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State/Territory Name: Alaska

State Plan Amendment (SPA) #: 14-0008

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

Disabled & Elderly Health Programs Group

February 5, 2015

William J. Streur, Commissioner
Department of Health and Social Services
Post Office Box 110601
Juneau, Alaska 99811-0601

Dear Mr. Streur:

We are responding to your request to approve Alaska State Plan Amendment (SPA) 14-008 received in the Seattle Regional Office on August 18, 2014. In this SPA, the state proposes to use the National Drug Acquisition Cost (NADAC) prices, as provided by the Centers for Medicare and Medicaid Services (CMS), as the state maximum allowable cost (SMAC) for both brand and generic drugs. The proposed effective date of this SPA is July 1, 2014.

CMS FINDINGS AND ANALYSIS

While we review proposed SPAs to ensure their consistency with the relevant provisions of the Social Security Act, we conducted our review of your submittal with particular attention to the statutory requirements at section 1902(a)(30)(A) of the Act ("Section (30)(A)"). Section (30)(A) of the Medicaid Act requires that state plans contain "methods and procedures...to assure that payment are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." 42 U.S.C. § 1396(a)(30)(A). As we explain in greater detail below, we find that the state's submission is consistent with the requirements of the Act, including those set forth in Section (30)(A).

States must submit information sufficient to allow CMS to determine whether a proposed amendment to a state plan is consistent with the requirements of section 1902 of the Act. However, consistent with the statutory text, CMS does not require a state to submit any particular type of data, such as a provider cost studies, to demonstrate compliance. *See* Proposed Rule, Dep't of Health & Human Servs. Ctrs. For Medicare & Medicaid Servs., 76 Fed. Reg. 26342, 26344 (May 6, 2011). Rather, as explained in more detail in the May 6, 2011 proposed rule, CMS believes that the appropriate focus on Section (30)(A) is on beneficiary access to

quality care and services. CMS has followed this interpretation for many years when reviewing proposed SPAs.[1]

This interpretation---which declines to adopt a bright line rule requiring the submission of provider cost studies---is consistent with the text of Section (30)(A) for several reasons. First, Section (30)(A) does not mention the submission of any particular type of data or provider costs; the focus of the Section is instead on the availability of services generally. Second, the Medicaid Act defines the "medical assistance" provided under the Act to mean "payment of *part* or all of the cost" of the covered services. *See* 42 U.S.C. § 1396d(a)(emphasis added). Third, when Congress has intended to require states to base Medicaid payment rates on the costs incurred in providing a particular service, it has said so expressly in the text of the Act. For example, the now-repealed Boren Amendment to the Medicaid Act required states to make payments based on rates that "are reasonable and adequate to meet the costs which must be incurred by efficiently and economically operated facilities." 42 U.S.C. § 1396a(a)(13)(A). By contrast, Section (30)(A) does not set forth any requirement that a state consider costs in making payments. Finally, CMS observes that several federal courts of appeals have interpreted Section (30)(A) to give states flexibility in demonstrating compliance with the provision's access requirement and have held that provider costs need not always be considered when evaluating a proposed SPA. *See Managed Pharm. Care v. Sebelius, 716 F.3d 1235 (9th Cir. 2013); Rite Aid of Pa., Inc. v. Houstoun,* 171 F.3d 842, 853 (3d Cir. 1999); *Methodist Hosps., Inc. v. Sullivan,* 91 F.3d 1026, 1030 (7th Cir. 1996); *Minn. Homecare Ass'n v. Gomez,* 108 F.3d 917, 918 (8th Cir.1997) (per curiam). These decisions suggest that CMS's interpretation of Section (30)(A) is a reasonable one. "

CMS's interpretation does not, of course, *prevent* states or CMS from considering provider costs.[2] CMS believes it is reasonable to consider costs as part of the SPA approval process.

The state furnished documentation which CMS evaluated in the course of its SPA review. In particular, CMS relied on the following factors identified by the state as justification for the proposed SPA's compliance with Section (30)(A)'s access requirement:

- The state has done outreach to providers about NADAC pricing, issued a Public Notice and had consultation with the Tribes. Tribal entities opposed the transition to NADAC because they were concerned that NADAC rates would be lower than the acquisition costs for drugs in Alaska. The state analyzed the payment data for a month after the implementation of NADAC including both tribal and non-tribal pharmacies and determined that the payments to tribal providers were sufficient. The state intends to continue monitoring the impact of NADAC and addressing access issues if they arise.

