

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF MEDICAID AND MEDICAL ASSISTANCE
Statutory Authority: 31 Delaware Code, Section 512 (31 **Del.C.** §512)

FINAL

ORDER

Vaccines

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance initiated proceedings to amend Title XIX Medicaid State Plan regarding Vaccines, specifically, to modify the reimbursement methodology for vaccines and vaccine administration. The Department's proceedings to amend its regulations were initiated pursuant to 29 **Del.C.** §10114 and its authority as prescribed by 31 **Del.C.** §512.

The Department published its notice of proposed regulation changes pursuant to 29 **Del. C.** §10115 in the October 2024 *Delaware Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by October 31, 2024, at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

SUMMARY OF PROPOSAL

The purpose of this notice is to advise the public that Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) is proposing to amend Title XIX Medicaid State Plan regarding Vaccines.

Background

On June 27, 2023, the Centers for Medicare & Medicaid Services (CMS) issued guidance on section 11405 of the IRA (Pub. L. 117-169). Statutory amendments made by section 11405 of the IRA require Medicaid coverage and payment for approved adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and their administration, without cost sharing.

Vaccines administered to recommended populations at recommended intervals can reduce morbidity, hospitalizations, and deaths, and save costs. Vaccines may reduce the overall burden 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. An estimated 150,000 individuals per year are hospitalized because of pneumococcal pneumonia. In 2020, there were 5 newly reported cases of hepatitis B per 100,000 persons. The human papillomavirus (HPV) causes more than 37,000 cases of cancer each year.

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.

DMMA will pay for vaccines that are recommended by the Advisory Committee on Immunization Practices (ACIP) and will be covered for adults 18 and older with no cost share.

Statutory Authority

- Inflation Reduction Act (IRA)
- Section 1905(r)(1)(B)(iii) and (5) of the Act
- 42 CFR § 438.4(a)
- 42 CFR § 438.6(c)

Purpose

The purpose of this regulation is to comply with the Inflation Reduction Act (IRA) requirement to attest to the coverage of all Advisory Committee on Immunization Practices (ACIP) recommended vaccines and their administration.

Summary of Proposed Changes

Effective October 1, 2024, the DHSS/DMMA proposes to amend Title XIX Medicaid State Plan to modify the reimbursement methodology for vaccines and vaccine administration.

Public Notice

In accordance with the *federal* public notice requirements established at Section 1902(a)(13)(A) of the Social Security Act and 42 CFR 440.386 and the *state* public notice requirements of Title 29, Chapter 101 of the **Delaware Code**, DHSS/DMMA gave public notice and provided an open comment period for 30 days to allow all stakeholders an opportunity to provide input on the proposed regulation. Comments were to have been received by 4:30 p.m. on October 31, 2024.

Centers for Medicare and Medicaid Services Review and Approval

The provisions of this state plan amendment (SPA) are subject to approval by the Centers for Medicare and Medicaid Services (CMS). The draft SPA page(s) may undergo further revisions before and after submittal to CMS based upon public comment and/or CMS feedback. The final version may be subject to significant change.

Provider Manuals and Communications Update

Also, there may be additional provider manuals that may require updates as a result of these changes. The applicable Delaware Medical Assistance Program (DMAP) Provider Policy Specific Manuals and/or Delaware Medical Assistance Portal will be updated. Manual updates, revised pages or additions to the provider manual are issued, as required, for new policy, policy clarification, and/or revisions to the DMAP program. Provider billing guidelines or instructions to incorporate any new requirement may also be issued. A newsletter system is utilized to distribute new or revised manual material and to provide any other pertinent information regarding DMAP updates. DMAP updates are available on the Delaware Medical Assistance Portal website: <https://medicaid.dhss.delaware.gov/provider>

Fiscal Impact Statement

	Federal Fiscal Year 2024	Federal Fiscal Year 2025
General (State) funds	\$16,061	\$8,335
Federal funds	\$0	\$0

Summary of Comments Received with Agency Response and Explanation of Changes

There were no public comments received.

IMPACT ON THE STATE'S GREENHOUSE GAS EMISSIONS REDUCTION TARGETS AND RESILIENCY TO CLIMATE CHANGE:

The DMMA Division Director has reviewed the proposed regulation as required by 29 Del. C. §10118(b)(3) and has determined that if promulgated, the regulation would have a de minimis impact on the State's resiliency to climate change because neither implementation nor compliance with the regulation would reasonably involve the increase in greenhouse gas emissions.

FINDINGS OF FACT:

The Department finds that the proposed changes as set forth in the October 2024 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend Title XIX Medicaid State Plan regarding Vaccines, specifically, to modify the reimbursement methodology for vaccines and vaccine administration and shall be final effective December 11, 2024.

