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**State/Territory Name: Florida**

**State Plan Amendment (SPA) #: 19-0015**

This file contains the following documents in the order listed:

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**

March 25, 2020

Ms. Beth Kidder
Deputy Secretary for Medicaid
Agency for Health Care Administration
2727 Mahan Drive, Mailstop #20
Tallahassee, FL 32308

Dear Ms. Kidder,

The CMS Division of Pharmacy team has reviewed Florida's State Plan Amendment (SPA) 19-0015 received in the CMS Division of Program Operations on December 30, 2019. This SPA proposes to allow the state to comply with the Medicaid Drug Utilization Review (DUR) provisions included in Section 1004 of the Substance Use-Disorder Prevention that promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (P.L. 115-271).

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that FL SPA 19-0015 is approved with an effective date of October 1, 2019. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Florida's state plan, will be forwarded by the CMS Division of Program Operations.

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

Sincerely,

/s/

Cynthia R. Denemark, R.Ph.
Deputy Director
Division of Pharmacy
DEHPG/CMCS/CMS

cc: Cole Giering, MPH, Florida State Plan Coordinator
James G. Scott, CMS, Director, Division of Program Operations
Cheryl L Brimage, CMS Division of Program Operations

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

| **TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL**<br><br>**FOR: HEALTH CARE FINANCING ADMINISTRATION** | 1. TRANSMITTAL NUMBER:<br>19-0015 | 2. STATE<br>Florida |
|---|---|---|
| | 3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID) | |
| TO: REGIONAL ADMINISTRATOR<br>HEALTH CARE FINANCING ADMINISTRATION<br>DEPARTMENT OF HEALTH AND HUMAN SERVICES | 4. PROPOSED EFFECTIVE DATE<br>October 1, 2019 | |

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN x☐ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

| 6. FEDERAL STATUTE/REGULATION CITATION:<br>1902(a)(85) of SSA & 1004 of SUPPORT Act | 7. FEDERAL BUDGET IMPACT:<br>a. FFY 19-20 $ 0<br>b. FFY 20-21 $ 0 |
|---|---|
| 8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:<br><br>Section 4.26 (pages 7 4-7 4c, add 7 4d) | 9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:<br><br>Section 4.26 (pages 74-74c) |

10. SUBJECT OF AMENDMENT:
Update State Plan to be in compliance with the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for and Communities (SUPPORT) Act

11. GOVERNOR'S REVIEW *(Check One)*:
☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
x☐ OTHER, AS SPECIFIED:

| 12. SIGNATURE OF STATE AGENCY OFFICIAL:<br>//s// | 16. RETURN TO:<br>Beth Kidder<br>Agency Secretary for Medicaid<br>2727 Mahan Drive, Mail Stop #8<br>Tallahassee, FL 32308<br><br>Attention: Cole Giering |
|---|---|
| 13. TYPED NAME: Beth Kidder | |
| 14. TITLE:<br>Deputy Secretary for Medicaid | |
| 15. DATE SUBMITTED: | |

| 17. DATE RECEIVED:<br>12/30/19 | 18. DATE APPROVED: 03/25/20 |
|---|---|
| PLAN APPROVED – ONE COPY ATTACHED | |
| 19. Effective Date of Approved Material: 10/01/19 | 20. SIGNATURE OF REGIONAL OFFICIAL:<br>//s// |
| 21. TYPED NAME:<br>James G. Scott | 22. TITLE: Director,<br>Division of Program Operations |

23. REMARKS:

State/Territory FLORIDA

**Citation:** 4.26 Drug Utilization Review Program

1927(g)
42 CFR 456.700

A.1. The Medicaid agency meets the requirements of Section 1927(g) of the Act for a drug utilization review (DUR) program for outpatient drug claims.

