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

Disclaimer: The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

March 15, 2021

Table of Contents

Focus of this Toolkit*** 4
I. UPDATED: Clinical & Operational Considerations for Potential COVID-19 Vaccines*** 5
II. Medicaid, CHIP, and BHP Coverage and Reimbursement 8
A. The Families First Coronavirus Response Act (FFCRA) (Pub. L. 116-127) 8
B. UPDATED: Adults Covered under Traditional Medicaid** 9
C. Beneficiaries Enrolled in Alternative Benefit Plans (ABPs) 13
D. UPDATED: Children Covered under Medicaid** 15
E. Medicaid Beneficiaries Receiving Limited Benefit Packages 16
F. UPDATED: Separate CHIP Coverage & Reimbursement** 18
G. BHP Coverage & Reimbursement 19
III. UPDATED: Medicaid & CHIP Managed Care** 23
A. Coverage 23
B. Credentialing & Contracting 23
IV. UPDATED: Medicaid and CHIP SPA Templates, BHP Blueprints, and Streamlined Review Process*** 25
A. Medicaid 25
B. CHIP & BHP 31
V. Other Federal Requirements & Considerations* 31
A. PREP Act 31
B. HHS PREP Act Authorizations Related to COVID-19 Vaccinations 32
C. PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures 34
D. Implications of HHS's COVID-19 PREP Act Declaration and Authorizations for Medicaid and CHIP Coverage and Reimbursement of COVID-19 Vaccinations 36
VI. UPDATED: Medicaid & CHIP Reporting Requirements & Implications* 38
VII. UPDATED: Provider Enrollment in Medicaid & CHIP* 39
A. Summary of Medicaid & CHIP 39
B. Data Sharing Systems & Process for Provider Enrollment 39
C. Emergency Flexibilities Available during All Public Health Emergencies 40
VIII. Education & Outreach 41

A. Coverage & Access 41
B. Payment 41
C. Engaging with Stakeholders 42
D. Immunization Reporting 42
E. Outreach & Education 42
COVID-19 Federal Resources from the CDC & HHS 44
Glossary of Terms & Resources 45

* Updated November 23, 2020
** Updated December 17, 2020
*** Updated March 15, 2021

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

UPDATED: Focus of this Toolkit

Updated March 15, 2021

UPDATE: This version of the toolkit reflects the updated Medicare vaccine administration payment rates. The American Rescue Plan Act (ARPA)(P.L. 117-2) was signed by President Biden on March 11, 2021 and included 100 percent FMAP for COVID-19 vaccines and their administration as well as an expansion of individuals eligible for COVID-19 vaccine administration coverage. The toolkit does not yet reflect all changes made by the ARPA and will be updated to reflect the legislation shortly.

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 74.6 million Medicaid and CHIP beneficiaries and the nearly 900,000 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 Centers for Medicare & Medicaid Services (CMS) expects that the initial supply of COVID-19 vaccines will be federally purchased, this toolkit primarily focuses on coverage of vaccine administration. 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. CMS will also provide links to vaccine information, including data on vaccine efficacy and safety, when it becomes available.

Within this toolkit, we address:

- Clinical and operational considerations of potential COVID-19 vaccines, and the vaccination planning that should be undertaken across the three programs;
- 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(b) of the Social Security Act (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 need to take, if any;

[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 eligible for Medicaid under Alternative Benefit Plans, or individuals limited by statute or an existing 1115 demonstration to a narrow range of benefits that would not ordinarily include vaccine coverage.

- 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. UPDATED: Clinical & Operational Considerations for Potential COVID-19 Vaccines

Updated March 15, 2021

While this toolkit does not describe all clinical and operational considerations for COVID-19 vaccines, it highlights important details related to COVID-19 vaccines and distribution.

1. **Cold-chain:** While most COVID-19 vaccines are stored in a standard refrigerator or freezer, some COVID-19 vaccines require ultra-low temperature storage (e.g., -70° Celsius). This may prove challenging for transporting, storing, and handling of the vaccines as temperature fluctuations at any point across the cold chain may influence the efficacy of the vaccine. States should identify capacities for vaccine distribution and administration based on these important distinctions, as well as in determining reimbursement for administration.

2. **Dose sequence:** Candidate vaccines may be a single-dose vaccination or part of a two dose series. States and organizations should proactively address planning for and identifying resources to engage patients for both initial vaccination and then completion of the vaccine series in advance of vaccine receipt.

3. **UPDATED: Vaccination planning:** The Centers for Disease Control and Prevention (CDC) guidance[2] outlines what to expect for vaccination planning, including actions states can take now in order to plan for COVID-19 vaccinations. The CDC indicated that planning must be flexible as several vaccine candidates are in development. The initial priority populations for vaccination are healthcare personnel and residents of long-term care facilities (see more on Phase 1a in *Priority of overall vaccine distribution* below). CDC has provided guidance on requirements for reporting the administration of COVID-19 vaccines into a state

[2] This guidance can be found at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html

immunization registry or other vaccine tracking system, which is available on the CDC's website. Links to CDC documents that provide guidance on planning, such as "The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine" (https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf) are located at the end of this toolkit under *Resources*.

