Kewa Pueblo Health Corporation

P.O. BOX 340 • 85 W HIGHWAY 22
SANTO DOMINGO PUEBLO, NEW MEXICO 87052

Phone: 505-465-3060 • Fax: 505-465-1191

January 21, 2020

Kewa Pueblo Health Corporation (KPHC), Health Board
PO Box 340 * 85 West Hwy 22
Santo Domingo, NM 87052

RE: **SBAR Submission #2020-02**
Approval to request Tribal Consultation on New Mexico State Plan Amendment (SPA) #17-0003 relating to Covered Outpatient Drugs (COD) final rule.

Dear Members of the Health Board,

The purpose of this SBAR Submission is to obtain approval to request Tribal Consultation on New Mexico State Plan Amendment (SPA) #17-0003 relating to Covered Outpatient Drugs (COD) final rule. To this end, I submit the following SBAR for your consideration and action:

Approval to request Tribal Consultation on New Mexico State Plan Amendment (SPA) #17-0003 relating to pharmacy Covered Outpatient Drug (COD) final rule	
Situation	New Mexico SPA 17-0003 (Attachment #1) was implemented by CMS on March 20, 2018 (retroactive back to April 1, 2017) to bring New Mexico in compliance with federal law on reimbursement for Covered Outpatient Drugs (COD). However, the methodology does not represent the best possible option for IHS and tribal facilities in the state.
Background	1) A Written Notification Letter dated March 17, 2017 (Attachment #2) invited tribal comments on SPA 17-0003. This proposal dealt with the reimbursement rates for Covered Outpatient Drugs (CODs) as required by federal law. 2) Although the possible use of the OMB rate is invoked in this document, no projections are provided and no further discussion was engaged. Moreover, despite the timing of this notification letter, the topic of SPA 17-0003 and OMB reimbursement was not discussed at the next Native American Technical Advisory Committee (NATAC) meeting on April 10, 2017 (Attachment #3). 3) A call to the HSD Native American (NA) Liaison on December 23, 2019 confirmed no comments were received and no "face-to-face" tribal consultation was engaged on this topic prior to the implementation of SPA 17-0003.

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Assessment

A summary review of contributing factors to our final recommendation includes the following dates/data/events:

1) A State Health Official letter (SHO) #16-001 (Attachment #4) from CMS and dated February 11, 2016 clarifies that "States that pay IHS and tribal providers through encounter rates [OMB rates] can continue to pay at that rate since this will satisfy [federal regulations]" (page 3).
2) Fifteen (15) states operate under COD SPAs that call for reimbursement to IHS and tribal facilities at the OMB rate. While most of these SPAs allow only one (1) pharmacy encounter per day per patient/facility regardless of the number of prescriptions made to a patient, two (2) states---Oregon and Wyoming (Attachments #5 & #6)---consider each prescription an encounter and therefore reimburse the OMB rate per prescription dispensed with counseling.
3) The Written Notification Letter makes the point of projecting a $613,000 dollar increase in professional dispensing fees for all IHS and tribal pharmacies due to SPA 17-0003. However, IHS and tribal sites have the potential to realize much greater benefits under reimbursement at the OMB rate. For example, actual pharmacy collections data for the Santo Domingo Health Center (SDHC) for FY 2017 (since April 1st), FY 2018 and FY 2019 is as follows:

	2017	2018	2019
# of Medicaid scripts	5,861	12,292	11,757
Total $ Collected	$263,407	$592,511	$625,728
Avg. $ per script	$44.94	$48.16	$53.22

In this case, dispensing fees are reimbursed for each prescription per SPA 17-0003 and the trending increase in average $ per script is visible. However, if the same methodology---as adopted by Oregon and Wyoming---is applied with the OMB reimbursement rate, IHS and tribal program collections increase tenfold:

	2017	2018	2019
# of Medicaid scripts	5,861	12,292	11,757
OMB Reimbursement Rate	$391	$427	$455
Total $ Collections	$2,291,651	$5,253,381	$5,349,435

Even if the more common interpretation of OMB reimbursement for encounters assumes one (1) encounter and payment per day, the result is still significantly higher---approximately $1.1 million over actual collections in FY 2019 alone:

	2017	2018	2019
# of Medicaid scripts	5,861	12,292	11,757
Avg. # of scripts/encounter	2.93	3.23	3.14
OMB Reimbursement Rate	$391	$427	$455
Total $ Collections	$782,133	$1,624,980	$1,703,642

