Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE

Part XXIX. Pharmacy

Chapter 1. General Provisions

§101-103. Reserved.

§105. Medicaid Pharmacy Benefits Management System Point of Sale—Prospective Drug Utilization Program

- A. The Louisiana Medicaid Pharmacy Benefits Management System (LMPBM) includes a Point-of-Sale/Prospective Drug Utilization Review component.
- B. The Department of Health and Hospitals reserves the right for ultimate decision making relative to certain drug class information and drug contraindications or interactions.
- C. Formulary Management. The formulary is managed through the use of Federal Upper Limits (FUL) and the Louisiana Maximum Allowable Costs (LMAC) limitations. Federal Upper Limits and Louisiana Maximum Allowable Costs limitations provide for dispensing of multiple source drugs at established limitations unless the prescribing physician specifies that the brand product is medically necessary for a patient. Establishment of co-payments also provides for formulary management. The Medicaid Program has established a broad formulary with limited exceptions.
- D. Reimbursement Management. The cost of pharmaceutical care is managed through Estimated Acquisition Costs (EAC) of drug ingredient costs through Average Wholesale Price (AWP) discounting, the Louisiana Maximum Allowable Costs (LMAC) limitations and compliance with Federal Upper Limits (FUL) regulations, and the establishment of the maximum allowable overhead costs, drug rebates and copayments.
- E. Claims Management. The claims management component is performed through the processing of pharmacy claims against established edits. Claim edit patterns and operational reports are analyzed to review the effectiveness of established edits and to identify those areas where the development of additional edits are needed.
- F. Program Integrity. Program integrity is maintained through the following mechanisms:
 - 1. retrospective drug utilization review;
 - 2. Lock-In Program for patient education;
- 3. Surveillance and Utilization Review Program which provides for on-going review processes for misutilization, abuse and fraud, and audits of the providers of the Pharmacy Program.
- G. Pharmacy Provider Network. Enrolled Medicaid pharmacy providers are required to comply with all applicable federal and state laws and regulations.

H. Point-of-Sale Prospective Drug Utilization Review System. This on-line point-of-sale system provides electronic claims management to evaluate and improve drug utilization quality. Information about the patient and the drug will be analyzed through the use of eight therapeutic modules in accordance with the standards of the National Council of Prescription Drug Plan. The purpose of prospective drug utilization review is to reduce in duplication of drug therapy, prevent drug-to-drug interactions, and assure appropriate drug use, dosage and duration. The PRO-DUR modules may screen for drug interactions, therapeutic duplication, improper duration of therapy, incorrect dosages, clinical abuse/misuse and age restrictions. Electronic claims submission sends on-line messages to pharmacists informing them of potential drugrelated problems and the pharmacists must document their responses by using interventions codes. By using these codes, pharmacists will document prescription reporting and outcomes of therapy for Medicaid recipients.

I. POS/PRO-DUR Requirements Provider Participation

- 1. Point-of-sale (POS) enrollment amendment and certification is required prior to billing POS/PRO-DUR system. Annual recertification is required.
- 2. All Medicaid enrolled pharmacy providers will be required to participate in the Pharmacy Benefits Management System.
- 3. All Medicaid enrolled pharmacy providers whose claim volume exceeds 100 claims or \$4,000 per month and all providers enrolled on January 1, 1996 will be required to participate in Point-of-Sale System. Long term care pharmacy provider claims may be processed through electronic media claims (EMC).
- 4. Providers accessing the POS/PRO-DUR system will be responsible for the purchase of all hardware for connection to the switching companies and any fees associated with connection or transmission of information to the fiscal intermediary. The Bureau of Health Services Financing will not reimburse the provider for any initial ongoing fees incurred by the provider to access the POS/PRO-DUR system.
- 5. Providers are required to verify eligibility with the monthly eligibility card and a copy of the card should be retained for processing the claim.
- 6. Pharmacy providers and physicians may obtain assistance with clinical questions from the Northeast Louisiana University, School of Pharmacy.

