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State/Territory Name: North Dakota

State Plan Amendment (SPA) #: ND-16-0011

This file contains the following documents in the order listed:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, MD 21244-1850

Center for Medicaid & State Operations

Disabled and Elderly Health Programs Group

February 14, 2017

Maggie D. Anderson, Executive Director
North Dakota Department of Human Services
600 East Boulevard Avenue, Department 325
Bismarck, ND 58505-0250

Dear Ms. Anderson:

We have reviewed the North Dakota State Plan Amendment (SPA) TN# 16-0011 received in the Denver Regional Office on November 18, 2016, and we are pleased to inform you that it is approved, effective October 1, 2016. Under this SPA, the State of North Dakota specifies how it will revise its pharmacy reimbursement methodology to comply with the key provisions of the Covered Outpatient Drug Final Rule (81 FR 5170) that was published in the Federal Register on February 1, 2016. The rule requires states to pay pharmacies based on the drug ingredient cost, defined as the actual acquisition cost (AAC), plus a professional dispensing fee. North Dakota has determined that the weighted average cost of dispensing prescriptions to North Dakota Medicaid beneficiaries is $12.46.

The Denver Regional Office will forward to you a copy of the CMS-179 form, as well as the pages approved for incorporation into the North Dakota Medicaid State Plan. If you have any questions regarding this amendment, please contact Renee Hilliard at (410) 786-2991.

Sincerely,

[redacted]

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

cc: Richard Allen, ARA, Denver Regional Office

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Denver Regional Office
1961 Stout Street, Room 08-148
Denver, CO 80294

REGION VIII – DENVER

February 14, 2017

Maggie Anderson
Medicaid Director
North Dakota Department of Human Services
Medical Services Division
600 E. Boulevard Avenue, Dept. 325
Bismarck, ND 58505

Re: SPA ND-16-0011 Companion Letter

Dear Ms. Anderson:

This letter is being sent as a companion to our approval of ND-16-0011, which amends the state plan to implement required changes from the Covered Outpatient Drug Final Rule and to update page numbering in section 4.19-B of the state plan. Our review of this amendment included an overall assessment of the submitted Attachment 4.19-B pages of the North Dakota State Plan. Based on this review, CMS determined that North Dakota needs to address the following regarding federally qualified health centers (FQHCs).

Federally Qualified Health Centers (FQHCs), Attachment 4.19-B, page 5, 5a, and 5b, item 31

1. Through previous conversations with North Dakota regarding wraparound language on the FQHC pages and through reviewing the language from the contract between an MCO and the North Dakota Department of Human Services, it is CMS understanding that the MCO is required to reimburse FQHCs and RHCs in accordance with the requirements of Section 1902(bb) of the Social Security Act. In particular, the MCO makes payments for services to eligible beneficiaries that are at least equal to the prospective payment system amount and that such payments are reviewed every 4 months for accuracy.

   As described in State Health Official Letter #16-006 published on April 26, 2016, titled "FQHC and RHC Supplemental Payment Requirements and FQHC, RHC, and FBC Network Sufficiency under Medicaid and CHIP Managed Care," states that require a managed care entity to provide payment to FQHCs for services provided to beneficiaries must do so as an alternative payment methodology (APM) which must be described in the State plan. This APM must include two conditions: 1) the state and FQHC agrees to use the APM and 2) the APM results in FQHCs receiving at least their full PPS reimbursement rate from the MCO. Should an FQHC decide not to be paid under the APM, the State is required to make the wraparound payment. CMS requests the state to add language to their FQHC pages describing this APM.

2. Page 5a, item 31, B2 describes a one-time adjustment for FQHC's APM rate(s). CMS requests the state replace the word "rebase" with "modify" in order to clarify the state's ability to adjust certain types of FQHC rates.

