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State/Territory Name: Nevada

State Plan Amendment (SPA) #: 14-010

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

JUN 30 2015

Romaine Gilliland, Director
Department of Health and Human Services
4126 Technology Way
Suite 100
Carson City, Nevada 89706

Dear Mr. Gilliland:

We have reviewed Nevada's State Plan Amendment (SPA) 14-010, received in the San Francisco Regional Office on December 30, 2014. This amendment proposes to increase the professional dispensing fee and to implement a new drug pricing methodology using National Average Drug Acquisition Cost (NADAC) files.

While we review proposed SPAs to ensure their consistency with the relevant provisions of the Social Security Act (the 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 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." 42 U.S.C. § 1396a(a)(30)(A). As we explain in greater detail below, we find that the state's proposed SPA 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 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 of 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 service. *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 Pharmacy 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]

The state furnished documentation and new information in its response to our request for additional information 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 collaborated with providers and issued a Public Notice and Consultation Meeting with Tribes.
- The state supplied documentation for the proposed increase in the professional dispensing fee from $4.76 to $10.17 by sharing the results of their cost of dispensing report that was prepared by Myers and Stauffer LC.
- The state gave rationale for amending their reimbursement methodology to the National Average Drug Acquisition Cost (NADAC) as their best representation of a pricing file to meet their definition of actual acquisition cost (AAC). They stated that by utilizing a nationally available pricing file, the state would avoid the costs of individually contracting for an ingredient cost survey and would assure efficiency and economy in their states' delivery system.
- The state provided the cost of dispensing fee report prepared in June, 2014 which provided justification on the usage of Wholesale Acquisition Cost (WAC) as the pricing algorithm for those drugs not available on the NADAC files.

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[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.

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 rates on the costs incurred by providers, the payment proposal is designed to provide payment based on information concerning acquisition costs and dispensing fees of the drugs subject to this proposed SPA. We believe that the criteria are reasonable because the state has identified specific drug categories and drugs which pharmacy providers might not be able to acquire at the reduced rate. Accordingly, 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 requirements 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 Ass'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 neither efficient nor economical. Consistent with this view, HHS has 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, as increased in this SPA, 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 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 statutes 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 plan's proposed effective date is permissible under the Medicare 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 statutes 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 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 service are available to the general population in the geographic area.

Because we find that this amendment complies with all applicable requirements, we are pleased to inform you that the Nevada SPA 14-010 is approved, effective November 1, 2015. A copy of the CMS-179 form,

as well as the pages approved for incorporation into the Nevada State Plan will be forwarded by the San Francisco Regional Office. If you have any questions regarding this approval, please contact Lisa Ferrandi at (410)-786-5445.

Sincerely,

[redacted]

John M. Coster, PhD, RPh
Director, Division of Pharmacy

cc: Hye Sun Lee, ARA, San Francisco Regional Office
Peter Banks, San Francisco 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: **14-010**

2. STATE: **NEVADA**

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

~~Effective date of change is the first day of the quarter after CMS' approval of the State Plan Amendment but not sooner than January 1, 2015.~~ November 1, 2015

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:

State Plan Under Title XIX of the Social Security Act: 42 CFR 447

7. FEDERAL BUDGET IMPACT:

a. FFY 2015 ($250,000) *
b. FFY 2016 ($500,000)

*** The fiscal impact for FFY 2015 was computed by estimating an effective date of April 1, 2015.**

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment 4.19-B, Page 3

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:

Attachment 4.19-B, Page 3

10. SUBJECT OF AMENDMENT:

The Division of Health Care Financing and Policy (DHCFP) is proposing a change to the State Plan that is necessary to amend language to increase the professional dispensing fee from $4.76 to ~~$9.47~~ $10.17, and to include the use of National Average Drug Acquisition Cost (NADAC) in the definition of actual acquisition cost (AAC). Wholesale Acquisition Cost (WAC) ~~+3%~~ is being proposed as part of the pricing algorithm for those drugs not available on the NADAC. Pharmaceuticals given by Long Term Care pharmacists and Home Infusion Therapy providers will receive the proposed dispensing fee in accordance with retail pharmacists. These changes are a result of the proposed rule dated February 2, 2012, 42 CFR Part 447, Medicaid Program; Covered Outpatient Drugs; Proposed Rule.