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Assessment	4) Per the NA Liaison and New Mexico HSD State-Tribal Consultation Protocol, tribal consultation is mandatory when a "Pueblo Governor or Tribal President initiates a request for consultation." **BASED ON THIS INFORMATION/DATA AS WELL AS THE EXPRESSED POSITION OF GOVERNOR LUHAN-GRISHAM TO BETTER PARTNER WITH AND ASSIST NATIVE AMERICANS IN NEW MEXICO, KPHC LEADERSHIP CONCLUDES THE FOLLOWING:** *1) KPHC and other tribal programs would have/would benefit much more from the use of OMB reimbursement rates for CODs than the methodology outlined in SPA 17-0003, and can do so without additional burden to the State of New Mexico (e.g. 100% FMAP).* *2) Although tribes were invited to provide comments on this action, tribal programs are uneven in their development and understanding of state legislation, and the method of soliciting feedback and guidance from tribes was very passive in nature. The potential for tribal benefit should have prompted a request for consultation on some level.* *3) Given the historic underfunding of IHS and tribal health programs, any opportunity providing the benefit of increased resources for services and improved sustainability deserves careful and close consideration by the State.* *4) The Governor and Tribal Council for the Santo Domingo Pueblo have the power to initiate a tribal consultation session on this and other issues as needed.*
Recommendation(s)	KPHC Leadership recommends the Health Board engage the Governor and Tribal Council of the Santo Domingo Pueblo through resolution to initiate a tribal consultation session with the State of New Mexico to review the methodology for COD reimbursement to IHS and tribal health programs. ELT Vote: ___ For ___ Against ___ Abstaining SLT Vote: ___ For ___ Against ___ Abstaining

If you have any further questions or concerns regarding this request, I invite you to contact me at your earliest convenience.

Sincerely,

Alan Barlow, KPHC Chief Executive Officer
Cc: KPHC Executive Leadership Team
KPHC Supervisory Leadership Team

II. Payment for Prescribed Drugs.

For the New Mexico Medicaid Fee-for-Service program,

1. Payment:
Reimbursement for the drug ingredient cost shall be the lowest of:

   a. The Affordable Care Act Federal Upper Limit (FUL) plus the professional dispensing fee (PDF);
   b. The National Average Drug Acquisition Cost (NADAC) plus the PDF;
   c. The Wholesaler's Average Cost (WAC) + 6% plus the PDF;
   d. The pharmacy's reported ingredient cost plus the PDF; or
   e. The usual and customary charge (U&C).

   The PDF is $10.30.

   When the drug item is for a brand name drug that is also a multi-source drug, the Actual Acquisition Cost, (AAC) will be calculated using the generic equivalent of the brand name drug unless the prescriber has written in his or her own hand "brand medically necessary" on the prescription in which case reimbursement will be at the AAC of the NADAC for the brand name drug item plus a $10.30 PDF, not to exceed the pharmacy's U&C.

2. Allowed Fees in Addition to the Professional Dispensing Fee (PDF)
Reimbursement for compounding fees is limited to the provider's usual additional charge for compounding not to exceed $12.00.

3. Payment Provisions for Blood Clotting Factors
Reimbursement for clotting factors will be at the lower of the submitted ingredient cost or WAC plus 6%, plus a $10.30 PDF, not to exceed the pharmacy's U&C.

4. Payment Provisions for 340B Drugs
Payment to 340B covered entities for drugs purchased at 340B prices authorized under Section 340B of the Public Health Services Act will be at the 340B actual acquisition cost plus a $10.30 PDF, not to exceed the pharmacy's U&C.

5. Payment Provisions for Drugs Acquired under Federal Supply Schedule (FSS) Pricing
Payment for drugs purchased at FSS prices will be at the FSS actual acquisition cost of the drug plus a $10.30 PDF, not to exceed the pharmacy's U&C.

6. Payment to Indian Health Service Pharmacies and Tribal 638 Healthcare Pharmacies
Reimbursement for the drug ingredient cost shall be the lowest of:

   a. The Affordable Care Act Federal Upper Limit (FUL) plus the professional dispensing fee (PDF);
   b. The National Average Drug Acquisition Cost (NADAC) plus the PDF;
   c. The Wholesaler's Average Cost (WAC) + 6% plus the PDF;
   d. The pharmacy's reported ingredient cost plus the PDF; or
   e. The usual and customary charge (U&C).

   The PDF is $10.30.