4. **UPDATED: Priority of overall vaccine distribution:** While the federal government expects that there will be a sufficient supply of vaccine to distribute to all beneficiaries, distribution is being conducted in phases. The Advisory Committee on Immunization Practices (ACIP) and the CDC have issued guidance on the initial groups identified for vaccination, Phase 1a, and will provide additional guidance on the additional groups in Phase 1 as well as the other phases of vaccine distribution. ACIP recommendations are available at: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html. It is important to note that states are establishing their own prioritization based on the ACIP recommendations. Therefore, state Medicaid and CHIP agencies should coordinate with their state health departments, as well as a wide range of other public and private sector partners and providers to implement this guidance. In addition, states should develop plans to outreach to populations that are traditionally hard to reach.

5. **Pharmacy and provider 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. Under the 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. Following vaccination, vaccine recipients must be provided with emergency use authorization (EUA) Fact Sheets on the vaccine and vaccination cards. Providers must also administer the vaccine in accordance with CDC and ACIP requirements, and must meet storage and recordkeeping requirements, including recording the administration of the vaccine to patients in their own systems within 24 hours, and to public health data systems as soon as practical, and within 72 hours. For more information on the CDC recordkeeping requirements, see the link located in the *Education & Outreach section, item 4, Immunization Reporting*, below: https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf. Providers administering the vaccine to people without health insurance or whose insurance does not provide coverage of the vaccine, can request reimbursement for the administration of the COVID-19 vaccine through the Health Resources & Services Administration (HRSA) COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured Fund, see https://www.hrsa.gov/CovidUninsuredClaim.

6. **UPDATED: Pediatric vaccine distribution:** The Pfizer-BioNTech COVID-19 vaccine is recommended by the ACIP for those age 16 and over. This means that Medicaid beneficiaries age 16-18 receiving care in long term care facilities, or Medicaid and CHIP beneficiaries volunteering or working in healthcare facilities may be able to immediately receive the Pfizer-BioNTech COVID-19 vaccine in Phase 1a, based on state vaccine

distribution prioritization. Distribution of the Pfizer-BioNTech and other EUA approved COVID-19 vaccines for those under age 19 will be through the COVID-19 Vaccination Program, just as for adults. To provide vaccine to this age group, a provider will need to be enrolled to be a COVID-19 vaccine provider. Because vaccine distribution is outside of the VFC program, a provider does not need to be enrolled in the VFC program to administer a COVID-19 vaccine to child eligible for the VFC program (i.e., under age 19). It is expected that a COVID-19 vaccine for younger children will become available in 2021.

7. **Beneficiary incentives:** CMS will be providing more information regarding whether beneficiary incentives will be permitted in connection with COVID-19 vaccination during the PHE.

8. **UPDATED: 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 published[3] codes for two potential vaccines on November 10, 2020. States should continue to monitor the AMA CPT code publications to stay current on the COVID-19 vaccine product codes as they are published.

9. **UPDATED: Medicare Payment:** On March 15, 2021, CMS is updating 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 vaccine. This means that starting on March 15, 2021, for single dose 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. This rate reflects 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. The rate will be geographically adjusted based on where the service is furnished.

   CMS recognizes that Medicare's announcement of changes in the payment for COVID-19 vaccine administration, combined with authorization of a temporary 100 percent FMAP effective April 1, 2021 in the American Rescue Plan Act 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 for vaccine administration. States with questions on the impact of these changes on their program should contact CMS for technical assistance. CMS intends to provide additional guidance to states on implementation of the 100 percent FMAP available for payments to providers for administering the COVID-19 vaccines.

[3] COVID-19 CPT coding and guidance, November 10, 2020: https://www.ama-assn.org/practice management/cpt/covid-19-cpt-coding-and-guidance

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

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 a COVID-19 vaccine 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 are also geographically adjusted.[4]

II. Medicaid, CHIP, and BHP Coverage and Reimbursement [5]

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

Under section 6008 of the FFCRA, state and territorial Medicaid programs may receive a temporary 6.2 percentage point increase in the Federal Medical Assistance Percentage (FMAP). This temporary FMAP increase could be available through the end of the quarter in which the COVID-19 PHE ends, if the state claims the increase in that quarter. 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;[6] and the state must maintain the enrollment of beneficiaries who were enrolled as of or after March 18, 2020.[7] 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 FFCRA section 6008.

As of the time of the publication of this document, CMS is not aware of any states or territories not currently claiming this temporary FMAP increase, or of any states or territories that intend to cease claiming it. Accordingly, Medicaid coverage of COVID-19 vaccines and their administration, without cost sharing is expected to be available for most Medicaid beneficiaries

[4] Note: these rates do not apply for entities that are reimbursed for preventive vaccines and their administration at reasonable cost

[5] As the vaccine will be federally purchased, normal third party liability rules will apply for vaccine administration.

