# DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop: S2-26-12 Baltimore, Maryland 21244-1850



#### SHO# 23-003

**RE:** Mandatory Medicaid and Children's Health Insurance Program Coverage of Adult Vaccinations under the Inflation Reduction Act

June 27, 2023

Dear State Health Official:

The Centers for Medicare & Medicaid Services (CMS) is issuing this guidance on section 11405 of the Inflation Reduction Act (IRA) (Pub. L. 117-169). Beginning October 1, 2023, statutory amendments made by section 11405 of the IRA require Medicaid and Children's Health Insurance Program (CHIP) coverage and payment for approved adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and their administration, without cost sharing.

#### Overview

CMS interprets the statutory amendments made by the IRA to require state Medicaid and CHIP programs to cover, without cost sharing obligations, vaccines and their administration, provided that the vaccine is approved<sup>1</sup> by the U.S. Food and Drug Administration (FDA) for use by adult populations and is administered in accordance with recommendations of ACIP.<sup>2</sup> This coverage requirement will go into effect on October 1, 2023, and applies in both fee-for-service and managed care. Also, effective October 1, 2023, the statutory amendments made by the IRA modify the requirements that states must meet in order to claim a one percentage point increase in the federal medical assistance percentage (FMAP) for certain services described in sections 1905(a)(13)(A) and (B) and 1905(a)(4)(D) of the Social Security Act (the Act). The IRA adult vaccination<sup>3</sup> coverage requirements and the IRA's changes to the availability of this one percentage point FMAP increase are discussed in detail beginning on page 5 of this letter.

### **Background**

Vaccines administered to recommended populations at recommended intervals can reduce morbidity, hospitalizations, and deaths, and save costs. Vaccines may reduce the overall burden

<sup>1</sup> "Licensed" is the statutory term under section 351 of the Public Health Service (PHS) Act for what is commonly referred to as approval of a biological product. When CMS uses the term "approval" to refer to FDA approval in this document, that term includes FDA licensure under section 351 of the PHS Act.

<sup>&</sup>lt;sup>2</sup> To the extent possible, CMS has aligned its interpretation of section 11405 of the IRA with its interpretation of similar language added to the Medicare statute by section 11401 of the IRA. See CMS Center for Medicare's "Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin," <a href="https://www.cms.gov/files/document/irainsulinvaccinesmemo09262022.pdf">https://www.cms.gov/files/document/irainsulinvaccinesmemo09262022.pdf</a>.

<sup>&</sup>lt;sup>3</sup> In this document, CMS uses the term "vaccination" to refer both to a vaccine product and its administration. Similarly, "immunization," as used in the document, includes both a product and its administration.

of infections, which remain high in the United States. For example, the Centers for Disease Control and Prevention (CDC) estimates that influenza has resulted in between 140,000 to 710,000 hospitalizations and 12,000 to 52,000 deaths annually between 2010 and 2020.<sup>4</sup> An estimated 150,000 individuals per year are hospitalized because of pneumococcal pneumonia.<sup>5</sup> In 2020, there were 5 newly reported cases of hepatitis B per 100,000 persons.<sup>6</sup> The human papillomavirus (HPV) causes more than 37,000 cases of cancer each year.<sup>7</sup>

Vaccination rates are suboptimal for all adults, regardless of health coverage, but for adults enrolled in Medicaid, the vaccination rates for a range of vaccinations are lower than for adults with private health insurance coverage, including influenza, tetanus, herpes zoster, hepatitis A, hepatitis B, and HPV vaccinations. Additionally, the COVID-19 public health emergency (PHE) had a negative impact on the rate of children receiving routine childhood vaccinations. Although child vaccination rates have rebounded since the beginning of the COVID-19 PHE, there is still a gap in child vaccinations compared to prior years. 9

### Current (Pre-IRA) Medicaid and CHIP Vaccination Coverage

As discussed below, prior to the effective date of the IRA's amendments, Medicaid coverage of vaccines and vaccine administration is mandatory in certain circumstances; otherwise, coverage is at a state's option.

