

## **Table of Contents**

**State/Territory Name: Florida**

**State Plan Amendment (SPA)#: 22-0002**

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) Companion Letter
- 3) CMS 179 Form
- 4) Approved SPA Pages



**Center for Medicaid and CHIP Services**  
**Disabled and Elderly Health Programs Group**

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April 26, 2023

Mr. Tom Wallace  
Deputy Secretary for Medicaid  
Agency for Health Care Administration  
2727 Mahan Drive, Mail Stop #8  
Tallahassee, FL 32308

Dear Tom Wallace,

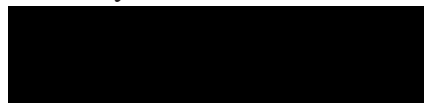
The CMS Division of Pharmacy team has reviewed Florida's State Plan Amendment (SPA) 22-0002 received in the CMS Medicaid & CHIP Operations Group on March 4, 2022. This SPA proposes to update physician administered drug reimbursement, over-the-counter drug coverage, and current age restrictions on existing vaccination language that includes coverage of certain vaccines to individuals that reside in institutions.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that FL-22-0002 is approved with an effective date of January 1, 2022. Our review was limited to the materials necessary to evaluate the SPA under applicable federal laws and regulations.

We are attaching a copy of the signed CMS-179 form, as well as the pages approved for incorporation into Florida's state plan. Additionally, a companion letter to the Centers for Medicare & Medicaid Services (CMS) approval of the Florida State Plan Transmittal Notice (TN) 22-0002 is included with this approval package. CMS determined that the applicable state plan pages do not reflect current CMS practice, under which vaccination language is not typically addressed on the prescribed drug pages of the state plan. However, pursuant to statutory amendments made by section 11405 of the Inflation Reduction Act (P.L. 117-169) (IRA), Florida will be required to cover approved adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), and their administration, for many adult Medicaid beneficiaries, without cost-sharing, beginning October 1, 2023. More details can be found in the attached companion letter.

If you have any questions regarding this request, please contact Michael Forman at 410-786-2666 or [michael.forman@cms.hhs.gov](mailto:michael.forman@cms.hhs.gov).

Sincerely,



Cynthia R. Denemark, R.Ph.  
Acting Director  
Division of Pharmacy

cc: Austin Noll, Florida, Agency for Health Care Administration  
Cole Giering, Florida, Agency for Health Care Administration  
Kelly Rubin, Florida, Agency for Health Care Administration  
Catherine McGrath, Florida, Agency for Health Care Administration  
Ann Dalton, Florida, Agency for Health Care Administration  
Tandra Hodges, CMS, Medicaid & CHIP Operations Group

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services 7500  
Security Boulevard, Mail Stop S2-14-26 Baltimore,  
Maryland 21244-1850



**Center for Medicaid and CHIP Services**  
**Disabled and Elderly Health Programs Group**

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April 26, 2023

Tom Wallace  
Deputy Secretary for Medicaid  
Agency for Health Care Administration  
2727 Mahan Drive, Mail Stop #8  
Tallahassee, FL 32308

Dear Tom Wallace,

This letter is being sent as a companion to the Centers for Medicare & Medicaid Services (CMS) approval of the Florida State Plan Transmittal Notice (TN) 22-0002, which amends the state plan to update the prescribed drug pages of the state plan. This amendment addresses, in part, over-the-counter drug coverage, update to the PAD reimbursement methodology and age restrictions related to coverage of certain vaccines for individuals that reside in institutions. The changes in this state plan amendment (SPA) are effective as of January 1, 2022.

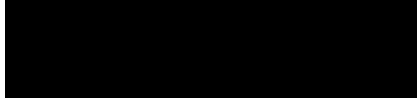
During the review process for SPA 22-0002, CMS determined that the applicable state plan pages do not reflect current CMS practice, under which vaccination language is not typically addressed on the prescribed drug pages of the state plan. Additionally, because the state restricts coverage of vaccinations to only certain individuals residing in institutions, the current state plan is potentially inconsistent with comparability requirements at 1902(a)(10)(B) of the Social Security Act and 42 CFR 440.240. Moreover, pursuant to statutory amendments made by section 11405 of the Inflation Reduction Act (P.L. 117-169) (IRA), Florida will be required to cover approved adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), and their administration, for many adult Medicaid beneficiaries, without cost-sharing, beginning October 1, 2023.