[6] 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 without jeopardizing the state's eligibility for the temporary 6.2 percentage point FMAP increase.

[7] 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 October 28, 2020.

through the end of the quarter in which the COVID-19 PHE ends in states and territories that continue to claim the 6.2 percentage point increase in FMAP throughout the entire period.

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, including vaccines and 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 (see *Section E. Medicaid Beneficiaries Receiving Limited Benefit Packages* below for more information).

The FFCRA section 6008(b)(4) requirement does 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.

B. UPDATED: Adults Covered under Traditional Medicaid

Updated December 17, 2020

1. UPDATED: COVID Vaccines & Vaccine Administration Coverage

As CMS expects that the initial supply of COVID-19 vaccines will be federally purchased, states would not be expected to provide Medicaid coverage and reimbursement for the vaccine itself. The following sections describe coverage of vaccine administration.

During the PHE
Coverage of COVID-19 vaccine administration is mandatory for most Medicaid beneficiaries, without cost sharing, during any quarter for which the state or territory claims the temporary FMAP increase under FFCRA section 6008. The FMAP increase is available through the end of the quarter in which the COVID-19 PHE ends, if the state claims the temporary FMAP increase in that quarter. This includes compensating Medicaid providers with a vaccine administration fee or reimbursement for a provider visit during which a vaccine dose is administered. States are not required to provide this coverage for certain beneficiaries receiving limited benefit packages. (See Section E. Medicaid Beneficiaries Receiving Limited Benefit Packages below for more information.)

If a state provides for COVID-19 vaccine administration coverage and/or payment under a Disaster Relief Medicaid SPA, and wishes to claim the FFCRA section 6008 temporary FMAP increase in the quarter in which the COVID-19 PHE ends, the state would need to prepare to have a SPA in place under the traditional SPA submission process after its Disaster Relief Medicaid SPA expires, to effectuate coverage and payment for COVID-19 vaccinations at least through the end of the quarter in which the COVID-19 PHE ends. The traditional SPA submission process includes, under 42 CFR § 447.205, publication of notice before the SPA's

effective date for any significant proposed change in the state's methods and standards for setting payment rates for services.

Outside of the PHE
Outside of the period in which FFCRA section 6008(b)(4) applies, coverage of ACIP-recommended vaccinations without cost sharing will be mandatory for adults enrolled in an ABP (see Section C. 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 opt to receive a one percent increase in 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 other clinical preventive services.[8] In electing such coverage, states must adhere to the following parameters:

- States claiming the one percent 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 vaccines and their administration.
- The one percent increase in the FMAP, pursuant to section 1905(b) of the Act, applies to expenditures for services provided through fee-for-service (FFS) or managed care, or under a benefit package under an ABP. States that seek the one percent FMAP increase would need to include coverage of ACIP-recommended COVID-19 vaccines for adults in their Medicaid programs.
- Most state Medicaid programs cover at least some of the ACIP-recommended vaccines and the administration of those vaccines for adults. Therefore, it is possible that states might cover ACIP-recommended COVID-19 vaccine(s) for adults, and, at their option, states could also cover vaccines authorized by the FDA.

Outside of the period in which FFCRA section 6008(b)(4) applies, 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).

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

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

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.

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

Gaps in Coverage
As described above, after the period when FFCRA section 6008(b)(4) applies, states have discretion to cover COVID-19 vaccine administration to many adult eligibility groups outside of the PHE that are not eligible for mandatory coverage. In addition, even during the period when FFCRA section 6008(b)(4) applies, coverage is not available for beneficiaries receiving limited benefit packages as described further below.

The COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment, and Vaccine Administration for the Uninsured Fund (COVID-19 Claims Reimbursement program) administered by HRSA is available for reimbursement of a COVID-19 vaccine and vaccine administration costs for individuals who would not receive Medicaid coverage for a COVID-19 vaccine or its administration.

SPA/Waiver Requirements for Coverage
A SPA is not required for coverage of the initial supply of COVID vaccine(s) as they will be federally purchased.

A state may need to submit a SPA to newly add or amend coverage of the administration of the vaccine under the preventive services or OLP benefits. If a state includes vaccine administration under one of the mandatory benefits noted above, or under the optional clinic benefit, a state would not need to submit a SPA, as CMS does not require states to enumerate all the services or items covered under these benefits.

For the period of the PHE, a state can elect to use the Medicaid disaster relief SPA template (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 the COVID-19 vaccine(s) administration is mandatory for most adults, without cost sharing, during any quarter for which the state or territory claims the temporary FMAP increase under section 6008(b)(4) of FCCRA, including through the end of the quarter in which the COVID-19 PHE ends, if the state claims the temporary FMAP increase in that quarter.

Outside of the period when FFCRA section 6008(b)(4) applies, coverage of ACIP-recommended vaccines and vaccine administration is mandatory and must be provided without cost sharing to populations receiving coverage through an ABP, and to adults in states that have opted to implement section 1905(a)(13)(A) and (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 a SPA to impose cost sharing where permitted, outside of the PHE.