States must cover, for beneficiaries under age 21 who are eligible for the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit (including beneficiaries enrolled in Medicaid-expansion CHIPs who are eligible for EPSDT), appropriate immunizations (according to age and health history) on the CDC/ACIP pediatric immunization schedule. In addition, other vaccinations recommended by ACIP (including those that are recommended on the CDC/ACIP

<sup>&</sup>lt;sup>4</sup> Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 2022. Disease Burden of Flu. Atlanta, GA: CDC. Available

 $at: \underline{https://www.cdc.gov/flu/about/burden/index.html\#:\sim:text=CDC\%20estimates\%20that\%20flu\%20has, \underline{annually\%20between\%202010\%20and\%202020}\ .$ 

<sup>&</sup>lt;sup>5</sup> Centers for Disease Control and Prevention. U.S. Department of Health and Human Services, 2023: Fast Facts You Need to Know About Pneumococcal Disease. Atlanta, GA: CDC. Available at: <a href="https://www.cdc.gov/pneumococcal/about/facts.html#:~:text=Pneumococcal%20pneumonia%20causes%20an%20estimated,the%20United%20States%20in%202019">https://www.cdc.gov/pneumococcal/about/facts.html#:~:text=Pneumococcal%20pneumonia%20causes%20an%20estimated,the%20United%20States%20in%202019</a> .

<sup>&</sup>lt;sup>6</sup> Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 2022. Hepatitis B Surveillance 2020. Atlanta, GA: CDC. Available at: <a href="https://www.cdc.gov/hepatitis/statistics/2020surveillance/hepatitis-b.htm">https://www.cdc.gov/hepatitis/statistics/2020surveillance/hepatitis-b.htm</a>.

<sup>&</sup>lt;sup>7</sup> Centers for Disease Control and Prevention. U.S. Department of Health and Human Services. 2022. How Many Cancers are Linked with HPV Each Year. Atlanta, GA. CDC. Available at: <a href="https://www.cdc.gov/cancer/hpv/statistics/cases.htm">https://www.cdc.gov/cancer/hpv/statistics/cases.htm</a>.

<sup>&</sup>lt;sup>8</sup> Estimates were based on an analysis of 2015–2018 National Health Interview Survey data. Medicaid and CHIP Payment and Access Commission (MACPAC). March 2022 Report to Congress on Medicaid and CHIP: Chapter 2: Vaccine Access for Adults Enrolled in Medicaid. 2022. Available at: <a href="https://www.macpac.gov/wp-content/uploads/2022/03/Chapter-2-Vaccine-Access-for-Adults-Enrolled-in-Medicaid.pdf">https://www.macpac.gov/wp-content/uploads/2022/03/Chapter-2-Vaccine-Access-for-Adults-Enrolled-in-Medicaid.pdf</a>.

https://www.cdc.gov/mmwr/volumes/70/wr/mm7023a2.htm; https://www.medicaid.gov/state-resource-center/downloads/covid-19-medicaid-data-snapshot-07312022.pdf.

adult immunization schedule<sup>10</sup> for beneficiaries aged 19 or 20) and non-ACIP-recommended vaccines and vaccine administration are covered for beneficiaries eligible for EPSDT, if the service is determined to be medically necessary for the beneficiary based on an individualized assessment and state medical necessity criteria.<sup>11</sup>

Coverage of certain vaccines and vaccine administration is also mandatory for certain adult Medicaid beneficiaries, including individuals enrolled in the Medicaid expansion group described at section 1902(a)(10)(A)(i)(VIII) of the Act, who receive their services through an alternative benefit plan (ABP) authorized under section 1937 of the Act. <sup>12</sup> In accordance with section 1937(b)(5) of the Act and 42 CFR 440.347(a), ABPs must include coverage of 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 coverage, without cost sharing, of vaccinations that have in effect a recommendation for routine use from ACIP with respect to the individual involved. <sup>13</sup>

