.pdf</u>; Sixth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures against COVID-19, 86 Fed. Reg. 9516, (Feb. 16, 2021), <u>https://www.govinfo.gov/content/pkg/FR-2021-02-16/pdf/2021-03106.pdf</u>; Notice of Correction, Sixth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures against COVID-19, 86 Fed. Reg. 10,588, (Feb. 22, 2021), <u>https://www.govinfo.gov/content/pkg/FR-2021-02-22/pdf/2021-03526.pdf</u>; Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness and Emergency Preparedness Act for Medical Countermeasures against COVID-19, 86 Fed. Reg. 10,588, (Feb. 22, 2021), <u>https://www.govinfo.gov/content/pkg/FR-2021-02-22/pdf/2021-03526.pdf</u>; Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness and Emergency Preparedness Act for Medical Countermeasures Act for Medical Countermeasures against COVID-19, 86 Fed. Reg. 14,462, (Mar. 16, 2021), <u>https://www.govinfo.gov/content/pkg/FR-2021-03-16/pdf/2021-05401.pdf</u>



ordinarily prescribe, dispense, or administer vaccines; (2) certain healthcare providers whose licenses or certifications became inactive, lapsed, or expired; and (3) students in a healthcare profession training program, subject to appropriate training, supervision, and other specified requirements.⁴⁸ Following the Tenth Amendment to the declaration,⁴⁹ sections V(f) through V(h) of the declaration include the following list of persons authorized to administer COVID-19 vaccines, in addition to the pharmacy professionals and pharmacies described above.

Qualified Persons

- Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any state as of February 2, 2021, or who was authorized under the HHS COVID-19 PREP Act authorizations for pharmacists and pharmacy interns. These persons are authorized to prescribe, dispense, or administer COVID-19 vaccines in any jurisdiction where the PREP Act applies, other than the state in which the license or certification is held, in association with a COVID-19 vaccination effort by a federal, state, local, Tribal or territorial authority, or by an institution in the state in which the COVID-19 vaccine is administered, as long as the license or certification of the healthcare professional has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline, or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Indivdiuals/Entities maintained by the Office of Inspector General, subject to: documentation of completion of the CDC COVID-19 Vaccine Training Modules and, for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering intramuscular injections is in their ordinary scope of practice, who confirms competency of the healthcare provider in preparation and administration of the COVID-19 vaccine(s) to be administered. Thus, these qualified providers of COVID-19 vaccinations are authorized to practice across state lines. (Category first added in the Fifth Amendment.)
- Any member of a uniformed service (including members of the National Guard in a Title 32 duty status) ("service members") or Federal government employee, contractor, or volunteer who prescribes, administers, delivers, distributes, or dispenses a covered countermeasure (such as COVID-19 vaccines) on or after February 16, 2021. Such Federal government service members, employees, contractors, or volunteers are qualified

⁴⁸ This amendment revised and reorganized subsections V(f), (g), and (h) of the HHS COVID-19 PREP Act Declaration. The Seventh Amendment also added new categories of qualified persons under the PREP Act under subsection (h) and expanded the category of practitioners with expired licensure or certification that was added in the Fifth Amendment. Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures against COVID-19, 86 Fed. Reg. 14,462 (Mar. 16, 2021), https://www.govinfo.gov/content/pkg/FR-2021-03-16/pdf/2021-05401.pdf.

⁴⁹ The Tenth Amendment republished section V of the declaration but did not make changes to sections V(f) through V(h). Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 87 Fed. Reg. 982 (Jan. 7, 2022), at

https://www.federalregister.gov/documents/2022/01/07/2022-00151/tenth-amendment-to-declaration-under-thepublic-readiness-and-emergency-preparedness-act-for-medical.



persons if the following requirement is met: the executive department or agency by or for which the Federal service member, employee, contractor, or volunteer is employed, contracts, or volunteers has authorized or could authorize that service member, employee, contractor, or volunteer to prescribe, administer, deliver, distribute, or dispense the COVID-19 vaccine as any part of the duties or responsibilities of that service member, employee, contractor, or volunteer, even if those authorized duties or responsibilities or duties or responsibilities authorized duties or responsibilities or duties or

