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State/Territory Name: Minnesota

State Plan Amendment (SPA) #: 17-0009

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form (with 179-like data)
- 3) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850



Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

December 18, 2017

Ms. Ann Berg
Deputy Medicaid Director
Minnesota Department of Human Services
P.O. Box 64998
St. Paul, MN 55164-0998

Dear Ms. Berg:

We have reviewed Minnesota's State Plan Amendment (SPA) 17-0009, Prescribed Drugs, received in the Chicago Regional Office on September 22, 2017. This amendment proposes to cover stiripentol for children with certain medical conditions.

Based on the information provided, we are pleased to inform you that consistent with the regulations at 42 CFR 430.20, SPA 17-0009 is approved with an effective date of July 1, 2017. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into the Minnesota state plan will be forwarded by the Chicago Regional Office.

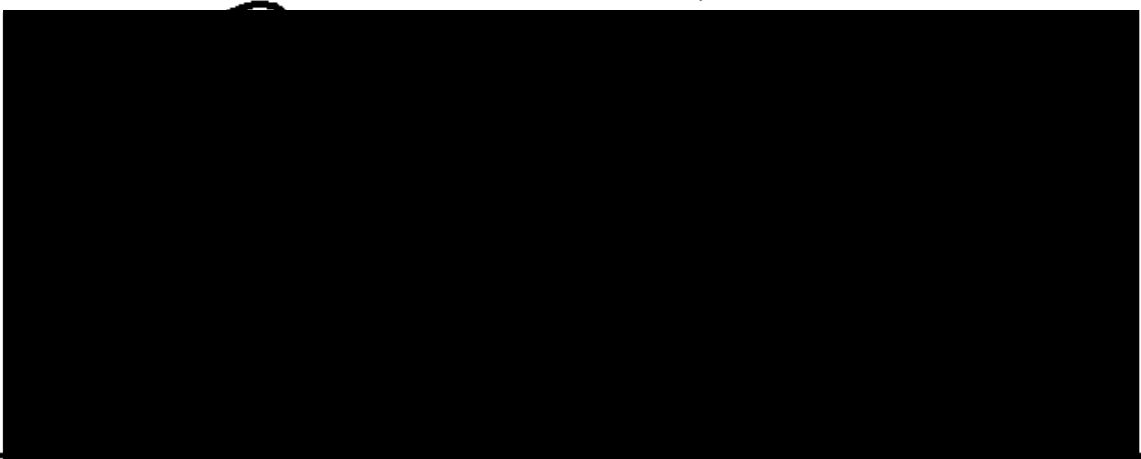
If you have any questions regarding this amendment, please contact Lisa Shochet at (410) 786-5445 or lisa.shochet@cms.hhs.gov.

Sincerely,

/s/

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

CC: Ruth Hughes, ARA, CMS, Chicago Regional Office
Sandra Porter, CMS, Chicago Regional Office
Sean Barrett, Minnesota Department of Human Services

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL		1. TRANSMITTAL NUMBER: 17-09	2. STATE Minnesota
FOR: CENTER FOR MEDICARE & MEDICAID SERVICES		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, 2017	
5. TYPE OF PLAN MATERIAL (Check One): <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 (Separate Transmittal for each amendment)			
6. FEDERAL STATUTE/REGULATION CITATION: 42 CFR § 440.120(a) Section 1905(r) of the Social Security Act		7. FEDERAL BUDGET IMPACT (in thousands): a. FFY '18 \$45 b. FFY '19 \$45	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A, pages 17 and 46c Attachment 3.1-B, pages 16 and 45c		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): Same	
10. SUBJECT OF AMENDMENT: Coverage of Prescribed Drugs			
11. GOVERNOR'S REVIEW (Check One): <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: September 22, 2017			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED: September 22, 2017		18. DATE APPROVED: December 18, 2017	
PLAN APPROVED – ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: July 1, 2017		20. SIGNATURE OF REGIONAL OFFICIAL: /s/	
21. TYPED NAME: Ruth A. Hughes		22. TITLE: Associate Regional Administrator	
23. REMARKS:			

4.b. Early and periodic screening, diagnosis, and treatment services:

- Early and periodic screening, diagnosis and treatment service is a service provided to a recipient under age 21 to detect, prevent, and correct physical and mental conditions or illnesses discovered by screening services, and to provide diagnosis and treatment for a condition identified according to 42 CFR 441.50 and according to section 1905(r) of the Social Security Act.
- Initial and periodic screenings are provided as indicated by the periodicity schedule. Inter-periodic screens are available to recipients based on medical necessity. An EPSDT service can be requested by the recipient or performed by a provider at any time if medically necessary.
- Initial face-to-face and written notifications of recipients are followed up by county agencies with telephone contacts, letters, and/or home visits. Annual or periodic written notifications may also be supplemented by personal contacts.
- 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, except for stiripentol, which is described in item 12.a.

A diagnostic assessment is a written report that documents clinical and functional face-to-face evaluation of a recipient's mental health, including the nature, severity and impact of behavioral difficulties, functional impairment, and subjective distress of the recipient, and identifies the recipient's strengths and resources. A diagnostic assessment is necessary to determine a recipient's eligibility for mental health services.

An interactive diagnostic assessment, usually performed with children, may use physical aids and nonverbal communication to overcome communication barriers because the recipient demonstrates one of the following:

- Has lost or has not yet developed either the expressive language communication skills to explain his/her symptoms and response to treatment
- Does not possess the receptive communication skills needed to understand the mental health professional if he/she were to use adult language for communication or
- Needs an interpreter, whether due to hearing impairment or the recipient's language is not the same as the provider's, in order to participate in the diagnostic assessment

Brief Diagnostic Assessment

The Brief Diagnostic Assessment includes a written clinical summary that explains the diagnostic hypothesis which may be used to address the recipient's immediate needs or presenting problem. The assessment collects sufficient information to apply a provisional clinical hypothesis. Components includes:

- The recipient's current life situation
- Recipient's description of symptoms (including reason for referral)
- A mental status exam
- Screenings used to determine a recipient's substance use, abuse, or dependency, and other standardized screening instruments

Standard Diagnostic Assessment

- All components of Brief Diagnostic assessment
- Conducted in the cultural context of the recipient
- An assessment of the recipient's needs based on baseline measurements, symptoms, behavior, skills, abilities, resources, vulnerabilities, and safety
- Assessment methods and use of standardized assessment tools Clinical summary, recommendations, and prioritization of needed mental health, ancillary or other services

Approved: 12/18/17

Supersedes: 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. Drugs acquired through the federal 340B drug pricing program and dispensed by 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

4.b. Early and periodic screening, diagnosis, and treatment services:

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