1927(g)(1)(a)

2. The DUR program assures that prescriptions for outpatient drugs are:

- Appropriate
- Medically necessary
- Are not likely to result in adverse medical results

1927(g)(1)(a)
42 CFR 456.705(b) and 456.709(b)

B. The DUR program is designed to educate physicians and pharmacists to identify and reduce the patterns of fraud, abuse, gross overuse, or the inappropriate or medically unnecessary care among physicians, pharmacists, and patients or associated with specific drugs as well as:

- Potential and actual adverse drug reactions
- Therapeutic appropriateness
- Overutilization and underutilization
- Appropriate use of generic products
- Therapeutic duplication
- Drug disease contraindications
- Drug-Drug Interactions
- *Drug-allergy interactions
- Clinical abuse/misuse

1927(g)(1)(B)
42 CFR 456.703 (d) and (f)

C. The DUR program shall assess data use against predetermined standards whose source materials for their development are consistent with peer-reviewed medical literature which has been critically reviewed by unbiased independent experts and the following compendia:

- American Hospital Formulary Service Drug Information
- United States Pharmacopeia-Drug Information
- American Medical Association Drug Evaluations

* Our DUR program will not target individual drug allergies, as that information cannot be maintained in the recipient information file. However, as part of the Pharmacy Practice Act requiring prescription/patient profiles, all pharmacists will be expected to capture drug allergy information before filling any prescriptions.

State/Territory FLORIDA

**Citation:**

1927(g)(1)(D)
42 CFR 456.703(b)

D. DUR is not required for drugs dispensed to residents of nursing facilities that are in compliance with drug regimen review procedures set forth in 42 CFR 483.60. The State has never-the-less chosen to include nursing home drugs in:

X Prospective DUR
X Retrospective DUR

1927(g)(2)(A)
42 CFR 456.705(b)

E.I. The DUR program includes prospective review of drug therapy at the point of sale or point of distribution before each prescription is filled or delivered to the Medicaid recipient.

1927(g)(2)(A)(i)
42 CFR 456.705(b),
(1)-(7))

2. Prospective DUR includes screening each prescription filled or delivered to an individual receiving benefits for potential drug therapy problems due to:

- Therapeutic Duplication
- Drug-disease contraindications
- Drug-drug interactions
- Drug-interactions with non-prescription or over-the-counter drugs
- Incorrect drug dosage or duration of drug treatment
- Drug allergy interactions
- Clinical abuse/misuse

1927(g)(2)(A)(ii)
42 CFR 456.705
(c) and(d)

3. Prospective DUR includes counseling for Medicaid recipients based on standards established by State law and maintenance of patient profiles.

1927(g)(2)(B)
42 CFR 456.709(a)

F.I. The DUR program includes retrospective DUR through its mechanized drug claims processing and information retrieval system or otherwise which undertakes ongoing periodic examination of claims data and other records to identify:

- Patterns of fraud and abuse
- Gross overuse
- Inappropriate or medically unnecessary care among physicians, pharmacists, Medicaid recipients, or associated with specific drugs or groups of drugs.

State/Territory FLORIDA

**Citation:**

1927(g)(2)(C)
42 CFR 456.709(b)

F.2. The DUR program assesses data on drug use against explicit predetermined standards including but not limited to monitoring for:

- Therapeutic appropriateness
- Overutilization and underutilization
- Appropriate use of generic products
- Therapeutic duplication
- Drug-disease contraindications
- Drug-Drug Interactions
- Incorrect drug dosage/duration of drug treatment
- Clinical abuse/misuse

1927(g)(2)(D)
42 CFR 456.711

3. The DUR program through its State DUR Board, using data provided by the Board, provides for active and ongoing educational outreach programs to educate practitioners on common drug therapy problems to improve prescribing and dispensing practices.