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

3. UPDATED: Reimbursement of the Vaccine and Vaccine Administration

Since CMS expects that the initial supply of COVID-19 vaccines will be federally purchased, Medicaid would not reimburse providers for the vaccine; as such, no SPA submission would be necessary to describe reimbursement of the vaccine product.

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 professional 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 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.

SPA/Waiver Requirements for Reimbursement

States will need to submit SPAs to describe payment for the vaccine administration to the extent that the payment is different from what 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 authorize the payments through the Disaster Relief Medicaid SPA template, which 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*).

C. Beneficiaries Enrolled in Alternative Benefit Plans (ABPs)

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 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

As CMS expects that the initial supply of COVID-19 vaccines will be federally purchased, states would not be expected to provide Medicaid coverage and reimbursement for the vaccine itself. The following sections describe coverage of vaccine administration.

During the PHE
As mentioned earlier, coverage of COVID-19 vaccine administration without cost sharing is mandatory for most Medicaid beneficiaries, including all children and adults enrolled in ABPs, during any quarter for which the state or territory claims the temporary FMAP increase under FFCRA section 6008. In addition, due to updates made to 45 CFR §147.130 in the Interim Final Rule to Address the Impact of COVID-19 released on October 28, 2020, Medicaid ABPs must provide coverage for and must not impose any cost sharing for "qualifying coronavirus preventive services," including a COVID vaccine during the PHE. For managed care, this applies regardless of whether the vaccine is delivered by an in-network or out-of-network provider.

Outside of the PHE
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 and a vaccine is recommended by ACIP.

SPA/Waiver Requirements for Coverage
No SPA is necessary to amend the coverage provisions of an ABP when a state implements coverage of new ACIP recommendations, either during or outside the period in which FFCRA section 6008(b)(4) applies.

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

2. Cost Sharing

There is no cost sharing for ACIP-recommended vaccines provided through an ABP.

3. Reimbursement

Since CMS expects that the initial supply of COVID-19 vaccines will be 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 policy options as are discussed above under *Section B. Adults in Medicaid.*

SPA/Waiver Requirements for Reimbursement
A state will need to amend its reimbursement page if the state uses a vaccine administration reimbursement methodology that is different from the currently approved methodology or establishes vaccine administration under the ABP specific to a COVID-19 vaccine product that is not otherwise covered and paid as a Medicaid state plan service.

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

D. UPDATED: Children Covered under Medicaid

Updated December 17, 2020

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

The Pfizer-BioNTech vaccine is recommended for those age 16 and over. Approval of a vaccine for children under age 16 is expected in 2021. Just as for adults, the initial supply of pediatric COVID-19 vaccines will be federally purchased; therefore, states would not be expected to provide Medicaid coverage and reimbursement for the vaccine itself. The following sections describe pediatric coverage of vaccine administration.

During the PHE
As discussed above, under section 6008(b)(4) of FFCRA, coverage of COVID-19 vaccine administration without cost sharing is mandatory for most Medicaid beneficiaries, including most children, without cost sharing, during any quarter for which the state or territory claims the temporary FMAP increase.

In general, coverage of vaccine administration for ACIP-recommended vaccines is mandatory for Medicaid-enrolled 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). Therefore, ACIP-recommended COVID-19 vaccine administration is mandatory for children enrolled in Medicaid through age 20.

Outside of the PHE
As stated above, coverage of administration for all ACIP-recommended vaccines is mandatory for Medicaid-enrolled 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 Medicaid-eligible children through age 18, at this time, all EUA approved COVID-19 vaccines will be provided through the COVID-19 Vaccination Program, other COVID-19 and therefore, outside of the VFC program.

Gaps in Coverage
There are no gaps in coverage of a COVID-19 vaccine approved by ACIP for Medicaid-enrolled children through age 20 who are eligible for the EPSDT benefit, either during or outside the period in which FFCRA section 6008(b)(4) applies.

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.

2. Cost Sharing

During the period in which FFCRA section 6008(b)(4) applies, cost sharing may not be imposed for vaccine administration during any quarter for which the state or territory claims the temporary FMAP increase under FFCRA section 6008.

Outside of the period in which FFCRA section 6008(b)(4) applies, 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 services 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.

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

3. UPDATED: Reimbursement of the Vaccine and Vaccine Administration

Since CMS expects that the initial supply of COVID-19 vaccines will be federally purchased, Medicaid would not reimburse providers for the vaccine so no SPA submission would be necessary to describe reimbursement of the vaccine product.

State Medicaid programs pay providers a state-determined administration fee for administering a vaccine. Because the Pfizer-BioNTech vaccine for individuals aged 16–18 will be distributed outside of the VFC program, the VFC regional maximum administration fees do not apply. States should review existing vaccine reimbursement SPAs to determine if they want to make changes to the vaccine administration fee for those under age 19.

SPA/Waiver Requirements for Reimbursement
No SPA is required unless the state adds or amends a payment methodology or administration fee rate.