State: New Mexico
Received Date: 29 June, 2017
Approved Date: 20 March, 2018
Effective Date: 1 April, 2017
Transmittal Number: NM 17-0003 PHARM

Transmittal Number: 17-0003 Date Approved: 3-20-2018 Date Effective: 4-1-2018
Supersedes TN: 12-06B

ATTACHMENT #2

HUMAN SERVICES
DEPARTMENT

Susana Martinez, Governor
Brent Earnest, Secretary
Nancy Smith-Leslie, Director

March 17, 2017

RE: Tribal Notification to Request Advice and Comments Letter 17-03: New Mexico Compliance with the federal Covered Outpatient Drug Rule

Dear Tribal Leadership, Indian Health Service, Tribal Health Providers, and Other Interested Parties:

Seeking advice and comments from New Mexico's Indian nations, tribes, pueblos and their health care providers is an important component of the government-to-government relationship with the State of New Mexico. In accordance with the New Mexico Human Services Department's (HSD's) Tribal Notification to Request Advice and Comments process, this letter is to inform you that HSD, through the Medical Assistance Division (MAD), is accepting written comments until **5:00pm Mountain Standard Time (MST) on Wednesday, April 19, 2017,** regarding changes in the reimbursement of pharmacy claims.

HSD is providing this notice for the purpose of receiving comment on proposed changes to pharmacy reimbursement to ensure that the New Mexico Medical Assistance Program payments comply with the federal Covered Outpatient Drug Rule. The federal Covered Outpatient Drug Rule (CODR) was published in the Federal Register on Monday, February 1, 2016 (Volume 81, No. 20) as a final rule to be included in 42 CFR Part 447 (refer to the web link, below).

The CODR specifies the maximum drug ingredient costs that may be paid on a pharmacy claim. HSD has prepared a draft State Plan Amendment that specifies that the allowed ingredient cost will be calculated as the lower of the National Average Drug Acquisition Cost (NADAC), the ingredient cost reported by the provider, or any other applicable federal upper limit. The draft State Plan Amendment also specifies that if there is not a NADAC amount, the Wholesale Acquisition Cost as reported by national drug pricing services will be used. The CODR also specifies that a provider is required to report the 340-B acquisition ingredient cost for any drug item purchased at 340-B prices. A provider who dispenses any drug item purchased through the Federal Supply Schedule (FSS) or drug pricing program under 38 U.S.C. 1826, 42 U.S.C. 256b, or 42 U.S.C. 1396-8, other than the 340-B drug pricing program, must bill the actual acquisition cost as the ingredient cost of the drug item. These requirements are included in the draft State Plan Amendment.

Additionally, the CODR requires each state Medicaid agency to review their current dispensing fee. The rule redefines the dispensing fee as a Professional Dispensing Fee to cover other professional

services that the pharmacy may provide in addition to dispensing the drug item. In the draft State Plan Amendment, HSD is proposing a professional dispensing fee of $10.30 to be used in the calculations that determine a final payment to a pharmacy. This amount was developed after considering other state studies and proposed professional dispensing fees, and particularly the profession dispensing fees developed by neighboring states. New Mexico's current dispensing fee is $3.65.

The draft State Plan Amendment includes federally required payment limitations on Medicaid-covered drug items purchased under federal government provisions. Specifically, a provider is required to report the actual acquisition ingredient cost for any drug item purchased at 340-B prices, the Federal Supply Schedule (FSS) or drug pricing program under 38 U.S.C. 1826, 42 U.S.C. 256b, or 42 U.S.C. 1396-8.

The draft State Plan Amendment also includes new wording to clarify that: (1) drug items that are for investigational use only are not covered under the New Mexico Medical Assistance program; (2) prior to dispensing controlled substances prescribed at amounts that exceed high codes limits, the pharmacy must verify the prescription with the prescriber (otherwise, the payment for the prescription may be subject to recoupment); and (3) dispensing of controlled substances that have not been reported as required to the New Mexico Board of Pharmacy Prescription Monitoring Program are subject to recoupment.

Estimated Total Financial Impact and Impact on IHS and Tribal Healthcare Facilities

The calculated financial impact is to the Medicaid fee-for-service (FFS) program.

- For all pharmacy providers, the impact of implementing a professional dispensing fee of $10.30 and the required changes to the ingredient cost calculations, a decrease in payment to pharmacy providers is anticipated to be $1.95 million annually in state and federal funds.

