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State/Territory Name: MN

State Plan Amendment (SPA) #: 13-029

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 S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

May 27, 2014

Ms. Ann Berg
Deputy Medicaid Director
Minnesota Department of Human Services
P.O. Box 64983
St. Paul, MN 55164-0983

Dear Ms. Berg:

We have reviewed Minnesota State Plan Amendment (SPA) 13-029, Prescribed Drugs, received in the Regional Office on November 4, 2013. This amendment proposes to revise payment rates and coverage for 340B drugs and proposes to allow prescribers to indicate the need to dispense a brand name drug using an electronic alternative to hand writing

We are pleased to inform you that the amendment is approved, effective January 1, 2014. A copy of the CMS-179 form, as revised, as well as the pages approved for incorporation into the Minnesota state plan, will be forwarded by the Chicago Regional Office. If you have any questions regarding this amendment, please contact Lisa Ferrandi at (410) 786-5445.

Sincerely,

/s/

Joseph L. Fine
Acting Director
Division of Pharmacy

cc: Sean Barrett, Minnesota Department of Human Services
Verlon Johnson, ARA, Chicago Regional Office
Courtenay Savage, Chicago Regional Office

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: 13-29	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 January 1, 2014	

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 '14 $(3,924,000) b. FFY '15 $(5,570,000)
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A, page 46c, page 46b Attachment 3.1-B, page 45c, page 45b Attachment 4.19-B, page 37 – 37a	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: Same

10. SUBJECT OF AMENDMENT:
Pharmacy Payment Rates

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: November 4, 2013	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: November 4, 2013	18. DATE APPROVED: May 27, 2014
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: January 1, 2014	20. SIGNATURE OF REGIONAL OFFICIAL: /s/
21. TYPED NAME: Verlon Johnson	22. TITLE: Associate Regional Administrator
23. REMARKS: Pen and Ink change to Box #8 adding page 46b and 45b from Attachment 3.1 A/B.	

FORM CMS-179 (07-92)

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, or indicated the medical necessity of a brand name drug using an electronic prescription. Effective January 2, 2004, even if the practitioner has indicated the medical need for a brand name drug, 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.

11. Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies 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:

Over-the-counter drugs must be listed in the Department's "Health Care Programs Provider Manual," on a remittance

12.a. Prescribed drugs. (continued)

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12.a. Prescribed drugs. (continued)

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

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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

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12a. Prescribed Drugs

Payment is determined in accordance with 42 CFR §§447.512-518.

For drugs dispensed by a pharmacy, payment is the lower of:

1) the estimated actual acquisition costs of the drugs or the maximum allowable cost set by the State agency, plus a fixed dispensing fee; or

2) the provider's usual and customary charge to the general public.

The maximum allowable cost set by the State agency for multiple source drugs will not exceed, in the aggregate, the upper limits established under 42 CFR §447.512.

Effective September 1, 2011, the State agency establishes the actual acquisition cost to equal 104% of the wholesale acquisition cost (wholesale acquisition cost plus four percent) for independently owned pharmacies located in a small rural or isolated rural Minnesota location, and 102% of the wholesale acquisition cost (wholesale acquisition cost plus two percent) for all other pharmacies. A pharmacy is considered independently owned if it is one of four or fewer stores under the same ownership nationally.

The State agency establishes the acquisition cost of drugs acquired through the federal 340B drug pricing program at sixty percent of wholesale acquisition cost (wholesale acquisition cost minus forty percent).

Payment for over-the-counter drugs follows the methodology for drugs dispensed by a pharmacy described above. If the pharmacy is not accessible to, or frequented by, the general public, or if the over-the-counter drug is not on display for sale to the general public, the usual and customary charge is the actual acquisition costs plus a 50 percent add-on based on the actual acquisition cost.

12a. Prescribed Drugs (continued);

For drugs administered in an outpatient setting, payment for prescription drugs is the lower of the provider's usual and customary charge to the general public, 106% of the average sales price, or the maximum allowable cost set by the State Agency. If the average sales price is not available, payment will be the lower of the provider's usual and customary charge to the general public, the wholesale acquisition cost, or the maximum allowable cost set by the State Agency. For drugs acquired through the federal 340B drug pricing program, payment is equal to 80% of the payment amount calculated using the methodology described in this paragraph.

Effective for services provided on or after October 1, 2011, the rate for specialty pharmacy products is the maximum allowable cost set by the State Agency. The rate used is dependent upon the actual acquisition cost for the product. Specialty pharmacy products are those used by a small number of recipients or recipients with complex and chronic diseases that require expensive and challenging drug regimens.