- Beginning with the Seventh Amendment, the declaration authorizes a wide range of additional healthcare professionals and students in a healthcare profession training program to administer COVID-19 vaccinations, subject to certain requirements described below. The effective date of these authorizations is March 11, 2021, except for physicians and nurses with recently expired licenses who had previously been authorized in the Fifth Amendment effective February 2, 2021; however additional requirements were added in the Seventh Amendment for these earlier-authorized physicians and nurses that became applicable as of March 11, 2021. These authorizations include:
 - a. Any midwife, paramedic, advanced or intermediate emergency medical technician (EMT), physician assistant, respiratory therapist, dentist, podiatrist, optometrist, or veterinarian, licensed or certified to practice under the law of any state, who prescribes, dispenses, or administers COVID-19 vaccines in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a state, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine is administered;
 - b. Any physician, advanced practice registered nurse, registered nurse, practical nurse, pharmacist, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, respiratory therapist, dentist, physician assistant, podiatrist, optometrist, or veterinarian who has held an active license or certification under the law of any state within the last five years, which is inactive, expired, or lapsed, who prescribes, dispenses, or administers COVID-19 vaccines in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a state, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine is administered, so long as the license or certification was not revoked by the licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General (a version of this authorization was included with the Fifth Amendment but included fewer practitioners);
 - c. Any medical, nursing, pharmacy, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, physician assistant, respiratory therapy, dental, podiatry, optometry, or veterinary student with appropriate training in administering vaccines as determined by his or her school or training program and supervision by a currently



practicing healthcare professional experienced in administering intramuscular injections who administers COVID-19 vaccines in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a state, local, Tribal or territorial authority, or by an institution in which the COVID-19 vaccine is administered.

- d. The above listed practitioners in (a)-(c) are subject to the following conditions and requirements:
 - The vaccine must be authorized, approved, or licensed by the FDA;
 - Vaccination must be ordered and administered according to CDC's/ACIP's⁵⁰ COVID-19 vaccine recommendation(s);
 - The healthcare professionals and students must have documentation of completion of the CDC COVID–19 Vaccine Training Modules and, if applicable, such additional training as may be required by the state, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID–19 vaccines;
 - The healthcare professionals and students must have documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering vaccinations is in their ordinary scope of practice, who confirms competency of the healthcare provider or student in preparation and administration of the COVID-19 vaccine(s) to be administered and, if applicable, such additional training as may be required by the state, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID-19 vaccines;
 - The healthcare professionals and students must have a current certificate in basic cardiopulmonary resuscitation;
 - The healthcare professionals and students must comply with recordkeeping and reporting requirements of the jurisdiction in which they administer vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the state or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine; and
 - The healthcare professionals and students comply with any applicable requirements (or conditions of use) as set forth in the CDC COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

⁵⁰ As noted above, where CDC/ACIP recommendations or similar language is used in the HHS COVID-19 PREP Act declaration and related guidance and opinions, this includes both direct CDC recommendations as well as recommendations adopted by the CDC Director after recommendation by ACIP, which are commonly referred to as ACIP recommendations.



4. Implications of HHS COVID-19 PREP Act Authorizations for State Medicaid and CHIP Provider Enrollment

The OASH authorization for pharmacies described above, in section V.B.2, has the following implications for state Medicaid and CHIP provider enrollment:

- Some states enroll pharmacies as Medicaid or CHIP providers, but do not provide a pathway
 to enrollment for individual pharmacists, pharmacy interns, or pharmacy technicians. These
 states need not begin to enroll pharmacists, pharmacy interns, or pharmacy technicians in
 order to provide Medicaid or CHIP coverage and reimbursement for COVID-19 vaccinations
 ordered or administered by these individuals in accordance with the HHS COVID-19 PREP
 Act declaration and authorizations. Instead, such a state may reimburse the enrolled
 pharmacy as the furnishing provider.
- In states that do recognize individual pharmacists as a Medicaid provider type eligible to enroll, individual pharmacists would be considered the furnishing Medicaid providers of the COVID-19 vaccinations they are authorized to administer and order under the HHS COVID-19 PREP Act declaration and authorizations, and must be enrolled in order to be reimbursed for such vaccinations. In this latter scenario, a pharmacy may bill for and receive Medicaid payment on behalf of its enrolled employee pharmacists who have reassigned their right to payment consistent with Medicaid regulations at 42 C.F.R. § 447.10(g)(1). While the provisions in 42 C.F.R. § 447.10 do not apply to separate CHIPs, pharmacies may also bill state CHIP agencies on behalf of their enrolled pharmacists to the extent permitted under state law.

States still must meet all other applicable federal requirements for covering the applicable benefit, such as reimbursing only those providers that are enrolled as Medicaid or CHIP providers and covering vaccinations only for eligible individuals.

For purposes of Medicaid and CHIP coverage and reimbursement, except as discussed above with respect to individual pharmacists, each of the healthcare professionals and individuals determined to be qualified persons under the HHS COVID-19 PREP Act declaration must generally be enrolled in Medicaid or CHIP, or work under the supervision of an enrolled practitioner, in order to be paid by the state Medicaid program or CHIP for prescribing, dispensing, or administering COVID-19 vaccines.