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

E. Medicaid Beneficiaries Receiving Limited Benefit Packages

1. COVID-19 Vaccine & Vaccine Administration Coverage

As the initial supply of COVID-19 vaccines will be federally purchased, states would not be expected to provide Medicaid coverage and reimbursement for the vaccine itself. The following sections describe coverage of vaccine administration.

During & Outside of the PHE
Medicaid includes several eligibility groups that receive limited benefit packages under statutory authority or existing section 1115 demonstration authority. States are not required to cover COVID-19 vaccine administration for these groups either during or after the period in which FFCRA section 6008(b)(4) applies.

Gaps in Coverage
As discussed in the Interim Final Rule to Address the Impact of COVID-19 released on October 28, 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. Additionally, after FFCRA section 6008(b)(4) no longer applies in a state, the state would generally lack authority to cover COVID-19 vaccinations for these 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 both during and outside of the period in which FFCRA section 6008(b)(4) applies:

- Individuals eligible only for family planning benefits: Although states may furnish vaccines under preventive services, typically these vaccines would be limited to those 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 the treatment of tuberculosis and do not include vaccines;
- Individuals eligible for the optional COVID-19 testing group: Benefits and services for this group do not include vaccines; and
- Section 1115(a)(2) expenditure authority limited benefit group(s): Several states have 1115(a)(2) demonstration authority to provide a limited benefit package to select beneficiaries not otherwise eligible for Medicaid.

HRSA COVID-19 Claims Reimbursement is available for reimbursement of COVID-19 vaccine administration costs for individuals receiving Medicaid coverage for only limited benefit packages.

In addition, states wishing to address these gaps in vaccine coverage could choose to use 1115(a)(2) expenditure authority to add coverage for COVID-19 vaccines to these benefit packages, subject to federal approval. 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.

F. UPDATED: Separate CHIP Coverage & Reimbursement

Updated December 17, 2020

1. UPDATED: COVID-19 Vaccine & Vaccine Administration Coverage
As the initial supply of COVID-19 vaccines will be federally purchased, states would not be 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 for those age 16 and over. Approval of a vaccine for children under age 16 is expected in 2021.

During and Outside of the PHE
FFCRA section 6008(b)(4) does not apply to separate CHIPs.[9] Coverage requirements for vaccine administration in a separate CHIP are the same during and outside of the PHE.

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 16 and over. Therefore, the administration fee for the Pfizer-BioNTech vaccine is a mandatory benefit for children age 16 and over enrolled in a separate CHIP.

Gaps in Coverage
Vaccines are not required for pregnant women covered through a separate CHIP, although all states that cover pregnant women through a separate CHIP currently cover vaccines and their administration without cost sharing for this population. Should any state opt not to provide coverage of a COVID-19 vaccination to this population, the HRSA COVID-19 Claims Reimbursement program may be used to cover COVID-19 treatment, including the administration of vaccines, for this population.

SPA/Waiver Requirements for Coverage
No SPA is required to cover any newly recommended vaccines.

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 children enrolled in CHIP. There are no federal rules related to cost sharing for vaccines provided to pregnant women enrolled in CHIP.

[9] 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.

3. Reimbursement

Separate CHIP programs determine the rate and manner of reimbursement of the administration fees. States can claim federal financial participation (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.

G. 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

As CMS expects that the COVID-19 vaccine(s) will be 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) does 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.

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 and Outside the PHE *

Population	Coverage During the PHE	Cost Sharing During the PHE	Reimburse-ment During the PHE	Coverage Outside the PHE	Cost Sharing Outside the PHE	Reimburse-ment Outside the PHE
Adults Covered Under Traditional Medicaid	Mandatory	None	State-established reimburse-ment rates	Mandatory in states receiving extra 1% FMAP for preventive services as described in section 1905(b); optional for others	None in states receiving extra 1% FMAP for preventive services as described in section 1905(b); otherwise at state option for certain populations**	State-established reimburse-ment rates
Beneficiaries Enrolled in ABPs (Including Expansion Adults)	Mandatory	None	State-established reimburse-ment rates	Mandatory	None	State-established reimburse-ment rates
Children Covered Under Medicaid	Mandatory	None	State-established reimburse-ment rates	Mandatory	None for individuals under age 18; at state option for individuals ages 19 and 20	State-established reimburse-ment rates
Limited Benefit Group Enrollees	Available only at state option through 1115(a)(2) authority or through HRSA's COVID-19 Claims Reimburse-ment program	N/A	N/A	Available only at state option through 1115 (a)(2) authority or through HRSA's COVID-19 Claims Reimbursement program	N/A	N/A

Population	Coverage During the PHE	Cost Sharing During the PHE	Reimburse-ment During the PHE	Coverage Outside the PHE	Cost Sharing Outside the PHE	Reimburse-ment Outside the PHE
CHIP Enrollees	Mandatory	None	State-established reimburse-ment rates	Mandatory	None	State-established reimburse-ment rates
BHP Enrollees	Mandatory	None	State-established reimburse-ment rates	Mandatory	None	State-established reimburse-ment rates

*The PHE is defined for purposes of this chart to encompass the period in which FFCRA section 6008 is in effect, which extends through the last day of the quarter in which the PHE expires.

