

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

March 19, 2013

J. Ruth Kennedy
State Medicaid Director
Louisiana Department of Health and Hospitals
628 N. 4th Street
P.O. Box 91030
Baton Rouge, Louisiana 70821

Attention: Darlene York

Dear Ms. Kennedy:

We have reviewed Louisiana State Plan Amendment (SPA) 12-66 received in the Dallas Regional Office on December 20, 2012. Under this SPA, the state proposes to revise the current pharmacy reimbursement methodology for estimated acquisition cost (EAC) from average acquisition cost (AAC) to AAC of the drug dispensed adjusted by a multiplier of 1.1 for multiple source drugs and 1.01 for single source drugs. If there is not an AAC available, the state proposes that the EAC is equal to Wholesale Acquisition Cost (WAC), as reported in the drug pricing compendia. In addition, the state proposes WAC adjusted by a multiplier 1.05 for department –defined specialty therapeutic classes. The state also proposes to increase the dispensing fee from \$10.13 to \$10.51 for single source drugs, multiple source drugs other than drugs subject to a physician certification and for drugs obtained through the Public Health Services 340B Program. The effective date for this SPA is November 1, 2012.

After review of these documents, further clarification and additional information is needed before we can continue processing this SPA. Therefore, we are formally requesting additional information (RAI) pursuant to Section 1915(f) of the Social Security Act. Please respond to the following questions so that we may determine whether this SPA meets the requirements for approval.

CMS 179 Form

1. On the CMS 179, the state submitted the following budget impact information with the SPA submission packet.

Block 4: Proposed Effective Date: November 1, 2012

Block 7: Federal Budget Impact

- a. FFY 2012 (\$3,022.98)
- b. FFY 2013 (\$11,437.11)

Blocks 8 and 9: Page Numbers SPA Sections and Page Numbers of Current State Plan and Superseded Pages

Block 8: Attachment 4.19-B, Item 12a Page 2, 4, 5, 7

Block 9: Pending (TN 12-55)

- a. Since the correct budget impact period is November 1, 2012 through September 30, 2013 for Federal Fiscal Year (FFY) 2013 and October 1, 2013 through September 30, 2014 for Federal Fiscal Year 2014, please provide “pen and ink” authorization to correct the FFY’s under block 7 from FFY 2012 to FFY 2013 and FFY 2013 to FFY 2014.
- b. Since Louisiana SPA 10-13 and Louisiana SPA 12-55 were approved after the state’s submission of Louisiana SPA 12-66 to the Centers for Medicare and Medicaid Services (CMS), please confirm that the estimated budget impact is correct as specified under Block 7 or submit “pen and ink” authorization and identify the revisions for the CMS 179 under Block 7.
- c. In addition, please provide a clear explanation supporting how the state estimated the budget impact to result in cost savings and not higher expenditures for Louisiana SPA 12-66 when the state’s proposed ingredient cost and dispensing fee are higher than the superseded approved Louisiana SPA 12-55.
- d. Under Block 8, please confirm and identify changes that the state is proposing under pages 4 and 5. If pages 4 and 5 are not being amended, please provide “pen and ink” authorization to delete these pages from Blocks 8 and 9 on the CMS 179.
- e. Under Block 9, please specify the correct superseded pages now that Louisiana SPA 12-55 has been approved by CMS on February 8, 2013.

State Plan Amendment Page: Attachment 3.1-A, Item 12.a. Pages 2 & 7

2. CMS approved Louisiana SPA 12-55, effective September 5, 2012, uses the AAC reimbursement methodology for Medicaid covered outpatient drugs. Effective November 1, 2012, Louisiana SPA 12-66 proposes to revise the recently approved pharmacy reimbursement methodology from AAC to AAC adjusted by a multiplier of 1.1 for multiple source drugs and 1.01 for single source drugs. Please explain why the state is proposing to change its AAC reimbursement methodology from one based on actual survey invoice prices to that of a reimbursement model that uses an inflated factor increase replacing the methodology in effect approximately two months earlier.
3. Please describe the state’s rationale and provide the documentation for determining that the proposed reimbursement change from AAC to AAC adjusted by a multiplier of 1.1 for multiple source drugs and 1.01 for single source drugs under Louisiana SPA 12-66 complies with federal requirements for EAC.
4. On SPA page 2, the state proposes that EAC is WAC adjusted by a multiplier 1.05 for department –defined specialty therapeutic classes. Please provide an explanation how the state defines specialty therapeutic classes and clarify how the state’s proposed WAC adjusted by a multiplier 1.05 for department–defined specialty therapeutic classes is in accordance with EAC.