However, as noted, the Seventh Amendment to the HHS COVID-19 PREP Act declaration also authorized certain practitioners unlikely to be Medicaid- or CHIP-covered or enrolled practitioners, such as veterinarians, to prescribe, dispense, or administer COVID-19 vaccines, both if they are actively licensed or certified to practice and if their license or certification recently became inactive (provided certain conditions are met, as described above). Therefore, in order to more quickly effectuate payment for COVID-19 vaccinations provided by such practitioners, states may wish to seek waivers under section 1135 of the Act to streamline or modify federal provider screening and enrollment requirements in order to enroll these practitioners more quickly in Medicaid or CHIP during the period in which the HHS COVID-19 PREP Act declaration is effective. CMS notes, however, that the period of time for which any



section 1135 waiver is in effect may be different than the period of time for which the HHS COVID-19 PREP Act declaration may be in effect, and additional guidance may be issued by CMS.

C. UPDATED: Implications of HHS's COVID-19 PREP Act Declaration and Authorizations for Medicaid and CHIP Coverage and Reimbursement of COVID-19 Vaccinations

Various federal Medicaid and CHIP statutes and regulations expressly refer to state licensure or scope of practice laws. In particular, several CMS regulations governing Medicaid and CHIP benefits that states could use to cover COVID-19 vaccinations require that services be prescribed, furnished, recommended, or provided by practitioners acting within the scope of their practice as defined by state law. *See* 42 C.F.R. §§ 440.60 and 440.130(c), and 42 C.F.R. § 457.402(x). CMS interprets references to state law in federal Medicaid and CHIP laws and regulations as incorporating the PREP Act preemption of state law. In other words, if a state law is currently preempted by the PREP Act and HHS's COVID-19 PREP Act declaration and authorizations, CMS would interpret a reference in a federal Medicaid or CHIP statute or regulation to that state law to refer instead to the federal law preempting the state law. This means that if a person who is authorized to order and/or administer COVID-19 vaccines under the HHS COVID-19 PREP Act declaration and authorizations, a state may not deny Medicaid or CHIP coverage or reimbursement for the vaccine administration on the basis that state law does not authorize that person to order and/or administer it.

Additionally, consistent with Medicaid's freedom of choice requirement at section 1902(a)(23)(A) of the Act, CMS will expect states to provide Medicaid coverage for COVID-19 vaccinations ordered and administered by anyone who is authorized by the HHS COVID-19 PREP Act declaration and related authorizations to do so, during any time period when the HHS COVID-19 PREP Act declaration and related authorizations are in effect and Medicaid coverage of COVID-19 vaccinations is mandatory (such as during the ARP coverage period or the period when the state is subject to FFCRA section 6008(b)(4)). As discussed above, states are required to provide Medicaid coverage for COVID-19 vaccinations throughout the entire ARP coverage period. Additionally, as is also discussed above, if a state wants to claim the temporary FMAP increase under section 6008 of the FFCRA, section 6008(b)(4) of the FFCRA requires that the state provide Medicaid coverage for COVID-19 vaccinations, without the imposition of cost-sharing, during any quarter in which it claims the temporary FMAP increase, and this Medicaid coverage must include reimbursement of a vaccine administration fee or reimbursement for a provider visit during which a vaccine dose is administered, even if the vaccine dose is furnished to the provider at no cost.⁵¹ Section 1902(a)(23)(A) of the Act and 42 C.F.R. § 431.51 require

⁵¹ As discussed in the preamble to CMS-9912-IFC, there are some very limited circumstances in which the FFCRA section 6008(b)(4) coverage requirements would not apply. CMS does not interpret FFCRA section 6008(b)(4) to require states to provide COVID-19 testing and treatment services without cost-sharing to eligibility groups whose coverage is limited by statute or under an existing section 1115 demonstration to a narrow range of benefits that would not ordinarily include this coverage, such as groups that receive Medicaid coverage only for family planning



that Medicaid beneficiaries be able to obtain Medicaid-covered services from any qualified and willing provider. As discussed above, while they are in effect, HHS's COVID-19 PREP Act declaration and authorizations would essentially make any person who is authorized by and meets the conditions specified in the PREP Act, the declaration, and the authorizations qualified to administer COVID-19 vaccinations, notwithstanding state law to the contrary. Accordingly, during any period when Medicaid coverage of COVID-19 vaccinations is mandatory and when the HHS COVID-19 PREP Act declaration and related authorizations are in effect, CMS expects all state Medicaid programs, including in states where a state scope of practice of law is preempted by the HHS COVID-19 PREP Act declaration and authorizations, to identify a pathway to reimbursing persons for COVID-19 vaccinations provided to Medicaid beneficiaries if those persons are authorized by the HHS COVID-19 PREP Act declaration and authorizations to order and/or administer COVID-19 vaccines. States still must meet all other applicable federal requirements for covering the applicable benefit, such as reimbursing only those providers that are enrolled as Medicaid providers and covering vaccinations only for eligible individuals. CMS is available to provide technical assistance to states about how to ensure Medicaid reimbursement to the persons authorized to administer COVID-19 vaccines under the HHS COVID-19 PREP Act declaration and authorizations.