- 7. Physicians and pharmacy providers will be required to participate in the educational and intervention features of the Pharmacy Benefits Management System.
- J. Recipient Participation. Pharmacy patients are encouraged to take an active role in the treatment or management of their health conditions through participation in patient counseling efforts with their physicians and pharmacists.
- K. Disease and Outcomes Management. Disease management will be focused on improving the drug therapy for certain disease states by developing procedures to assure direct interventions and increasing compliance of patients. Patient populations will be targeted for disease therapy monitoring and educational efforts
- L. Peer Counseling and Conference Management. The department will analyze data for individual prescribers and pharmacists. Quality management strategies will be used for peer counseling and conferences with prescribers and/or pharmacists to assure appropriate prescribing and dispensing.

AUTHORITY NOTE: Promulgated in accordance with R.S, 46:153, Title XIX of the Social Security Act, and the 1995-96 General Appropriate Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1053 (June 2006)

§109. Medicare Part B

A. The Department of Health and Hospitals, Bureau of Health Services Financing pays the full co-insurance and the Medicare deductible on pharmacy claims for services provided to Medicaid recipients covered by Medicare Part B.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1055 (June 2006).

§111. Copayment

A. Payment Schedule

1. A copayment requirement in the Pharmacy Program is based on the following payment schedule.

| Calculated | |
|--------------------|-----------|
| State Payment | Copayment |
| \$10.00 or less | \$0.50 |
| \$10.01 to \$25.00 | \$1.00 |
| \$25.01 to \$50.00 | \$2.00 |
| \$50.01 or more | \$3.00 |

- 2. The pharmacy provider shall collect a copayment from the Medicaid recipient for each drug dispensed by the provider and covered by Medicaid. The following pharmacy services are exempt from the copayment requirement.
- a. services furnished to individuals under 21 years of age;
- b. services furnished to pregnant women if such services are related to the pregnancy, or to any other medical condition which may complicate the pregnancy;
- c. services furnished to any individual who is an inpatient in a hospital, long term care facility, or other medical institution;
- d. emergency services provided in a hospital, clinic, physician office or other facility equipped to furnish emergency care;
 - e. family planning services and supplies.
- B. In accordance with federal regulations, the following provisions apply.
- 1. The provider may not deny services to any eligible individual on account of the individual's inability to pay the copayment amount. However, this service statement does not apply to an individual who is able to pay, nor does an individual's inability to pay eliminate his or her liability for the copayment.
- 2. Providers shall not waive the recipient copayment liability.
- 3. Departmental monitoring and auditing will be conducted to determine provider compliance.
- 4. Violators of this §111 will be subject to a penalty such as suspension from the Medicaid Program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:153 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, LR 32:1055 (June 2006).

compendia on a weekly basis to update the Medicaid Management Information System (MMIS).

Brand Name—any registered trade name commonly used to identify a drug.

Legend Drugs—drugs which bear the federal legend: "Caution: federal law prohibits dispensing without a prescription."

Multiple Source Drug—a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1061 (June 2006), amended LR 34:87 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1558 (July 2010).

§903. Claims Documentation

A. The manufacturer number, product number, and package number for the drug dispensed shall be listed on all claims. This information shall be taken from the actual package from which the drug is usually purchased by a provider, from a supplier whose products are generally available to all pharmacies and reported in one or more national compendia. Repackaged drug products supplied through co-ops, franchises, or other sources not readily available to other providers shall not be used. In such instances, the manufacturer number, product number, and package number for the largest package size, as reported in one or more national compendia for the drug shall be listed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Finances, LR 32:1062 (June 2006).