3. Page 5, item 31A claims that the state uses a "Medicare interim rate" for paying an entity that first qualifies as an FQHC after January 1, 2003. We assume this is the rate assigned by Medicare to the new facility. It is unclear to CMS why North Dakota has chosen to use the Medicare interim rate to reimburse for services provided to Medicaid beneficiaries in new FQHCs. The Benefits Improvement and Protection Act of 2000 (BIPA) established PPS as the required payment methodology for Medicaid FQHC services. On September 12, 2001 CMS (then HCFA) published guidance on the BIPA provisions in the form of Qs and As. Question 31 of the Benefits Improvement and Protection Act of 2000 (BIPA) Qs and As indicates that the rate for a new facility should be based on the costs used to set the PPS rate for like FQHCs with similar caseloads in the same or adjacent area of the state. CMS is requesting additional clarification regarding the state's usage of the Medicare interim rate for new FQHCs. This may include why this rate was chosen, how this rate is economic and efficient, comparability to the Medicaid interim rate for FQHCs, or any other information to help CMS understand.

4. Page 5-5b includes Section B, Alternative Payment Methodology Rates. This section needs an effective date for the establishment of the APM rates described on these pages, which is consistent with the included effective date for the PPS language. CMS suggests adding effective date language to item 3 on page 5a. This addition will be considered a technical correction. The state will be able to include the effective date the language currently on the page regarding APMs was added. Below is some suggested language for item 3, on page 5a:

   Effective for dates of service on or after (insert effective date of SPA that added the original APM language), the state implemented an APM medical and dental rate. Beginning in calendar year 2013, the State shall adjust the APM medical and dental rates on January 1 of each year by the MEI for that year.

   In addition to adding effective date language, please confirm that these APM rates were paid to providers on or after the effective date the APM language was originally added to the state plan.

Please respond within 90 days of receipt with a corrective action plan describing how the State will resolve the issues identified above. During this 90-day period, CMS welcomes the opportunity to work with you and your staff to resolve the issues described in this letter. Should you or your staff have questions regarding this request, please contact Kirstin Michel at (303) 844-7036.

Sincerely,

[redacted]

Richard C. Allen
Associate Regional Administrator
Division of Medicaid and Children's Health Operations

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE AND MEDICAID SERVICES	1. TRANSMITTAL NUMBER: **16-0011**	2. STATE **North Dakota**
	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 **October 1, 2016**	

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 CFR Part 447**	7. FEDERAL BUDGET IMPACT: a. FFY **2017** $0 b. FFY **2018** $0
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 4.19- B Page 3 Attachment 4.19-B Page 5, 5a and 5b Attachment 4.19-B Page 6 and 6a Attachment 4.19-B Page 6b	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*: Attachment 4.19- B Page 3 Attachment 4.19-B Page 6 and 6a Attachment 4.19-B Page 2a Attachment 4.19-B Page 3d

10. SUBJECT OF AMENDMENT:
Amends the North Dakota State Plan to implement required changes from the Covered Outpatient Drug Final Rule (CMS 2345-FC) and to update page numbering in section 4.19-B of the state plan.

11. GOVERNOR'S REVIEW *(Check One)*:
☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☒ OTHER, AS SPECIFIED:
Maggie D. Anderson, Executive Director, Department of Human Services

12. SIGNATURE OF STATE AGENCY OFFICIAL: [redacted]	16. RETURN TO: **Maggie D. Anderson, Executive Director** **ND Department of Human Services** **600 East Boulevard Avenue Dept 325** **Bismarck ND 58505-0250**
13. TYPED NAME: **Maggie D. Anderson**	
14. TITLE: **Executive Director, Department of Human Services**	
15. DATE SUBMITTED: **November 18, 2016**	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: November 18, 2016	18. DATE APPROVED: February 14, 2017
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: October 1, 2016	[redacted] FFICIAL:
21. TYPED NAME: Richard C. Allen	22. TITLE: ARA, DMCHO

23. REMARKS:

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES - OTHER TYPES OF CARE:

18. Covered outpatient drugs submitted on a professional claim form will be reimbursed at the lower of the fee schedule established by the state agency or the estimated acquisition cost for the national drug code as outlined on item 32 on pages 6 and 6a of Attachment 4.19-B.

19. Nurse Practitioners are paid at the lower of billed charges or 75% of the professional services fee schedule. North Dakota Medicaid providers will receive a three percent inflationary increase in reimbursement effective for dates of service July 1, 2015, for services reimbursed from the Professional Services Fee Schedule, as authorized and appropriated by the 2015 Legislative Assembly.