Additionally, under amendments made by the American Rescue Plan Act of 2021 (ARP) (Pub. L. 117-2), state Medicaid programs are required to cover COVID-19 vaccines and their administration described in section 1905(a)(4)(E) of the Act, without cost sharing, for nearly all Medicaid beneficiaries, including most eligibility groups receiving limited benefit packages under the state plan or a section 1115 demonstration. <sup>14</sup> This coverage requirement generally applies during the period beginning on March 11, 2021, and ending on the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act <sup>15</sup> (referred to herein as the ARP coverage period). The COVID-19 emergency period described in section 1135(g)(1)(B) of the Act ended on May 11, 2023, and therefore the last day of the ARP coverage period is September 30, 2024. <sup>16</sup>

Aside from the COVID-19 vaccinations described in section 1905(a)(4)(E) of the Act, for all populations in Medicaid not eligible for EPSDT or receiving coverage through an ABP, coverage of vaccines and vaccine administration is currently optional. States can elect to cover vaccines

<sup>&</sup>lt;sup>10</sup> The pediatric immunization schedule identifies ACIP-recommended vaccines for those through age 18 and is available at: <a href="https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf">https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf</a>. The adult immunization schedule identifies ACIP-recommended vaccines for those age 19 and older and is available at: <a href="https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf">https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf</a>.

<sup>&</sup>lt;sup>11</sup> Section 1905(r)(1)(B)(iii) and (5) of the Act.

<sup>&</sup>lt;sup>12</sup> Additionally, in accordance with 42 CFR § 440.345(a), states with ABPs must assure access to EPSDT services for eligible individuals under 21 years of age who are receiving coverage through an ABP. This would include vaccinations covered under EPSDT that would not otherwise be covered under the ABP.

<sup>&</sup>lt;sup>13</sup> 42 CFR § 440.347(a)(9), 45 CFR §§ 156.110(a)(9), 156.115(a)(4), 147.130(a)(1)(ii).

<sup>&</sup>lt;sup>14</sup> Additional information about the beneficiaries to whom this coverage requirement applies is provided in the COVID-19 vaccine toolkit, available at: <a href="https://www.medicaid.gov/state-resource-center/downloads/covid-19-vaccine-toolkit.pdf">https://www.medicaid.gov/state-resource-center/downloads/covid-19-vaccine-toolkit.pdf</a>.

<sup>&</sup>lt;sup>15</sup> The COVID-19 emergency period described in section 1135(g)(1)(B) of the Act is the period during which there exists the public health emergency (PHE) declared by the Secretary of Health and Human Services pursuant to section 319 of the PHS Act on January 31, 2020, entitled "Determination that a Public Health Emergency Exists Nationwide as the Result of the 2019 Novel Coronavirus," and any renewal of that declaration.

<sup>&</sup>lt;sup>16</sup> See <a href="https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html">https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html</a> and <a href="https://www.hhs.gov/about/news/2023/02/09/letter-us-governors-hhs-secretary-xavier-becerra-renewing-covid-19-public-health-emergency.html">https://www.hhs.gov/about/news/2023/02/09/letter-us-governors-hhs-secretary-xavier-becerra-renewing-covid-19-public-health-emergency.html</a>.

and vaccine administration for these populations under various mandatory benefits such as inpatient hospital services (42 CFR § 440.10), outpatient hospital services (42 CFR § 440.20(a)), physicians' services (42 CFR § 440.50(a)), and under certain optional benefits such as services of other licensed practitioners (42 CFR § 440.60), clinic services (42 CFR § 440.90), and preventive services (42 CFR § 440.130(c)) depending on how the state defines the amount, duration, and scope parameters for these benefits. States currently may also elect to cover approved adult vaccines recommended by ACIP and their administration as described in section 1905(a)(13)(B) of the Act (and must do so if they opt to claim a one percentage point FMAP increase for their Medicaid expenditures on certain services). As described in more detail below, the IRA makes coverage of the services described in section 1905(a)(13)(B) mandatory for all states, beginning October 1, 2023.

Any Medicaid cost sharing that a state elects to charge, including cost sharing for vaccines and vaccine administration, must be nominal and comply with requirements at sections 1916 and 1916A of the Act and regulations at 42 CFR § 447.50 through 440.57. Certain populations and services must be exempted from any Medicaid cost sharing, including pregnancy-related services, most beneficiaries under age 18 (under age 21 at state option), and American Indians/Alaska Natives who are currently receiving or have ever received items or services furnished by an Indian health care provider or through referral under contract health services.

