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State/Territory Name: MN

State Plan Amendment (SPA) #: 16-0001

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 5, 2016

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) 16-001, Prescribed Drugs, received in the Regional Office on February 17, 2016. This amendment proposes to revise the state plan to cover the dispensing of over-the counter drugs in a nursing facility through the use of an automated dispensing system.

We are pleased to inform you that the amendment is approved, effective September 1, 2016. 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/

John M. Coster, Ph.D., R.Ph.
Director
Division of Pharmacy

cc: Sean Barrett, Minnesota Department of Human Services
Verlon Johnson, ARA, Chicago Regional Office
Sandra Porter, Chicago Regional Office
Mara Siler-Price, 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: 16-01	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 September 1, 2016 ~~January 1, 2016~~	

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 (in thousands): a. FFY '16 ($1) b. FFY '17 ($3)
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A, pages: 46a and 46b Attachment 3.1-B, pages: 45a and 45b Attachment 4.19-B, page 37d	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: Same

10. SUBJECT OF AMENDMENT:
Payment of Pharmacy Services

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: February 17, 2016	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: February 17, 2016	18. DATE APPROVED: May 5, 2016
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: September 1, 2016	20. SIGNATURE OF REGIONAL OFFICIAL: /s/
21. TYPED NAME: Ruth A. Hughes	22. TITLE: Associate Regional Administrator
23. REMARKS: Pen and Ink change to Box #4 changing the effective date to September 1, 2016.	

FORM CMS-179 (07-92)

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) contraceptive drugs dispensed in quantities not exceeding a 90-day supply; and
   b) over-the-counter medications dispensed in a quantity that is the lesser of:
      - the number of doses in the manufacturer's unopened package,
      - the number of dosage units required to complete the recipient's course of therapy, or
      - the number of doses used during a retrospective billing cycle.

   Retrospective billing is a billing practice in which the pharmacy bills only for the quantity of medication actually used by the recipient during the retrospective billing cycle established by the pharmacy. A retrospective billing cycle must be between 30 and 34 days in length.

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, or is billing retrospectively for a quantity dispensed to a resident in a long-term care facility via unit dose or an automated dispensing system. 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 overdose 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.

12.a. Prescribed drugs. (continued)

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.

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)

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) contraceptive drugs dispensed in quantities not exceeding a 90-day supply;
   b) over-the-counter medications dispensed in a quantity that is the lesser of:
      - the number of doses in the manufacturer's unopened package,
      - the number of dosage units required to complete the recipient's course of therapy, or
      - the number of doses used during a retrospective billing cycle.

   Retrospective billing is a billing practice in which the pharmacy bills only for the quantity of medication actually used by the recipient during the retrospective billing cycle established by the pharmacy. A retrospective billing cycle must be between 30 and 34 days in length.

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, or is billing retrospectively for a quantity dispensed to a resident in a long-term care facility via unit dose or an automated dispensing system. 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 overdose 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.

12.a. Prescribed drugs. (continued)

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.

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.

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   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:

12a. Prescribed Drugs (continued):

With the following exceptions, the dispensing fee is $3.65 plus an additional $.30 dispensing fee allowed for legend drug prescriptions dispensed using a pharmacy packaging unit-doses blister card system and dispensed to recipients residing in a nursing facility or intermediate care facility for persons with developmental disabilities.

1) The dispensing fee for intravenous drugs that require mixing by the pharmacist is $8.00, except cancer chemotherapy IVs, which is $14.00, unless item (2), below, applies.

2) The dispensing fee for total parenteral nutrition products which require mixing by the pharmacist is $30.00 for those dispensed in 1-liter quantity, and 44.00 for those dispensed in a quantity greater than 1 liter.

3) The dispensing fee for over-the-counter drugs when provided to residents of a long-term care facility through the use of an automated dispensing system or a unit dose, unit-of-use, or strip packaging, and billed using a retrospective billing cycle, is $1.31 if the quantity dispensed during the cycle is less than the quantity contained in the manufacturer's package.

In addition, the State agency will receive a rebate for prescribed drugs in accordance with the manufacturer's contract with the Centers for Medicare & Medicaid Services.

The base rates as described in this item are adjusted by the following paragraph(s) of Supplement 2:

cc. Supplemental payment for medical education