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State/Territory Name: Minnesota

State Plan Amendment (SPA) #: 19-0006

This file contains the following documents in the order listed:

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



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

February 3, 2020

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

Dear Ms. Berg:

We have reviewed Minnesota's State Plan Amendment (SPA) 19-0006, Prescribed Drugs, received in the Chicago Regional Operations Group on August 23, 2019. This SPA proposes to bring Minnesota into compliance with the reimbursement requirements in the Covered Outpatient Drug final rule with comment period (CMS-2345-FC).

Minnesota SPA 19-0006 includes reimbursement methods that use, among others, the National Average Drug Acquisition Cost (NADAC), plus a professional dispensing fee of \$10.48 for covered outpatient drugs. This SPA also includes reimbursement rates for 340B drugs, long-term care and specialty drugs, drugs purchased at a nominal price, and physician administered drugs. In addition, this SPA modifies the coverage pages to include updates to the state's covered over-the-counter drug listing.

In keeping with the requirements of section 1902 (a)(30)(A) of the Social Security Act, we believe the state has demonstrated that their reimbursement rates are consistent with efficiency, economy, and quality of care, and are sufficient to ensure that care and services are available to Medicaid beneficiaries at least to the extent they are available to the general population in the geographic area. We believe that there is evidence regarding the sufficiency of Minnesota's pharmacy provider network at this time to approve SPA 19-0006. The state provided data to demonstrate that the acquisition cost methodologies and pharmacy dispensing fees being paid are sufficient to ensure the program's beneficiaries will have access to pharmacy services at least to the extent that they are available to the general population.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 19-0006 is approved with an effective date of July 1, 2019. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into Minnesota's state plan will be forwarded by the Chicago Regional Operations Group.

If you have any questions regarding this request, please contact Lisa Shochet at 410-786-5445 or lisa.shochet@cms.hhs.gov.

Sincerely,

/s/

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

cc: Ruth Hughes, Deputy Division Director, Chicago Regional Operations Group
Sandra Porter, Chicago Regional Operations Group

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTER FOR MEDICARE & MEDICAID SERVICES	1. TRANSMITTAL NUMBER: MN-19-006	2. STATE Minnesota
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	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)
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TO: REGIONAL ADMINISTRATOR CENTER FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE July 1, 2019
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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: 42 C.F.R. §§ 447.500 to 447.522	7. FEDERAL BUDGET IMPACT: a. FFY 2020 (16,826) b. FFY 2021 (30,758)
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8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Att. 3.1-A, pp 46a – 46g Att. 3.1-B, pp 45a – 45g Att. 4.19-B, pp 37, 37a – 37d	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>): Att. 3.1-A, pp 46a – 46g Att. 3.1-B, pp 45a – 45g Att. 4.19-B, pp 37, 37a – 37d
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10. SUBJECT OF AMENDMENT:
Prescribed Drugs

11. GOVERNOR'S REVIEW (*Check One*):

GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED:

COMMENTS OF GOVERNOR'S OFFICE ENCLOSED

NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. SIGNATURE OF STATE AGENCY OFFICIAL: 	16. RETURN TO: Ann Berg Minnesota Department of Human Services 540 Cedar Street, PO Box 64983 St. Paul, MN 55164-0983
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13. TYPED NAME:
Ann Berg

14. TITLE:
Deputy Medicaid Director

15. DATE SUBMITTED:
8/23/2019

FOR REGIONAL OFFICE USE ONLY	
17. DATE RECEIVED: August 23, 2019	18. DATE APPROVED: February 3, 2020

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: July 1, 2019	20. SIGNATURE OF REGIONAL OFFICIAL: /s/
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21. TYPED NAME: James G. Scott	22. TITLE: Director, Division of Program Operations
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23. REMARKS:

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, t~~The dispensed quantity of a prescribed drug must not exceed a 34-day supply, unless authorized by the Department. Contraceptive drugs dispensed in quantities not exceeding a three-month supply ~~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 professional dispensing fee per 30- to 34-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 pharmacy dispensing an over-the-counter drug shall receive no more than one dispensing fee per claim and the dispensing fee shall be prorated if less than the manufacturer's original package size is dispensed. A pharmacy dispensing an over-the-counter drug shall receive no more than one dispensing fee per claim if dispensing multiple packages.
8. 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.
9. 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.
10. The following limits apply to legend 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:

STATE: MINNESOTA

ATTACHMENT 3.1-A

Effective: July 1, 2019

Page 46c

TN: 19-06

Approved: February 3, 2020

Supersedes: 19-04 (17-09, 13-29, 12-19, 05-09, 04-09, 03-36)

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.

11. Delivery charges for a drug are not covered.

12. Medical assistance covers drugs purchased through the federal 340B drug pricing program by 340B covered entities and dispensed by 340B covered entities, and contract pharmacies owned by the 340B covered entity when the 340B contract pharmacy requests in writing and receives approval from the Department, to use these drugs for Minnesota Medicaid beneficiaries. Drugs acquired through the federal 340B drug pricing program and dispensed by other 340B contract pharmacies are not covered.