For all separate CHIP enrollees, similar to the Medicaid ARP coverage requirement, states must cover COVID-19 vaccines and their administration, without cost sharing, in accordance with section 2103(c)(11)(A) and (e)(2) of the Act (as added/amended by the ARP) during the ARP coverage period. State CHIP programs must also cover ACIP-recommended vaccines and their administration for children enrolled in a separate CHIP, with no cost-sharing, per 42 CFR §§ 457.410(b)(2) and 457.520(b)(4). As of December 2022, all states that cover pregnant adults through a separate CHIP under section 2112 of the Act voluntarily cover ACIP-recommended vaccines and their administration for these beneficiaries, without cost-sharing. This coverage is optional until the IRA coverage mandate takes effect on October 1, 2023.

### Current (Pre-IRA) Increase in FMAP for Certain Adult Vaccinations and Other Services

Pursuant to section 1905(b) of the Act, as amended by section 4106 of the Affordable Care Act, states that elect to cover the adult vaccinations described in section 1905(a)(13)(B) of the Act, as well as services described in section 1905(a)(13)(A) of the Act, without cost sharing, receive a one percentage point increase in the FMAP for their Medicaid expenditures for these services and for their Medicaid expenditures on the tobacco cessation services for pregnant individuals described in section 1905(a)(4)(D) of the Act. <sup>17</sup> This will change after October 1, 2023, under the IRA's amendments, as further discussed below.

## Advisory Committee on Immunization Practices (ACIP)

<sup>&</sup>lt;sup>17</sup> Additional information is available at: <a href="https://www.medicaid.gov/federal-policy-guidance/downloads/SMD-13-002.pdf#:~:text=This%20letter%20provides%20guidance%20to%20states%20on%20section,package%20%28referred%20to%20as%20an%20alternative%20benefit%20plan%29 and https://www.medicaid.gov/affordable-careact/provisions/downloads/4106-faqs-clean.pdf.

ACIP is a federal advisory committee composed of medical and public health experts, as well as a consumer representative, that provides advice and guidance to the Director of the CDC on the most effective means to prevent vaccine preventable diseases in the United States. Recommendations made by the ACIP are reviewed by the CDC Director and, if adopted, are published as official CDC recommendations in the Morbidity and Mortality Weekly Report. <sup>18</sup> <sup>19</sup>

ACIP also develops written recommendations—subject to adoption by the CDC Director—for the routine use <sup>20</sup> of vaccines for both pediatric and adult populations for inclusion on the CDC/ACIP immunization schedules. To inform its advice to the CDC Director, ACIP considers disease epidemiology, burden of disease, vaccine efficacy and effectiveness, vaccine safety, the quality of evidence reviewed, economic analyses, and implementation issues.

The ACIP makes vaccination recommendations for different groups of people. Recommendations are by age group (as shown in Table 1 of the annual adult immunization schedule) or by risk group (some of which are shown in Table 2 of the annual adult immunization schedule), including risk due to underlying condition, occupation, or travel. Some of ACIP's recommendations are not considered routine (that is, are not included on the adult or pediatric immunization schedules) but reflect the same considerations as vaccines included on the immunization schedules.

Most of ACIP's recommendations, including those both on and off the adult immunization schedule as described above, are for vaccinations for everyone (without contraindication) in a designated age or risk group (standard recommendations). ACIP also makes recommendations for shared clinical decision-making, in which the health care provider and the patient or parent/guardian consider whether or not to vaccinate. These other recommendations are not always included on the annual immunization schedules. Vaccination recommendations for shared clinical decision-making that are listed on the CDC/ACIP immunization schedules are considered to be for routine use. However, when these recommendations are not included on the CDC/ACIP immunization schedules, they would not be considered to be for routine use. The key distinction between standard recommendations and shared clinical decision-making recommendations relates to whether there should be a default decision to vaccinate. For standard recommendations, the default decision should be to vaccinate the patient based on age group or other indication, unless contraindicated. For shared clinical decision-making recommendations, there is no default—the decision about whether or not to vaccinate may be informed by the best available evidence of who may benefit from vaccination; the individual's characteristics, values,

<sup>&</sup>lt;sup>18</sup> The ACIP holds three regular meetings each year, in addition to emergency sessions. For more information, see: https://www.cdc.gov/vaccines/acip/committee/role-vaccine-recommendations.html.