5. In addition, the state proposes to increase the dispensing fee from \$10.13 to up to \$10.51 per prescription. Please provide information that sufficiently documents the proposed dispensing fee increase from \$10.13 to \$10.51 is reasonable. Please explain how the proposed dispensing fee change from \$10.13 to \$10.51 is consistent with the definition of the cost of dispensing as specified at 42 CFR 447.502. In addition, please explain why the state is proposing to increase the \$10.13 dispensing fee rate that was just approved under Louisiana SPA 10-13 on February 7, 2013.
6. Please explain the state's efforts to assure beneficiary access. In addition, please describe how the state intends to monitor access in order to verify that beneficiary access has not been negatively impacted by the change in the reimbursement methodology. Please indicate the general time frame after implementation of the new reimbursement rates the state intends to implement the process to monitor decreases in the pharmacy network to ensure that patient access is not negatively impacted.

State Plan Reimbursement Funding Questions for Louisiana SPA 12-66

Section 1903(a)(1) of the Social Security Act provides that Federal financial participation is only available for expenditures made by states for services under the approved State Plan. To ensure that program dollars are used only to pay for Medicaid services, we are asking states to confirm to CMS that pharmacies retain 100 percent of the payments provided to them as indicated in attachment 4.19B. Specifically, please answer the following questions regarding the proposed amendment and current reimbursement made under the Medicaid plan for pharmacy providers:

- a. Do pharmacy providers retain all of the state and Federal Medicaid payments (including dispensing fees, ingredient costs, benefit management costs, etc.) or are providers obligated to return any portion of the Medicaid payment to the state or local government entity, or any other intermediary organization or entity?
- b. If pharmacy providers are obligated to return any portion of the payment, the state must provide a full description of the repayment methodology including: a complete list of pharmacy providers that return their payments; the amount or percentage of the payment; and the disposition and use of the funds once they are returned to the state (i.e. general revenue fund, medical services account, etc.).

Section 1902(a)(2) provides that the lack of adequate funds from local sources will not result in the lowering the amount, duration, scope, or quality of care and services available under the plan. Please describe how the state share of the State's Medicaid pharmacy payment in attachment 4.19B is funded, including the payments made under the proposed amendment. Specifically:

- c. Describe whether the state share is from appropriation from the legislature, through intergovernmental transfer agreements (IGT), certified public

expenditures (CPE), provider taxes, or any other mechanism used by the state to provide the state share.

- d. Please provide the estimate of total expenditures and state share amounts for the State's Medicaid pharmacy payment.
- e. If any of the state share is being funded by IGTs or CPEs, please fully describe the matching arrangement. If CPEs are used, please describe how the state verifies that the expenditures being certified are eligible for Federal matching funds in accordance with 42 CFR 433.51(b).

Section 1902(a)(30) of the Act requires that payments for services be consistent with efficiency, economy, and quality of care. Section 1903(a)(1) provides for FFP to states for expenditures for services under an approved state plan. If you are providing, or propose to provide under this amendment, an enhanced or supplemental payment to pharmacy providers under section 4.19B of the plan, please provide the following information:

The total amount for each enhanced or supplemental payment provided to pharmacy providers and the precise service cost this payment is covering.

- f. Indicate whether there are public pharmacy providers and if they are receiving payments in accordance with attachment 4.19B that in the aggregate exceed its reasonable costs of providing services. If the payment exceeds the reasonable costs of services (for pharmacy that would be a reasonable dispensing fee and ingredient cost) please indicate whether the state recoups the excess and returns the Federal share of the excess to CMS on the quarterly expenditure report.

This request for additional information is made pursuant to Section 1915(f) of the Social Security Act and will stop the 90-day period for CMS' review and approval of a SPA. Upon receipt of your additional information, a new 90-day period will begin. In accordance with our guidelines to all State Medicaid Directors, dated January 2, 2001, we request that you provide a formal response to this request for additional information no later than 90-days from the date of this letter. If you do not provide us with a formal response by that date, we will conclude that the State has not established that the proposed SPA is consistent with all statutory and regulatory requirements and will initiate disapproval action on the amendment.

Because this Amendment was submitted after January 2, 2001 and is effective on or after January 1, 2001, please be advised that we will defer Federal Financial Participation (FFP) for State payments made in accordance with this Amendment until it is approved. Upon approval, FFP will be available for the period beginning with the effective date through the date of actual approval.

We ask that you respond to this request for additional information via the Dallas Regional Office SPA/Waiver mailbox at SPA_Waivers_Dallas_R06@cms.hhs.gov with a copy to me at larry.reed@cms.hhs.gov, Bernadette Leeds of the Division of Pharmacy at

bernadette.leeds@cms.hhs.gov and Ford Blunt of the Dallas Regional Office at ford.blunt@cms.hhs.gov.

If you have any questions regarding this request, please contact Bernadette Leeds at (410) 786-9463.

Sincerely,

/s/

Larry Reed
Director
Division of Pharmacy

cc: Bill Brooks, ARA, Dallas Regional Office
Ford Blunt, Dallas Regional Office
Amanda Caire, Louisiana Department of Health and Hospitals
Keydra Singleton, Louisiana Department of Health and Hospitals