

## **Table of Contents**

**State Name:** Delaware

**State Plan Amendment (SPA) #:** 14-0005

This file contains the following documents in the order listed:

- 1) CO Approval Letter
- 2) RO Approval Letter
- 3) CMS 179 Form
- 4) 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



**Disabled & Elderly Health Programs Group**

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April 24, 2014

Mr. Stephen M. Groff  
Director  
Division of Medicaid and Medical Assistance  
P.O. Box 906  
New Castle, Delaware 19720-0906

Dear Mr. Groff:

We have reviewed Delaware State Plan Amendment (SPA) 14-0005, Prescribed Drugs, received in the Regional Office on March 26, 2014. This amendment proposes to remove benzodiazepines and barbiturates from the excludable drug list and provides coverage of tobacco cessation drugs in accordance with 1927(d)(7) of the Social Security Act.

Based on the information provided, we are pleased to inform you that SPA 14-0005 is approved with an effective date of January 1, 2014. A copy of the CMS-179 form, as well as the pages approved for incorporation into the Delaware state plan, will be forwarded by the Philadelphia Regional Office. If you have any questions regarding this amendment, please contact Lisa Ferrandi at (410) 786-5445.

Sincerely,



Joseph L. Fine  
Acting Director  
Division of Pharmacy

cc: Francis T. McCullough, ARA, Philadelphia Regional Office  
Michael Cleary, Philadelphia Regional Office

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
150 S. Independence Mall West  
Suite 216, The Public Ledger Building  
Philadelphia, Pennsylvania 19106-3499



Region III/Division of Medicaid and Children's Health Operations

SWIFT #033120144032

**MAY 02 2014**

Mr. Stephen M. Groff, Director  
Division of Medicaid and Medical Assistance  
P.O. Box 906  
New Castle, DE 19720-0906

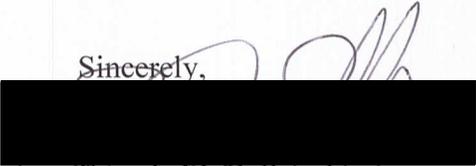
Dear Mr. Groff:

We are pleased to inform you of the approval of Delaware State Plan Amendment (SPA) 14-0005. This amendment proposes to remove benzodiazepines, barbiturates, and smoking cessation drugs from the list of drugs a state can exclude from coverage or restrict.

Enclosed is a copy of the approved SPA pages and the signed CMS-179 form. The effective date of this amendment is January 1, 2014.

If you have any questions, you may contact Michael Cleary at (215) 861-4282.

Sincerely,

  
Francis McCullough  
Associate Regional Administrator

Enclosures

**TRANSMITTAL AND NOTICE OF APPROVAL OF  
STATE PLAN MATERIAL**

1. TRANSMITTAL NUMBER:  
SPA #14-0005

2. STATE  
DELAWARE

FOR: HEALTH CARE FINANCING ADMINISTRATION

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE  
SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR  
HEALTH CARE FINANCING ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE  
January 1, 2014

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

- NEW STATE PLAN       AMENDMENT TO BE CONSIDERED AS NEW PLAN       AMENDMENT

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

6. FEDERAL STATUTE/REGULATION CITATION:

Patient Protection and Affordable Care Act, P.L. 111-148, enacted March 23, 2010 and the Health Care and Education Reconciliation Act of 2010, P.L. 111-152, enacted March 30, 2010 (collectively referred to as the Affordable Care Act, Section 2502; 1927(d)(7) of the Social Security Act, Non-Excludable Drugs; and, 42 CFR §440.120, Prescribed Drugs

7. FEDERAL BUDGET IMPACT:

- a. FFY 2014      \$ N/A  
b. FFY 2015      \$ N/A

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment 3.1-A Page 5 Addendum  
Attachment 3.1.A.1 Page 2a  
Attachment 3.1.A.1 Page 2b

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (*If Applicable*):

Attachment 3.1-A Page 5 Addendum  
Attachment 3.1.A.1 Page 2a  
Attachment 3.1.A.1 Page 2b

10. SUBJECT OF AMENDMENT: **Prescribed Drugs: Removal of Barbiturates, Benzodiazepines and Agents used to Promote Smoking Cessation from Exclusion Lists – Affordable Care Act Section 2502**

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

OTHER, AS SPECIFIED:  
Governor's comments under separate correspondence

12. SIGNATURE OF STATE AGENCY OFFICIAL:

//Stephen M. Groff – signature//

16. RETURN TO:

Stephen M. Groff  
Director  
Division of Medicaid and Medical Assistance  
P.O. Box 906  
New Castle, Delaware 19720-0906

13. TYPED NAME:

Stephen M. Groff, Director, Division of Medicaid and Medical Assistance

14. TITLE: Designee for Rita M. Landgraf, Secretary, Delaware Health and Social Services

15. DATE SUBMITTED:

March 26, 2014

**FOR REGIONAL OFFICE USE ONLY**

17. DATE RECEIVED:

MAR 26 2014

18. DATE APPROVED:

APR 24 2014

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

JAN 01 2014

20. SIGNATURE OF REGIONAL OFFICIAL:

[Redacted Signature]

