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TO: Health Care Provider - Pharmacy

DATE: February 1, 2002

SUBJECT: Update Transmittal No. 55

REMOVE		INSERT	
Page	**Date**	**Page**	**Date**
Table of Contents	Dates Vary	Table of Contents	2-1-02
II-11 through II-13	9-1-01	II-11 through II-13	2-1-02
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Explanation of Updates

Page II-11, section 216.202, has been included to add a new section regarding the regulations governing cycle-fill for long-term care facilities.

Page II-12, section 216.302, has been included because information was moved to another section.

Page II-13, section 216.303, was created to improve the organization of policy material.

Page II-19, section 240, has been included to add the requirement of an actual signature from the prescriber on all prior authorization requests.

Page II-20, section 251.100, subpart A, has been included to clarify that the usual and customary charge for any drugs must be limited to the lowest shelf price when available as an over-the-counter drug that is covered by the Medicaid Program. Also, information regarding discounts has been deleted from this section and included as a separate section. Other minor wording changes were made for the clarification of policy material.

Page II-21, section 251.100, subpart B, has been included to clarify policy regarding special prices given to select customers. Section 251.101 is a new section that has been added to clarify discounts and other promotions.

Page II-22, section 251.300 and section 251.301, has been included because of repagination and to make minor wording changes.

Explanation of Updates (con't)

Page II-23, section 253, has been included to revise the heading and replace information to clarify policy pertaining to compound drug prescriptions. Also, section 254 has been included because of minor wording changes.

Page II-24, section 255, has been added because of repagination.

A change bar in the left margin denotes a revision.

Attached are updated pages to file in your provider manual.

If you need this material in an alternative format, such as large print, please contact our Americans with Disabilities Act Coordinator at (501) 682-1461 (voice) or (501) 682-6789 and 1-877-708-8191 (TDD).

If you have questions regarding this transmittal, please contact the EDS Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and Out-of-State at (501) 376-2211.

Thank you for your participation in the Arkansas Medicaid Program.

Ray Hanley, Director
Division of Medical Services

Arkansas Medicaid provider manuals (including update transmittals), official notices and remittance advice (RA) messages are available for downloading from the Arkansas Medicaid website: **www.medicaid.state.ar.us.**

216.200 Prescription Benefits for Long-Term Care Facility Residents

Prescriptions for Medicaid-eligible LTC facility residents are not subject to a monthly prescription limit, however, the drug product must be covered under the Arkansas Medicaid Pharmacy Program. (Refer to section 210.000 for program coverage, section 212 for exclusions and section 252 for reimbursement to LTC facilities.)

216.201 Prescription Benefits for Hospice Patients in Long-Term Care Facilities

Medicaid recipients who have elected to receive hospice services in LTC facilities may only use their prescription drug benefits to treat conditions not directly related to their terminal illness. These recipients are only allowed three (3) prescriptions per month. If additional prescriptions are needed, an extension of drug benefits may be requested for up to a total of six (6) maintenance medications per month. *Drugs related to the terminal illness must be furnished by the hospice.*

216.202 Regulations Governing Cycle-Fill and Pharmacy Notification for Long-Term Care Facilities

Only oral solid medications may be cycle-filled. However, if an oral solid medication meets one of the categories below, then that oral solid medication **may not** be cycle-filled.

A. PRN or "as needed" medications;
B. Controlled drugs (CII – CV);
C. Refrigerated medications;
D. Antibiotics; or
E. Anti-infectives.

When a facility notifies a pharmacy in writing of any change of condition that affects the medication status of a resident, the pharmacy shall immediately amend the filling of the prescription to conform to the changed medication requirement of the resident.

For purposes of this section, *change of condition* includes death, discharge or transfer of a resident, as well as medical changes of condition that necessitate a change to the medication prescribed or the dosage given.

216.300 Pharmacy Drug Distribution Systems for Long-Term Care Facility Residents

Generally, there are two (2) types of drug distribution systems used in long-term care facilities. They are the traditional packaging system and unit dose system. The Pharmacy Program does not utilize a different dispensing fee to calculate reimbursement for various types of drug distribution systems.

Pharmacy providers for long-term care facilities must supply 24-hour service to their patients regardless of the drug distribution system used.

216.301 Traditional Packaging System

The traditional packaging system uses individual vials for each prescription. When this system is used by the facility, each resident has the freedom of choice to select a Medicaid pharmacy provider to supply his or her prescriptions.