13. Drugs that are considered investigational, drugs that are provided to a recipient during the clinical trial designed to test the efficacy of the provided drug, or drugs that have not been approved for general use by the U.S. Food and Drug Administration are not covered. ~~The Department covers stiripentol as a specialty pharmacy product for children with certain medical conditions.~~

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)

~~advice message, or in a Department-issued provider update. The following~~
~~Over-the-counter drugs are covered when added to the fomulary in~~
~~consultation with the Drug Formulary Committee. 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. Covered over-the-counter drugs~~
~~include:~~

- a) antacids;
- b) acetaminophen;
- c) aspirin;
- d) family planning ~~products~~ drugs;
- e) ~~insulin;~~ nicotine replacement;
- f) ~~products~~ drugs for the treatment of lice;
- g) ~~vitamins for adults with documented vitamin deficiencies;~~ topical antifungals;
- h) ~~vitamins for children under the age of seven and pregnant or nursing women;~~ and antihistamines;
- i) laxatives;
- j) any other drugs identified by the Department, in consultation with
recommended for coverage by the Drug Formulary Committee.

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

- a) 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 C.F.R. § 310.6(b) (1) (DESI drugs)).
- f) Drugs or active pharmaceutical ingredients for which medical value has not been established.

Effective: July 1, 2019

TN: 19-06

Approved: February 3, 2020

Supersedes: 13-15 (13-02, 12-19, 05-09, 04-09, 03-36)

12.a. Prescribed drugs. (continued)

2. 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.
3. 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.
4. Medicaid will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

STATE: MINNESOTA

ATTACHMENT 3.1-A

Effective: July 1, 2019

Page 46f

TN: 19-06

Approved: February 3, 2020

Supersedes: 17-04 (13-10, 13-02, 12-19, 08-01, 05-09, 04-09, 03-36)

12.a. Prescribed drugs. (continued)

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).

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 effective for ~~January 1, 2017~~ July 1, 2019, 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.

STATE: MINNESOTA

ATTACHMENT 3.1-A

Effective: July 1, 2019

Page 46g

TN: 19-06

Approved: February 3, 2020

Supersedes: 12-10 (05-09, 04-09, 03-36)

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
- the drug is part of the recipient's current course of treatment.

Medicaid covers the following prescribed drugs not eligible for rebate:

- vitamins for adults with documented vitamin deficiencies
- vitamins for children under the age of seven and pregnant or nursing women

STATE: MINNESOTA

ATTACHMENT 3.1-B

Effective: July 1, 2019

Page 45a

TN: 19-06

Approved: February 3, 2020

Supersedes: 16-01 (12-19, 05-09, 04-09, 03-36)

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, t~~The dispensed quantity of a prescribed drug must not exceed a 34-day supply, unless authorized by the Department.
Contraceptive drugs dispensed in quantities not exceeding a three-month supply ~~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 professional dispensing fee per 30-to 34-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 pharmacy dispensing an over-the-counter drug shall receive no more than one dispensing fee per claim and the dispensing fee shall be prorated if less than the manufacturer's original package size is dispensed. A pharmacy dispensing an over-the-counter drug shall receive no more than one dispensing fee per claim if dispensing multiple packages.
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 - 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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 - 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.
11. Delivery charges for a drug are not covered.
12. Medical assistance covers drugs purchased through the federal 340B drug pricing program by 340B covered entities and dispensed by 340B covered entities, and contract pharmacies owned by the 340B covered entity when the 340B contract pharmacy requests in writing and receives approval from the Department, to use these drugs for Minnesota Medicaid beneficiaries. Drugs acquired through the federal 340B drug pricing program and dispensed by other 340B contract pharmacies are not covered.
13. Drugs that are considered investigational, drugs that are provided to a recipient during the clinical trial designed to test the efficacy of the provided drug, or drugs that have not been approved for general use by the U.S. Food and Drug Administration are not covered. ~~The Department covers stiripentol as a specialty pharmacy product for children with certain medical conditions.~~

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 Manual₇," ~~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 when added to the formulary in~~
~~consultation with the Drug Formulary Committee. 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. Covered over-the-counter drugs~~
~~include:~~

- a) antacids;
- b) acetaminophen;
- c) aspirin;
- d) family planning ~~products~~ drugs;
- e) ~~insulin~~ nicotine replacement;
- f) topical antifungals;
- g) antihistamines;
- h) laxatives;
- i) ~~products~~ drugs for the treatment of lice; and
- j) ~~vitamins for adults with documented vitamin deficiencies;~~
- k) ~~vitamins for children under the age of seven and pregnant or nursing~~
~~women;~~ drugs recommended for coverage by the Drug Formulary
Committee.
- l) ~~any other drug identified by the Department, in consultation with~~
~~the Drug Formulary Committee.~~
- m) ~~—~~

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

- a) 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.