**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.

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 *
During and Outside the PHE

Population	Is a SPA/Blueprint needed for coverage purposes?	Is a SPA/Blueprint needed for reimbursement purposes?
Adults Covered Under Traditional Medicaid	No for mandatory benefits and clinic benefit. Yes for optional benefits if not otherwise covered.	Yes, if different from approved administration rates.
Beneficiaries Enrolled in ABPs (Including Expansion Adults)	No SPA required.**	Yes, if different from approved administration rates.
Children Covered Under Medicaid	State option to submit a SPA to explicitly detail coverage provisions.	Yes, if different from approved administration rates.
Beneficiaries Receiving Limited Benefit Packages	Not applicable	Not applicable
CHIP	No	No
BHP	No	No

*The initial supply of COVID-19 vaccines will be federally purchased.

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

III. UPDATED: Medicaid & CHIP Managed Care

Last Updated December 17, 2020

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 section 6008(b)(4) of the FFCRA (see 42 CFR §§ 438.206 and 457.1230(a)). This means, as noted above, that coverage of COVID-19 vaccine administration is mandatory for most Medicaid beneficiaries, without cost sharing, during the period when FFCRA section 6008(b)(4) applies to a state, regardless of the Medicaid delivery system in which the Medicaid 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, 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).

Consistent with the changes to 45 CFR § 147.130 detailed in the CMS-9912-IFC, during the COVID-19 PHE, BHP plans and Medicaid ABPs 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.[10]

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

[10] Additional detail on these coverage requirements may be found in the preamble to CMS-9912-IFC. This IFC appeared in the Federal Register on November 6, 2020, and the changes made to CMS regulations through it generally have a November 2, 2020 effective date, although the preamble discussions of Medicaid and CHIP vaccines coverage generally only describe current policy and existing law, and do not change current CMS policy (except when discussing the changes to 45 CFR § 147.130 detailed in CMS-9912-IFC). *See* 85 FR 71142, 71148-50, at https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency.

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 should consider setting specific network adequacy standards for pharmacy providers who furnish COVID-19 vaccines. Further, managed care plans should consider offering additional network provider agreements to pharmacy providers who can 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 subject to compliance 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.[11]

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.

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

Updated March 15, 2021

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.

In March 2020, CMS created a Disaster Relief Medicaid SPA template 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.

Importantly, if a state claims the temporary FMAP increase under section 6008 of the FFCRA in the quarter in which the COVID-19 PHE ends, it must provide coverage and payment for COVID-19 vaccine administration through the end of that quarter. However, 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, and wants to claim the FFCRA section 6008 temporary

[11] See Medicare's memo regarding the COVID-19 vaccine: https://www.cms.gov/files/document/hpms-memo-covid-19-vaccine-significant-cost-determination.pdf. 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 https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency.

FMAP increase in the quarter in which the COVID-19 PHE ends, it would likely need to have another SPA in place to effectuate coverage and payment for COVID-19 vaccinations at least through the end of the quarter in which the COVID-19 PHE ends.

Therefore, 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 (to extend beyond the duration of the COVID-19 PHE), especially if they intend to claim the temporary FMAP increase under FFCRA section 6008 in the quarter in which the COVID-19 PHE ends.

Please note that in an effort to streamline the development and submission of COVID-19 vaccine administration SPAs, applicable state plan language only needs to describe the qualifications of the practitioners who may order and administer the vaccine(s) under the benefit(s) under which vaccinations would be covered. Further, a SPA governing reimbursement for COVID-19 vaccine administration is necessary only if the payment methodology for COVID-19 vaccine administration 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. 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 payments to 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.

Options for States to Cover and Pay for Vaccine Administration

States may cover and pay for vaccine administration through a variety of benefits, including the physician services and other licensed practitioner services benefits, as well as under benefits provided by institutional providers such as hospitals and nursing facilities. As discussed in Section V.D. Implications of HHS's COVID-19 PREP Act Declaration and Authorizations for Medicaid and CHIP Coverage and Reimbursement of COVID-19 Vaccinations, CMS will expect

states to provide Medicaid coverage for COVID-19 vaccinations ordered and administered by licensed pharmacists, or administered by pharmacy interns or pharmacy technicians, as authorized by the HHS COVID-19 PREP Act declaration and related authorizations, during any time period when the HHS COVID-19 PREP Act declaration and related authorizations are in effect and the state is subject to FFCRA section 6008(b)(4).

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.

- 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: 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 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 a 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 vaccine. This means that starting on March 15, 2021, for single dose 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 7 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.

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.

Sample Approaches to State Plan Payment Language - Stand-alone Page

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

A similar approach that would also limit the time necessary for CMS review is to submit a stand-alone 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 second dose administration rate paid to physicians and/or other licensed practitioners, 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.

