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State/Territory Name: MN

State Plan Amendment (SPA) #: 12-019

This file contains the following documents in the order listed:

Department of Health & Human Services
Centers for Medicare & Medicaid Services
233 North Michigan Avenue, Suite 600
Chicago, Illinois 60601-5519

December 19, 2012

Carol Backstrom, State Medicaid Director
Minnesota Department of Human Services
P.O. Box 64983
St. Paul, MN 55164-0983

Subject: State Plan Amendment

Dear Ms. Backstrom:

Enclosed for your records are documents related to State Plan Amendment number 12-019, which was approved in an December 18, 2012 letter to you from Larry Reed, Director of Pharmacy. The enclosure includes a signed copy of the CMS-179 and copies of the approved pages.

If you have any questions, please contact Courtenay Savage at (312) 353-3721 or by e-mail at Courtenay.Savage@cms.hhs.gov.

Sincerely,

[redacted]

Verlon Johnson
Associate Regional Administrator
Division of Medicaid and Children's Health Operations

Enclosure

cc: Courtenay Savage

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTER FOR MEDICARE & MEDICAID SERVICES	1. TRANSMITTAL NUMBER: 12-19	2. STATE Minnesota
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTER FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE July 1, 2012	

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: 42 CFR § 440.120(a)	7. FEDERAL BUDGET IMPACT: a. FFY '13 $0 b. FFY '14 $0
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A, page 46 – 46g Attachment 3.1-B, page 45 – 45g	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: Same

10. SUBJECT OF AMENDMENT:
Pharmacy

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

12. SIGNATURE OF STATE AGENCY OFFICIAL: [redacted]	16. RETURN TO: Sean Barrett Minnesota Department of Human Services Federal Relations Unit PO Box 64983 St. Paul, MN 55164-0983
13. TYPED NAME: Ann Berg	
14. TITLE: Deputy Medicaid Director	
15. DATE SUBMITTED: September 19, 2012	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: September 19, 2012	18. DATE APPROVED: 12/18/12

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: July 1, 2012	20. SIGNATURE OF REGIONAL OFFICIAL: [redacted]
21. TYPED NAME: Verlon Johnson	22. TITLE: Associate Regional Administrator
23. REMARKS:	

FORM CMS-179 (07-92)

12.a. Prescribed drugs.

The following providers are eligible for payment for dispensing prescribed drugs:

1. A pharmacy that is licensed by the Minnesota Board of Pharmacy.
2. An out of state pharmacy that complies with the licensing and certification requirements of the state in which it is located.
3. A physician located in a local trade area where there is no Medicaid enrolled pharmacy. To be eligible for payment, the physician shall personally dispense the prescribed drug according to applicable Minnesota Statutes and shall adhere to the labeling requirements of the Minnesota Board of Pharmacy.
4. A physician, physician assistant or nurse practitioner employed by or under contract with a community health board, for the purposes of communicable disease control.

The following limitations apply to pharmacy services:

1. The prescribed drug must be a drug or compounded prescription for which medical value has been established and that is made by a manufacturer that has a rebate with the Centers for Medicare & Medicaid Services (CMS) and included in the Minnesota Department of Human Services drug formulary. The formulary is established in accordance with §1927(d)(4) of the Social Security Act. See Drug Formulary.

   a) An "active pharmaceutical ingredient (API)" is defined as a substance that is represented for use in a drug and when used in the manufacturing, processing or packaging of a drug, becomes an active ingredient of the drug product. An "excipient" is defined as an inert substance used as a diluent or vehicle for a drug. The commissioner shall establish a list of active pharmaceutical ingredient and excipients which are included in the medical assistance formulary. Medical assistance covers selected active pharmaceutical ingredients and excipients used in compounded prescriptions when the compounded combination is specifically approved by the commissioner or when a commercially available product:
      i. Is not a therapeutic option for the patient;
      ii. Does not exist in the same combination of active ingredients in the same strengths as the compounded prescription; and
      iii. Cannot be used in place of the active pharmaceutical ingredient in the compounded prescription.