216.302 Unit Dose System

The Arkansas Medicaid Pharmacy Program does recognize through the drug cost reimbursement formula, unit dose packaging when manufacturer's unit dose packages are used. The Pharmacy Program also recognizes that a Pharmacy may have a different usual and customary charge up to a maximum of estimated acquisition cost (EAC) plus dispensing fee for long-term care facility patients when a unit dose packaging system is used, since it is not the same as the traditional prescription packaging used for regular prescriptions.

A unit dose system must meet the following requirements:

A. When a facility uses a unit dose system, they must restrict Medicaid pharmacy providers to those that comply with the system.

B. The unit dose system must be approved by the Division of Medical Services. Evidence of approval must be on file in the facility.

C. The facility must advise their patients that a unit dose system could be more expensive for those drugs/medications that are not covered by Medicaid.

D. All facilities must document each Medicaid patient's consent to use a unit dose system. If the patient is incapable of making this decision, the consent must be made by a family member, legal guardian or other responsible person. The consent form on page II-14, properly executed, will be accepted as appropriate documentation of consent to participate in an approved unit dose system. The consent form states that the patient agrees to participate in the facility's unit dose system, which will be provided by one pharmacy and that the patient agrees to use this pharmacy as long as this drug dispensing system remains in effect.

Medicaid patients residing in a facility **prior** to implementation of a unit dose system retain their right to freedom of choice, regardless of which drug distribution system a facility uses.

A facility may decline to accept a new recipient if he or she declines to accept the unit dose system used by the facility.

216.303 Administering the Unit Dose System

There are two (2) methods used in administering the unit dose systems in long-term care facilities:

A. Modified Unit Dose Packaging System

This system is based on a thirty-one (31) day unit dose packaging system, usually using 'blister cards'.

B. True Unit Dose System

The true unit dose system is administered as follows:

1. All medication orders are filled from an original or direct copy of the physician's order.

2. Pharmacies must maintain medication profiles on each patient and refer to these profiles each time a medication order is filled.

3. Each patient's prescription requirements are individually packaged and labeled. Before a system can be considered a true unit dose system, all doses of all medications must be dispensed in unit-of-use packaging. The physical appearance of the unit dose package will vary according to the system, but always include clear product identification, clear patient identification and instructions for administration of the medication.

4. Doses of medication for each patient are placed into an individual patient container, bin, compartment or drawer and, whenever possible, are subdivided by dose and administration time.

5. The true unit dose system is based on a 24-hour change-out with a maximum change-out of 72 hours once weekly for weekend coverage.

6. Hardware for storing the trays and delivering the medication to the patients is included as part of the system.

CONSENT FORM TO PARTICIPATE
IN APPROVED UNIT DOSE DRUG DISTRIBUTION SYSTEM

I, _____, understand that in order to gain admittance to
(patient's name)

_____ Nursing Home, I must agree to purchase prescription
(name of facility)

drugs from _____ in order that my drugs may be implemented
(name of provider pharmacy)

into the _____ system. I understand that this system meets
(type of system)

all requirements of a unit dose system as outlined by both the State and Federal agencies and that this facility has permission from the Division of Medical Services to implement such a system. I also understand that this system requires more of the Pharmacist's time and more materials; therefore, the cost may be more than customary.

Signed _____
(patient or guardian signature)

Witness_____

Date

240 PRIOR AUTHORIZATION

Prescription drugs are available for reimbursement under the Arkansas Medicaid Program pursuant to an order from an authorized prescriber.

Prior authorization (PA) requests are not valid unless they are *actually* signed by the prescriber. Rubber stamps are not acceptable. Pharmacies should not process PA requests unless they contain the signature of the prescriber.

Refer to Section V-D (Prior Authorization) of this manual for information relative to:

A. Drugs Requiring Prior Authorization (A current listing is also available on the website at: www.medicaid.state.ar.us)

B. Criteria for Drugs Requiring Prior Authorization

C. Drugs Subject to Specific Prescribing Requirements

D. Criteria for Drugs Subject to Therapy Limitations

E. Requests for Prior Authorization

F. Request to Exceed the Prescription Drug Per Month Benefit Limit

250 REIMBURSEMENT

251.000 Method of Reimbursement

Medicaid payments are made according to federal regulations. For each prescription, reimbursement is based on one (1) of the following:

A. The lowest of the pharmacy's usual and customary charge to the general public;

B. The Estimated Acquisition Cost (EAC) of the drug dispensed plus dispensing fee based on the formula: EAC + $5.51. *(EAC equals Average Wholesale Price [AWP] minus 10.5%. Dispensing fee equals $5.51.)*;

or

C. The State/Federal Generic Upper Limit (GUL) plus a dispensing fee based on the formula: State/Federal GUL + $5.51. *(Dispensing fee equals $5.51.)*

Pricing files are updated weekly.