The same expectations do not apply, however, to separate CHIPs. Importantly, separate CHIPs are not subject to Medicaid's free choice of willing and qualified provider requirement. Thus, states operating separate CHIPs generally have flexibility to determine which health care providers they would reimburse for providing covered services, including COVID-19 vaccinations. That said, as outlined above, the HHS COVID-19 PREP Act declaration and authorizations establish that various individuals may order and/or administer COVID-19 vaccinations, if they do so consistently with the PREP Act and the HHS COVID-19 PREP Act declaration and authorizations. Accordingly, states operating separate CHIPs may not *deny* CHIP reimbursement to a CHIP provider for a covered COVID-19 vaccination on the basis that the provider is not licensed or authorized under state law to provide a COVID-19 vaccination, if the PREP Act and HHS' COVID-19 PREP Act declaration and authorizations permit that provider to do so. However, the PREP Act does not require the state's separate CHIP to pay providers or provider types it would not otherwise pay under the state plan.

For instance, if the state enrolls respiratory therapists as a CHIP provider type, but respiratory therapists are not licensed or authorized under state law to administer COVID-19 vaccines, then the state cannot deny CHIP payment for administering a COVID-19 vaccine to any respiratory therapist who is an enrolled CHIP provider and meets the conditions for the HHS COVID-19 PREP Act authorization on the basis that state law does not authorize the respiratory therapist to provide the COVID-19 vaccination. The same is true in Medicaid. However, if that respiratory therapist is not otherwise enrolled as a CHIP provider the state CHIP would not have to enroll and pay that respiratory therapist for a COVID-19 vaccination they administered to a CHIP beneficiary. In contrast, a state Medicaid program would have to enroll and pay that respiratory

services and supplies, or tuberculosis-related services. *See* CMS-9912-IFC, 85 Fed. Reg. 71,142, 71,148-50 (Nov. 6, 2020), at <u>https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency</u>. As outlined in *Section II.A. The American Rescue Plan Act of 2021*, the ARP closed most of these coverage gaps with respect to COVID-19 vaccination coverage.



therapist for a COVID-19 vaccination provided to a Medicaid beneficiary, provided that the therapist met all federal requirements to enroll as a Medicaid provider (such as screening requirements). Additionally, if a state CHIP does not already enroll respiratory therapists as a CHIP provider type, the state CHIP would not have to begin doing so solely to reimburse respiratory therapists for COVID-19 vaccinations that they are authorized to provide under the HHS COVID-19 PREP Act declaration and authorizations. In contrast, state Medicaid programs are expected to give all provider types authorized to administer COVID-19 vaccinations under the HHS COVID-19 PREP Act declaration and authorizations an opportunity to enroll as Medicaid providers and receive Medicaid payment for COVID-19 vaccinations provided to Medicaid beneficiaries.

Additionally, states operating separate CHIPs should be mindful of their obligation to ensure access to covered services under section 2102(a)(7) of the Act and 42 C.F.R. § 457.495. During this public health emergency, and for the reasons set forth in the HHS COVID-19 PREP Act declaration, states should consider whether ensuring access to vaccines requires them to reimburse the full array of persons authorized to administer COVID-19 vaccines under the HHS COVID-19 PREP Act declaration and authorizations—particularly for medically underserviced populations and populations facing transportation obstacles. For example, over 90 percent of Americans live within 5 miles of a pharmacy, and pharmacies often offer hours that are convenient.

VI. Medicaid & CHIP Reporting Requirements & Implications

Updated February 11, 2022

CMS intends to publicly report about vaccinations (at an aggregated, summary level) using data from the Transformed Medicaid Statistical Information System (T-MSIS), a uniform, national data system for Medicaid and CHIP.

On November 10, 2020, the AMA released the first CPT codes for reporting of immunizations for the novel coronavirus (SARS-CoV-2). These CPT codes are unique for each COVID-19 vaccine, and include administration codes unique to each such vaccine. The new codes are effective upon the relevant vaccine receiving Emergency Use Authorization or licensure from the FDA. For more COVID-19 CPT coding information, see https://www.ama-assn.org/practice-management/cpt/covid-19.



| Vaccine Code and Description | Vaccine Administration Code(s) | Vaccine Name(s) | NDC10/NDC11 Labeler Product ID (Vial) | Dosing Interval |
|--|---|--|--|--|
| 91300 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus diseases [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3mL dosage, diluent reconstituted, for intramuscular use. | 0001A (1 st dose) 0002A (2 nd dose) 0003A (3 rd dose) 0004A (Booster) | Pfizer- BioNTech COVID- 19 Vaccine | 59267-1000-1 59267-1000-01 | 1st Dose to 2nd Dose: 21 Days 2nd Dose to 3rd Dose (CDC recommended population[s] [eg, immunocompromised]): 28 or More Days Booster: Refer to FDA/CDC Guidance |
| 91305 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use. | 0051A (1st Dose) 0052A (2nd Dose) 0053A (3rd Dose) 0054A (Booster) | Pfizer- BioNTech COVID- 19 Vaccine | 59267-1025-1 59267-1025-01 | 1st Dose to 2nd Dose: 21 Days 2nd Dose to 3rd Dose (CDC recommended population[s] [eg, immunocompromised]): 28 or More Days Booster: Refer to FDA/CDC Guidance |
| 91307 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, trissucrose formulation, for intramuscular use | 0071A (1st Dose) 0072A (2nd Dose) 0073A (3rd Dose) | Pfizer- BioNTech COVID- 19 Vaccine | 59267-1055-1 59267-1055-01 | 1st Dose to 2nd Dose: 21 Days 2nd Dose to 3rd Dose (CDC recommended population[s] [eg, immunocompromised]) 28 or More Days |