Use of Medicare Fee Schedule 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, pending SPAs, and states considering payment changes related to vaccine administration. Accordingly, states with proposed or approved state plan pages that include specific payment rates, or states with more general references to Medicare fee schedules, might need to update their approved or pending state plan amendment(s) to reflect the change to

Medicare payment if they intend to pay 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.

On March 15, 2021, CMS is updating 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 vaccine. This means that starting on March 15, 2021, for single dose 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 7 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 will be approximately $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 furnished before March 15, 2021 for vaccines 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.

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

A CHIP SPA is not necessary for coverage and payment for a COVID-19 vaccine and administration.

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

V. Other Federal Requirements & Considerations

Added November23, 2020

A. PREP Act

The Public Readiness and Emergency Preparedness (PREP) Act authorizes the Secretary of the Department 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.[12] 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).[13] With promulgation of the third amendment to the HHS COVID-19 PREP Act declaration on August 24, 2020, 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.[14]

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 licensing and scope of practice laws that would otherwise prohibit or effectively prohibit licensed pharmacists from ordering and administering these covered countermeasures.[15]

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

As an "Authority Having Jurisdiction" under the HHS COVID-19 PREP Act declaration, the Office of the Assistant Secretary for Health (OASH) issued an authorization 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.[16]

---

[12] https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx

[13] *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.

[14] Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity Under the PREP Act, OASH, (Apr. 8, 2020), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf; 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-pharmacy-interns-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), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf

[15] Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf.

[16] 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-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf.

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.[17]

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, qualified state-licensed pharmacists, state-authorized pharmacy interns, and qualified pharmacy technicians[18] must satisfy the following requirements:

- The vaccine must be FDA-authorized or FDA-licensed.
- If the vaccination is administered by a qualified state-authorized pharmacy intern or qualified pharmacy technician, it must be ordered by the supervising qualified pharmacist.
- 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 vaccination must be ordered and administered according to the ACIP's COVID-19 vaccine recommendation(s).
- The qualified pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (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 qualified pharmacy technician or state-authorized pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines.
- The qualified pharmacist, qualified pharmacy technician, or state-authorized pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
- The qualified pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each state licensing period.
- The qualified pharmacy technician must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during the relevant state licensing period(s).
- The qualified 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

[17] 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.

[18] 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.*

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. These requirements also apply when the pharmacist is supervising the administration of a COVID-19 vaccination by a qualified pharmacy technician or state-authorized pharmacy intern.

- The qualified pharmacist, qualified pharmacy technician, or state-authorized pharmacy intern must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.
- The qualified pharmacist 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). This requirement also applies when the pharmacist is supervising the administration of a COVID-19 vaccination by a qualified pharmacy technician or state-authorized pharmacy intern.

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.

C. PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures

OASH issued an authorization under the HHS COVID-19 PREP Act declaration on October 29, 2020,[19] 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 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,[20] 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*

[19] PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, OASH, (Oct. 29, 2020), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf.
[20] *See* 42 U.S.C. 247d-6d(i)(3), (6), (8)(B).

administration or use of FDA-authorized or FDA-licensed COVID-19 vaccines or ACIP-recommended 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, ACIP-recommended 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.

The OASH authorization for pharmacies 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 consistently 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.

D. 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 licensed pharmacist orders and administers a COVID-19 vaccination consistently with the HHS COVID-19 PREP Act declaration and authorizations, or a pharmacy intern or pharmacy technician administers it consistently with the HHS COVID-19 PREP Act declaration and authorizations, a state may not deny Medicaid or CHIP coverage or reimbursement for the vaccination administration on the basis that state law does not authorize these individuals to order and/or administer it.

Additionally, consistent with Medicaid's freedom of choice requirement at section 1902(a)(23) of the Act, CMS will expect states to provide Medicaid coverage for COVID-19 vaccinations ordered and administered by licensed pharmacists, or administered by pharmacy interns or pharmacy technicians, as authorized by the HHS COVID-19 PREP Act declaration and related authorizations, during any time period when the HHS COVID-19 PREP Act declaration and related authorizations are in effect and the state is subject to FFCRA section 6008(b)(4). 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.[21] Section 1902(a)(23) of the Act and 42 C.F.R. § 431.51 require that Medicaid beneficiaries be able to obtain Medicaid-covered services from any qualified and willing provider. While they are in effect, HHS's COVID-19 PREP Act declaration and authorizations would essentially make any pharmacy, pharmacist, pharmacy intern, or pharmacy technician who meets the conditions

[21] 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 services and supplies, or tuberculosis-related services. *See* CMS-9912-IFC, 85 FR 71142, 71148-50 (Nov. 6, 2020), at https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency.

specified in the PREP Act, the declaration, and the authorizations qualified to administer COVID-19 vaccinations, notwithstanding state law to the contrary. Accordingly, CMS expects all state Medicaid programs subject to FFCRA section 6008(b)(4), including in states where a state law governing pharmacy, pharmacist, pharmacy intern, or pharmacy technician scope of practice is preempted by the HHS COVID PREP Act declaration and authorizations, to identify a pathway to reimbursing pharmacies and/or pharmacists for COVID-19 vaccinations ordered and administered by pharmacists, or administered by pharmacy interns and pharmacy technicians, in a manner that is consistent with the HHS COVID-19 PREP Act declaration and authorizations issued pursuant to the declaration. 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.