12.a. Prescribed drugs. (continued)

2. A prescribed drug must be dispensed in the quantity specified on the prescription unless the pharmacy is using unit dose dispensing, the specified quantity is not available in the pharmacy when the prescription is dispensed, or the specified quantity exceeds a 34-day supply.
3. Effective October 1, 2003, the dispensed quantity of a prescribed drug must not exceed a 34-day supply, unless authorized by the Department. The following do not require prior authorization:

   a) over-the-counter medications must be dispensed in a quantity that is the lesser of:
      - the number of doses in the manufacturer's unopened package, and
      - the number of dosage units required to complete the recipient's course of therapy.

      ~~Sorbitol may be repackaged.~~
   b) contraceptive drugs may be dispensed in quantities not exceeding a 90-day supply.

4. An initial or refill prescription for a maintenance drug shall be dispensed in not less than a 30-day supply unless the pharmacy is using unit dose dispensing. No additional dispensing fee shall be paid until that quantity is used by the recipient.
5. Except as provided in item (6), coverage of the dispensing fee for a particular pharmacy or dispensing physician for a maintenance drug for a recipient is limited to one fee per 30-day supply.
6. More than one dispensing fee per calendar month for a maintenance drug for a recipient is allowed if:

   a) the record kept by the pharmacist or dispensing physician documents that there is a significant chance of overdosage by the recipient if a larger quantity of drug is dispensed, and if the pharmacist or dispensing physician writes a statement of this reason on the prescription; or
   b) the drug is clozapine.

7. A refill of a prescription must be authorized by the practitioner. Refilled prescriptions must be documented in the prescription file, initialed by the pharmacist who refills the prescription, and approved by the practitioner as consistent with accepted pharmacy practice under Minnesota Statutes.

12.a. Prescribed drugs. (continued)

8. Generic drugs must be dispensed to recipients if:

   a) the generically equivalent drug is approved and is determined as therapeutically equivalent by the FDA;
   b) in the pharmacist's or dispensing physician's professional judgment, the generically equivalent drug is safely interchangeable with the prescribed drug;
   c) the charge for the substituted generically equivalent drug does not exceed the charge for the drug originally prescribed; and
   d) the practitioner has not written in his or her own handwriting "Dispense as Written-Brand Necessary" or "DAW-Brand Necessary" on the prescription. Effective January 2, 2004, even if the practitioner has written "Dispense as Written-Brand Necessary" or "DAW-Brand Necessary" on the prescription, authorization is required to dispense brand name drugs.

9. The following limits apply to drugs dispensed under unit dose packaging:

   a) Dispensing fees for drugs dispensed in unit dose packaging shall not be paid more often than once per calendar month or when a minimum of 30 dosage units have been dispensed, whichever results in the lesser number of dispensing fees.
   b) Only one dispensing fee per calendar month will be paid for each maintenance drug, regardless of the type of unit dose system used or the number of times during the month the pharmacist dispenses the drug.
   c) An additional dispensing fee per prescription shall be paid to pharmacists using an in-pharmacy packaged unit dose system (except for over the¬-counter medications) approved by the Board of Pharmacy for the return of drugs when dispensing to recipients in a long-term care facility if:

12.a. Prescribed drugs. (continued)

i. the pharmacy is registered with the Department by filing an addendum to the provider agreement;

ii. a minimum 30-day supply of the drug is dispensed, although a lesser quantity may be dispensed for an acute course of medication therapy for a specified time period;

iii. the national drug code from the drug stock container used to fill the unit dose package is identified to the Department;

iv. the unit dose package containing the drug meets the packaging standards set forth in Minnesota Statutes that govern the return of unused drugs to the pharmacy for reuse and documentation that unit dose packaging meets permeability standards of the Board of Pharmacy; and

v. the pharmacy provider credits the Department for the actual acquisition cost of all unused drugs that are eligible for return and reuse.

10. Delivery charges for a drug are not covered.

Drug Formulary:

All drugs and compounded prescriptions made by a manufacturer that are covered under a signed rebate agreement with CMS are included in the drug formulary, with the following limitations on coverage:

1. Over-the-counter drugs must be listed in the Department’s “Health Care Programs Provider Manual,” on a remittance

12.a. Prescribed drugs. (continued)

advice message, or in a Department-issued provider update. The following over-the-counter drugs are covered only when prescribed by a licensed practitioner or a licensed pharmacist who meets standards established by the Department, in consultation with the Board of Pharmacy:

a) antacids;
b) acetaminophen;
c) aspirin;
d) family planning products;
e) insulin;
f) products for the treatment of lice;
g) vitamins for adults with documented vitamin deficiencies;
h) vitamins for children under the age of seven and pregnant or nursing women; and
i) any other drug identified by the Department, in consultation with the Drug Formulary Committee.