| Vaccine Code and Description | Vaccine Administration Code(s) | Vaccine Name(s) | NDC10/NDC11 Labeler Product ID | Dosing Interval |
|---|---|---|--|--|
| 91301 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus diseases [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5mL dosage, for intramuscular use. 91308 | 0011A (1 st dose) 0012A (2 nd dose) 0013A (3 rd dose) 0081A (1st | Moderna COVID- 19 Vaccine Pfizer- | (Vial) 80777-273-10 80777-0273-10 59267-0078-1 | 1st Dose to 2nd Dose: 28 Days2nd Dose to 3rd Dose (CDC recommended population[s] [eg, immunocompromised]): 28 or More Days1st Dose to 2nd Dose: |
| Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, trissucrose formulation, for intramuscular use | Dose) 0082A (2nd Dose) | BioNTech COVID- 19 Vaccine | 59267-0078-1 59267-0078-01 59267-0078-4 59267-0078-04 | 21 Days |
| 91306 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.25 mL dosage, for intramuscular use | 0064A (Booster) | Moderna COVID- 19 Vaccine | 80777-273-10 80777-0273-10 | Refer to FDA/CDC Guidance |
| 91303 Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x1010 viral particles/0.5mL dosage, for intramuscular use. | 0031A (Single dose) | Janssen (Johnson & Johnson) COVID- 19 Vaccine | 59676-580-05 59676-0580-05 | Not applicable |



The Seventh Amendment to the HHS COVID-19 PREP Act declaration added dentists to the list of qualified persons authorized to administer COVID-19 vaccines in all states. On March 15, 2021, the ADA released the first dental procedure codes (Code on Dental Procedures and Nomenclature, or CDT Code) for reporting of COVID-19 vaccine administration. Note that because CDT codes cannot accommodate most modifiers, there are unique codes for administration of each COVID-19 vaccine, including discrete procedure codes for the first and second doses of two-dose vaccine regimens. The new codes are effective upon the relevant vaccine receiving Emergency Use Authorization or licensure from the FDA. For more COVID-19 CDT coding information, see

http://www.ada.org/~/media/ADA/Publications/Files/CDT_COVID_19_VaccinationProcedureC odeGuidance_2021Mar.pdf.

States have the option to allow dentists to use these dental codes, the AMA CPT codes, or both.

| Vaccine Code and Nomenclature | Descriptor |
|---|-----------------------------------|
| D1701 | SARSCOV2 COVID-19 VAC mRNA |
| | 30mcg/0.3mL IM DOSE 1 |
| Pfizer-BioNTech Covid-19 vaccine | |
| administration – first dose | |
| D1702 | SARSCOV2 COVID-19 VAC mRNA |
| | 30mcg/0.3mL IM DOSE 2 |
| Pfizer-BioNTech Covid-19 vaccine | |
| administration – second dose | |
| D1703 | SARSCOV2 COVID-19 VAC mRNA |
| | 100mcg/0.5mL IM DOSE 1 |
| Moderna Covid-19 vaccine administration - | |
| first dose | |
| D1704 | SARSCOV2 COVID-19 VAC mRNA |
| | 100mcg/0.5mL IM DOSE 2 |
| Moderna Covid-19 vaccine administration - | |
| second dose | |
| D1707 | SARSCOV2 COVID-19 VAC Ad26 5x1010 |
| | VP/.5mL IM SINGLE DOSE |
| Janssen Covid-19 vaccine administration | |

States should ensure that their Medicaid and CHIP providers use these standard procedure codes for COVID-19 vaccination claims and encounters and are submitting data to the state in a timely manner. States will send these standard codes to CMS through their monthly T-MSIS data submissions. T-MSIS will ensure that procedure codes meet applicable standards.

For purposes of claiming FFP associated with vaccine administration, states are expected to meet existing federal requirements regarding supporting documentation. (See, for example, 45 CFR Part 75 and 42 CFR §§ 430.30 and 433.32).



