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State/Territory Name: North Dakota

State Plan Amendment (SPA) #: 19-0004

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) 179
- 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

September 24, 2019

Mr. Erik Elkins, Assistant Director
North Dakota Department of Human Services
Medical Services Division
600 East Boulevard Avenue
Department 325
Bismarck, ND 58505-0250

Dear Mr. Elkins:

We have reviewed North Dakota State Plan Amendment (SPA) 19-0004 received in the Centers for Medicare and Medicaid Services (CMS) Denver Regional Operations Group on August 23, 2019. This SPA proposes for the state to allow selective 340B contract pharmacies to acquire drugs through the federal 340B drug pricing program as an exception to the current policy.

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 July 1, 2019. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into North Dakota's state plan will be forwarded by the Denver 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,

A black rectangular box redacting the signature of John M. Coster.

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

cc: Richard Allen, Director, Western Regional Operations Group, Denver Regional Office
Mary Marchioni, Program Branch Manager, Denver Regional Office
Kirstin Michels, Denver Regional Office
Nicole Lemmon, Denver Regional Office

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL		1. TRANSMITTAL NUMBER: <div style="text-align: center; font-size: 1.2em;">19-0004</div>	2. STATE <div style="text-align: center; font-size: 1.2em;">North Dakota</div>
FOR: CENTERS FOR MEDICARE AND MEDICAID SERVICES		3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE AND MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES		4. PROPOSED EFFECTIVE DATE <div style="text-align: center; font-size: 1.2em;">July 1, 2019</div>	
5. TYPE OF PLAN MATERIAL (<i>Check One</i>): <div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> NEW STATE PLAN <input type="checkbox"/> AMENDMENT TO BE CONSIDERED AS NEW PLAN <input checked="" type="checkbox"/> AMENDMENT </div> <div style="text-align: center; font-size: 0.8em;"> COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (<i>Separate Transmittal for each amendment</i>) </div>			
6. FEDERAL STATUTE/REGULATION CITATION: <div style="text-align: center; font-size: 1.1em;">1927 of the Act</div>		7. FEDERAL BUDGET IMPACT: a. FFY <u>2019</u> \$0 b. FFY <u>2020</u> \$0	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 4.19-B, page 6		9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (<i>If Applicable</i>): Attachment 4.19-B, page 6	
10. SUBJECT OF AMENDMENT: Amends the State Plan to allow the coverage of certain prescription drugs acquired through the federal 340B program.			
11. GOVERNOR'S REVIEW (<i>Check One</i>): <div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <input type="checkbox"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="checkbox"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="checkbox"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL </div> <div style="width: 35%;"> <input checked="" type="checkbox"/> OTHER, AS SPECIFIED: <u>Erik Elkins, Assistant Director</u> <u>Medical Services Division</u> </div> </div>			
12. SIGNATURE OF STATE AGENCY OFFICIAL: <div style="background-color: black; width: 200px; height: 30px; margin: 5px 0;"></div>		16. RETURN TO: Erik Elkins, Assistant Director Medical Services Division ND Department of Human Services 600 East Boulevard Avenue Dept 325 Bismarck ND 58505-0250	
13. TYPED NAME: <div style="text-align: center; font-size: 1.1em;">Erik Elkins</div>			
14. TITLE: <div style="text-align: center; font-size: 1.1em;">Assistant Director, Medical Services Division</div>			
15. DATE SUBMITTED: <u>8/23/19</u>			
FOR REGIONAL OFFICE USE ONLY			
17. DATE RECEIVED: <div style="text-align: center; font-size: 1.1em;">August 23, 2019</div>		18. DATE APPROVED: <div style="text-align: center; font-size: 1.1em;">September 24, 2019</div>	
PLAN APPROVED – ONE COPY ATTACHED			
19. EFFECTIVE DATE OF APPROVED MATERIAL: <div style="text-align: center; font-size: 1.1em;">July 1, 2019</div>		20. SIGNATURE OF REGIONAL OFFICIAL: <div style="background-color: black; width: 150px; height: 30px; margin: 5px 0;"></div>	
21. TYPED NAME: <div style="text-align: center; font-size: 1.1em;">Richard C. Allen</div>		22. TITLE: <div style="text-align: center; font-size: 1.1em;">Director, WROG</div>	
23. REMARKS:			

32. For prescribed drugs, including specific North Dakota Medicaid covered non-legend drugs that are prescribed by an authorized prescriber and legend drugs prescribed by an authorized prescriber, North Dakota Medicaid will reimburse at the following lesser of methodology (in all instances, the professional dispensing fee will be \$12.46):
1. The usual and customary charge to the public, or
 2. North Dakota Medicaid's established Maximum Allowable Cost (MAC) for that drug plus the professional dispensing fee (ND Medicaid's MAC is acquisition cost based and includes all types of medications, including specialty and hemophilia products), or
 3. The current National Average Drug Acquisition Cost (NADAC) for that drug plus the professional dispensing fee, or if there is no NADAC for a drug, the current wholesale acquisition cost (WAC) of that drug plus the professional dispensing fee; In compliance with 42 Code of Federal Regulations (C.F.R.) 447.512 and 447.514, reimbursement for drugs subject to Federal Upper Limits (FULs) may not exceed FULs in the aggregate.
 4. For 340B purchased drugs, the lesser of logic will include the 340B MAC pricing (ceiling price) plus the professional dispensing fee.
 - a. Covered entities as described in section 1927 (a)(5)(B) of the Social Security Act are required to bill no more than their actual acquisition cost plus the professional dispensing fee.
 - b. Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not covered, unless the State approves an exception.
 5. All Indian Health Service, tribal and urban Indian pharmacies are paid the encounter rate by ND Medicaid regardless of their method of purchasing.
 6. For Federal Supply Schedule purchased drugs, their provider agreements will require them to bill at no more than their actual acquisition cost plus the professional dispensing fee.
 7. Drugs not distributed by a retail community pharmacy (such as a long-term care facility) will be reimbursed as outlined in items 1-6 above and 8-13 below in this section.
 8. Drugs not distributed by a retail community pharmacy and distributed primarily through the mail (such as specialty drugs) will be reimbursed as outlined in items 1-7 above and 9-13 below in this section since ND Medicaid's MAC is acquisition cost based and includes all types of drugs.
 9. Clotting factors from Specialty Pharmacy, Hemophilia Treatment Centers (HTC), Center of Excellence will be reimbursed as outlined in items 1-8 above and 10-13 below in this section since ND Medicaid's MAC is acquisition cost based and includes all types of drugs.
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