Subchapter B. Maximum Allowable Overhead Cost

§915. Cost Determination

A. Definitions

Adjustment Factors—

- a. CPI-all item factor;
- b. CPI-medical care factor;
- c. Wage Factor. Each of the above adjustment factors is computed by dividing the value of the corresponding index for December of the year preceding the overhead year and by the value of the index one year earlier (December of the second preceding year);
- d. ROI. One year treasury bill rate applied to a portion of prescription drug cost (17 percent) in recognition

Chapter 9. Methods of Payment Subchapter A. General Provisions

§901. Definitions

Average Wholesale Price—the wholesale price of a drug product as reported to the agency by one or more national

of inventories maintained for the purpose of filling prescriptions.

Base Rate—the rate calculated in accordance with §917.A.2, plus any base rate adjustments which are in effect at the time of calculation of new rates or adjustments. The base rate was initially calculated using the 1990/91 fee survey findings of average cost for pharmacies representative of the average pharmacy participating in Medicaid reimbursement (15,000 - 50,000 Rx volume). This rate was then inflated forward to December 1990 to establish the first overhead cost maximum.

Base Rate Components—the base rate is the summation of the components shown below. Each component is intended to set the maximum allowable for the costs indicated by its name.

| Base Rate Component | Adjustment Factor |
|------------------------|--------------------------------|
| Pharmacist Salaries | CPI-Medical Care |
| Other Salaries | WAGE |
| Other Routine Services | CPI-All Items |
| | |
| Inventory Cost | ROI(1) |
| Fixed Cost | None(2) |
| Return on Equity | None (3) |
| | (1)No return on equity allowed |
| | (2)No inflation allowed |
| | (3)Adjusted by ROE Factor |
| | (4)Indices |

- a. CPI—All Items. *The Consumer Price Index for all Urban Consumers Southern Region* (all items line of Table 12) as published by the United States Department of Labor.
- b. CPI—Medical Care. *The Consumer Price Index* for all Urban Consumers Southern Region (Medical Care line of Table 12) as published by the United States Department of Labor.
- c. Wage. The average annual wage for production or nonsupervisory service workers as furnished by the Dallas Regional Office of the Bureau of Labor Statistics of the U.S. Department of Labor. This figure will be obtained by telephone in May and will be utilized to calculate the adjustment factor based upon the change which has occurred since December of the preceding year.
- d. ROI; Interest Rates—Money and Capital Markets. The average percent per year for one year U.S. Treasury bills taken from the *Federal Reserve Bulletin* report on Money Market Rates (line 17) for the preceding calendar year.

Maximum Allowable Overhead Cost—overhead cost is determined through use of cost survey results adjusted by various indices to assure recognition of costs which must be incurred by efficiently and economically operated providers. The cost determined is referred to as a maximum allowable to reflect application of the "lesser of" methodology for determining total reimbursement.

Overhead Year—the one-year period from July 1 - June 30 of the next calendar year during which a particular rate is in effect. It corresponds to a state fiscal year.

B. Determination of Limits. Limits on overhead cost are established through the overhead cost survey process which classifies cost in accordance with generally accepted accounting principles and Medicare principles regarding the allowability of cost.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1558 (July 2010).

§917. Maximum Allowable Overhead Cost Calculation

A. The most recent cost survey results will be utilized to establish base cost for professional salaries; other salaries; other routine costs; and fixed cost. Claims processing data for claims paid in the current overhead period will be utilized to determine average drug cost. Seventeen percent of this cost will be utilized as base prescription inventory. The base prescription inventory amount shall not be added to the overhead cost maximum allowable. Base prescription inventory is recognized as an allowable investment subject to a return on investment only. Calculation of maximum allowable overhead cost per prescription shall be performed as follows:

1. NORC = ORC \times CPIF:

- a. NORC is the new other routine cost component;
- b. ORC is the current (base) routine cost component;
- c. CPIAI is the CPI All items Economic Adjustment Factor.