VII. Provider Enrollment in Medicaid & CHIP

Updated November 23, 2020

A. Summary of Medicaid & CHIP

In order for states to reimburse for vaccine administration, providers must enroll and periodically revalidate their enrollment in Medicaid. The same requirement applies to CHIP.⁵²

Section 1902(a)(27) of the Act requires states to execute Medicaid provider agreements with every person or institution providing services under the Medicaid state plan. These provider agreements are an important element of provider enrollment and require the person or institution to keep records as are necessary to fully disclose the extent of the services provided to individuals receiving assistance under the state plan, and to furnish the state agency with the needed information regarding any payments claimed by such person or institution for providing services under the Medicaid state plan. The provider agreement requirement does not apply to CHIP. In addition, section 1902(a)(78) of the Act requires all states that pay for medical assistance on a fee-for-service basis enroll all providers furnishing, ordering, prescribing, referring or certifying eligibility for Medicaid services. This provision is also applicable to CHIP pursuant to section 2107(e)(1)(D) of the Act.

Furthermore, as required by sections 1932(d)(6) and 2107(e)(1)(Q) of the Act, participating providers in the networks of Medicaid and CHIP managed care entities are required to be enrolled with state Medicaid and CHIP programs. See also 42 CFR §§ 438.608(b) and 457.1285 (expanding the requirement to additional types of managed care plans).

Notwithstanding these federal requirements for provider enrollment, states are encouraged to streamline their enrollment processes to the extent feasible, and work with entities such as state pharmacy boards to maximize efficiencies in registration and training processes.

B. Data Sharing Systems & Process for Provider Enrollment

In an effort to increase provider enrollment, CMS currently has a Medicare and Medicaid data sharing system and process in place to share the Medicare provider enrollment data with all state Medicaid and CHIP programs. The system for sharing this data is the CMS Data Exchange (DEX) system, which houses all state Medicaid termination data and Medicare revocation data. DEX also contains secure file sharing capability to allow for quick and secure transfer of Medicare screening and enrollment data.

CMS will use the DEX system to share data with the states on all existing and newly enrolling providers that will be administering the COVID-19 vaccine in Medicare in order to reduce the duplication and burden of provider-screening efforts across programs. CMS will also share results of provider screenings performed by Medicare, including verification of the provider's

⁵² These provider enrollment requirements do not apply to BHP.



licensure and practice location, so that states are not required to rescreen these same providers and can rely on the screening conducted by Medicare as authorized under 42 CFR § 455.410(c). If states have any questions about how to access the DEX system, they can reach out to DEXsupport@cms.hhs.gov.

As an additional approach to streamlining the provider enrollment process, Medicare Administrative Contractors (MACs) will share with newly enrolling providers contact information and/or the enrollment website for each state Medicaid program in order to facilitate the provider's next steps with regard to enrollment with the state. This process will ensure more continuity of providers across both programs and reduce state and provider burden.

These data sharing systems and processes may be used to enroll mass immunizers under the Medicare program into the Medicaid program. Medicare mass immunizers offer vaccines to large numbers of people and may operate in locations like supermarkets or drug stores. Medicare mass immunizers must be licensed in the state in which they operate, if applicable, and must utilize roster billing. States may consider similar processes under Medicaid.

C. Emergency Flexibilities Available during All Public Health Emergencies

States may seek waivers under section 1135 of the Act to temporarily waive or modify certain Medicaid and CHIP requirements to ensure that sufficient health care items and services are available to meet the needs of beneficiaries during a PHE.⁵³ On March 22, 2020, CMS shared with states a checklist template of relevant and commonly requested section 1135 waiver authorities to expedite their ability to apply for and receive approval for these waivers.⁵⁴ In particular, states may request the ability to waive certain screening requirements to allow for a temporary and more expedient provider enrollment process.

During the PHE, states may request a section 1135 waiver to temporarily enroll providers who are not enrolled with another state Medicaid agency or Medicare for the duration of the PHE by waiving certain screening and enrollment requirements, such as payment of application fee, criminal background fingerprint-based checks, site visits and temporarily ceasing revalidation. If permissible under state law, states may also request 1135 flexibility to waive the provider agreement requirement. With this flexibility, states will be required to maintain documentation regarding each provider's enrollment application, disclosures, and screening results, but a signed provider agreement will not be required until after the PHE has ended.

However, states must cease payment to providers who are temporarily enrolled within six months from the date that the disaster designation is lifted, unless a provider has submitted an application that meets all requirements for Medicaid participation and that application was subsequently reviewed and approved by the state.

⁵³ https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers

⁵⁴ https://www.medicaid.gov/resources-for-states/disaster-response-toolkit/section-1135-waiver-flexibilities/index.html



VIII. Education & Outreach

Updated February 11, 2022

Education and outreach will be critical to ensuring that beneficiaries and providers are aware of the availability of the COVID-19 vaccine(s), and that beneficiaries understand where they can receive a COVID-19 vaccine(s), the number of required and available doses and spacing between doses (if a multi-dose vaccine is used), and how to obtain additional information.