<sup>&</sup>lt;sup>19</sup> ACIP also has a statutorily defined role with respect to the Vaccines for Children (VFC) program. For more information, please see: <a href="https://www.cdc.gov/vaccines/programs/vfc/index.html">https://www.cdc.gov/vaccines/programs/vfc/index.html</a>; <a href="https://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html">https://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html</a>.

<sup>&</sup>lt;sup>20</sup> As defined for purposes of the vaccination coverage that must be included in Medicaid ABP coverage, ACIP recommendations for "routine use" are those that are listed on the CDC/ACIP immunization schedules. See 45 CFR 147.130(a)(1)(ii). References to "routine" vaccinations or "routine" ACIP recommendations in this SHO letter have that same meaning.

<sup>&</sup>lt;sup>21</sup> https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html

and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered.<sup>22</sup>

## Section 11405 of the IRA – New Mandatory Medicaid and CHIP Adult Vaccination Coverage

Section 11405(a)(1) of the IRA amended section 1902(a)(10)(A) of the Act to include, effective October 1, 2023, items and services described in section 1905(a)(13)(B) in the list of Medicaid benefits that must be available to categorically needy individuals (subject to the coverage limitations for certain eligibility groups in the language following section 1902(a)(10)(G)). This same provision of the IRA amended section 1902(a)(10)(C)(iv) of the Act to require, also effective October 1, 2023, Medicaid coverage of the items and services described in section 1905(a)(13)(B) of the Act for certain medically needy beneficiaries. 23 Section 11405(b)(1) of the IRA added mandatory coverage of the services described in section 1905(a)(13)(B) for CHIP enrollees at section 2103(c)(12) of the Act. Section 11405 also amended sections 1916(a)(2), 1916(b)(2), 1916A(b)(3)(B), and 2103(e)(2) of the Act to specify that states cannot impose cost sharing with respect to the vaccination coverage that is described in sections 1905(a)(13)(B) and 2103(c)(12) of the Act. Under these amendments, beginning October 1, 2023, state Medicaid and CHIP programs must cover approved adult vaccines recommended by ACIP, and their administration, without cost sharing; these requirements apply in both fee-for-service and managed care.

### Section 1905(a)(13)(B) of the Act

CMS interprets section 1905(a)(13)(B) of the Act as follows, including for purposes of the IRA's amendments requiring state Medicaid and CHIP programs to cover the vaccinations described in that section, without cost sharing obligations. Section 1905(a)(13)(B) describes the following services: "with respect to an adult individual, approved vaccines recommended by the [ACIP] ... and their administration[.]" CMS interprets this language to describe vaccines that are approved by the FDA for use by adult populations and administered in accordance with recommendations of ACIP. CMS does not interpret "approved" to include vaccines that FDA has authorized for use under emergency use authorization, but has not approved. The coverage described in section 1905(a)(13)(B) is both of the vaccines themselves (i.e., the vaccine doses), and their administration.

<sup>22</sup> All ACIP recommendations by vaccine are available here: https://www.cdc.gov/vaccines/hcp/acip-

recs/index.html.

23 States that cover the medically needy must choose their medically needy benefit package. If a state that covers the medically needy elects to make services in institutions for mental diseases and/or intermediate care facilities for the developmentally disabled available to any medically needy group, the state's medically needy benefit package for all medically needy groups must include at least the services described in one of two options identified in section 1902(a)(10)(C)(iv) of the Act. Prior to the IRA's enactment, one of these options was "the care and services listed in paragraphs (1) through (5) and (17) of section 1905(a)," and section 11405(a)(1) of the IRA amended section 1902(a)(10)(C)(iv) to add section 1905(a)(13)(B) to this particular option. The other option in section 1902(a)(10)(C)(iv) is "the care and services listed in any 7 of the paragraphs numbered (1) through (24) of [section 1905(a)]." A state that elects the latter option for its medically needy benefit package could, but would not be required to, include the items and services described in section 1905(a)(13)(B) in its medically needy benefit package.