The same expectations do not apply, however, to separate CHIPs. In separate CHIPs, states must cover ACIP-recommended vaccines and their administration for all children under age 19 with no cost sharing. When pediatric COVID-19 vaccines or COVID vaccines that target the general population but may be appropriate for teenagers become available, and are authorized or approved by the FDA, ACIP may then recommend these COVID-19 vaccines for the pediatric population. For example, on December 12, 2020, ACIP recommended the Pfizer-BioNTech vaccine for those age 16 and over. In other scenarios where there may be pediatric COVID-19 vaccines that are FDA-authorized or FDA-licensed but ACIP has not yet recommended the vaccines, CHIPs could opt to cover a COVID-19 vaccination for beneficiaries under regulatory authority at 42 C.F.R. § 457.402(x). 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, the HHS COVID-19 PREP Act declaration and authorizations establish that qualified pharmacists may order and administer, and qualified pharmacy interns and pharmacy technicians may 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 for a covered COVID-19 vaccination to a pharmacy or pharmacist on the basis that the pharmacy, pharmacist, pharmacy intern, or pharmacy technician 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 pharmacy or pharmacy professional 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.

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 third amendment to the HHS COVID-19 PREP Act declaration, states should consider whether ensuring safe access to vaccines requires pharmacy and pharmacy-professional reimbursement for COVID-19 vaccine administration—particularly for medically underserviced populations and populations facing transportation obstacles. Over 90 percent of Americans live within 5 miles of a pharmacy, and pharmacies often offer hours that are convenient.

VI. UPDATED: Medicaid & CHIP Reporting Requirements & Implications

Updated November 23, 2020

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, also known as COVID-19). 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-cpt-vaccine-and-immunization-codes.

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 (1st dose) 0002A (2nd dose)	Pfizer-BioNTech COVID-19 Vaccine	59267-1000-1 59267-1000-01	21 days
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.	0011A (1st dose) 0012A (2nd dose)	Moderna COVID-19 Vaccine	80777-273-10 80777-0273-10	28 days

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. UPDATED: 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.[22]

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.

[22] These provider enrollment requirements do not apply to BHP.

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 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.[23] 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.[24] 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.

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

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

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.

VIII. Education & Outreach

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 doses and spacing between doses (if a multi-dose vaccine is used), and how to obtain additional information. CMS encourages states to start developing a strategy for conducting COVID-19 vaccine education and outreach. States may use Medicaid and CHIP administrative matching funds for beneficiary and provider education and outreach.

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.

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. Preliminary information is available in CDC's "COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations".

E. Outreach & Education

- Section 12 of CDC's "COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations" references COVID-19 vaccination program communication. CDC recommends that COVID-19 messaging is developed prior to vaccine availability and that there is clear and consistent messaging. CDC also recommends that states and other jurisdictions regularly review the resources available at the CDC COVID-19 Communications Resources.
- 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, 2020, and CDC's website includes a flu campaign toolkit,

social media toolkit, and well as other information about flu. In addition, CMS has information on flu vaccinations for the Medicare population on cms.gov.

COVID-19 Federal Resources from the CDC & HHS

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

From the Factory to the Frontlines - The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine:
https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf

HHS Fact Sheet: Explaining Operation Warp Speed
https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html

COVID-19-FFCRA-FAQs, 04-13-2020:
https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-faqs.pdf

Version 1.0 "COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations", 09-16-2020:
https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf (Includes information on provider enrollment to administer vaccines: "To receive/administer COVID-19 vaccine, constituent products, and ancillary supplies, vaccination provider facilities/organizations must enroll in the federal COVID-19 Vaccination Program coordinated through their jurisdiction's immunization program. Enrolled COVID-19 vaccination providers must be credentialed/licensed in the jurisdiction where vaccination takes place and sign and agree to the conditions in the *CDC COVID-19 Vaccination Program Provider Agreement*.")

Operation Warp Speed Vaccine Distribution Process (Graphic), 09-16-2020:
https://media.defense.gov/2020/Sep/16/2002498504/-1/-1/1/OWS-VACCINE-DISTRIBUTION-GRAPHIC.pdf

CDC Press Release on Funding for Vaccine Preparedness, 09-23-2020:
https://www.cdc.gov/media/releases/2020/p0924-200-million-jurisdictions-covid-19-preparedness.html

Glossary of Terms & Resources

Term	Resources
ABP (Alternative Benefit Plan)	More information available at https://www.medicaid.gov/medicaid/benefits/alternative-benefit-plan-coverage/index.html
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 https://www.medicaid.gov/chip/benefits/index.html
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 https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html
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.

Term	Resources
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 https://www.medicaid.gov/medicaid/eligibility/index.html.
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