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:
The Governor's Office does not wish to review the State Plan Amendment.

12. SIGNATURE ~~OF STATE~~ AGENCY OFFICIAL:

[redacted]

13. TYPED NAME:
Romaine Gilliland

14. TITLE:
Director, Department of Health and Human Services

15. DATE SUBMITTED: December 30, 2014

16. RETURN TO:

Tammy Moffitt, Chief of Program Integrity
DHCFP/Medicaid
1100 East William Street, Suite 101
Carson City, NV 89701

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 12/30/14

18. DATE APPROVED: 6/30/15

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 4/1/15

20. SIGNATURE OF REGIONAL OFFICIAL: /s/

21. TYPED NAME: Hye Sun Lee

22. TITLE: Associate Regional Administrator (Acting)

23. REMARKS:

Pen and Ink change to Box #10 changing professional dispensing fee to $10.17 and changing rate of reimbursement to WAC for drugs not available on the NADAC.

FORM HCFA-179 (07-92) Pen and Ink change to Box to 4 to update effective date to 11/1/15.

12. a. Nevada Medicaid will meet all reporting and provision of information requirements of section 1927(b)(2) and the requirements of subsections (d) and (g) of section 1927.

The State assures that the State will not provide reimbursement for an innovator multi-source drug, subject to the Federal Upper Limits (42 CFR 447.332(a)), if, under applicable State law, a less expensive non-innovator multi-source drug could have been dispensed.

1. Payment for multi-source drugs shall be the lowest of (a) Federal Upper Limit (FUL) as established by the Centers for Medicare and Medicaid Services (CMS) for listed multi-source drugs plus a professional dispensing fee; (b) State Maximum Allowable Cost (MAC) plus dispensing fee; (c) Actual Acquisition Cost (AAC) plus a dispensing fee; (d) the pharmacist's usual and customary charge; (e) Department of Justice pricing less 15% plus dispensing fee or (f) billed charge.

2. Payment for covered drugs other than multi-source drugs subject to the FUL shall not exceed the lower of (a) AAC plus a dispensing fee; (b) the pharmacist's usual and customary charge to the general public; or (c) providers actual charge to Medicaid agency.

3. Actual Acquisition Cost (AAC) is defined by Nevada Medicaid as the Agency's determination of the actual prices paid by pharmacy providers to acquire drug products marked or sold by specific manufacturers and is based on the National Average Drug Acquisition Cost (NADAC). Wholesale Acquisition Cost (WAC) + 0% will be offered for those drugs not available on NADAC.

4. The FUL for multi-source drugs for which an upper limit has been set does not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary for a particular recipient, and the statement "brand medically necessary" appears on the face of the prescription.

5. A generic drug may be considered for MAC pricing if there are 2 or more therapeutically equivalent, multi-source, non-innovator drugs with a significant cost difference. The SMAC will be based on drug status (including non-rebateable, rebateable, obsolete, therapeutic equivalency ratings) marketplace availability and cost. The obsolete drug status will be taken into account to ensure that the MAC pricing is not influenced by the prices listed for obsolete drugs. The SMAC will be based on drug prices obtained from a nationally recognized comprehensive data file maintained by a vendor under contract with the Department.

6. The State's dispensing fees are defined as those given to outpatient retail pharmacists at a rate of $10.17 per prescription; Pharmaceuticals given by Long Term Care pharmacists and for Home Infusion Therapy providers receive dispensing fees in accordance with retail pharmacists.

7. There is no co-payment requirement on medications for beneficiaries.