Bobby Jindal
GOVERNOR

Kathy H. Kliebert
SECRETARY

State of Louisiana

Department of Health and Hospitals
Bureau of Health Services Financing

June 14, 2013

Larry Reed
Department of Health and Human Services
Centers for Medicare and Medicaid Services
CMSO-DEHPG-Division of Pharmacy
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850

RE: LA SPA 12-66 RAI Response
Pharmacy Benefits Management Program – Methods of Payment

Dear Mr. Reed:

Please refer to our proposed amendment to the Medicaid State Plan submitted under transmittal number (TN) 12-66 with a proposed effective date of November 1, 2012. This amendment proposes to revise the provisions governing the methods of payment for prescription drugs covered under the Pharmacy Program. We are providing the following additional information as requested in your correspondence dated March 19, 2013 which stopped the clock on this transmittal.

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   Blocks 8 and 9: Page Numbers SPA Sections and Page Numbers of Current State Plan and Superseded Pages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

Response: The State authorizes a "pen and ink" change to correct the Federal fiscal years under block 7 on the CMS 179 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.

Response: The State requests a "pen and ink" change to the CMS 179 under block 7 to an increased cost of $727,671 for FFY 2013 and $2,753,070 for FFY 2014 (See Attachment A).

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.

Response: The change in policy as a result of TN 12-66 would result in $11,552,406 in savings over the reimbursement methodology in place before September 5, 2012. The gross budget impact from the adjustment in AAC reimbursement from SPA 12-55 to SPA 12-66 (which adjusted the methodology implemented by SPA 12-55) is estimated as an increased cost of $2,780,822. The estimated increase in cost was calculated by taking the difference in the cost from the increase in cost from September 5, 2012 and the November 1, 2012 figures.

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.

Response: Pages 4 and 5 were amended with TN 12-55. The State requests a pen and ink change to delete both pages 4 and 5 from block 8 of 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.

Response: Under block 9 of the CMS 179, please make a pen and ink change to specify the approved LA SPA TN 12-55 is the correct supersede by removing the word "pending".

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.

Response: Over the course of June and July of 2012, DHH published a pharmacy reform concept paper and held numerous public forums and stakeholder discussions about reforms in the Medicaid Pharmacy Program. Part of these discussions involved the transition from Average Wholesale Price (AWP) reimbursement to Average Acquisition Cost (AAC) reimbursement for outpatient pharmacy services in the Medicaid fee-for-service program, a policy change that had been under discussion with providers for several years.

In August 2012, DHH published a final pharmacy reform concept and promulgated an emergency rule that revised its reimbursement methodology for pharmacy services to Average Acquisition Cost (AAC) model with no markup and a dispensing fee of up to $10.13, based on a cost of dispensing survey conducted in June 2011. Effective September 5, 2012, Medicaid began reimbursing pharmacists for their prescription services to Medicaid enrollees at this new methodology.

DHH received numerous concerns from community pharmacists, legislators and other stakeholders about this change in reimbursement. In order to incorporate feedback from pharmacists, DHH convened a workgroup of both independent and chain pharmacists to discuss the new reimbursement structure. After careful analysis, including a detailed review of the cost and reimbursement data through the information submitted by community pharmacists, DHH has made several enhancements to the reimbursement methodology to better align reimbursement for pharmacy services. This included:

i. **A markup of 10 percent above the AAC rate for generic drugs, and 1 percent for brand name generics;**

ii. **An increase in the dispensing fee paid to pharmacy providers as part of their reimbursement from $10.13 to $10.51, based on a factor of consumer price index inflation (one complaint DHH received was that the cost of dispensing survey was outdated by the time of its implementation);**

iii. **A move to reimburse certain classes of specialty drugs, which cost more and are more complex to stock and dispense than mass-market prescription drugs, at their Wholesale Average Cost (WAC) plus 5 percent; and**

iv. **An agreement to closely monitor drug-pricing updates that manufacturers make on product and pass along to pharmacists, to ensure Medicaid can adjust to the updated pricing quickly and accurately, which will limit instances where pharmacy reimbursement is below the cost of acquisition.**

These changes helped complete the policy change to AAC for Louisiana, preventing further legislative intervention which could have forced the State to revert back to the AWP methodology.