20. Other Practitioner Services, unless otherwise specified, are paid at the lower of billed charges or 75% of the professional services fee schedule. North Dakota Medicaid providers will receive a three percent inflationary increase in reimbursement effective for dates of service on or after July 1, 2015, for services reimbursed from the Professional Services Fee Schedule. The fee schedule was last updated on July 1, 2015 and is effective for dates of service on or after that date.

21. Vacated

22. Vacated

23. Personal Care Services

    a. Authorized personal care services provided to an individual who receives personal care services from a provider on less than a 24-hour-a-day-seven-day-a-week basis shall be paid based on a maximum 15-minute unit rate established by the department. Rates will be established for individual and agency providers.

       North Dakota Medicaid providers will receive a three percent inflationary increase in reimbursement effective for dates of service July 1, 2015, as authorized and appropriated by the 2015 Legislative Assembly. Providers who travel at least twenty-one miles round-trip to provide personal care services to individuals in rural areas, will receive a rate adjustment effective for dates of service January 1, 2015.

    b. Authorized personal care service provided to an individual by a provider who provides personal care services on a 24-hour-a-day-seven-day-a-week basis shall be paid using a prospective per diem rate for each day personal care services are provided.

       1) The maximum per diem rate for an individual or agency provider shall be established using the provider's allowable hourly rate established under paragraph a. multiplied times the number of hours per month authorized in the individual's care plan times twelve and divided by 365. The provider may bill only for days in which at least 15 minutes of personal care service are provided to the individual. The maximum per diem rate for an individual or agency may not exceed the maximum per diem rate for a residential provider as established in subparagraph 2.

31. The payment methodology for Federally Qualified Health Clinics (FQHCs) shall conform to section 702 of the Benefits Improvement and Protection Act (BIPA) of 2000. A center that agrees in writing to the use of an alternative payment methodology shall be reimbursed using an alternative payment methodology (APM) identified in subsection B of this section. A center which does not agree to the state's alternative payment methodology shall be reimbursed on a prospective payment system (PPS) identified in subsection A of this section. On an annual basis the state will compare the APM rate established to the PPS rate to ensure that the APM rate is at least equal to the PPS rate. At any time the APM rate is less than the PPS rate, a supplemental payment equal to the difference between the APM rate and the PPS rate times the number of visits shall be made quarterly.

A. Prospective Payment System (PPS) Rate

A center shall be reimbursed using a prospective payment system for services furnished on or after January 1, 2001 using a payment rate based on the center's reasonable costs for the center's fiscal years 1999 and 2000. Reasonable costs for each year are divided by the number of visits for the year and the PPS rate will be the average of the rates for the two years. The PPS rate shall be effective January 1, 2001 and will be adjusted on January 1 of each year by the Medicare Economic Index (MEI).

In any case in which an entity first qualifies as a FQHC after January 1, 2003 the rate for the first year, or partial year thereof, in which services are first provided shall be the Medicare interim rate. For purposes of this section, a "new FQHC" is an FQHC that meets all applicable licensing or enrollment requirements, and qualifies as an FQHC on or after January 1, 2003. Sites of an existing FQHC that are newly recognized by the Health Resources and Services Administration (HRSA) are not new FQHCs. The rate established shall not be subject to settlement. Beginning January 1 of the year following the year an entity first qualifies as an FQHC, the previous year's Medicare interim rate shall be adjusted by the MEI. Beginning January 1 of the second year following the year an entity first qualifies as an FQHC a PPS rate shall be established based on the FQHC's Medicare cost report for the first full year of operation.

Upon the FQHC's application, the PPS rate shall be adjusted to reflect any increase or decrease in the scope of services furnished by the FQHC.

B. Alternative Payment Methodology (APM) Rates

Two APM rates shall be established for each FQHC: one rate for medical and other services (i.e., all Medicaid-covered services other than dental services); and one rate for dental services (the "dental APM rate"). These APM rates are fixed rates and are not subject to adjustment or reconciliation except as provided for below.

The FQHC's medical and dental APM rates shall be established according to a two-step process, as follows:

1. Establishment of APM Rate:

   (a) The medical APM rate shall be equal to an amount (calculated on a per visit basis) that is:

      i. For an FQHC that qualified as an FQHC before fiscal year 1999, equal to 100 percent of the average of the reasonable costs of the FQHC of furnishing FQHC services (other than dental services) during fiscal years 1999 and 2000; or

      ii. For an FQHC that first qualified as an FQHC in or after fiscal year 1999, equal to 100 percent of the reasonable costs of the FQHC of furnishing FQHC services (other than dental services) during the first full fiscal year after the date on which the entity qualified as an FQHC.