2. $NPS = PS \times CPIMC$:

- a. NPS is the new pharmacist salaries cost component;
- b. PS is the current (base) pharmacist salaries cost component;
- c. CPIMC is the CPI Medical Care Economic Adjustment Factor.
 - 3. $NOS = OS \times W$:
 - a. NOS is the new other salaries cost component;
 - b. OS is the current (base) salaries cost component;
 - c. W is the Wage Economic Adjustment Factor.
 - 4. $NROI = ROI \times IR$:
- a. NROI is the new return on investment component;
- b. ROI is 17 percent of the current average drug cost;
- c. IR is the Interest Rate Money and Capital Markets

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- 5. Rate = (NORC + NPS + NOS + FCC) x ROEF + NROI where:
- a. NORC, NPS, NOS, and NROI are computed by formulae in Paragraphs 1-4 above;
- b. FCC is the fixed cost component which does not include prescription drug inventory;
- c. ROEF is the return on equity factor of 1.05 applied to all cost components except return on investment which is calculated separately.
- B. After formal adoption of the new maximum allowable overhead cost, the components computed above will become the base components used in calculating the next year's overhead maximum allowable, unless they are adjusted as provided in §911 below.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1559 (July 2010).

§919. Parameters and Limitations

- A. Method of Calculation. All calculations described herein shall be carried out algebraically.
- B. Rounding in all calculations the base maximum allowable and the base components will be rounded to the nearest one cent (two decimal places) and the economic adjustment factors will be rounded to four decimal places.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1560 (July 2010).

§921. Interim Adjustment to Overhead Cost

- A. If an unanticipated change in conditions occurs which affects the overhead costs of at least 50 percent of the enrolled providers by an average of five percent or more, the maximum allowable overhead cost may be adjusted. Medicaid of Louisiana will determine whether or not the maximum allowable overhead cost limit should be changed when requested to do so by 10 percent of the enrolled pharmacies. The burden of proof as to the extent and cost effect of the unanticipated charge will rest with the entities requesting the change. Medicaid of Louisiana, however, may initiate an adjustment without a request to do so.
- 1. Temporary Adjustments. Temporary adjustments do not affect the base cost used to calculate a new maximum allowable overhead cost limit. Temporary adjustments may be made in the rate when changes which will eventually be reflected in the economic indices, such as a change in the minimum wage, occur after the end of the period covered by the index, i.e., after the December preceding the limit calculation. Temporary adjustments are effective only until the next overhead cost limit calculation which uses economic adjustment factors based on index values computed after the change causing the adjustment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1560 (July 2010).

§923. Cost Survey

- A. Every three years a cost survey shall be conducted which includes cost data for all enrolled pharmacy providers. Participation shall be mandatory for continued enrollment as a pharmacy provider. Cost data from providers who have less than 12 months of operating data shall not be utilized in determining average overhead cost or grouping providers by prescription volume. Pre-desk reviews shall be performed on all cost surveys to determine an average provider profile based upon total prescription volume. Through statistical analysis, minimum and maximum volume ranges shall be established which represent the majority of providers participating in Medicaid reimbursement. Cost surveys of providers whose prescription volumes are above or below the volume range established, shall not be utilized in calculating average overhead cost. Information submitted by participants shall be desk reviewed for accuracy and completeness. Field examination of a representative sample of participants shall be primarily random, but geographic location and type of operation shall be taken into consideration in order to ensure examination of pharmacies in various areas of the state and representative of various types of operations.
- B. Cost Finding Procedures. The basic analytical rationale used for cost finding procedures shall be that of full costing. Under full costing, all costs associated with a particular operation are summed to find the total cost. The objective of cost finding shall be to estimate the cost of dispensing prescriptions through generally accepted accounting principles.
- C. Inflation Adjustment. Where data collected from participating pharmacies represents varying periods of time, cost and price data may be adjusted for the inflation that occurred over the relevant period. The appropriate Consumer Price Index Indicator (Table 12, Southern Region, *Urban Consumer*) and wage indicator produced by the U.S. Department of Labor Statistics shall be utilized.
- D. In addition to cost finding procedures, a usual and customary survey shall be included in the survey instrument. This instrument shall be used to determine the following:
- 1. an average usual and customary charge, or gross margin for each pharmacy;
- 2. the computation of the net margin per prescription (gross margin less computed dispensing cost per prescription) in order to approximate the average profit per prescription;
- 3. computation of the average percentage of markup per prescription; and
- 4. the computation of average usual and customary charges shall include adjustments to allow comparability

with upper limits for prescription reimbursement utilized by Medicaid of Louisiana.