Additionally, CMS interprets an "adult individual," for purposes of section 1905(a)(13)(B) of the Act, to refer to beneficiaries 19 years of age or older, which is consistent with the adult immunization schedule that identifies ACIP-recommended vaccines for those age 19 and older. This also aligns with how CMS has historically interpreted section 1905(a)(13)(B) for purposes of the one percentage point FMAP increase established by section 4106 of the Affordable Care Act,<sup>24</sup> and is also aligned with the age at which a CHIP beneficiary is no longer a child for purposes of eligibility (as defined at section 2110(c)(1) of the Act).

As noted earlier, there are multiple categories of ACIP recommendations for adult vaccines, including recommendations described on the CDC/ACIP adult immunization schedule (as determined by age and risk and recommendations for shared clinical decision-making), and recommendations based on risk due to health condition, occupation, and travel. Beginning October 1, 2023,<sup>25</sup> CMS interprets the reference to ACIP recommendations in section 1905(a)(13)(B) of the Act to include any category of ACIP recommendations. The IRA coverage requirement is therefore not limited to vaccines that ACIP includes on the immunization schedules or recommends for routine use.<sup>26</sup> States should establish processes to monitor and implement any new or updated ACIP recommendations.

As previously explained, state Medicaid and CHIP programs are currently required to cover, without cost sharing, the COVID-19 vaccines and their administration described in section 1905(a)(4)(E) of the Act (for Medicaid) and 2103(c)(11)(A) of the Act (for CHIP) during the ARP coverage period, which will end on September 30, 2024. At the conclusion of the ARP coverage period, COVID-19 vaccinations that are approved by the FDA for use by adult populations and that are administered in accordance with any category of ACIP recommendations would be covered, without cost sharing, as part of the IRA-required adult vaccination coverage described in sections 1905(a)(13)(B) and 2103(c)(12) of the Act. However, states are currently required to cover COVID-19 vaccinations for a broader range of Medicaid eligibility groups than will receive the mandatory adult vaccination coverage under the IRA. For example, the ARP COVID-19 vaccination coverage requirements apply to certain limited-benefit eligibility groups, such as individuals eligible for family planning benefits, that will not receive the mandatory adult vaccination coverage under the IRA. This means that individuals in certain Medicaid eligibility groups that currently receive coverage of COVID-19 vaccinations described in section 1905(a)(4)(E) of the Act will not receive coverage for these services as part of the IRA-required adult vaccination coverage after the ARP coverage period ends.<sup>27</sup>

<sup>&</sup>lt;sup>24</sup> Questions & Answers on ACA Section 4106 Improving Access to Preventive Services for Eligible Adults in Medicaid: <a href="https://www.medicaid.gov/affordable-care-act/provisions/downloads/4106-faqs-clean.pdf">https://www.medicaid.gov/affordable-care-act/provisions/downloads/4106-faqs-clean.pdf</a>.

<sup>&</sup>lt;sup>25</sup> See footnote 28.

<sup>&</sup>lt;sup>26</sup> As noted earlier, to the extent possible, CMS has aligned its interpretation of section 11405 of the IRA with its interpretation of similar language added to the Medicare statute by section 11401 of the IRA. See <a href="https://www.cms.gov/files/document/irainsulinvaccinesmemo09262022.pdf">https://www.cms.gov/files/document/irainsulinvaccinesmemo09262022.pdf</a>.

<sup>&</sup>lt;sup>27</sup> Coverage of COVID-19 vaccinations described in section 1905(a)(4)(E) is required for nearly all Medicaid beneficiaries, including most eligibility groups receiving limited benefit packages under the state plan or a section 1115 demonstration, while the IRA-required adult vaccination coverage described in section 1905(a)(13)(B) is