- Specifically for IHS and for tribal healthcare pharmacies, the anticipated annual increase in the professional dispensing fee is anticipated to be $613,000. This is approximately a 10 percent increase in payments to these pharmacies.

- For an IHS or tribal healthcare pharmacy that currently bills an ingredient cost on their pharmacy claims based on federal supply schedules or another discounted purchasing amount, it is not anticipated that there would be a significant change in the payment for ingredient costs on their pharmacy claims. For an IHS or tribal healthcare pharmacy that does not bill ingredient costs based on federal supply schedules or another discounted purchasing amounts, but begins to do so under this State Plan Amendment, it is estimated that there could be a 6 percent decrease in payments for the ingredient cost of the drug item.

Other Tribal Impact

In general, complying with the CMS Covered Outpatient Drug Rule will result in increased reimbursements to IHS and tribal healthcare pharmacies. However, there is specific wording in the rule that may change the reimbursement levels for these pharmacies with regard to payment for the cost of the ingredients in a drug item. It may also be necessary for these pharmacies to change how they bill

pharmacy claims with regard to ingredient costs, depending on how the pharmacies currently bill the Medicaid program.
The Department would very much appreciate receiving comments on the following issues regarding reporting ingredient costs of drug items on the pharmacy claim form:

- The CODR specifies that a provider is required to report the 340-B acquisition ingredient cost for any drug item purchased at 340-B prices. A provider who dispenses any drug item purchased through the Federal Supply Schedule (FSS) or drug pricing program under 38 U.S.C. 1826, 42 U.S.C. 256b, or 42 U.S.C. 1396-8, other than the 340-B drug pricing program must bill the actual acquisition cost as the ingredient cost of the drug item.

  HSD/MAD's understanding is that IHS and tribal healthcare pharmacy providers generally purchase drug items at the Federal Supply Schedule. If so, the pharmacy would be required to report the ingredient cost on the pharmacy claim. It is not known if IHS and tribal healthcare pharmacy providers currently state the ingredient cost on their claims, and if the amount is actually at the acquisition cost from their purchase source.

  HSD is seeking information from tribal health care providers on the following questions:

  a. Will this requirement require changes in how an IHS or tribal healthcare provider bills pharmacy claims?

  b. Will this require IHS or tribal healthcare providers to make technical system changes?

  c. Do IHS and tribal healthcare pharmacies need more time to implement this change, such that HSD/MAD should discuss delaying this requirement with CMS?

  d. There have been some initial discussions with IHS and tribal healthcare providers on following some other states, in paying for pharmacy claims at a client OMB rate. Do IHS and tribal healthcare providers believe that New Mexico should propose this option to CMS?

Tribal Advice and Comments
Tribes and tribal health care providers may view proposed State Plan Amendment (SPA) 17-003 on the HSD webpage at http://www.hsd.state.nm.us/public-notices-proposed-rule-and-waiver-changes-and-opportunities-to-comment.aspx.

SPA 17-003 Covered Outpatient Drug Rule

A written copy of these proposed documents may be requested by contacting the HSD Medical Assistance Division (HSD/MAD) in Santa Fe at (505) 827-6252.

Important Dates
Following federal requirements, the effective date of these changes is April 1, 2017. If changes to the draft State Plan Amendment are required based upon tribal comments or as requested by CMS, any claims paid on or after April 1, 2017 will be adjusted retroactively to reflect the final approval by CMS.

HSD intends to file the State Plan amendment after the public comment period, but no later than April 20, 2017.

OPPORTUNITY TO VIEW DOCUMENTS AND MAKE COMMENTS: Medicaid providers, Medicaid recipients, and other interested parties are invited to make comments on this proposal.

Written advice and comments must be received no later than 5:00 pm MST on Wednesday, April 19, 2017. Please send your advice, comments or questions to the MAD Native American Liaison, Theresa Belanger, at (505) 827-3122 or by email to theresa.belanger@state.nm.us.

All comments and responses will be compiled and made available after April 15, 2017.

