

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part XXIX. Pharmacy

Chapter 1. General Provisions

§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 Louisiana Department of Health reserves the right for ultimate decision making relative to certain drug class information and drug contraindications or interactions.

C. Covered Drug List. The list of covered drugs is managed through multiple mechanisms. Drugs in which the manufacturer entered into the Medicaid Drug Rebate Program with CMS are included in the list of covered drugs. Average acquisition costs, federal upper payment limits (FUL) and usual and customary charges assist in managing costs on the covered drug list. Federal upper limits provide for dispensing of multiple source drugs at established limitations unless the prescribing practitioner specifies that the brand product is medically necessary for a patient. Establishment of co-payments also provides for management.

D. Reimbursement Management. The cost of pharmaceutical care is managed through average acquisition cost (AAC) of the ingredient or through wholesale acquisition cost (WAC) when no AAC is assigned, and compliance with FUL regulations, and the establishment of the professional dispensing fee, drug rebates and copayments. Usual and customary charges are compared to other reimbursement methodologies and the “lesser of” is reimbursed.

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. Pharmacy 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 Systems (SURS) Program processes which provide for on-going review for mis-utilization, abuse and fraud and audits of the pharmacy providers.

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 therapeutic modules in accordance with the standards of the National Council of Prescription Drug Programs. The purpose of prospective drug utilization review is to reduce duplication of drug therapy, prevent drug-to-drug interactions, and assure appropriate drug use, dosage and duration. The prospective modules may screen for drug interactions, therapeutic duplication, improper duration of therapy, incorrect dosages, clinical abuse/misuse and age restrictions. Electronic claims submission inform pharmacists of potential drug-related problems and pharmacists 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. Eligibility verification is determined at the point of sale.

4. Pharmacy providers and prescribing providers may obtain assistance with clinical questions from the University of Louisiana at Monroe.

5. Prescribers and pharmacy providers are 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 prescribing providers 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. 36:254, 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), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1180 (June 2017), LR 43:1553 (August 2017).

Chapter 9. Methods of Payment

Subchapter A. General Provisions

§901. Definitions

Average Acquisition Cost (AAC)—the average of net payments that pharmacists made to purchase a drug product, after taking into account such items as purchasing allowances, discounts and rebates as determined through the collection and review of pharmacy invoices and other information deemed necessary by the Medicaid Program, and in accordance with applicable state and federal law.

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.

Professional Dispensing Fee—the fee paid by the Medicaid Program to reimburse for the professional services provided by a pharmacist when dispensing a prescription. Per legislative mandate, the provider fee assessed for each prescription filled in the state of Louisiana, or shipped into the state of Louisiana, will be reimbursed separately.

Single Source Drug—a drug mandated or sold by one manufacturer or labeler.

Usual and Customary Charge—the price the provider most frequently charges the general public for the same drug.

Wholesale Acquisition Cost (WAC)—the manufacturer's published catalog price for a drug product to wholesalers as reported to Medicaid by one or more national compendia on a weekly basis.

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), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1184 (June 2017), LR 43:1554 (August 2017).

Subchapter C. Estimated Acquisition Cost

§935. Estimated Acquisition Cost Formula

A. *Estimated acquisition cost (EAC)* is the average acquisition cost of the drug dispensed. If there is not an AAC available, the EAC is equal to the wholesale acquisition cost, as reported in the drug pricing compendia utilized by the department's fiscal intermediary/pharmacy benefits manager (PBM).

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), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1184 (June 2017).

Subchapter D. Maximum Allowable Costs

§945. Reimbursement Methodology

A. Maximum Pharmaceutical Price Schedule

1. The maximum payment by the agency for a prescription shall be no more than the cost of the drug established by the state plus the established professional dispensing fee.

B. Payment will be made for medications in accordance with the payment procedures for any fee-for-service (FFS) Medicaid eligible person. On a periodic basis as ingredient costs change, the department will post a link on its website containing average acquisition cost of drugs.

C. The pharmacy must be licensed to operate in Louisiana except:

1. as provided for a person residing near the state line; or
2. as provided for a recipient visiting out-of-state.

D. Payment will be made only to providers whose records are subject to audit.

E. Payment will be made to providers only for medications furnished to persons eligible for medical vendor

payments on a prescription written by a practitioner who is authorized to prescribe in Louisiana and is enrolled in FFS Medicaid.

F. Payments will be made only for the drugs covered under Louisiana Medicaid's Pharmacy Program.

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), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1184 (June 2017).

§949. Fee for Service Cost Limits

A. Brand Drugs. The department shall make payments for single source drugs (brand drugs) based on the lower of:

1. average acquisition cost (AAC):
 - a. if no AAC is available, use the wholesale acquisition cost (WAC) plus the professional dispensing fee; or
2. the provider's usual and customary charges to the general public not to exceed the department's "maximum payment allowed."
 - a. For purposes of these provisions, the term *general public* does not include any person whose prescriptions are paid by third-party payors, including health insurers, governmental entities, and Louisiana Medicaid.

