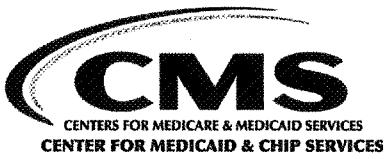
DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850



Center for Medicaid and CHIP Services
Disabled and Elderly Health Programs Group

June 26, 2012

Toby Douglas
Director, California Department of Health Care Services
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

Dear Mr. Douglas:

I am responding to your request to approve California State Plan Amendment (SPA) 11-018 received in the San Francisco Regional Office on September 29, 2011. This proposed SPA would establish a payment methodology for physician administered drugs equal to the Medicare Part B reimbursement rate for drugs and biologicals. That reimbursement rate is defined under section 1847A of the Social Security Act (the Act) as Average Sales Price (ASP) plus 6 percent. Under the proposed SPA, if a Medicare Part B reimbursement rate is not available or published by CMS for a physician administered drug, the reimbursement rate for physician administered drugs would be as follows:

- If based on a National Drug Code (NDC), the NDC rate of reimbursement shall be equal to the pharmacy rate of reimbursement, or
- If based on a Healthcare Common Procedure Coding System (HCPCS) code, the HCPCS code rate of reimbursement shall be equal to the volume-weighted average of the pharmacy rate of reimbursement for generically equivalent drugs.

Under the proposed SPA, "physician administered drug" means any legend, nonlegend drug, or vaccine administered or dispensed to a beneficiary by a Medi-Cal provider other than a pharmacy provider and billed to the department on a fee-for-service basis.

For purposes of the proposed SPA, "pharmacy rate" means the Estimated Acquisition Cost (EAC), which is based on the lowest of the average wholesale price (AWP) minus seventeen percent, the Maximum Allowable Ingredient Cost (MAIC); the federal upper limit of reimbursement for listed multiple source drugs (called "Federal Upper Limit", or FUL), or the provider's usual and customary charge to the public. In accordance with the current State plan, the Department's policy was to reimburse providers for physician administered drugs at a rate of AWP minus five percent.

While we review proposed SPAs to ensure their consistency with the relevant provisions of 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 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 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 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. In this respect, CMS's interpretation differs from that first adopted by the Ninth Circuit in *Orthopaedic Hosp. v. Belshe*, 103 F.3d 1491, 1496 (9th Cir. 1997), which established a bright line rule requiring a State to rely on "responsible cost studies, its own or others', that provide reliable data as a basis for its rate setting."[2]

CMS's interpretation does not, of course, *prevent* states or CMS from considering provider costs. Indeed, we recognize that for certain proposed SPAs, such as the SPA at issue here, provider cost information may be useful to CMS as it evaluates proposed changes to payment methodologies. This is in part because, under the authority of Section (30)(A), the Secretary has issued regulations prescribing the state rate setting procedures and requirements for covered outpatient drugs. Longstanding requirements in Federal regulations, presently codified at 42 C.F.R. § 447.512, provide that payments for drugs are to be based on ingredient costs of the drug (calculated based on estimated acquisition costs) and a reasonable dispensing fee. When federal regulations expressly base payment rates for a particular service on costs, CMS believes it is reasonable to consider costs as part of the SPA approval process.

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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.

In addition, 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 Myers and Stauffer study provides that the Medicare reimbursement in the aggregate is 10.8 percent greater than the average acquisition cost of products.

Section 14105.456 of California's Welfare & Institutions Code establishes reimbursement for physician administered drugs to be set at the Medicare rate or the pharmacy rate of reimbursement, but not lower than the Medicare rate. DHCS' rationale for using ASP plus 6 percent is based on the Medicare reimbursement rate for Part B drugs and biologicals, which is a nationally accepted benchmark that is sufficient to ensure beneficiary access. In situations where the Medicare rates are not available, the State would calculate rates based on the "pharmacy rate," which the State is not proposing to change. Although the pharmacy rate has not previously been used for physician administered drugs, the State believes this rate, which is used to pay pharmacies, is sufficient to ensure access.

Applying our interpretation of Section (30)(A) to this proposed SPA, we believe that the Myers and Stauffer study that the State has provided 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, this payment proposal is designed to provide payment based on the Medicare payment rates for the physician administered drugs utilizing ASP as defined in section 1847A(c) or pharmacy rates, where Medicare rates are not available. We believe that using these rates, which are in excess of provider acquisition costs, will ensure access consistent with the 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. As these provisions reflect, we believe that States must balance access concerns with efficiency and economy concerns. Applying our interpretation of the statute to the proposed SPA at issue here, we believe that payment for physician administered drugs based on the Medicare rate is 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 physician administered drugs will continue to meet FDA quality standards. *But see Orthopaedic*, 103 F.3d at 1497 ("The Department, itself, must satisfy the requirement that the payments themselves be consistent with quality care.").