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.

   Response: The federal requirements for EAC state that "Estimated acquisition cost (EAC) means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of the drug most frequently purchased by providers."

   Based on discussions, research and analysis of information submitted by providers, a modest multiplier was used to assure that the State's pricing provided fair and accurate reimbursement and limited the cases where the State was reimbursing below the provider's costs.

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.

Response: Based on discussions, research and analysis of information submitted by providers, a change to WAC plus a multiplier was used to assure that that State's pricing reflects what is generally and currently paid by providers for the specialty classes and other costs associated with dispensing those drugs. These classes were determined by DHH pharmacists in conjunction with discussions with stakeholders. The therapeutic classes listed below have been identified as specialty drug classes:

Pulmonary Anti-Hypertension, Endothelin Receptor Antagonists	**B1B**
Pulmonary Anti-Hypertension, Sel.C-Gmp Phosphodiesterase T5 Inhibitors	**B1D**
Pancreatic Enzymes	**D8A**
Antihemophilic Factors	**M0E**
Factor IX Preparations	**M0F**
Growth Hormones	**P1A**
Antineoplastic Lhrh(Gnrh) Agonist,Pituitary Su	**V1O**
Antineoplastic Systemic Enzyme Inhibitors	**V1Q**
Antineoplastic Egf Receptor Blocker Mclon Antibody	**V1W**
Antineoplast Hum Vegf Inhibitor Recomb Mc Antibody	**V1X**
Antivirals, General	**W5A**
Antivirals, HIV-Specific, Protease Inhibitors	**W5C**
Antivirals, HIV-Specific, Nucleotide Analog	**W5I**
Antivirals, HIV-Specific, Nucleoside Analog	**W5I**
Antiviral Monoclonal Antibodies	**W5D**
Hepatitis B Treatment Agents	**W5F**
Hepatitis C Treatment Agents	**W5G**

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.

Response: Based on Louisiana's cost of dispensing survey dated June 2011, the statewide average (mean) cost of dispensing, weighted by Medicaid volume, was $10.13 per prescription. In the cost of dispensing analysis, the data from all pharmacies was previously inflation-adjusted to a common point of December 31, 2010 (the midpoint of State fiscal year ending 6/30/2011). This adjustment was variable depending on the fiscal year end date of the survey received from the pharmacy. Inflation factors were based on the Employment Cost Index (health care and social assistance).

Based on concerns from providers that the survey information was already dated by the time of implementation, the State continued the inflation factor index to current at that time (Q3 2012). This brought the average cost of dispensing from $10.13 to an inflation-adjusted cost of dispensing of $10.51.

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.

   Response: The State will closely monitor any benefit access issues that may arise due to the change in reimbursement. The State has good communication and meets regularly with the pharmacy stakeholders and their associations. Even though the State is aware that this will be a transition that providers will have to plan and budget for, there are not any access concerns at this time.

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?

Response: The pharmacy providers are required to return a portion of the Medicaid payment received in the form of the provider fee.

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.).

Response: All Louisiana Medicaid pharmacy providers are assessed the provider fee. The provider fee is 10 cents per pharmacy claim.

Attached is Louisiana Revised Statute 46:2625 which mandates the provider fee (Attachment B).

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.

Response: The non-Federal share of all pharmacy provider payment comes from a General Fund appropriation by the State legislature and the Medicaid agency.

d. Please provide the estimate of total expenditures and state share amounts for the State's Medicaid pharmacy payment.

Response: The estimated annual total expenditures for prescription drugs for SFY2012, before any drug rebates, is $940,838,536. The State share is estimated to be $288,461,095.

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).

Response: IGTs and CPEs are not applicable. Funding for the State share comes from appropriation from the legislature.