2. The following categories of drugs are not covered pursuant to §1927(d)(2):

a) ~~Effective August 1, 2003, d~~ Drugs or active pharmaceutical ingredients used for weight loss, except that medically necessary lipase inhibitors may be covered for recipients with type 2 diabetes.
b) Agents or active pharmaceutical ingredients when used to promote fertility.
c) Agents or active pharmaceutical ingredients when used for cosmetic purposes or hair growth.
d) Covered outpatient drugs that 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.
e) Drugs described in §107(c)(3) of the Drug Amendments of 1962 and identical, similar, or related drugs (within the meaning of 21 CFR §310.6(b)(1) (DESI drugs)).
f) Drugs or active pharmaceutical ingredients for which medical value has not been established.

12.a. Prescribed drugs. (continued)

3. The following categories of drugs are covered with limitations pursuant to §1927(d)(2):

   a) Agents when used for the symptomatic relief of cough and colds must be listed in the Department's "Minnesota Health Care Programs Provider Manual," on a remittance advice message, or in a Department-issued provider update.
   b) Prescription vitamins and mineral products for children, pregnant and nursing women, and recipients with documented vitamin deficiencies. The limitations do not apply to fluoride treatments. Prenatal vitamins are restricted to pregnant and nursing women.

   Notwithstanding the above paragraph, some vitamins and mineral products are available for the treatment or prevention of certain diseases:

   1)niacin;
   2)calcium and calcium/vitamin D; and
   3)generic preparations equivalent to Ocuvite.

4. ~~Effective January 1, 2006,~~ Medicaid does not cover drugs or active pharmaceutical ingredients when used for the treatment of sexual or erectile dysfunction. Sexual or erectile dysfunction drugs and active pharmaceutical ingredients are covered when used for the treatment of other conditions or indications approved by the FDA.

Prior Authorization:

A. The following requirements, found in §1927(d)(5) of the Act, are met:
   - The prior authorization program provides a response by telephone or other telecommunication device within 24 hours of a request
   - The prior authorization program provides for the dispensing of at least a 72-hour supply of a covered drug in an emergency situation (except for those drugs that are excluded or restricted from coverage, as noted above)

12.a. Prescribed drugs. (continued)

B. Prior authorization, for a period of not more than 180 days, may automatically be required for drugs approved by the FDA on or after July 1, 2005. The 180-day period begins no later than the first day that a drug is available for shipment to pharmacies within Minnesota. The Department's Drug Formulary Committee will establish general authorization criteria to be used during the 180-day period.

C. Based on the requirements in §1927, the State has the following policies for the supplemental drug rebate program for Medicaid recipients:
   1. CMS has authorized the State of Minnesota to enter into the Michigan Multi-State Pooling Agreement (MMSPA) also referred to as the National Medicaid Pooling Initiative (NMPI) for drugs provided to Medicaid beneficiaries. The NMPI Supplemental Rebate Agreement (SRA) and the amendment to the SRA submitted to CMS on April 30, 2004 have been authorized for pharmaceutical manufacturers' existing agreements through their current expiration dates. The updated NMPI SRA submitted to the CMS on January 29, 2008, has been authorized for renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid beneficiaries.
   2. Supplemental drug 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 drug rebate agreement.
   3. Manufacturers with supplemental rebate agreements are allowed to audit utilization data.

12.a. Prescribed drugs. (continued)

4. The unit rebate amount is confidential and will not be disclosed except in accordance with §1927(b)(3)(D) of the Act.
5. A drug that the Department determines comes within its multi-state supplemental drug rebate program for Medicaid recipients as allowed by §1927, but for which a manufacturer has not signed a supplemental drug rebate agreement authorized by CMS, will be prior authorized.

   Even if a manufacturer has not signed a supplemental drug rebate agreement, there is never prior authorization for any atypical antipsychotic drug prescribed for the treatment of adult mental illness if:
   - there is no generically equivalent drug available; and
   - the drug was initially prescribed for the recipient before July 1, 2003; or
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