- E. Statistical Analysis. Statistical analysis shall be undertaken to estimate the cost to pharmacies of dispensing prescriptions. Such analysis shall include, but not be limited to:
 - 1. an average dispensing cost for pharmacies;
- 2. analysis of the correlations among overhead costs and parameters deemed relevant to pharmacy costs;
- 3. the statistical relationship between independent variables and dispensing cost shall be analyzed using the techniques of simple linear and stepwise multiple regression. Independent variables may include annual volume of prescriptions filled, pharmacy location, type of ownership, and number of Medicaid claims paid:
- a. before regression analysis is performed, efforts shall be made to insure that the data collected during the surveys was accurate and representative, and that errors made during data entry are corrected. Efforts should include tabulations, cross tabulations, data plotting, and visual data inspection.

F. Survey Results

- 1. Medicaid of Louisiana shall consider survey results in determining whether the maximum allowable overhead cost should be rebased. Where the overhead cost survey findings demonstrate the current maximum allowable is below average cost or above the eightieth percentile of cost, rebasing shall be required.
- 2. Medicaid of Louisiana may review the survey data and establish a new cost base utilizing the cost survey findings and any other pertinent factors, including, but not limited to:
 - a. inflation adjustment;
 - b. application of return on equity;
 - c. recognition of inventory investment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1560 (July 2010).

§925. Dispensing Fee

A. Maximum Allowable Overhead Cost

- 1. The maximum allowable overhead cost will remain at the level established for state fiscal year 1994-95. This maximum allowable overhead cost will remain in effect until the dispensing survey is completed and an alternate methodology is determined.
- 2. No inflation indices or any interim adjustments will be applied to the maximum allowable overhead costs.
- B. Provider participation in the Louisiana Dispensing Fee Survey shall be mandatory. Failure to cooperate in the Louisiana Dispensing Fee Survey by a provider shall result

in removal from participation as a provider of pharmacy services under Title XIX. Any provider removed from participation shall not be allowed to re-enroll until a dispensing fee survey document is properly completed and submitted to the bureau.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1064 (June 2006), amended LR 34:88 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1561 (July 2010).

Subchapter C. Average Wholesale Price

§935. Estimated Acquisition Cost Formula

- A. Estimated Acquisition Cost (EAC) is the modified average wholesale price of the drug dispensed, identified by the manufacturer number, product number, and package number usually purchased by a provider, from a supplier whose products are generally available to all pharmacies and reported in one or more national compendia. Repackaged drug products supplied through co-ops, franchises, or other sources not readily available to other providers shall not be used to estimate provider acquisition cost. In such instances, the average wholesale price for the drug product used by the repackager identified by the manufacturer number, product number, and largest reported package size in one or more national compendia shall be utilized by the agency to estimate acquisition cost.
- B. The agency shall make payments for multiple source drugs other than drugs subject to "physician certifications" based on the lower of:
- 1. Average Wholesale Price (AWP) minus 13.5 percent for independent pharmacies and AWP minus 15 percent for chain pharmacies. This applies to:
 - a. single source drugs;
- b. multiple source drugs that do not have a state maximum allowable cost (MAC) or federal upper limit; and
- c. those prescriptions subject to MAC overrides based on the physician's certification that a brand name product is medically necessary;
- 2. Louisiana's maximum allowable cost limitation plus the maximum allowable overhead cost;
- 3. federal upper limits plus the maximum allowable overhead cost; or
- 4. provider's usual and customary charges to the general public. *General Public* is defined here as all other non-Medicaid prescriptions including:
 - a. third-party insurance;
 - b. pharmacy benefit management; and
 - c. cash.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1064 (June 2006), amended LR 34:88 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1561 (July 2010).

