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**State Name:** Delaware

**State Plan Amendment (SPA) #13-001**

This file contains the following documents in the order listed:

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

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 #050920134007

**JUN 13 2013**

Mr. Stephen M. Groff, Director  
Division of Medicaid and Medical Assistance  
P.O. Box 906  
New Castle, DE 1970-0906

Dear Mr. Groff:

We are pleased to inform you of the approval of Delaware State Plan Amendment (SPA) 13-001. This amendment proposes to exclude from coverage benzodiazepines for all conditions and barbiturates for the treatment of epilepsy, cancer and chronic mental health disorders for full benefit dual eligible as Medicare Part D will provide this coverage, and to update quality limits for opioid analgesics.

Enclosed is a copy of the approved SPA pages and the signed CMS-179 form. The effective date of this amendment is January 1, 2013.

If you have any questions, you may contact Alice Robinson Penn at (215) 861-4261.

Sincerely,

Francis T. McCullough  
Associate Regional Administrator

Enclosures

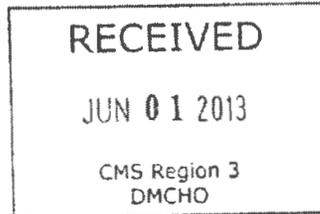
Cc: Glyne Williams, DHSS  
Sharon Summers, DHSS

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop S2-26-12  
Baltimore, Maryland 21244-1850



**Center for Medicaid and CHIP Services**

**Disabled and Elderly Health Programs Group**



**MAY 22 2013**

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

Dear Mr. Groff:

We have reviewed Delaware State Plan Amendment (SPA) 13-001, Prescribed Drugs, received in the Regional Office on March 22, 2013. This amendment proposes to exclude from coverage benzodiazepines for all conditions and barbiturates for the treatment of epilepsy, cancer and chronic mental health disorders for full benefit dual eligible as Medicare Part D will provide this coverage. This SPA also proposes to update the quantity limits for opioid analgesics.

We are pleased to inform you that the amendment is approved, effective January 1, 2013. 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,

Larry Reed  
Director  
Division of Pharmacy

cc: Francis T. McCullough, ARA, Philadelphia Regional Office  
Alice Robinson Penn, Philadelphia Regional Office

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

1. TRANSMITTAL NUMBER:  
SPA #13-001

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, 2013**

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:  
**1860D-2(E)(2)(A) OF THE SOCIAL SECURITY ACT, AS AMENDED BY  
SECTION 175 OF THE MEDICARE IMPROVEMENT FOR PATIENTS AND  
PROVIDERS ACT OF 2008 (MIPPA)**

7. FEDERAL BUDGET IMPACT:  
a. FFY **2013**      \$ **(\$50,500.00)**  
b. FFY **2014**      \$ **(\$50,500.00)**

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

ATTACHMENT 3.1-A PAGE 5 ADDENDUM  
ATTACHMENT 3.1-A PAGE 5 ADDENDUM CONTINUED  
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  
NEW PAGE  
ATTACHMENT 3.1.A.1 PAGE 2a  
ATTACHMENT 3.1.A.1 PAGE 2b

10. SUBJECT OF AMENDMENT: **COVERAGE OF BARBITURATES AND BENZODIAZEPINES FOR DUAL ELIGIBLES AS A MEDICARE PART D  
DRUG AND UPDATE QUANTITY LIMITS FOR OPIOID ANALGESICS**

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:

16. RETURN TO:

13. TYPED NAME:

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

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

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

15. DATE SUBMITTED:

**March 22, 2013**

**FOR REGIONAL OFFICE USE ONLY**

17. DATE RECEIVED:

**3-22-2013**

18. DATE APPROVED:

**5-22-13**

**PLAN APPROVED - ONE COPY ATTACHED**

19. EFFECTIVE DATE OF APPROVED MATERIAL:

**1-1-2013**

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:

**FRANCIS T. McCULLOUGH**

22. TITLE:

**ASSOCIATE REGIONAL ADMINISTRATOR**

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;
  - f. Effective January 1, 2013, barbiturates for dual eligible individuals, when used in the treatment of epilepsy, cancer, or a chronic mental health disorder (as Medicare Part D will cover);
  - g. Effective January 1, 2013, benzodiazepines for dual eligible individuals (as Medicare Part D will cover).
- 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. SPA #13-001  
Supersedes  
TN No. SP-412