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.

Response: Not applicable. No supplemental or enhanced payments are to be paid to pharmacy providers.

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.

Response: Not applicable. No supplemental or enhanced payments are to be paid to pharmacy providers.

It is anticipated that this additional information will be sufficient to result in the approval of the pending plan amendment. Please consider this a formal request to begin the 90-day clock. If further information is required, you may contact Darlene Adams at (225) 342-3881 or by email to Darlene.Adams@la.gov.

We appreciate the assistance of Ford Blunt in resolving these issues.

Sincerely,

J. Ruth Kennedy
Medicaid Director

JRK/DA/ks

Attachments (2)

LOUISIANA TITLE XIX STATE PLAN
TRANSMITTAL #: **12-66**
TITLE: **Pharmacy Benefits Management Program - Methods of Payment**
EFFECTIVE DATE: **November 1, 2012**

FISCAL IMPACT
Increase

	year	% inc.	*# mos	range of mos.	dollars
1st SFY	2013	N/A	8	November 2012 - June 2013	$2,780,822
2nd SFY	2014	3.0%	12	July 2013- June 2014	$4,296,370
3rd SFY	2015	3.0%	12	July 2014 - June 2015	$4,425,261

*#mos-Months remaining in fiscal year

Total Decrease in Cost FFY **2013**

SFY	2013	$2,780,822	for	8	months	November 2012 - June 2013			
		$2,780,822	/	8 X	3 months	July 2012 - September 2012	=	$1,042,808	
								$1,042,808	

FFP (FFY 2013)= $1,042,808 X 69.78% = $727,671

Total Decrease in Cost FFY **2014**

SFY	2013	$2,780,822	for	8	months	November 2012 - June 2013			
		$2,780,822	/	8 X	9	October 2012 - June 2013	=	$3,128,425	
SFY	2014	$4,296,370	for	12	months	July 2013- June 2014			
		$4,296,370	/	12 X	3	July 2013 - September 2013	=	$1,074,093	
								$4,202,518	

FFP (FFY 2014)= $4,202,518 X 65.51% = $2,753,070

Attachment A

§2625. Fees on health care providers; disposition of fees

A.(1) The Department of Health and Hospitals is hereby authorized to adopt and impose fees for health care services provided by the Medicaid program on every nursing facility, every intermediate care facility for people with developmental disabilities, every pharmacy in the state of Louisiana and certain out-of-state pharmacies, dispensing physicians, and medical transportation providers. The amount of any fee shall not exceed the total cost to the state of providing the health care service subject to such fee. In addition, the amount of the fees imposed under the rules and regulations adopted shall not exceed the following:

(a) Ten dollars per occupied bed per day for nursing facilities.

(b) Thirty dollars per occupied bed per day for intermediate care facilities for people with developmental disabilities.

(c) Ten cents per out-patient prescription.

(d) Ten cents per out-patient out-of-state prescription.

(e) Ten cents per out-patient prescription dispensed by dispensing physicians.

(f) Seven dollars and fifty cents per medical service trip for medical transportation providers.

(2) Any fee authorized by and imposed pursuant to this Section shall be considered an allowable cost for purposes of insurance or other third party reimbursements and shall be included in the establishment of reimbursement rates.

(3) Subject to the exceptions contained in Article VII, Section 9(A) of the Constitution of Louisiana, all fees collected pursuant to the authority granted in this Section shall be paid into the state treasury and shall be credited to the Bond Security and Redemption Fund. Out of the funds remaining in the Bond Security and Redemption Fund after a sufficient amount is allocated from that fund to pay all obligations secured by the full faith and credit of the state which become due and payable within any fiscal year, the treasurer shall, prior to placing such remaining funds in the state general fund, pay into the Louisiana Medical Assistance Trust Fund an amount equal to the total amount of such fees collected.