### Increased FMAP

As explained earlier, states that currently provide Medicaid coverage for services described in sections 1905(a)(13)(A) and (B) of the Act, without cost sharing, receive a one percentage point increase in their FMAP for their Medicaid expenditures for these services, as well as for their Medicaid expenditures for the tobacco cessation services for pregnant individuals described in section 1905(a)(4)(D) of the Act. Section 11405(a)(3) of the IRA amended section 1905(b) of the Act to specify that states that were covering, as of the date of enactment of the IRA (August 16, 2022), vaccinations described in section 1905(a)(13)(B) without cost sharing will receive a one percentage point increase in the FMAP for their Medicaid expenditures for these vaccination services for the first eight fiscal quarters that begin on or after October 1, 2023. At the conclusion of the eight fiscal quarters (September 30, 2025), these states' Medicaid expenditures for vaccines and vaccine administration described in section 1905(a)(13)(B) of the Act will be matched at the applicable regular FMAP.

Effective October 1, 2023, states that opt to cover preventive services described in section 1905(a)(13)(A) of the Act without cost sharing will receive a one percentage point FMAP increase in their Medicaid expenditures for those services and for the tobacco cessation services for pregnant individuals described in section 1905(a)(4)(D) of the Act, and can continue to receive that FMAP increase even after September 30, 2025.

### **Provider Qualifications for Vaccinations**

States generally have broad flexibility to establish Medicaid provider qualifications (subject to the Medicaid free choice of provider requirement), including qualifications for providers that administer vaccines. States may have licensure and scope of practice laws and regulations, and/or other policies governing who is authorized to administer vaccines. CMS encourages states to review current state laws and policies to ensure that a broad array of providers who work in diverse settings (e.g., physician offices, clinics, pharmacies, hospitals) are authorized to administer vaccines as this could help to maximize beneficiaries' access to vaccines.

mandatory for all full-benefit categorically needy beneficiaries and (depending on the state's decisions about its Medicaid benefit packages) certain medically needy beneficiaries. Individuals in nearly all Medicaid eligibility groups are eligible for the ARP COVID-19 vaccination coverage described in section 1905(a)(4)(E) of the Act, including the following limited-benefit eligibility groups: individuals eligible only for family planning benefits; individuals eligible for tuberculosis-related benefits; and section 1115(a)(2) expenditure authority limited-benefit

In previous guidance about the one percentage point FMAP increase, CMS referenced the CDC/ACIP adult immunization schedule and did not explain whether states should cover approved adult vaccines administered according to the full range of ACIP recommendations (including vaccines not on the CDC/ACIP adult immunization schedule). See <a href="https://www.medicaid.gov/federal-policy-guidance/downloads/smd-13-002.pdf">https://www.medicaid.gov/federal-policy-guidance/downloads/smd-13-002.pdf</a>. Therefore, states can continue to receive the one percentage point FMAP increase after October 1, 2023, if, on August 16, 2022, they were providing the vaccination coverage that, under CMS's guidance as of August 16, 2022, permitted them to claim the one percentage point FMAP increase. Beginning on October 1, 2023, all states, including those who keep receiving the one percentage point FMAP increase after that date, will have to provide coverage in alignment with this guidance (i.e., the full range of ACIP recommendations).

Although states generally have broad flexibility to set Medicaid provider qualifications, states are reminded that HHS Public Readiness and Emergency Preparedness (PREP) Act declarations might identify certain practitioners as "covered persons" authorized to administer certain vaccines, such as those for COVID-19 and mpox.<sup>29</sup> These HHS PREP Act authorizations preempt conflicting state scope of practice or licensure laws and thus have Medicaid payment implications, as a result of the Medicaid free choice of provider requirement. Specifically, when a state covers a vaccination for a beneficiary, and a practitioner (such as a pharmacist or pharmacy technician) is authorized to administer that vaccine under an HHS PREP Act declaration, the state Medicaid program would be required to provide a pathway to paying that practitioner for the covered vaccine administration, when provided in accordance with the provisions of the HHS PREP Act 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.

### **Payment for Vaccinations**

Within the parameters of section 1902(a)(30)(A) of the Act, states have flexibility to set Medicaid payment rates for vaccines and vaccine administration. To help improve access to these services for Medicaid beneficiaries, CMS encourages states to consider setting payment rates for vaccines at actual acquisition cost and an adequate professional fee for administration to incentivize access to and availability of vaccines.