Sincerely,

Nancy Smith-Leslie
Director

cc: Kari Armijo, HSD/MAD Deputy Director
Theresa Belanger, Native American Liaison, HSD/MAD
HSD/MAD Centennial Care Bureau
HSD/MAD Program Policy Bureau

ATTACHMENT #3

HUMAN SERVICES DEPARTMENT

Native American Technical Advisory Committee (NATAC)

Minutes for April 10, 2017

Time: Start 1:30pm End: 3:30 pm Place: Albuquerque Area IHS

Chair: Nancy Smith-Leslie, Director (MAD)

Committee Members: Michael Nelson, HSD Deputy Secretary; Nancy Smith-Leslie, MAD Director; Angela Medrano, MAD Deputy Director; Theresa Belanger, MAD NA Liaison; Samuel Peinado, HSD/ISD; Marisa Vigil, HSD/ISD; Volelle Zamora (Pueblo of Isleta); Debra Feathers (AAIHS); Sandra Winfrey (AAIHS); Harriet Zamora (Taos Pueblo), Erik Lujan (APCG);Rufus Greene, Charlotte Little (San Felipe Pueblo); Mark Freeland (Navajo Nation), Iris Reano, Anthony Yepa (Cochiti Pueblo), Emily Haozous (Ft. Sill Apache)

Call In: Mary Scott (Pueblo of Laguna); Carrie Sarnicky (Sandia Pueblo); Lisa Maves (Jemez Pueblo); Nathan Tsosie (Santa Ana Pueblo)

Absent Members: LeAnne Siow (Acoma Pueblo); Thelma Gonzales (San Ildefonso Pueblo); Jean Pino (Zia Pueblo); Sandra Platero (Mescalero); Sharon Krantz (Santa Clara Pueblo); Birdena Sanchez (Zuni Pueblo)

DISCUSSION ITEM	OUTCOME	FOLLOW-UP ACTION	RESPONSIBLE PERSON/ DEPARTMENT	EXPECTED OR REQUIRED COMPLETION DATE
I. Invocation/Introductions	No invocation was given. Introductions were done.	None	All	Completed
II. History of NATAC Approval of 12/05/2016 minutes	Nancy Smith Leslie gave an introduction of the history of NATAC for new members.	None	Nancy Smith Leslie	Completed
III. Medicaid Update	• 2016 Native American report data – Theresa went over the information on Native American enrollment numbers, highest number of outpatient claims paid based on provider, community benefit utilization, most utilized value added services, emergency use for non emergent conditions and a graph of the Completion of Health Risk Assessments by MCO/Year for 2015-16. It was noted that claims mining triggers a health risk assessment. Care coordination levels 2 and 3 get a Comprehensive Needs Assessment (CNA) each year. As of July, 2016 MCOs were not required to do an HRA annually on individuals who had a care coordination level 1. The question was asked how the numbers determined if someone is from the main Navajo reservation or the Checkerboard area. The answer is what the member indicated on their Medicaid application under reservation. • 100% FMAP update – Albuquerque Area IHS (AAIHS) has an arrangement with UNMH for the 100% FMAP based to the historical	Ongoing Ongoing	Nancy Smith Leslie Nancy Smith Leslie/Theresa Belanger	Next meeting Next meeting

DISCUSSION ITEM	OUTCOME	FOLLOW-UP ACTION	RESPONSIBLE PERSON/ DEPARTMENT	EXPECTED OR REQUIRED COMPLETION DATE
	agreement that was already in place. MAD is waiting for CMS to provide more direction on this unique arrangement in order to claim the 100% FMAP. AAIHS is in the process of completing a Care Coordination Agreement (CCA) with Presbyterian Health Care Services. • 1115 Waiver Renewal – The 1115 Waiver renewal meetings started in October of 2016 with stakeholders from the Medicaid Advisory Committee (MAC) and the NATAC. Five meetings were held. Based on the comments and input from the five meetings, the Centennial Care 2.0 Concept Paper was developed. The NATAC recommendations were sent out 3/28/2017. The concept paper will be released in a few weeks and will include comments from the NATAC 1115 waiver renewal sub committee meetings. Tribal Consultation on the concept paper is scheduled for June 23, 2017 at the All Pueblo Cultural Center (APCC). Once we compile all the feedback from the public input meetings around the state and the Tribal Consultation, we will send the concept paper to CMS. We are also working on the renewal of the 1115 waiver application. That is due to CMS by November, 2017. We will have another formal Tribal Consultation in the fall on the 1115 waiver application. • Status of 2018 MCO Contract Procurement – Nancy provided an update that under the next contract procurement MCOs will be asked to contract with Tribal programs and Community Health Representatives (CHRs) for care coordination activities. There will be a transition agreement with provisions holding capitation payments until all claims are paid. • CareLink NM Health Home - Theresa provided an update on the program which provides intensive care coordination to adults diagnosed with Serious Mental Illness (SMI) or children diagnosed with Serious Emotional Disturbance (SED). The program is currently in two counties (San Juan and Curry) but as of 01/01/2018 we will be expanding it to seven more counties, two of which have Native Americans/Pueblos – Bernalillo and Sandoval county.	Ongoing None None	Nancy Smith Leslie Nancy Smith Leslie Theresa Belanger	Next meeting Completed Completed
IV. Income Support Division Update	Sam Peinado and Marisa Vigil from the HSD Income Support Division attended the meeting to provide information on the Supplemental Nutrition Assistance Program (SNAP) proposed amendments that were sent out March 28, 2017 to Tribal leadership for comment. The proposed amendments are to make sure ISD is federally compliant with the program. The changes will be effective August, 2017. One of the changes is simplified reporting. Instead of reporting every six months, individuals will be	None	Sam Peinado / Marisa Vigil	Completed