To address these issues, the state should submit an additional SPA or SPAs, with an effective date of October 1, 2023, that (1) remove the current vaccination language from the prescribed drug pages (Attachments 3.1-A and 3.1-B) and (2) otherwise amend the state plan as needed to comply with the requirements under section 11405 of the IRA.

The state has 90 days from the date of this letter to respond to CMS, confirming that the state intends to submit a new SPA or SPAs to address these issues. During this period, CMS will provide any required technical assistance.

If you have any questions regarding this request, please contact Michael Forman at 410-786-2666 or michael.forman@cms.hhs.gov.

Sincerely,



Cynthia R. Denemark, R.Ph.  
Acting Director  
Division of Pharmacy

cc: Austin Noll, Florida, Agency for Health Care Administration  
Cole Giering, Florida, Agency for Health Care Administration  
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Catherine McGrath, Florida, Agency for Health Care Administration  
Ann Dalton, Florida, Agency for Health Care Administration  
Tandra Hodges, CMS, Medicaid & CHIP Operations Group

<b>TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</b>	1. TRANSMITTAL NUMBER <u>2 2 — 0 0 0 2</u>	2. STATE <u>FL</u>
	3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT <input checked="" type="radio"/> XIX <input type="radio"/> XXI	
TO: CENTER DIRECTOR CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE <b>January 1, 2022</b>	
5. FEDERAL STATUTE/REGULATION CITATION s. 1927(d)(2) and 1927(d)(7) of the Social Security Act	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a. FFY <u>21-22</u> \$ <u>(3,757,751)</u> b. FFY <u>22-23</u> \$ <u>(5,278,020)</u>	
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Att. 3.1-A pg 46 & 46a, Att. 3.1-B pg 45 & 45a, Att. 4.19-B 4	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Att. 3.1-A pg 46 & 46a, Att. 3.1-B pg 45 & 45a, Att. 4.19-B 4 & 4a	

9. SUBJECT OF AMENDMENT  
  
**Prescription Drugs**

10. GOVERNOR'S REVIEW (Check One)

GOVERNOR'S OFFICE REPORTED NO COMMENT                       OTHER, AS SPECIFIED:  
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED  
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. TYPED NAME Tom Wallace  13. TITLE Deputy Secretary for Medicaid  14. DATE SUBMITTED March 4, 2022	15. RETURN TO Mr. Tom Wallace Deputy Secretary for Medicaid Agency for Health Care Administration 2727 Mahan Drive, Mail Stop #8 Tallahassee, FL 32308  Attn: Cole Giering
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**FOR CMS USE ONLY**

16. DATE RECEIVED <u>03/04/22</u>	17. DATE APPROVED <u>04/26/23</u>
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**PLAN APPROVED - ONE COPY ATTACHED**

18. EFFECTIVE DATE OF APPROVED MATERIAL <u>01/01/22</u>	19. SIGNATURE OF APPROVING OFFICIAL 
20. TYPED NAME OF APPROVING OFFICIAL <u>Cynthia R. Denemark, R.Ph.</u>	21. TITLE OF APPROVING OFFICIAL <u>Acting Director, Division of Pharmacy</u>

22. REMARKS

PRESCRIBED DRUGS:Covered Legend Drugs:

Covered outpatient drugs are those produced by any manufacturer that has entered into and complies with an agreement under Section 1927(a) of the Act, and which are prescribed for a medically accepted indication. Drugs must be prescribed and dispensed in accordance with medically accepted indications for uses and dosages.

Coverage for immunizations is limited to the following recipients who are not covered by Medicare Part D:

- Influenza and pneumococcal vaccine for institutionalized recipients; and
- Herpes Zoster (Shingles) vaccine for institutionalized recipients.

Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B as provided by Section 1935 (d)(1) of the Act.

The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit –Part D.

As provided by Section 1927(d)(2) of the Act, certain outpatient drugs may be excluded from coverage. Those excluded are DESI drugs; experimental drugs; anorectics (unless prescribed for an indication other than obesity); non-legend drugs (except as specified below), aspirin, aluminum and calcium products used as phosphate binders, sodium chloride for specific medical indications; and any drugs for which the manufacturer has not entered into rebate agreements with the Department of Health and Human Services, the Veteran's Administration and the Public Health Service.