STATE: MINNESOTA

Effective: July 1, 2019

TN: 19-06

Approved: February 3, 2020

Supersedes: 13-15 (13-02, 12-19, 05-09, 04-09, 03-36)

ATTACHMENT 3.1-B

Page 45e

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.
4. 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.
5. Medicaid will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

STATE: MINNESOTA

ATTACHMENT 3.1-B

Effective: July 1, 2019

Page 45f

TN: 19-06

Approved: February 3, 2020

Supersedes: 17-05 (13-10, 13-02, 12-19, 08-01, 05-09, 04-09, 03-36)

12.a. Prescribed drugs. (continued)

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).

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 effective for ~~January 1, 2017~~ July 1, 2019, 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.

STATE: MINNESOTA

ATTACHMENT 3.1-B

Effective: July 1, 2019

Page 45g

TN: 19-06

Approved: February 3, 2020

Supersedes: 12-19 (05-09, 04-09, 03-36)

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
- the drug is part of the recipient's current course of treatment.

Medicaid covers the following prescribed drugs not eligible for rebate:

- vitamins for adults with documented vitamin deficiencies
- vitamins for children under the age of seven and pregnant or nursing women

STATE: MINNESOTA

ATTACHMENT 4.19-B

Effective: July 1, 2019

Page 37

TN: 19-06

Approved: February 3, 2020

Supersedes: 13-29 (11-20, 11-16, 09-23, 08-13, 07-12, 07-04, 05-09, 04-15(a), 03-29)

12a. Prescribed Drugs

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

For drugs dispensed by a retail community pharmacy, long term care pharmacy, or other outpatient 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~~ professional dispensing fee; ~~or~~
- 2) the state-established maximum allowable cost, plus a professional dispensing fee; or
- 3) 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 the National Average Drug Acquisition Cost (NADAC). For multiple source drugs, the actual acquisition cost is the NADAC for the generic drug, but for multiple source drugs prescribed in accordance with 42 CFR § 447.512(c) the acquisition cost will be NADAC for the brand drug. 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.~~

Drugs purchased through the Federal Supply Schedule and drugs purchased at nominal price are reimbursed at actual acquisition cost plus the professional dispensing fee. Nominal price means a price that is less than ten percent of average manufacturer price.

The state agency may establish a maximum allowable cost for drugs in instances where survey data indicates that pharmacies can purchase the drug at a price lower than NADAC or in instances that a NADAC price is not published. The maximum allowable cost shall reflect the acquisition cost of the drug, or for multiple source drugs, the acquisition cost of the generic drug except when prescribed in accordance with 42 C.F.R. § 447.512(c).

For drugs for which NADAC is not reported and the maximum allowable cost is not calculated, the agency establishes the actual acquisition cost to equal wholesale acquisition cost (WAC) minus two percent.

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The Department will calculate the actual acquisition cost of multiple course source drugs in conformity with the upper payment limits established under 42 C.F.R. § 447.512.

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).the 340B ceiling price, or the NADAC price, whichever is lower. For drugs that do not have a 340B ceiling price established, the agency shall establish the acquisition cost of the drugs acquired through the federal 340B drug pricing program at the lesser of the NADAC, maximum allowable cost, or wholesale acquisition cost minus two percent. For drugs for which NADAC is not reported and the maximum allowable cost is not calculated, the agency establishes the actual acquisition cost to equal wholesale acquisition cost minus two 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.

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~~71.4% of the payment amount calculated using the methodology described in this paragraph.

Effective for services provided on or after October 1, 2011, tThe rate for specialty pharmacy products is the maximum allowable cost set by the State Agency plus a professional dispensing fee of \$10.48 per prescription. 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.

The payment rate for hemophilia factor products uses the same reimbursement calculation as other drugs as defined in this section.

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12a. Prescribed Drugs (continued):

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12a. Prescribed Drugs (continued):

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12a. Prescribed Drugs (continued):

With the following exceptions, the professional dispensing fee is ~~\$3.65~~\$10.48 per prescription, for prescriptions filled using drugs that meet the definition of "covered outpatient drugs" according to 42 U.S.C. § 1396r-8(k)(2). ~~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 professional dispensing fee for intravenous drugs that require mixing by the pharmacist is ~~\$10.48 per bag.~~\$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.~~

2) The professional dispensing fee for over-the-counter drugs is \$10.48 for "outpatient prescription drugs" when dispensed in quantities equal to or greater than the manufacturer's package size. The dispensing fee is prorated based on the percent of the package dispensed when the pharmacy dispenses a quantity less than the manufacturer's package size. ~~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.~~

3) The professional dispensing fee for prescribed over-the-counter drugs that are not "covered outpatient drugs" shall be \$3.65. The dispensing fee is prorated based on the percent of the package dispensed when the pharmacy dispenses a quantity less than the manufacturer's package size.

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

d. The ingredient cost is adjusted to account for the Minnesota Wholesale Drug Tax.