If states utilize a managed care delivery system to provide coverage for vaccines and vaccine administration, states should carefully analyze and assess their current managed care contracts and capitation rates for any necessary revisions or amendments in light of this guidance. As with all covered benefits in a Medicaid managed care plan contract, 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). Payment to healthcare providers for vaccines and vaccine administration may be specified by the state in a Medicaid managed care plan's contract, subject to the CMS approval requirements for state directed payments in 42 CFR § 438.6(c),<sup>30</sup> or may be determined by each managed care plan.

For states that use a managed care delivery system for their separate CHIPs, payment rates from the state to the managed care entity must be based on public or private rates for comparable populations and comparable services, consistent with actuarially sound principles, and are subject to the rate development standards at 42 CFR § 457.1203(a). In addition, 42 CFR § 457.1203(b) allows for flexibility in setting higher rates if such rates are necessary to ensure

<sup>&</sup>lt;sup>29</sup> For more information on the Medicaid implications of the HHS COVID-19 PREP Act declaration, see: https://www.medicaid.gov/state-resource-center/downloads/covid-19-vaccine-toolkit.pdf; and for more information on the Medicaid implications of the HHS PREP Act declaration for smallpox, monkeypox, and orthopoxvirus medical countermeasures, see: <a href="https://www.medicaid.gov/resources-for-states/downloads/covid19allstatecall12062022.pdf">https://www.medicaid.gov/resources-for-states/downloads/covid19allstatecall12062022.pdf</a> and <a href="https://www.hhs.gov/sites/default/files/monkeypox-faq-pharmacy-partners.pdf">https://www.hhs.gov/sites/default/files/monkeypox-faq-pharmacy-partners.pdf</a>.

pharmacy-partners.pdf.

30 For more information on state directed payments, please visit: <a href="https://www.medicaid.gov/medicaid/managed-care/guidance/state-directed-payments/index.html">https://www.medicaid.gov/medicaid/managed-care/guidance/state-directed-payments/index.html</a>.

sufficient provider participation or provider access or to enroll providers who demonstrate exceptional efficiency or quality in the provision of services.

## **State Plan Amendments (SPAs)**

States that have not already included an attestation in the Medicaid state plan stating that they cover the vaccines and vaccine administration described in section 1905(a)(13)(B) of the Act must submit a coverage SPA with an effective date of no later than October 1, 2023. On the supplement to attachments 3.1-A and 3.1-B (if applicable) coverage pages for the preventive services benefit, states should attest to coverage under the Medicaid state plan of vaccines and vaccine administration described in section 1905(a)(13)(B) of the Act. States should provide an additional assurance stating that they have a method to ensure that, as changes are made to ACIP recommendations, they will update their coverage and billing codes to comply with those revisions. States that do not have an approved payment methodology for these services must also submit a payment SPA with an effective date of no later than October 1, 2023. As with any SPA submission, CMS expects states to comply with all applicable federal Medicaid SPA requirements.

States should generally not need to submit a Medicaid cost sharing SPA to attest to compliance with these requirements because standard language in the cost-sharing state plan templates already specifies that the state is compliant with requirements at sections 1916 and 1916A of the Act, which were amended by section 11405 of the IRA to prohibit cost sharing for the vaccines described in section 1905(a)(13)(B) and administration of such vaccines.

States will also need to submit a CHIP SPA pursuant to the CMS requirements at 42 CFR § 457.60(a). States should indicate that they are covering, without cost sharing, all approved adult vaccines that are administered in accordance with ACIP recommendations, per sections 2103(c)(12) and 2103(e)(2) of the Act. More information will be forthcoming about the CHIP SPAs.

#### **Conclusion**

Mandatory coverage of all approved ACIP-recommended adult vaccinations, without cost-sharing, will improve access to vaccinations for adult Medicaid and CHIP beneficiaries. This change also has the potential to prevent hospitalizations and deaths and reduce costs associated with preventable infections. Please submit any questions about this guidance to Kirsten Jensen, Director of the Division of Benefits and Coverage, at <a href="kirsten.jensen@cms.hhs.gov">kirsten.jensen@cms.hhs.gov</a>.

Sincerely,

Daniel Tsai Deputy Administrator and Director