1927(g)(3)(A)
42 CFR 456.716(a)

G.I. The DUR program has established a State DUR Board either:

X Directly, or
_ Under contract with a private organization

1927(g)(3)(B)
42 CFR 456.716
(A) and (B)

2. The DUR Board membership includes health professionals (one-third licensed actively practicing pharmacists and one-third but no more than 51% licensed and actively practicing physicians) with knowledge and experience in one or more of the following:

- Clinically appropriate prescribing of covered outpatient drugs.
- Clinically appropriate dispensing and monitoring of covered outpatient drugs.
- Drug use review, evaluation and intervention.
- Medical quality assurance.

1927(g)(3)(C)
42 CFR 456.716(d)

3. The activities of the DUR Board include:

- Retrospective DUR,
- Application of Standards as defined in section 1927(g)(2)(C), and
- Ongoing interventions for physicians and pharmacists targeted towards therapy problems or individuals identified in the course of retrospective DUR.

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**Citation:**

1927(g)(3)(C)
42 CFR 456.711
(a)-(d)

G.4. The interventions include in appropriate instances:

- Information Dissemination
- Written, oral, and electronic reminders
- Face-to-face discussion
- Intensified monitoring/review of prescriber/dispensers

1927(g)(3)(D)
42 CFR 456.711~~1~~2
(A)-(B)

H. The State assures that it will prepare and submit an annual report to the Secretary, which incorporates a report from the State DUR Board, and that the State will adhere to the plans, steps, procedures as described in the report

1927(h)(1)
42 CFR 456.722

X I.1. The State establishes, as its principal means of processing claims for covered outpatient drugs under this title, a point-of-sale electronic claims management system to perform on-line:

- real time eligibility verification
- claim data capture
- adjudication of claims
- assistance to pharmacists, etc. applying for and receiving payment.

1927(g)(2)(A)(i)
42 CFR 456.705(b)

2. Prospective DUR is performed using an electronic point of sale drug claims processing system.

1927(j)(2)
42 CFR 456.703(c)

J. Hospitals which dispense covered outpatient drugs are exempted from the drug utilization review requirements of this section when facilities use drug formulary systems and bill the Medicaid program no more than the hospital's purchasing cost for such covered outpatient drugs, in the hospital's per diem rate.

State/Territory: FLORIDA

Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act Provisions

**Citation:**

1902(a)(85) and Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)

K. The State shall perform the following reviews and actions for opioid claim limitations:

1. Prospective Point of Sale (POS) safety edits for opioid duplicate and early fills and exceeding State defined quantity and dosage limits. A prior authorization shall be required for an override.
2. Prospective POS safety edit for exceeding State defined Morphine Milligram Equivalents (MME) limits. An override by the pharmacist or a prior authorization by the physician may be required.
3. Retrospective reviews on opioid prescriptions exceeding the above limits on an ongoing periodic basis.
4. Prospective POS safety edits for members receiving concurrent opioids and benzodiazepines and for those receiving concurrent opioids and antipsychotics. An override by the pharmacist or a prior authorization by the physician may be required.
5. Retrospective reviews of concurrent utilization of opioids and benzodiazepines as well as opioids and antipsychotics on an ongoing periodic basis.

L. The State shall manage and monitor antipsychotic medications used by children in the following manner:

1. Prospective POS safety edits for children younger than the State specified age receiving antipsychotics. A prior authorization shall be required for an override.
2. Prospective POS safety edits for children less than 18 years of age receiving high dosages of antipsychotics. A prior authorization shall be required for an override.
3. Retrospective reviews shall be performed to evaluate the appropriateness of prescribing for children of all ages receiving antipsychotics, including children in foster care based on indications and clinical guidelines. Education shall be provided to practitioners prescribing these medications as deemed appropriate.

M. The State shall identify and respond to potential fraud and abuse using the following methods:

1. Potential fraud and/or abuse shall be identified via automatic claims review and referrals. Potential cases shall be reviewed by the State for possible referral to Medicaid Program Integrity, law enforcement, or the Medicaid fraud control unit.
2. Retrospective reviews shall be performed on opioid claims and discussed with the State DUR Board on an ongoing periodic basis. Education shall be provided to practitioners prescribing these medications.