Approval Date MAY 22 2013

Effective Date January 1, 2013

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: DELAWARE

LIMITATIONS

**12.a. Prescribed Drugs Continued:**

2. Quantity limits are placed on therapeutic categories that will allow for coordinated care and improve outcomes. Limits exist for:
  - a. Sedative hypnotics-15 doses per 30 days
  - b. Triptans, acute treatment of migraines, 9 doses per 45 days
  - c. Opioid analgesics-720 immediate release doses per 365 days
  - d. Skeletal muscle relaxants-120 tablets/capsules per 30 days
  - e. Benzodiazepines-120 tablets per 30 days
  - f. Tramadol-240 tablets per 30 days
  - g. Narcotic cough medications-480ml per 30 days
  - h. Adjunctive anticonvulsants-240 tablets/capsules per 30 days
  - i. Nebulizer solutions-3 acute exacerbations per 30 days
  - j. Clients utilizing greater than 15 unique medications per 30 days
  - k. Medications that are dosed once a day are limited to one dose per day unless that total dosage required is within the limits stated above and require more than one tablet/capsule to obtain the required therapeutic amount.
3. Duration of therapy
  - a. Nicotine cessation products are limited to the duration that has been approved by the FDA.
  - b. Palivizumab-6 months during the high viral period of the year.
4. Prescriptions are limited to a quantity not to exceed the greater of 100 dosing units or a 34-day supply except for drugs selected and received through mail order.

**Prior Authorization**

1. Prior authorization requirements may be established for certain drug classes or particular drugs, or a medically accepted indication for uses and doses.
2. The Drug Utilization Review Board (DUR) determines which drugs may require prior authorization. The Board assesses data on drug use in accordance with predetermined standards. The predetermined standards shall be:
  - a. monitoring for therapeutic appropriateness
  - b. overutilization and underutilization
  - c. appropriate use of generic products
  - d. therapeutic duplication
  - e. drug-disease contraindications
  - f. drug-drug interactions
  - g. incorrect drug dosage or duration of drug treatment
  - h. clinical efficacy
  - i. safety
  - j. medical necessity

TN No. SPA #13-001  
Supersedes  
TN No. SP-412

Approval Date MAY 22 2013  
Effective Date January 1, 2013

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)	<p><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)</p> <p><input checked="" type="checkbox"/> (h) barbiturates ALL [Except for dual eligible individuals, effective January 1, 2013, when used in the treatment of epilepsy, cancer or a chronic mental health disorder as Part D will cover those indications per 1860D-2(e)(2)(A) of the Social Security , as amended by Section 175 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA)] (see specific drug categories below)</p> <p><input checked="" type="checkbox"/> (i) benzodiazepines ALL [Except for dual eligible individuals, effective January 1, 2013, as Part D will cover all indications per 1860D-2(e)(2)(A) of the Social Security , as amended by Section 175 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA)] (see specific drug categories below)</p> <p>(The Medicaid agency lists specific category of drugs below)</p> <p>(a) Agents when used for anorexia, weight loss, weight gain: Megestrol Acetate, Somatropin, Lipase Inhibitor. Products in these categories require prior authorization.</p> <p>(d) Agents when used for the symptomatic relief cough and colds: Antihistamines, Antitussive, Decongestants, and Expectorants.</p> <p>(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</p>

TN No. SPA #13-001  
Supersedes  
TN No. SP-408

Approval Date MAY 22 2013  
Effective Date January 1, 2013

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)	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.

(h) Barbiturates: the Division of Medicaid & Medical Assistance covers all medications in these therapeutic categories [except for dual eligible individuals, effective January 1, 2013, when used in the treatment of epilepsy, cancer or a chronic mental health disorder as Part D will cover those indications per 1860D-2(e)(2)(A) of the Social Security, as amended by Section 175 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA)].

(i) Benzodiazepines: the Division of Medicaid & Medical Assistance covers all medications in these therapeutic categories [except for dual eligible individuals, effective January 1, 2013, as Part D will cover all indications per 1860D-2(e)(2)(A) of the Social Security, as amended by Section 175 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA)].

\_\_\_ No excluded drugs are covered.

TN No. SPA #13-001  
Supersedes  
TN No. SP-408

Approval Date MAY 22 2013  
Effective Date January 1, 2013