DISCUSSION ITEM	OUTCOME	FOLLOW-UP ACTION	RESPONSIBLE PERSON/ DEPARTMENT	EXPECTED OR REQUIRED COMPLETION DATE
	able to report every 12 or 24 months. The State has a waiver of Able Bodied Adults Without Dependent Children (ABAWD) until February, 2018. There was a comment that clients are being referred to the kiosks at the ISD offices without being told they can complete a paper application. ISD is developing training for all field offices on applications for services.			
V. Action Items				
VI. Other	The Tribal liaison for Taxation and Revenue is Peter Breen. Peter can be reached at peter.breen@state.nm.us The question was asked how we determine if Medicaid enrollees are from the checkerboard area or main Navajo reservation. This information is obtained from the member when they enroll in Medicaid.	7/10/2017	Theresa Belanger	Next NATAC
Next Meeting	Monday, July 10, 2017 at 1:30 pm at the Alb. Area IHS.	None	Theresa Belanger	Completed

Respectfully submitted:

Theresa Belanger
Recorder

June 15, 2017
Date

ATTACHMENT #4

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

SHO# 16-001
Affordable Care Act # 37

RE: Implementation of the Covered Outpatient Drug Final Regulation Provisions Regarding Reimbursement for Covered Outpatient Drugs in the Medicaid Program

February 11, 2016

Dear State Medicaid Director:

This letter is being issued to provide guidance to the states concerning implementation of the Covered Outpatient Drug final rule with comment (CMS-2345-FC) (81 FR 5170) published on February 1, 2016, concerning final regulations pertaining to reimbursement for covered outpatient drugs in the Medicaid program. It outlines the key changes that states need to address when determining their reimbursement methodologies, including the revised requirement in 42 CFR §447.512(b) for states to reimburse at an aggregate upper limit based on actual acquisition cost (AAC) plus a professional dispensing fee established by the agency; the implementation of the Affordable Care Act federal upper limit (FUL); and requirements for the 340B entities, 340B contract pharmacies, Indian Health Service (IHS), Tribal, and Urban Indian Organization (I/T/U) pharmacies. Also, this letter addresses the requirement for states to review both components of their total pharmacy reimbursement methodology when proposing changes to either the ingredient cost or the professional dispensing fee for all reimbursement methodologies to ensure that total reimbursement to the pharmacy provider is in accordance with the requirements of section 1902(a)(30)(A) of the Social Security Act (the Act). Lastly, this letter provides the information that states must include in a state plan amendment (SPA) relating to any proposed changes in reimbursement and the timeframe established for states to comply with the new requirements.

Background

States generally reimburse pharmacies for prescribed covered outpatient drugs dispensed to Medicaid beneficiaries based on a two-part formula consisting of the ingredient cost of a drug and a professional dispensing fee. States have flexibility to determine reimbursement amounts, consistent with applicable statutory and regulatory requirements. These reimbursement amounts are subject to review and approval by the Centers for Medicare & Medicaid Services (CMS) through the SPA process.

Outlined below are the major reimbursement provisions of CMS-2345-FC and important clarifications for states as they submit SPAs to implement these provisions.

Actual Acquisition Cost (AAC) for Drug Reimbursement

In accordance with the Affordable Care Act and requirements of §447.512(b) of the final regulation, states' reimbursement for ingredient costs for brand and certain multiple source drugs (that do not have a FUL calculated), will be established as an aggregate upper limit based on AAC, as opposed to an estimated acquisition cost. AAC is defined at §447.502 of the final regulation as the agency's determination of the pharmacy providers' actual prices paid to acquire drugs marketed or sold by specific manufacturers. CMS believes that changing this definition of ingredient cost reimbursement to AAC will provide a reference price consistent with the dictates of section 1902(a)(30)(A) of the Act.