B. Notwithstanding any other provision of law to the contrary, except the maximum fee of ten dollars as provided in R.S. 46:2625(A)(1)(a), the Department of Health and Hospitals shall not impose any new fee or increase any fee on any nursing home on or after April 1, 1992, without prior approval of the specific fee amount by record vote of a majority of the elected members of each house of the legislature while in session. Any such fee imposed or increased by the department on or after such date shall be null and of no effect.

C.(1) The department is hereby authorized and directed to adopt and promulgate, pursuant to the Administrative Procedure Act, such rules and regulations as are necessary to administer the fees imposed herein, including but not limited to rules and regulations regarding the collection and payment of the fees and the records necessary to be maintained and made available by the providers on whom the fees are imposed. Any such information, other than the amount of fees collected from each provider and the total amount of revenues generated by the fees authorized herein, which is received by any department or agency of the state pursuant to this Chapter shall be held confidential.

(2) The department is authorized and directed to adopt and promulgate, pursuant to the Administrative Procedure Act, rules and regulations governing the rights and obligations of those on whom said fees will be imposed. Such rules and regulations shall include the administrative appeal rights and procedures governing disputes arising out of the collection or administration of the fees authorized herein, subject to the provisions of Subsection E of this Section.

D. The governor, by executive order, may designate any agency, department, or division of state government to collect the fees authorized herein.

E.(1) All disputes arising from submission of reports and fees due from a pharmacy which are deemed untimely as described herein or disputes regarding the amount of fees due from a pharmacy pursuant to Paragraph A(1) of this Section shall be handled as provided in this Subsection. All other disputes regarding pharmacy fees pursuant to this Section which are not related to timeliness and accuracy of reports or fees due the department, or which involve fees due from a dispensing physician under this Section, shall be handled as provided for in rules promulgated pursuant to Paragraph C(2) of this Section.

(2) Beginning January 1, 2000, the Louisiana Board of Pharmacy, hereinafter "the board", shall take necessary action to suspend the registration and permit of any registered in-state or out-of-state pharmacy which fails to timely submit a quarterly statement with the Department of Health and Hospitals containing the number of prescriptions filled, compounded, or dispensed, and delivered in or into the state of Louisiana during the previous three-month period, or for failure to timely submit the appropriate prescription fees due pursuant to this Section. A report or fee shall be considered untimely if it is received by the department thirty days after the close of the most recent quarter. Each report of the quarterly statement shall be signed and verified as to accuracy of information contained therein by the preparer of the statement on a form provided by the department.

(3) The board in consultation with the department shall promulgate rules, in accordance with the Administrative Procedure Act, as necessary to comply with the requirements of the board herein, including rules to strictly define criteria for exceptions to the suspension requirements herein, and to provide rules for reinstatement procedures. Any revocation action taken pursuant to this Subsection shall proceed in accordance with laws and rules applicable to suspension of pharmacy permits in general, including the hearing and appeal rights provided pursuant to R.S. 37:1200 and 1201.

(4) The department shall promptly notify the board by certified mail of any reports or fees as described herein which are untimely as described herein, or fees in which the department considers the amount due from the pharmacy to be in dispute thirty calendar days after the date such fees are due to be received by the department. A copy of such notification shall also be sent by certified mail to the pharmacy which is the subject of the untimely reports or fees. The department shall promulgate rules, in accordance with the Administrative Procedure Act, as necessary to comply with the requirements of this Subsection, including rules to continuously apprise the board of fees and reports received by the department from any pharmacy which has been referred to the board for suspension proceedings.

(5) Nothing in this Subsection shall be construed to prevent the department from enforcing existing rules which assess monetary penalties against a pharmacy for late filing of reports or fees, which are not otherwise in conflict with the provisions herein.

Acts 1992, No. 260, §1, eff. June 10, 1992 (R.S. 46:2625(B) eff. April 1, 1992); Acts 1999, No. 1192, §1; Acts 2006, No. 163, §3.

{{NOTE: SEE ACTS 1992, NO. 260, §§3, 5, AND 6, EFF. JUNE 10, 1992.}}