Finally, the State's September 1, 2011, effective date is permissible under the Medicaid statute and our regulations, as set forth in 42 C.F.R. § 430.20 and 42 C.F.R. § 447.256. Those regulations provide that a State may implement amendments to its State plan prior to CMS approval. *See* Letter Br. of the United States as Amicus Curiae, *Douglas v. Independent Living Ctr.*, No. 09-958, at 7 (Nov. 11, 2001). Consistent with those provisions, 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.)[3]

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 that this amendment complies with all applicable requirements, we are pleased to inform you that the California SPA 11-018 is approved, effective September 1, 2011. A copy of the CMS-179 form, as well as the pages approved for incorporation into the California State Plan will be forwarded by the San Francisco Regional Office. If you have any questions regarding this approval, please contact Angel Davis (410) 786-4693.

Sincerely,

/s/

Larry Reed
Director
Division of Pharmacy

cc: Harry Hendrix, California Department of Health Care Services
Teresa Miller, California Department of Health Care Services
Gloria Nagle, ARA, DMCHO, San Francisco Regional Office
Kristin Dillon, San Francisco Regional Office

[3] *See, e.g.*, P.L. 110-161, Division G – Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008, Title II – Department of Health and Human Services (H.R. 2764, Consolidated Appropriations Act, 2008)("Payment under title XIX may be made for any quarter with respect to a State plan or plan amendment in effect during such quarter, if submitted in or prior to such quarter and approved in that or any subsequent quarter.").

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: 11-018

2. STATE: CA

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
September 1, 2011

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 U.S.C. 1396r–8

7. FEDERAL BUDGET IMPACT:
a. FFY 11-~~12~~ -~~$15,000,000~~ $2,375,000
b. FFY 12-~~13~~ -~~$15,000,000~~ $28,500,000

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
3a
Supplement 2 to Attachment 4.19-B, pages ~~8~~ and 11 (both are new pages)

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
None

10. SUBJECT OF AMENDMENT:
Physician Administered Drug Reimbursement Methodology

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:

13. TYPED NAME:
Toby Douglas

14. TITLE:
Director

15. DATE SUBMITTED: SEP 2 9 2011

16. RETURN TO:
Department of Health Care Services
Attn: State Plan Coordinator
1501 Capitol Avenue, Suite 71.3.26
P.O. Box 997417
Sacramento, CA 95899-7417

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 9/29/11

18. DATE APPROVED: JUN 2 6 2012

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 9/1/11

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME: Gloria Nagle

22. TITLE: Associate Regional Administrator

23. REMARKS:

Pen and Ink changes to Box 7 confirmed via email from the State on 5/2/12.

Pen and Ink changes to Box 8 confirmed via email from the State on 7/6/12.

FORM HCFA-179 (07-92)

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT STATE: California

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES - PRESCRIBED DRUGS

- "Physician-administered drug" means any legend, nonlegend drug, or vaccine administered or dispensed to a beneficiary by a Medi-Cal provider other than a pharmacy provider and billed to the department on a fee-for-service basis.
- "Pharmacy rate" means the Estimated Acquisition Cost (EAC) as defined in paragraph A.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT STATE: California

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES - PRESCRIBED DRUGS

PAYMENT METHODOLOGY FOR PHYSICIAN ADMINISTERED DRUGS

The reimbursement rate for physician administered drugs shall be equal to the Medicare Part B reimbursement rate for drugs and biologicals, when available for a particular product and published by CMS, as described in Section 1847A of the Social Security Act and currently defined as Average Sales Price (ASP) plus 6%.

When a Medicare Part B reimbursement rate is not available or published by CMS for a physician administered drug, the reimbursement rate will be determined as follows:

i. If based on a National Drug Code (NDC), the NDC rate of reimbursement shall be equal to the pharmacy rate of reimbursement, or

ii. If based on a Healthcare Common Procedure Coding System (HCPCS) code, the HCPCS code rate of reimbursement shall be equal to the volume-weighted average of the pharmacy rate of reimbursement for generically equivalent drugs.

Reimbursement for physician administered drugs shall be exempt from legislatively mandated provider payment reductions.