- The state notified providers that a provider may contact Myers and Stauffer, the CMS contractor providing NADAC prices, to initiate a NADAC price review if a provider has

[1] *See, e.g.* Br. of the United States as Amicus Curiae, *Douglas v. Independent Living Ctr.*, No. 09-958, at 9-10 (2010); Br. of United States as Amicus Curiae, *Belshe v. Orthopaedic Hosp.*, 1997 WL 33561790, at *6-*12 (1997).
[2] CMS also reserves the right to insist on cost studies to show compliance with Section (30)(A) in certain limited circumstances – particularly when considering a SPA that involves reimbursement rates that are substantially higher than the cost of providing services, thus implicating concerns about efficiency and economy.

encountered a pricing issue such as a pharmacy's acquisition cost for a drug being below the published NADAC price.

- The Alaska Pharmacists Association conducted a survey comparing NADAC prices to their members' acquisition costs. The study indicated that on average, the NADAC represented a mid-point estimate of provider's acquisition costs in Alaska.

- Since September 2011, the state has used SMAC pricing for the pricing of multi-source pharmacy claims and has been using a vendor to calculate the SMAC. The state believes it is justified in using the NADAC as the SMAC because it has found the NADAC to be a valid measure of drug invoice costs, and it is updated weekly. The state believes that using the publicly available NADAC as its SMAC will allow it to save on contracting with a vendor to calculate the SMAC.

In addition to the proposed use of NADAC, the state's reimbursement methodology to pharmacies includes professional dispensing fees. The dispensing fees, which were recently approved under a separate SPA, were determined from the results of a 2012 Cost of Dispensing Survey. With adequate dispensing fees in place along with the proposal to use NADAC pricing, the state believes that pharmacies will be adequately reimbursed and not cause access issues for Medicaid recipients.

Applying our interpretation of Section (30)(A) to this proposed SPA, we believe that the information that the state has provided, as described above, is sufficient to support its proposed payment change. Although Section (30)(A) of the Act does not require states to base payment on the costs incurred by providers, the payment proposal is designed to provide payment based on the cost of drug acquisition. We believe that the state's proposal to use NADAC is reasonable given that the state has provided adequate documentation that the revised rate, coupled with the dispensing fee, should cover the costs of providing drugs to Medicaid beneficiaries. We believe the State plan, as modified by the proposed SPA, will ensure access consistent with Section (30)(A).

We also conclude that the proposed SPA is consistent with the efficiency and economy requirement in Section (30)(A) of the Act. We have generally considered a proposed payment rate as being inefficient or uneconomical if it was substantially above the cost of providing covered services. *See Pa. Pharmacists Assn'n v. Houstoun,* 283.F.3d 531, 537 (3d Cir. 2002) ("What sort of payments would make a program inefficient and uneconomical? Payments that are too high."). For this reason we do not believe that it is appropriate for states to address potential access concerns by setting rates unreasonably high in relation to costs, such rates would necessarily be either efficient nor economical. Consistent with this view, HHS promulgated Upper Payment Limit ("UPL") regulations that "place an upper limit on overall aggregate payments" for certain types of services. 65 Fed.Reg. 60151-01. Applying our interpretation of the statute to the proposed SPA at issue here, we believe payment under the state plan, will be both economical and efficient, as doing so ensures that providers are not paid substantially in excess of their costs.

Furthermore, we conclude that the proposed payment methodology is consistent with the quality of care requirement in Section (30)(A) of the Act. CMS does not interpret Section (30)(A) of the Act as requiring a state plan by itself to ensure quality of care. As the text of the statute reflects, payments must be "consistent" with quality of care, but they do not need to directly assure quality of care by themselves. CMS therefore believes that Section (30)(A) leaves room to rely on factors external to a state plan to ensure quality of care. In this particular instance, for example, CMS relies on applicable statues and regulations including those promulgated by the Food and Drug Administration, to ensure the quality of covered outpatient drugs provided through the Medicaid program. CMS believes that it is reasonable to assume that covered outpatient drugs provided to Medicaid patients by pharmacy providers will continue to meet FDA quality standards.