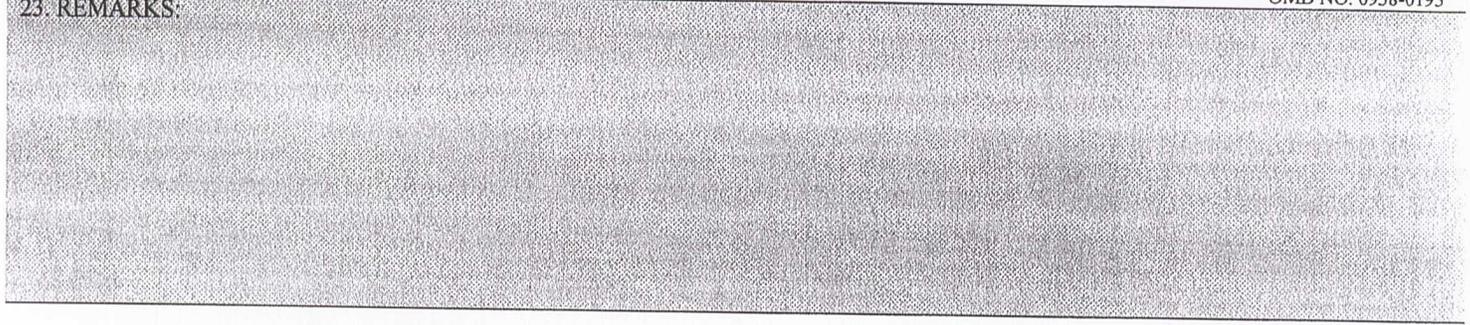
21. TYPED NAME:

FRANCIS McDULLOUGH

22. TITLE:

ASSOCIATE REGIONAL ADMINISTRATOR

23. REMARKS:



STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: DELAWARE

MEDICAID PROGRAM: REQUIREMENTS RELATING TO PAYMENT FOR COVERED  
OUTPATIENT DRUGS FOR THE CATEGORICALLY NEEDY

Citation (s)	Provision (s)
1927(d)(2) and 1935(d)(2)	<input type="checkbox"/> (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 (see specific drug categories below)  (The Medicaid agency lists specific category of drugs below)  (a) Agents when used for anorexia, weight loss, weight gain: Megestrol Acetate, Somatropin, Lipase Inhibitor. Products in these categories require prior authorization.  (d) Agents when used for the symptomatic relief cough and colds: Antihistamines, Antitussive, Decongestants, and Expectorants.  (e) Prescription vitamins and mineral products, except prenatal vitamins and fluoride: Single entity vitamins, Multiple vitamins w/minerals, Nicotinic acid, Calcium salts, and Dialysis replacement products

TN No. <u>SPA #14-0005</u> Supersedes TN No. <u>SPA #13-001</u>	Approval Date <u>APR 24 2014</u>  Effective Date <u>January 1, 2014</u>
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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: DELAWARE

MEDICAID PROGRAM: REQUIREMENTS RELATING TO PAYMENT FOR COVERED  
OUTPATIENT DRUGS FOR THE CATEGORICALLY NEEDY

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Citation (s)	Provision (s)
1927(d)(2) and 1935(d)(2)	CONTINUED

(f) Nonprescription drugs: Analgesic oral and rectal; Heartburn; Antiflatulents; Antidiarrheal; Antinauseants; Cough & Cold, oral; Cough & Cold, topical; Contraceptive Drugs; Laxatives & Stool Softeners; Lice Control Preparations; Nasal Drug Preparations; Nicotine Cessation Preparations; Ophthalmic Drug Preparations; Topical Anesthetics; Topical Antibacterials; Topical/Vaginal Fungicidals; and, Digestive Enzymes.

No excluded drugs are covered.

TN No. SPA #14-0005  
Supersedes  
TN No. SPA #13-001

Approval Date APR 24 2014  
Effective Date January 1, 2014

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: DELAWARE

LIMITATIONS

**12.a. Prescribed Drugs:**

Drug Coverage

- 1) Drug products are covered when prescribed or ordered by a physician, or other licensed practitioner within the scope of their practice and when obtained from a licensed pharmacy. Covered drugs, as defined in Section 1927(k)(2) of the Act, are those which are prescribed for a medically accepted indication, medically necessary, and produced by any pharmaceutical manufacturer, which has entered into and complies with a drug rebate agreement under Section 1927(a) of the Act.
- 2) Drugs excluded from coverage by Delaware Medicaid as provided by Section 1927(d)(2) of the Act, include:
  - a. Drugs designated less than effective by the FDA (DESI drugs) or which are identical, similar, or related to such drugs;
  - b. Drugs when used for cosmetic purposes or hair growth;
  - c. Drugs when used to promote fertility;
  - d. Drugs that have an investigational or experimental or unproven efficacy or safety status;
  - e. Drugs when used for anorexia, weight loss or weight gain.
- 3) Non-covered services also include: drugs used to correct sexual dysfunction and compound drugs (compound prescriptions must include at least one medication that on its own would be a covered entity).

Quantity and Duration

1. Dosage limits: Medications are limited to a maximum dose recommended by the FDA and appropriate medical compendia described in section 1927(k) of the Social Security Act, that indicate that doses that exceed FDA guidelines are both safe and effective or doses that are specified in regional or national guidelines published by established expert groups such as the American Academy of Pediatrics, or guidelines recommended by the Delaware Medicaid Drug Utilization Review (DUR) Board and accepted by the DHSS Secretary.

TN No. <u>SPA #14-0005</u> Supersedes TN No. <u>SPA #13-001</u>	Approval Date <u>APR 24 2014</u>  Effective Date <u>January 1, 2014</u>
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