B. Generic Drugs. The department shall make payments for multiple source drugs (generic drugs), other than drugs subject to "physician certifications", based on the lower of:

1. AAC:
 - a. if no AAC is available, use the WAC plus the professional dispensing fee;
2. federal upper payment limits plus the professional dispensing fee; or
3. the provider's usual and customary charges to the general public not to exceed the department's "maximum payment allowed."
 - a. For purposes of these provisions, the term *general public* does not include any person whose prescriptions are paid by third-party payors, including health insurers, governmental entities, and Louisiana Medicaid.

C. Federal Upper Payment Limits for Multiple Source Drugs

1. Except for drugs subject to "physician certification", the Medicaid Program shall utilize listings established by the Centers for Medicare and Medicaid Services (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. Medicaid shall utilize the maximum acquisition cost established by CMS in determining multiple source drug cost.

3. The Medicaid Program shall provide pharmacists who participate in Medicaid reimbursement with updated lists reflecting:

- a. the multiple source drugs subject to federal multiple source drug cost requirements;
- b. the maximum reimbursement amount per unit; and
- c. the date such costs shall become effective.

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 dated and 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. Fee-for-Service 340B Purchased Drugs. The department shall make payments for self-administered drugs that are purchased by a covered entity through the 340B program at the actual acquisition cost which can be no more than the 340B ceiling price plus the professional dispensing fee, unless the covered entity has implemented the Medicaid carve-out option, in which case 340B drugs should not be billed to or reimbursed by Medicaid. 340B contract pharmacies are not permitted to bill 340B stock to Medicaid. Fee-for-service outpatient hospital claims for 340B drugs shall use a cost to charge methodology on the interim and settled at cost during final settlement. Federally qualified health center (FQHC) and rural health clinic (RHC) claims for physician administered drugs shall be included in the all-inclusive T1015 encounter rate.

F. Fee-for-Service Drugs. Drugs acquired at federal supply schedule (FSS) and at nominal price shall be reimbursed at actual acquisition cost plus a professional dispensing fee.

G. Indian Health Service All-Inclusive Encounter Rate. Pharmacy services provided by the Indian Health Service (IHS) shall be included in the encounter rate. No individual pharmacy claims shall be reimbursed to IHS providers.

H. Mail Order, Long-Term Care and Specialty Pharmacy. Drugs dispensed by mail order, long-term care and/or specialty pharmacies (drugs not distributed by a retail community pharmacy) will be reimbursed using the brand/generic drug reimbursement methodology.

I. Physician-Administered Drugs. Medicaid-covered physician-administered drugs shall be reimbursed according to the Louisiana professional services fee schedule. Reimbursement shall be determined utilizing the following methodology, and periodic updates to the rates shall be made in accordance with the approved Louisiana Medicaid State Plan provisions governing physician-administered drugs in a physician office setting.

1. Reimbursement for Medicaid-covered physician-administered drugs in a physician office setting shall be established at the current Louisiana Medicare rate, which is average sales price (ASP) plus 6 percent, for drugs appearing on the Medicare file.

2. Reimbursement rates for physician-administered drugs in a physician office setting that do not appear on the

Medicare file shall be determined utilizing the following alternative methods:

- a. the wholesale acquisition cost (WAC) of the drug, if available;
- b. If the drug has no WAC available, one of the following methods shall be used:
 - i. the provider's actual cost of the drug as documented by invoice or other acceptable documentation as deemed appropriate by the department;
 - ii. Medicaid rate of other states;
 - iii. commercial payer rate; or
 - iv. medical consultant recommendation.

J. Clotting Factor. Pharmacy claims for clotting factor will be reimbursed using the brand/generic drug reimbursement methodology.

K. Investigational or Experimental Drugs. Investigational or experimental drugs shall not be reimbursed by Medicaid.

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), amended by the Department of Health, Bureau of Health Services Financing, LR 43:1185 (June 2017), LR 43:1554 (August 2017), LR 44:1020 (June 2018).

Subchapter E. 340B Program

§961. Definitions

Actual Acquisition Cost—the covered entity's net payment made to purchase a drug product.

Contract Pharmacy—a pharmacy under contract with a covered entity that provides services to the covered entity's patients, including the service of dispensing the covered entity's 340B drugs, in accordance with Health Resources and Services Administration (HRSA) guidelines (75 FR 10272, March 5, 2010). Contract pharmacies are not allowed to bill Medicaid for pharmacy claims.

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.

Estimated Acquisition Cost (EAC)—the average acquisition cost of the drug dispensed. If there is not an AAC available, the EAC is equal to the wholesale acquisition cost, as reported in the drug pricing compendia utilized by the department's fiscal intermediary.

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).

Professional Dispensing Fee—the fee paid by Medicaid for the professional services provided by a pharmacist when dispensing a prescription. Per legislative mandate, the \$0.10 provider fee assessed for each prescription filled in the state of Louisiana will be paid separately.

Wholesale Acquisition Cost (WAC)—the manufacturer's published catalog price for a drug product to wholesalers as reported to Medicaid by one or more national compendia on a weekly basis.

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 by the Department of Health, Bureau of Health Services Financing, LR 43:1186 (June 2017), LR 43:1555 (August 2017).