Finally, the state's July 1, 2014, effective date is permissible under the Medicaid regulations. Consistent with 42 C.F.R. § 430.20 and 42 C.F.R. § 447.256, a SPA that is approved may become effective as early as the first day of the quarter in which the amendment is submitted; however, Federal Financial Participation is not available until the SPA is approved. (We note that annual appropriations statues make Federal Financial Participation available as of the first day of the quarter in which a SPA is submitted.)

Based on the foregoing, we believe the state has demonstrated that the proposed payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Because we find this amendment complies with all applicable requirements, we are pleased to inform you that Alaska SPA 14-008 is approved, effective July 1, 2014. A copy of the signed CMS-179 form as well as the pages approved for incorporation into the Alaska state plan will be forwarded by the Seattle Regional Office. If you have any questions regarding this approval, please contact Emeka Egwim at (410) 786-1092.

Sincerely,

[redacted]

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

cc: Carol J.C. Peverly, ARA, Seattle Regional Office
Maria Garza, Seattle Regional Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 14 - 008

2. STATE: AK

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
07/01/2014

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN X☐ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
Section 1927 of the Social Security Act
42 CFR 440.120

7. FEDERAL BUDGET IMPACT:
a. FFY 2014 $ ($125,000)
b. FFY 2015 $ ($125,000)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Attachment 4.19-B, Page 8

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Attachment 4.19-B, Page 8

10. SUBJECT OF AMENDMENT:

Setting state's maximum allowable to NADAC.

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
x ☐ OTHER, AS SPECIFIED: No comment.

12. SIGNATURE OF STATE AGENCY OFFICIAL:
[redacted]

13. TYPED NAME: Craig Christenson

14. TITLE: Deputy Commissioner, DHSS

15. DATE SUBMITTED: August 18, 2014

16. RETURN TO:
Alaska Department of Health and Social Services
Health Care Services
4501 Business Park Blvd., Suite 24, Bldg L
Anchorage, AK 99503-7167

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 8/18/14

18. DATE APPROVED: 2.5.15

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 7/01/14

20. SIGNATURE OF REGIONAL OFFICIAL:
[redacted]

21. TYPED NAME: Frank Schneider

22. TITLE: Associate Regional Administrator
Division of Medicaid & Children's Health

23. REMARKS:
8.29/14: P&I change to box 7 authorized by the state.
11.26.14 P&I change to box 6 authorized by the state.

FORM HCFA-179 (07-92)

Methods and Standards for
Establishing Payment Rates: Other Types of Care

Bank as updated weekly plus 1 percent of that amount, the payment will not exceed the lower of the estimated acquisition cost plus the dispensing fee or the provider's lowest charge.

(f) The estimated acquisition cost is the wholesale acquisition cost plus 1 percent.

(g) The payment for compounding prescriptions will be the sum of the costs of each of the ingredients as established under (b) through (e) (above), plus the dispensing fee to reimburse no more than the provider's lowest charge.

(h) Effective 7/1/2014 the department will use the National Average Drug Acquisition Cost (NADAC), as calculated and supplied by the Centers for Medicare and Medicaid Services, as the state maximum allowable cost for both brand and generic drugs.

(i) Wholesale acquisition cost with respect to a drug or biological, means the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

(j) Practitioner administered drugs are reimbursed at the lower of the billed amount or Wholesale Acquisition Cost plus 1 percent without a dispensing fee.

(k) The dispensing fee is based on the results of surveys of in-state pharmacies' cost of dispensing prescriptions. For each pharmacy, the dispensing fee will be determined using the following schedule:
(1) for a pharmacy located on the road system, the dispensing fee is $13.36, to be paid no more than once every 22 days per individual medication strength;
(2) for a pharmacy not located on the road system, the dispensing fee is $21.28, to be paid no more than once every 22 days per individual medication strength; and
(3) for a mediset pharmacy the dispensing fee is $16.58, to be paid no more than once every 14 days per individual medication strength.
(4) The dispensing fee for an out-of-state pharmacy is $10.76, to be paid no more than once every 22 days per individual medication strength.