As discussed in Section II.J. (81 FR 5290) of the preamble for the final rule with comment, a state can implement an AAC model of reimbursement based on various pricing methodologies. Below are some examples.

1) States may develop an AAC model of reimbursement that is derived from a state survey of retail pharmacy providers' pricing. Several states have already implemented a state survey to develop an AAC model of reimbursement, and may continue to use such surveys to implement the AAC requirement provided the surveys align with the aggregate upper limit based on AAC as discussed in section II.J. of the preamble for the final rule with comment (81 FR 5290).

2) States may submit a SPA that uses a national survey, such as the National Average Drug Acquisition Cost (NADAC), to establish their AAC model of reimbursement. The NADAC files, which are published on a monthly basis and updated weekly, are designed to represent a national pricing methodology based upon a simple average of voluntarily-submitted retail pharmacy acquisition costs for most covered outpatient drugs. The files are derived by surveying randomly selected, retail community pharmacies nationwide on a monthly basis. CMS began posting the NADAC files in draft on the Medicaid.gov website in October 2012 and finalized the files in November 2013. Further information on the NADAC can be found on the Medicaid.gov website at http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/survey-of-retail-prices.html.

3) States may use published compendia prices, such as the wholesale acquisition cost, to establish an AAC model of reimbursement. However, published prices may not reflect the actual prices paid by retail pharmacies; therefore states will be expected to make adjustments to these benchmarks to reflect discounts and other price concessions that are commonly obtained by retail pharmacies. Furthermore, if a state chooses this approach, the burden is on the state in its SPA submission to demonstrate, with a survey or other reliable data that the proposed reimbursement based on published compendia pricing is consistent with the aggregate upper limit based on AAC as discussed in section II.J. of the preamble for the final rule with comment (81 FR 5290).

4) States may submit a SPA that establishes a reimbursement methodology using average manufacturer price (AMP)-based pricing. The state can determine the relationship between AMP and factors such as the wholesaler markup, which covers the cost of distribution and other service charges by the wholesaler, in order to determine a reasonable reimbursement that would appropriately compensate pharmacies in accordance with the requirements of the final

regulation. CMS notes that section 1927(b)(3)(D)(i) of the Act states, in part, that AMP may be disclosed as the Secretary determines it to be necessary to carry out section 1927 of the Act. Further, section 1927(b)(3)(D)(iv) of the Act permits disclosure of AMP data to states to carry out Title XIX; however, CMS reminds states that such information is confidential and should not be disclosed in a form which discloses the identity of a specific manufacturer or wholesaler, or the prices charged for drugs by the manufacturer or wholesaler, except for certain exceptions. CMS believes that these provisions, when read together, permit states to use AMP-based pricing for purposes of pharmacy reimbursement; however, we further note that any disclosure concerning AMP must be addressed by the state during the SPA submission process. During the SPA process, the state must demonstrate how such disclosure of the AMP-based prices is consistent with the confidentiality requirements set forth by the statute and other applicable federal regulations and statutory requirements.

The state should include in its SPA the reimbursement methodology that it will use to establish its AAC reimbursement model, as well as how the state will obtain and update that methodology. The state should also specify in its SPA any alternative methodology that will be used in the case where a pricing methodology that represents an AAC model of reimbursement is not available for a specific drug for a specific time period.

Reimbursement for 340B covered entities, 340B contract pharmacies, Indian Health Service (IHS), and IHS, Tribal, and Urban Indian Organization (I/T/U) pharmacies

In accordance with the requirements in §447.518(a)(2), the state's payment methodology for drugs dispensed by 340B covered entities, 340B contract pharmacies, and I/T/U pharmacies must be in accordance with the definition of AAC in §447.502 of the final regulation. For drugs purchased through the 340B program, reimbursement should not exceed the 340B ceiling price. If the drug is purchased outside the 340B program, the reimbursement should not exceed the provider's AAC.

For drugs purchased through the Federal Supply Schedule (FSS), reimbursement should not exceed the FSS price. States that pay IHS and Tribal providers through encounter rates can continue to pay at that rate since this will satisfy the requirements in §447.518(a)(2), which specify that the state's payment methodology for these entities must be in accordance with the definition of AAC in §447.502 of the final regulation.