   (b) The APM dental rate shall be equal to an amount (calculated on a per visit basis) that is:

      i. For an FQHC that provided dental services before 1999, equal to 100 percent of the average of the reasonable costs of the FQHC of furnishing dental services during fiscal years 1999 and 2000; or

      ii. For an FQHC that first provided dental services in or after 1999, equal to 100 percent of the reasonable costs of furnishing dental services during the first full fiscal year after the date on which the FQHC first provided dental services.

   (c) The calculation of the APM rates and any subsequent adjustments to those rates shall be on the basis of the reasonable costs of the FQHC as provided for under 42 C.F.R. part 413 without the application of provider screens and caps or limitations on costs or cost categories.

2. One-Time Adjustment: Each FQHC that is an enrolled provider on March 31, 2012 shall have one opportunity to rebase its APM medical rate, dental rate, or both its medical and dental rates. The FQHC shall choose a Medicare cost report utilizing either fiscal year 2010 or fiscal year 2011 as the basis for the rebased rate. For the year chosen, the APM medical and dental rates will be:

   (a) Adjusted by the Medicare Economic Index (MEI), and

   (b) Adjusted to reflect any increase or decrease in the scope of services.

3. Beginning in calendar year 2013, the State shall adjust the APM medical and dental rates on January 1 of each year by the MEI for that year.

4. Upon the FQHC's application, the medical or dental APM rates shall be adjusted to reflect any increase or decrease in the scope of services furnished by the FQHC.

5. Rate-Setting for New FQHCs

For the purpose of this Section, a "new FQHC" is an FQHC that meets all applicable licensing or enrollment requirements, and qualifies as an FQHC on or after April 1, 2012. Sites of an existing FQHC that are newly recognized by the Health Resources and Services Administration (HRSA) are not new FQHCs.

(a) Establishment of Interim Rate*:* The state shall pay new FQHCs under the methodology effective for services provided on or after the effective date the provider is an enrolled provider. The new FQHC shall choose between two options for interim medical and dental APM rates that shall be effective until new APM rates are established:

i. 90% of the average medical APM rate and average dental APM rate for all FQHCs in North Dakota; or

ii. A rate based on an actual or *pro forma* cost report.

(b) Establishment of APM Rates*:* The FQHC's medical and dental APM rates will be determined according to subsection B.1 and shall be effective on the first day of the second full fiscal year of operations.

(c) Reconciliation*:* Payments made to an FQHC under the interim rate described in subsection B.5 shall be subject to cost settlement, and the FQHC shall be entitled to receive the reasonable cost of providing covered services during the first two fiscal years of operation.

6. Behavioral Health Services Encounter

A behavioral health services encounter provided at a FQHC may be rendered by a licensed provider, within their scope of practice and who meets the provider qualifications for rehabilitative services under Attachment to Page 6 of Attachment 3.1-A and Attachment to Page 5 of Attachment 3.1-B.

The rate for a behavioral health encounter shall be equal to the medical APM rate. A behavioral health encounter may be reimbursed in addition to a separate medical encounter on the same day.

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.
    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.

10. Drugs acquired at Nominal Price (outside of 340B or FSS) will be reimbursed at no more than the actual acquisition plus the professional dispensing fee while also using the logic as outlined in items 1-9 above and 11-13 below in this section.
11. All of the logic as outlined in items 1-10 above in this section (with the exception of the professional dispensing fee being included in the calculations) will apply to Physician Administered Drugs (no professional dispensing fee will be paid for Physician Administered Drugs).
12. Investigational drugs are paid at invoice pricing which includes the cost of the drug, the international regulatory, shipping and handling fee, and next day delivery service.
13. A fee of fifteen cents per pill will be added to the dispensing fee for the service of pill splitting. Pill splitting is entirely voluntary for the patient and the pharmacist. Pill splitting will only be permitted under the following circumstances: when Medical Services determines it is cost effective, the pill is scored for ease of splitting, and the pharmacy staff splits the pill. This fee will only be allowed for medications that have been evaluated by the state for cost-effectiveness and entered into the Point-of-Sale system.