11/13/2024 | 9:15 AM EST

Date of Signature

Josette D. Manning Esq., Secretary, DHSS

Attachment 3.1-A
Page 6 Addendum 1

LIMITATIONS ON AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

13.c. Preventive Services

In accordance with section 4106 of the Affordable Care Act, Delaware Medicaid Covers and reimburses all preventative services assigned a grade of A or B by the United States Preventive Services Task Force (USPSTF), all approved vaccines and their administration, recommended by the Advisory Committee on Immunization Practices (ACIP), and behavioral interventions to treat Autism Spectrum Disorder (ASD) without cost-sharing. As changes are made to USPSTF recommendations, the State will update the coverage and billing codes to comply with these revisions.

The State covers all Federal Drug Administration (FDA) approved adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), and their administration, without cost-sharing. The state has methods to ensure that, as changes are made to ACIP recommendations, coverage and billing codes will be updated to comply with those revisions.

Preventative services are any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts acting within the scope of their practice under State law and include all preventive services not otherwise covered under the State Plan pursuant to Section §1905(r)(5) of the Social Security Act, *Early and Periodic Screening, Diagnostic, and Treatment Services*, for other necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State plan. Preventive Services are reimbursed according to the methodologies for services described in Attachment 4.19-B. *Methods and Standards for Establishing Payment Rates - Other Types of Care*, of the State Plan.

The State assures the availability of documentation to support the claiming of federal reimbursement for these preventative services.

The State assures that the benefit package will be updated as changes are made to the USPSTF and ACIP recommendation, and that the State will update the coverage and billing codes to comply with these revisions.

TN No. SPA # 16-010 <u>24-0012</u>	Approval Date January 12, 2017
Supersedes	
TN No. # 14-0007 <u>16-010</u>	Effective Date October 1, 2016 <u>October 1, 2024</u>

Attachment 4.19-B
Introduction - Page 6
OMB No. 0938-1148

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE/TERRITORY: **DELAWARE**

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES -
OTHER TYPES OF CARE

Physician Services

Increased Primary Care Service Payment 42 CFR 447.405, 447.410, 447.415

Attachment 4.19-B: Physician Services 42 CFR 447.405 Amount of Minimum Payment Continued

Effective Date of Payment

E & M Services

This reimbursement methodology applies to services delivered on and after January 1, 2013, ending on December 31, 2014 but not prior to December 31, 2014. All rates are published at

<http://www.dmap.state.de.us/home/index.htm>;

<https://medicaidpublications.dhss.delaware.gov/docs/search?EntryId=1080>

Vaccine Administration

This reimbursement methodology applies to services delivered on and after ~~January 1, 2013, ending on December 31, 2014~~ but not prior to ~~December 31, 2014~~ October 1, 2024. All rates are published at (<http://www.dmap.state.de.us/home/index.html>), <https://medicaidpublications.dhss.delaware.gov/docs/search?EntryId=1080>

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1148. The time required to complete this information collection is estimated to average 20 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-0S, Baltimore, Maryland 21244-1850.

TN No. SPA # 43-002 24-0012	Approval Date June 24, 2013
Supersedes	
TN No. # NEW PAGE 13-002	Effective Date January 1, 2013 <u>October 1, 2024</u>

Attachment 4.19-B
Introduction - Page 7.3
OMB No. 0938-1148

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE/TERRITORY: **DELAWARE**

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES -
OTHER TYPES OF CARE

Physician Services

Medicaid Payment for Primary Care Services CONTINUED

Effective Date of Payment

a. Evaluation & Management Services

This reimbursement methodology applies to services delivered on or after January 1, 2015. The fee schedule and any annual/periodic adjustments to the fee schedule are available on the Delaware Medical Assistance Program (DMAP) website at:

<http://www.dmap.state.de.us/downloads/feeschedules.html>
<https://medicaidpublications.dhss.delaware.gov/docs/search?EntryId=1080>

Except as otherwise noted in the plan, State developed fee schedule rates are the same for both government and private providers.

b. Vaccine Administration

This reimbursement methodology applies to services delivered on or after January 1, 2015. The fee schedule and any annual/periodic adjustments to the fee schedule are available on the Delaware Medical Assistance Program (DMAP) website at:

<http://www.dmap.state.de.us/downloads/feeschedules.html>
<https://medicaidpublications.dhss.delaware.gov/docs/search?EntryId=1080>

Except as otherwise noted in the plan, State-developed fee schedule rates are the same for both government and private providers.

TN No. SPA # ~~14-015~~ 24-0012

Approval Date ~~March 10, 2015~~

Supersedes

TN No. # ~~NEW PAGE~~ 14-015

Effective Date ~~January 1, 2015~~ October 1, 2024

***Please Note: Due to formatting of certain amendments to the regulation, they are not being published here. Copies of the documents are available at:**

<https://regulations.delaware.gov/register/december2024/final/66b Amended.pdf>

<https://regulations.delaware.gov/register/december2024/final/Attachment 4.19-B Intro Page 5 Amended.pdf>

28 DE Reg. 453 (12/01/24) (Final)