Table of Contents

State/Territory Name: Florida

State Plan Amendment (SPA)#: 25-0008

This file contains the following documents in the order listed

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

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



Medicaid Benefits and Health Programs Group

December 4, 2025

Brian Meyer State Medicaid Director Florida Agency for Health Care Administration 2727 Mahan Drive, Mail Stop #8 Tallahassee, FL 32308

Dear Brian Meyer,

We have reviewed Florida's State Plan Amendment (SPA) 25-0008 received in the Centers for Medicare and Medicaid Services (CMS) OneMAC application on September 29, 2025. This amendment authorizes Florida to enter into Value-Based Purchasing (VBP) Arrangements on a voluntary basis with drug manufacturers and removing vaccine language in the Covered Legend Drugs section.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that FL-25-0008 is approved with an effective date of September 30, 2025.

We are attaching a copy of the signed CMS-179 form, as well as the pages approved for incorporation into the Florida state plan. If you have any questions regarding this amendment, please contact Michael Forman at Michael.forman@cms.hhs.gov.

Sincerely,

Catherine A. Traugott, R.Ph., J.D. Acting Director Division of Pharmacy

cc: Ann Dalton, Florida, Agency for Health Care Administration Shanise Jackson, Florida, Agency for Health Care Administration Devona Pickle, Florida, Agency for Health Care Administration Edwin Lang, Florida, Agency for Health Care Administration Julianne Henry, Florida, Agency for Health Care Administration Mekia Jackson, Florida, Agency for Health Care Administration Jesseka Forbes, Florida, Agency for Health Care Administration Susan Hamrick, Florida, Agency for Health Care Administration Kia Carter-Anderson, CMS, Medicaid and CHIP Operations Group

CENTERS FOR MEDICARE & MEDICAID SERVICES	000000000000000000000000000000000000000		
TRANSMITTAL AND NOTICE OF APPROVAL O	1. TRANSMITTAL NUMBER 2. STATE		
STATE PLAN MATERIAL	F 2 5 — 0 0 0 8 F L		
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL		
TON. SERVERS FOR MEDICALE & MEDICALD SERVICES	SECURITY ACT XIX XXI		
TO: CENTER DIRECTOR	4. PROPOSED EFFECTIVE DATE		
CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	September 30, 2025		
5. FEDERAL STATUTE/REGULATION CITATION	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)		
Section 1927 of Social Security Act; 42 CFR 447.502	a FFY 2024-25 \$ 0 b. FFY 2025-26 \$ 0		
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION		
Attachment 3.1-A page 46	OR ATTACHMENT (If Applicable)		
Attachment 3.1-A page 46a	Attachment 3.1-A page 46 Attachment 3.1-A page 46a.1		
Attachment 3.1-A page 46a.1	Attachment 3.1-A page 46a Attachment 3.1-B page 45a.1		
Attachment 3.1-B page 45	Attachment 3.1-B page 45 Attachment 3.1-B page 45a		
Attachment 3.1-B page 45a Attachment 3.1-B page 45a.1	Attachment 5.1-b page 45a		
Attachment o. 1-b page 40a. 1			
9. SUBJECT OF AMENDMENT	•		
Value-Based Purchasing Arrangement (VBP) authority for Pharm	nacy		
	Arrangements on a voluntary basis with drug manufacturers		
and removing vaccine language in the Covered Legend Drug			
10. GOVERNOR'S REVIEW (Check One)			
O GOVERNOR'S OFFICE REPORTED NO COMMENT	OTHER, AS SPECIFIED:		
COMMENTS OF GOVERNOR'S OFFICE ENCLOSED	O o men, no or connect.		
NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
11. GENCY OFFICIAL	15. RETURN TO		
	Mr. Brian Meyer		
12. TYPED NAME	Deputy Secretary for Medicaid		
Brian Meyer	Agency for Health Care Administration		
13. TITLE	2727 Mahan Drive, Mail Stop #8		
Deputy Secretary for Medicaid	Tallahassee, Florida 32308		
14. DATE SUBMITTED 9-29-25	Constitution of the consti		
	Attention: Shanise Jackson		
FOR CMS	Nicoland Control of the Control of t		
16. DATE RECEIVED 09-29-2025	DATE APPROVED		
	12-04-2025		
PLAN APPROVED - O			
18. EFFECTIVE DATE OF APPROVED MATERIAL	19. SIGNATURE OF APPROVING OFFICIAL		
09-30-25			
20. TYPED NAME OF APPROVING OFFICIAL	21. TITLE OF APPROVING OFFICIAL		
Catherine A. Traugott, R.Ph., J.D.	Acting Director, Division of Pharmacy		

22. REMARKS

11/4/2025 - The state authorized a Pen & Ink change to Box 9, updating the subject language.

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.

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:

X	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
- $\hfill\Box$ (b) agents when used to promote fertility
- ⊠ None of the drugs under this drug class are covered
- ☑ (c) agents when used for the symptomatic relief cough and colds
 - Selective cough and cold drugs will be covered as listed on the State's website.

- ☑ (d) prescription vitamins and mineral products, except prenatal vitamins and fluoride.
- Selective prescription vitamins and mineral products will be covered as listed on the State's website.
- Legend vitamin and mineral products are covered for dialysis patients.
- ⋈ (e) nonprescription drugs

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

- ☐ (f) 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

<u>Drug Rebate Agreement</u>: The state will meet the requirements of Section 1927 of the Social Security Act. Based on the requirements for Section 1927 of the Act, the state has the following policies for the supplemental rebate program and value-based purchasing supplemental rebate program for Medicaid recipients:

- a. The state will be negotiating supplemental rebates and value-based purchasing supplemental agreements in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates.
- b. A supplemental rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on May 20, 2013, has been authorized by CMS.
- c. A value-based purchasing supplemental rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on September 29, 2025 has been authorized by CMS.
- d. Supplemental rebates and value-based purchasing supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.
- e. All drugs covered by the program, irrespective of a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.

INTENTIONALLY LEFT BLANK

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.

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:

X	The following	excluded	l drugs	are covered	i:

	(a) agents when used for anorexia, weight loss, weight gain
X	None of the drugs under this drug class are covered

(b) agents wher	n used to	promote	fertility

- ⋈ None of the drugs under this drug class are covered
- - Selective cough and cold drugs will be covered as listed on the State's website.

- (d) prescription vitamins and mineral products, except prenatal vitamins and fluoride.
 - Selective prescription vitamins and mineral products will be covered as listed on the State's website.
 - Legend vitamin and mineral products are covered for dialysis patients.
- ⊠ (e) nonprescription drugs
 □
 - Selective OTC drugs will be covered as listed on the State's website.
- (f) 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

<u>Drug Rebate Agreement</u>: The state will meet the requirements of Section 1927 of the Social Security Act. Based on the requirements for Section 1927 of the Act, the state has the following policies for the supplemental rebate program and value-based purchasing supplemental rebate program for Medicaid recipients:

- a. The state will be negotiating supplemental rebates and value-based purchasing supplemental agreements in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates.
- b. A supplemental rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on May 20, 2013, has been authorized by CMS.
- c. A value-based purchasing supplemental rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on September 29, 2025 has been authorized by CMS.
- d. Supplemental rebates and value-based purchasing supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.
- e. All drugs covered by the program, irrespective of a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.

INTENTIONALLY LEFT BLANK