CMS encourages states to review COVID-19 immunization messaging frequently to ensure it encompasses any new recommendations, and consider coordinating with local and state chapters of healthcare professional organizations, faith groups, community-based groups, tribes and tribal organizations, schools, and other groups that engage with children and their families to share updated messaging. States may use Medicaid and CHIP administrative matching funds for beneficiary and provider education and outreach. Allowable outreach activities can be matched at the 50 percent FFP rate under Medicaid, per 42 CFR 433.15(b)(7), and at the applicable EFMAP rate under CHIP, subject to the 10 percent limit on administrative expenditures, per 42 CFR 457.618. Examples of outreach activities eligible for administrative match include:

- Developing and/or disseminating materials to inform Medicaid and CHIP eligible children and their families about the availability of Medicaid and CHIP services such as COVID-19 vaccine administration;
- Distributing literature about the benefits and availability of the COVID-19 vaccine to Medicaid- and CHIP-eligible children and their families; and
- Participating in or coordinating provider trainings with enrolled Medicaid and CHIP providers regarding the benefits of Medicaid and CHIP covered services such as COVID-19 vaccine administration and how to assist children and their families in accessing such services.

It is also essential that states emphasize the importance of immunizations in general, as data shows that there have been significant decreases in routine immunizations during the PHE. In addition, it remains critical that Americans receive their flu vaccinations during the PHE.

Highlighted below are a number of actions that states might opt to take relating to outreach and education, as well as resources available to states. In general, states are encouraged to coordinate with their state and local health departments and to partner with other stakeholders to promote coordinated messaging. This is particularly important during the COVID-19 pandemic.

In addition to recommendations to improve education, outreach, and immunization rates, this toolkit provides links to a number of resources and immunization campaigns that include ready-to-use materials that can be used for state campaigns and messaging.



A. Coverage & Access

- Develop coverage language for the COVID-19 vaccine(s). Add that language to coverage materials, manuals, periodicity schedules, beneficiary materials, and your state's website. Share with stakeholders for inclusion in managed care and provider materials.
- Partner with your state and/or local public health agencies and to develop and share coordinated materials regarding coverage of COVID-19 vaccines.
- Assess the provider types that can administer immunizations in your state. Consider whether there should be expansions of providers, including mass immunizers. For more information, see Section V. C. Implications of HHS's COVID-19 PREP Act Declaration and Authorizations for Medicaid and CHIP Coverage and Reimbursement of COVID-19 Vaccinations.

B. Payment

- Review vaccine/vaccine administration reimbursement rates. Determine if the rates are sufficient and if they are accurately reflected in your Medicaid state plan, provider materials, physician fee schedule, etc.
- Ensure that the Medicaid state plan as well as payment and billing policies are updated to allow qualified providers to provide for vaccine administration and that providers have provider agreements with the state Medicaid agency. Note: In order to claim FFP for vaccine administration at alternative service sites, a provider must be qualified and have a provider agreement in place.
- Consider whether state billing manuals appropriately reflect policies to streamline and facilitate vaccine administration processes (e.g., through roster billing).
- Explain that, in accordance with regulations at 42 CFR § 447.15, providers may not balance bill Medicaid beneficiaries amounts additional to the amount paid by the state agency plus any deductible, coinsurance or copayment required by the state plan to be paid by the beneficiary.
- Consider implementing payment and reimbursement incentives to encourage improvement in immunization rates.
- Consider use of a uniform billing standard for vaccine claims (e.g., the National Council for Prescription Drug Programs (NCPDP) standard for pharmacy billings).

C. Engaging with Stakeholders

• Review immunization messaging to determine if it is accurate. Review the accuracy of translated materials and determine if the languages reflect state Medicaid, CHIP and BHP populations.



- Consider coordinating with state and local health departments, Women, Infant and Children (WIC) clinics, local health clinics, FQHCs, tribal organizations, and school-based health centers on messaging. Encourage these entities to provide immunizations within the scope of their services.
- Consider coordinating with faith groups, community based groups, tribal organizations, private schools, and other groups to share messaging.

D. Immunization Reporting

 CDC requires that vaccination providers report certain data elements for each COVID-19 dose administered within 24 hours of administration. Information on immunization reporting requirements as well as other requirements for providers participating in CDC's COVID-19 Vaccination program are available at <u>https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html</u>.

E. Outreach & Education

- CDC has developed communications resources for states and other stakeholders that include fact sheets, sample social media messaging relating to vaccine hesitancy, vaccine safety, and encouraging vaccination. These resources are available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/resource-center.html.
- FDA has developed communications resources for states and other stakeholders that include fact sheets, sample social media messaging relating to vaccine hesitancy, vaccine safety, and encouraging vaccination. These resources are available at www.fda.gov/covid19vaccines.
- CDC has also emphasized the importance of flu vaccinations in order to reduce hospitalizations and therefore reserve resources for COVID-19 response. CDC's flu campaign began on October 1, 2021, and information and flu campaign materials are available at <u>https://www.cdc.gov/flu/season/index.html</u>. In addition, CMS has information on <u>flu vaccinations for the Medicare population</u> on cms.gov.