In addition, in accordance with the requirements in §447.518(a)(1) of the final regulation, SPAs must comprehensively describe the payment methodology for reimbursement of drugs dispensed by 340B entities, 340B contract pharmacies, and I/T/U pharmacies, in accordance with the definition of AAC, as well as the payment methodology for how such entities are reimbursed, including stating if encounter rates will be used for IHS and Tribal providers. The state should include in its SPA the reimbursement methodology that the state plans to use to establish the AAC reimbursement model – e.g., state survey, discounted published compendia pricing data, 340B ceiling price, etc., – and state how this methodology will be incorporated into its pharmacy reimbursement policies.

Transmittal #17-0007
Attachment 4.19-B
Page 3-b

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
Medical Assistance Program

State/Territory: OREGON

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES

12. Prescribed Drugs (continued)

D. Indian Health Service/Tribal (I/T) Pharmacy:
An eligible I/T pharmacy may choose to participate in the Medicaid Program and receive reimbursement for Medicaid covered services under any of following options:

(1) I/T Pharmacy will receive reimbursement as a 340B entity outlined in this State Plan attachment section C (1) through (4);

(2) I/T pharmacy will receive the Indian Health Service (IHS) per visit outpatient encounter rate, called the All-Inclusive Rate (AIR). Under an encounter rate methodology, a single rate is be applied to "A face-to-face contact between a health care professional and an IHS beneficiary eligible for the Medical Assistance Program for services through an IHS, AI/AN Tribal Clinic or Health Center, or a Federally Qualified Health Clinic with a 638 designation within a 24-hour period ending at midnight, as documented in the client's medical record. The I/T Pharmacy will receive one encounter per prescription filled or refilled and will not be limited to a certain number of prescriptions per day.

(3) I/T Pharmacy operating as a non tribal retail pharmacy will receive reimbursement as outlined in Attachment 4.19-B of this state plan, section 12.A.

E. Pharmacies who purchase drugs at Nominal Price (outside of 340B or FSS) will be reimbursed their actual acquisition cost plus the usual professional dispensing fee.

F. Pharmacies who purchase drugs at the Federal Supply Schedule will be reimbursed their actual acquisition cost plus the usual professional dispensing fee.

G. Specialty Drugs (Not distributed by a Retail Pharmacy and distributed primarily through the Mail): The Authority reimburses at the AAC rate defined in this state plan attachment, plus the usual professional dispensing fee.

H. Long-Term Care Pharmacy: The Authority reimburses at the AAC rate defined in this state plan, plus the usual professional dispensing fee.

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ATTACHMENT 4.19B
Page 3

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State of WYOMING

POLICY AND METHODS OF ESTABLISHING PAYMENT RATE FOR EACH TYPE OF CARE PROVIDED

reimbursed no more than the actual acquisition cost for the drug plus a $10.65 professional dispensing fee.

7. Facilities purchasing drugs a Nominal Price (outside of 340B or FSS) will be reimbursed no more than the actual acquisition cost for the drug plus a $10.65 professional dispensing fee. Nominal Price as defined in §447.502 of the Code of Federal Regulation, Part 42 means a price that is less than 10 percent of the average manufacturer price (AMP) in the same quarter for which the AMP is computed.

8. Physician administered drugs (PADs) submitted under the medical benefit will be reimbursed at 100 percent of the Average Sales Price (ASP). PADs without an ASP on the CMS reference file will be reimbursed at an aggregate Wholesale Acquisition Cost (WAC) + 0% for the pertinent HCPCS code. PADs without and ASP or WAC will be reimbursed at an aggregate AWP for the HCPCS code. If it is clearly demonstrated by the provider that reimbursement at the ASP, WAC, or AWP rate will negatively impact a provider's ability to continue service delivery, the DHCF may reimburse for PADs up to 100% of the established Medicare rate for the same PAD. In accordance with section 5 above, covered entities using drugs purchased at the prices authorized under Section 340B of the Public Health Services Act for Medicaid members must bill Medicaid their actual acquisition cost (AAC).

9. Payment to all Indian Health Service, tribal, and urban Indian pharmacies shall be at the All Inclusive Rate (AIR) published annually in the Federal Register. One AIR reimbursement shall be made for each pharmacy claim paid by the Department. The applicable AIR shall be determined by the date of service submitted on the pharmacy claim. Pharmacies reimbursed using the AIR will not be eligible for a dispensing fee.

10. Investigational drugs are not a covered service under the Wyoming Medicaid program.

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