§949. Cost Limits

- A. Federal Upper Limits for Multiple Source Drugs
- 1. Except for drugs subject to "Physician Certification", the Medical Assistance Program shall utilize listings established by CMS that identify and set upper limits for multiple source drugs that meet the following requirements.
- a. All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of their publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications).
- b. At least three suppliers list the drug (which has been classified by the FDA as category "A" in the aforementioned publication based on listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.
- 2. The Medical Assistance Program shall utilize the maximum acquisition cost established by CMS in determining Multiple Source Drug Cost.
- 3. The Medical Assistance Program shall provide pharmacists who participate in Title XIX reimbursement with updated lists reflecting:
- a. the multiple source drugs subject to Federal Multiple Source Drug Cost requirements;
- $b. \quad \text{the maximum reimbursement amount per unit;} \\$
 - c. the date such costs shall become effective.
 - B. Louisiana Maximum Allowable Cost (LMAC) Limits
- 1. LMAC is the median AWP cost for a specific strength/unit drug determined by listing the wholesale costs for each readily available manufacturer, labeler, etc., and

taking the median of those AWP costs (one-half will be above the median cost and one-half will be below the median cost). LMAC limits may be adjusted by the agency based on changes in the availability and estimated acquisition costs (EAC) of the drugs.

- 2. The agency shall make determinations of which multiple source drugs are to be subject to LMAC regulation based on the availability of drugs in the Louisiana Medical Assistance Program. The availability of a drug product will be determined by review of provider claim data. Providers shall be given advanced notice of any additions, deletions, or adjustments in price. Any provider may request and receive at no charge, one complete listing annually.
- 3. In no case shall a recipient be required to provide payment for any difference in a prescription price that may occur with implementation of the LMAC limit, nor may BHSF use a cost which exceeds the established maximums except for physician certification for brand name drugs.
- C. Lower of Reimbursement for Multiple Source Drugs. The agency shall make payments for Multiple Source Drugs other than drugs subject to *physician certifications* based on the lower of:
- 1. the providers' usual and customary charges to the general public not to exceed the agency's "Maximum Pharmaceutical Price Schedule;
- 2. the agency's estimate of acquisition cost plus the agency's established dispensing fee;
- 3. any applicable Federal Upper Limit for Multiple Source Drugs plus the agency's established dispensing fee; or
- 4. any applicable Louisiana Maximum Allowable Cost limit plus the agency's established dispensing fee.

D. Physician Certifications

- 1. Limits on payments for multiple source drugs shall not be applicable when the prescriber certifies in his own handwriting that a specified brand name drug is medically necessary for the care and treatment of a recipient. Such certification may be written directly on the prescription or on a separate sheet which is attached to the prescription. A standard phrase in the prescriber's handwriting, such as "brand necessary" will be acceptable.
- 2. Any practice which precludes the prescriber's handwritten statement shall not be accepted as a valid certification. Such practices include, but are not limited to:
- a. a printed box on the prescription blank that could be checked by the prescriber to indicate brand necessity;
- b. a handwritten statement transferred to a rubber stamp and then stamped on the prescription blank;
- c. preprinted prescription forms using a facsimile of the prescriber's handwritten statement.
- E. Other Drug Cost Limits. The agency shall make payments for drugs other than multiple source drugs and

drugs subject to APhysician Certifications≡ based on the lower of:

- 1. the agency's estimate of acquisition cost plus the agency's established dispensing fee;
- 2. the providers' usual and customary charges to the general public not to exceed the agency's AMaximum Pharmaceutical Price Schedule≅.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1065 (June 2006), amended LR 34:88 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1561 (July 2010).

Subchapter E. 340B Program

§961. Definitions

Actual Acquisition Cost—the covered entity's net payment made to purchase a drug product, after taking into account such items as purchasing allowances, discounts, wholesaler fees and rebates.