COVID-19 Federal Resources from HHS

Updated February 11, 2022

Medicaid COVID-19 Resources: <u>https://www.medicaid.gov/resources-for-states/disaster-</u>response-toolkit/coronavirus-disease-2019-covid-19/index.html

COVID-19 Frequently Asked Questions for State Medicaid and Children's Health Insurance Program (CHIP) Agencies: <u>https://www.medicaid.gov/state-resource-center/downloads/covid-19-faqs.pdf</u>

Public Readiness and Emergency Preparedness Act (PREP Act) Declarations and Guidance: <u>https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx</u>

CDC COVID-19 Vaccine Information for Providers: <u>https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html</u>

CDC COVID-19 Vaccination Toolkits: <u>https://www.cdc.gov/vaccines/covid-19/toolkits/index.html</u>

ACIP COVID-19 Vaccine Recommendations: <u>https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html</u>

CDC Communication Resources for COVID-19 Vaccines: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/resource-center.html

FDA COVID-19 Vaccine Resources: <u>https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines</u>

FDA COVID-19 Vaccine Booster Eligibility: <u>https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/do-i-qualify-covid-19-vaccine-booster-and-which-one</u>

HHS COVID-19 Public Education Campaign: https://wecandothis.hhs.gov/

CDC COVID-19 Vaccine Effectiveness Information: <u>https://www.cdc.gov/vaccines/covid-19/effectiveness-research/protocols.html</u>

CDC COVID-19 Vaccine Safety Information: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html</u>

CDC COVID-19 Vaccine Information for Children Age 5-11:

https://www.cdc.gov/vaccines/covid-19/planning/children.html and



https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/childrenteens.html?CDC_AA_refVal=https% 3A% 2F% 2Fwww.cdc.gov% 2Fcoronavirus% 2F2019ncov% 2Fvaccines% 2Frecommendations% 2Fadolescents.html

Glossary of Terms & Resources

| Term | Resources |
|---|---|
| ABP (Alternative Benefit Plan) | More information available at <u>https://www.medicaid.gov/medicaid/benefits/alternative-benefit-plan-coverage/index.html</u> |
| ACIP (Advisory Committee on Immunization Practices) | More information available at https://www.cdc.gov/vaccines/acip/index.html. Recommendations made by the ACIP are reviewed by the CDC Director and, if adopted, are published as official CDC/HHS recommendations in the Morbidity and Mortality Weekly Report (MMWR). The CDC also publishes annual child and adult vaccine schedules, which reference ACIP recommendations. The vaccine schedules are available at https://www.cdc.gov/vaccines/schedules/index.html. |
| BHP (Basic Health Program) | PPACA gave states the option to offer Basic Health Programs (BHP) to certain individuals under 200% FPL; more information at https://www.medicaid.gov/basic-health-program/index.html. 42 CFR § 600.510(b) prohibits BHP from imposing cost-sharing with respect to the preventive health services or items, as defined in, and in accordance with 45 CFR § 147.130. |
| CHIP (Children's Health Insurance Program) | More information is available at https://www.medicaid.gov/chip/benefits/index.html. 42 CFR § 457.410 requires states with a separate CHIP to provide coverage for age-appropriate immunizations in accordance with the recommendations of the ACIP, regardless of the type of health benefits coverage; more information is available at <u>https://www.medicaid.gov/chip/benefits/index.html</u> |



| Term | Resources |
|--|--|
| EHB (Essential Health Benefits) | More information available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and- FAQs/ehb-2-20-2013 and https://www.healthcare.gov/preventive-care-adults/ |
| EPSDT (Early and Periodic Screening, Diagnostic, and Treatment benefit) | Defined at section 1905(r) of the Social Security Act; more information available at <u>https://www.medicaid.gov/medicaid/benefits/early-and-periodic-</u> <u>screening-diagnostic-and-treatment/index.html</u> |
| FMAP (Federal Medical Assistance Percentage) | The percentage of state expenditures on items and services defined as "medical assistance" in the Medicaid statute that is paid by the Federal Government. |
| PPACA (The Patient Protection and Affordable Care Act) | The Patient Protection and Affordable Care Act (Pub. L. 111– 148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this document, we refer to the two statutes collectively as the "Patient Protection and Affordable Care Act" or "PPACA." Authorized states to expand Medicaid coverage to individuals ages 19 through 64 with income at or below 133% of the federal poverty level (referred to as Group VIII Adults); more information available at <u>https://www.medicaid.gov/medicaid/eligibility/index.html</u> . |
| VFC (Vaccines for Children Program) | Authorized under section 1928 of the Social Security Act; more information at https://www.cdc.gov/vaccines/programs/vfc/about/index.html and https://www.medicaid.gov/medicaid/quality-of-care/quality- improvement-initiatives/quality-of-care-vaccines/index.html |