As provided by Section 1935(d)(2) of the ACT:

**The following excluded drugs are covered:**

- (a) agents when used for anorexia, weight loss, weight gain
- None of the drugs under this drug class are covered*
  
- (b) agents when used to promote fertility
- None of the drugs under this drug class are covered*
  
- (c) agents when used for cosmetic purposes or hair growth
- None of the drugs under this drug class are covered*
  
- (d) agents when used for the symptomatic relief cough and colds
- Some drugs categories covered under the drug class*
  - Legend cough and cold preparations, including antitussives, decongestants, and expectorants are covered for recipients under the age of 21 years.

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 Effective 1/1/2022  
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- Legend or OTC single entity guaifenesin products are covered for recipients under the age of 21 years.

(e) prescription vitamins and mineral products, except prenatal vitamins and fluoride.

*Some drug categories covered under the drug class*

- Legend vitamin and mineral products are covered for dialysis patients.

(f) nonprescription drugs

Selective OTC drugs will be covered as listed on the State's website.

(g) covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee

*None of the drugs under this drug class are covered*

Drug Rebate Agreement: The state is in compliance with Section 1927 of the Act. Based on the requirements for Section 1927 of the Act, the state has the following policies for drug rebate agreements:

- The drug file permits coverage of participating manufacturers' drugs.
- Compliance with the reporting requirements for state utilization information and restrictions to coverage.

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PRESCRIBED DRUGS

Florida Medicaid reimburses for prescribed drugs in accordance with the provisions of Title 42 Code of Federal Regulations, Section 447 Subpart I.

1. Florida Medicaid reimburses for covered drugs dispensed by an approved Florida Medicaid pharmacy provider, or a provider enrolled as a dispensing practitioner, in an amount not to exceed the lesser of the following four items:
  - a. The Actual Acquisition Cost (AAC) plus a professional dispensing fee (PDF) of \$10.24. The National Average Drug Acquisition Cost (NADAC) will be used for the AAC when available. If the NADAC is unavailable, the AAC will be equal to wholesaler acquisition cost.
  - b. The Wholesaler Acquisition Cost (WAC) plus a PDF of \$10.24.
  - c. The State Maximum Allowable Cost plus a PDF of \$10.24.
  - d. The provider's Usual and Customary Charge (U&C).

Florida Medicaid reimburses for the following utilizing the above payment methodology:

- Covered outpatient drugs dispensed by a retail community pharmacy
- Specialty drugs dispensed primarily through the mail
- Drugs not purchased pursuant to the 340B Program by a covered entity
- Drugs dispensed in an institutional or long-term care pharmacy when not included as part of an inpatient stay

Florida Medicaid utilizes the NADAC in the reimbursement methodology, which ensures that the Federal Upper Limit price in the aggregate will not be exceeded.

2. Florida Medicaid utilizes the actual purchased drug price plus a PDF in the reimbursement methodology for drugs acquired via the Federal Supply Schedule.
3. Florida Medicaid utilizes the actual purchased drug price plus a PDF in the reimbursement methodology for drugs acquired via nominal price.
4. Florida Medicaid reimburses for drugs purchased under the 340B program at the actual purchased drug price, which cannot exceed the 340B ceiling price, plus a dispensing fee of \$10.24. This provision only applies to covered entities, Indian Health Services, tribal organizations, urban Indian pharmacies and federally qualified health centers or the contracted agents that dispense drugs purchased at prices authorized under section 340B of the Public Health Service Act.
5. Florida Medicaid reimburses for clotting factor to the vendors awarded the State's hemophilia contract at the negotiated price.
6. Florida Medicaid reimburses for covered prescribed drugs administered by a licensed practitioner in an office setting as provided by the Centers for Medicare & Medicaid Services (CMS) quarterly in the format of drug pricing files, available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>, or when no ASP rate is available, at WAC.
7. Florida Medicaid reimburses for covered prescribed drugs purchased under the 340B program administered in an outpatient facility at an amount not to exceed the 340B ceiling price.
8. Florida Medicaid does not reimburse for investigational or experimental drugs.

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 Effective 1/1/2022  
 Supersedes 2017-005  
 Approval 04/26/2023