Contract Pharmacy—a pharmacy under contract with a covered entity that lacks its own pharmacy whereby the contract pharmacy is authorized to dispense 340B-discounted drugs on behalf of the covered entity in accordance with 1996 Health Resources and Services Administration (HRSA) guidelines (61 FR 43549, August 23, 1996). Contract pharmacies may also serve as billing agents for covered entities.

Covered Entity—a provider or program that meets the eligibility criteria for participating in the 340B Program as set forth in Section 340B(a)(4) of the Public Health Service Act. Covered entities include eligible disproportionate share hospitals that are owned by or under contract with state or local government, community health centers, migrant health centers, health centers for public housing, health centers for the homeless, AIDS drug assistance programs and other AIDS clinics and programs, black lung clinics, hemophilia treatment centers, native Hawaiian health centers, urban Indian clinics/638 tribal centers, 340s school-based programs, Title X family planning clinics, sexually-transmitted disease clinics, and tuberculosis clinics.

Dispensing Fee—the fee paid by Medicaid for the professional services provided by a pharmacist when dispensing a prescription, including the \$.10 provider fee assessed for each prescription filled in the State of Louisiana per legislative mandate.

Medicaid Carve-Out—a billing mechanism available to covered entities that implements the 340B requirement protecting manufacturers from giving a 340B discount and paying a Medicaid rebate on the same drug. If a covered entity elects to implement the Medicaid carve-out option, the covered entity only purchases through the 340B Program covered drugs dispensed to non-Medicaid patients; drugs

dispensed to Medicaid patients are purchased outside the 340B Program.

Patient—an individual eligible to receive 340B-discounted drugs from a covered entity by virtue of being the covered entity's patient as defined in HRSA's 1996 patient definition guideline (61 FR 55156, October 24, 1996).

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1066 (June 2006).

§963. Reimbursement

- A. Self-administered drugs that are purchased by a covered entity through the 340B program and dispensed to patients who are covered by Medicaid shall be billed to Medicaid at actual acquisition cost unless the covered entity has implemented the Medicaid carve-out option, in which case such drugs shall be billed in accordance with existing state Medicaid reimbursement methodologies.
- B. Contract Pharmacies. In the event that the covered entity has entered into a contract pharmacy arrangement and the contract pharmacy serves as the covered entity's billing agent, the contract pharmacy shall bill Medicaid at actual acquisition cost under the covered entity's Medicaid pharmacy billing number, unless the covered entity has implemented the Medicaid carve-out option, in which case such drugs shall be billed in accordance with existing state Medicaid reimbursement methodologies under the contract pharmacy's Medicaid pharmacy billing number.
- C. Dispensing Fees. The covered entity shall be paid a dispensing fee of \$8.10 for each prescription dispensed to a Medicaid patient, unless the covered entity has implemented the carve-out option, in which case the covered entity shall be paid the state's existing maximum allowable overhead cost. With respect to contract pharmacy arrangements in which the contract pharmacy also serves as the covered entity's billing agent, the contract pharmacy shall be paid the \$8.10 dispensing fee on behalf of the covered entity, unless the covered entity elects the Medicaid carve-out, in which case the contract pharmacy shall be paid the state's existing maximum allowable overhead cost.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1066 (June 2006), amended LR 34:88 (January 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1561 (July 2010).

Subchapter H. Vaccines

§991. Vaccine Administration Fees

- A. Effective for dates of service on and after October 10, 2009, the reimbursement to pharmacies for immunization administration (intramuscular or intranasal) performed by qualified pharmacists, is a maximum of \$15.22. This fee includes counseling, when performed.
- B. Effective for dates of service on or after January 1, 2011, the reimbursement for administration of the influenza vaccine for all recipients shall be reimbursed at \$15.22 for subcutaneous or intramuscular injection, \$10.90 for nasal/oral administration or billed charges, whichever is the lesser amount. This fee includes counseling, when performed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1783 (August 2010), amended LR 40:82 (January 2014).