

## **Table of Contents**

**State/Territory Name: Minnesota**

**State Plan Amendment (SPA) #: 19-0004**

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**

May 24, 2019

Ms. Marie Zimmerman  
State Medicaid Director  
Minnesota Department of Human Services  
PO Box 64983  
St. Paul, MN 55164

Dear Ms. Zimmerman:

We have reviewed Minnesota's State Plan Amendment (SPA) 19-0004, Prescribed Drugs, received in the Chicago Regional Operations Group on March 20, 2019. This SPA proposes to allow coverage of drugs purchased through the federal 340B drug pricing program for selective 340B contract pharmacies when the 340B contract pharmacy requests in writing and receives approval from the state to use these drugs for Minnesota Medicaid beneficiaries.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 19-0004 is approved with an effective date of January 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.

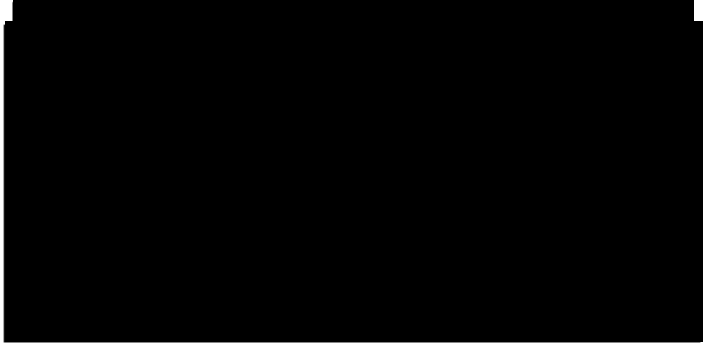
If you have any questions regarding this amendment, please contact Lisa Shochet at (410) 786-5445 or [lisa.shochet@cms.hhs.gov](mailto:lisa.shochet@cms.hhs.gov).

Sincerely,

/s/

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

cc: Ann Berg, Deputy Medicaid Director, MN Department of Human Services  
Ruth A. Hughes, Deputy Director, Chicago Regional Operations Group  
Sandra Porter, Chicago Regional Operations Group

<b>TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTER FOR MEDICARE &amp; MEDICAID SERVICES</b>		1. TRANSMITTAL NUMBER:  19-04	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, 2019	
5. TYPE OF PLAN MATERIAL ( <i>Check One</i> ):  <input type="checkbox"/> NEW STATE PLAN <input type="checkbox"/> AMENDMENT TO BE CONSIDERED AS NEW PLAN <input checked="" type="checkbox"/> AMENDMENT COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT ( <i>Separate Transmittal for each amendment</i> )			
6. FEDERAL STATUTE/REGULATION CITATION: 42 CFR § 440.120(a)		7. FEDERAL BUDGET IMPACT (in thousands): a. FFY '19 \$0 b. FFY '20 \$0	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A, page 46c Attachment 3.1-B, page 45c		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT ( <i>If Applicable</i> ): Same	
10. SUBJECT OF AMENDMENT: Coverage of Prescribed Drugs			
11. GOVERNOR'S REVIEW ( <i>Check One</i> ): <input checked="" type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="checkbox"/> OTHER, AS SPECIFIED: <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
12. SIGNATURE OF STATE AGENCY OFFICIAL:  		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: March 20, 2019			
<b>FOR REGIONAL OFFICE USE ONLY</b>			
17. DATE RECEIVED:  March 20, 2019		18. DATE APPROVED:  May 24, 2019	
<b>PLAN APPROVED – ONE COPY ATTACHED</b>			
19. EFFECTIVE DATE OF APPROVED MATERIAL:  January 1, 2019		20. SIGNATURE OF REGIONAL OFFICIAL:  /s/	
21. TYPED NAME:  Ruth A. Hughes		22. TITLE:  Deputy Director.	
23. REMARKS:			

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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;
  - 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:

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