251.100 Usual and Customary Charge

Audits of pharmacies will be conducted to determine whether the usual and customary charge is being accurately billed to Medicaid.

The Arkansas Medicaid Pharmacy Program requires that the amount a pharmacy bills to the Medicaid Program must be consistent with the pharmacy's usual and customary charge to the general public. The usual and customary charge is the price that is charged for 90% of the prescriptions for private pay customers for the same product and quantity. Stores that use computers in their pharmacy have the option of establishing a consistent pricing policy through the use of a computer-generated price. Multiplicity of pricing schemes in the competitive pharmacy environment is not conducive to consistent pricing. Providers should elect that method most suitable to their particular need and document their allowable Medicaid charge by consistent use of this method. Stores may choose the pricing method they desire, however, Medicaid reimbursement will be based upon audit verification of the usual and customary price. Stores found in violation of the usual and customary billing provisions will be subject to recoupment. Variations in excess of 10% from the usual and customary charge will invariably result in recoupment. Individual drug/quantity price variations will be noted. If the prices on more than 10 percent of the prescriptions for a given drug/quantity, such as 30 Dyazide, are found to vary in a given time frame, auditors will select the most prevalent price as the usual and customary charge. Items that must be considered when determining usual and customary charges include:

A. The usual and customary charge or billed amount for any drug, legend or over-the-counter (OTC), that is available as an OTC drug will be limited to the lowest shelf price of the product available to customers and which is covered by the Arkansas Medicaid Program.

251.100 Usual and Customary Charge (Continued)

B. All special prices, including, but not limited to, those prices given to family members or other select customers must be indicated (e.g., "special" or "SP") on all prescriptions. If special prices are not clearly identifiable on private pay prescriptions, auditors will use these prices to determine the pharmacy's usual and customary charge.

The provider's usual and customary charge shall be recorded on all submitted claim forms. For any claim submitted to the Medicaid Program, the charge submitted therein shall be documented by the pharmacy provider as its usual and customary charge. For verification purposes, program auditors shall have access to providers' non-Medicaid prescription files.

251.101 Discounts and Other Promotions

Discrimination against Medicaid recipients is prohibited. No Medicaid recipient shall be excluded from any temporary or promotional discount or price reduction available to persons who are not Medicaid recipients. If a temporary or promotional discount or price reduction is targeted to a specific population by a characteristic such as age, only Medicaid recipients who are similarly situated to persons to whom the promotion is directed are entitled to the discount or reduced price. Amounts billed to the Medicaid Program must be adjusted to reflect temporary or promotional discounts or price reductions irrespective of coupon or card presentation. If it is determined, by audit or otherwise, that one or more Medicaid recipients was excluded from any temporary or promotional discount or price reduction, the difference between the reduced or discounted price and the price paid will be recouped from the Medicaid provider.

This section applies only to price reductions and discounts, not to the provider's usual and customary charges, or to rates paid by other third party payers. Nothing in this section shall be construed in any manner that is inconsistent with any other provision in this manual, or with 42 U.S.C. § 1320a-7b.

251.200 Estimated Acquisition Cost

Estimated acquisition cost (EAC) is based on the average wholesale price of the drug minus 10.5%. The drug file used in the processing system contains all package sizes available for each covered drug product.

Drug cost is calculated according to the package size purchased by each individual provider. For example, if a pharmacy buys a particular drug in a bottle of 100, the pharmacy provider is to bill Medicaid with the National Drug Code (NDC) number for the 100-unit package size; the drug product cost is calculated based on the 100-unit size. Whereas another pharmacy could buy the same drug in a bottle of 1000, that pharmacy provider is to bill Medicaid with the NDC number for the 1000-unit package size; the drug cost is calculated based on the 1000-unit size.

Drug companies are responsible for notifying First DataBank of any product and price revisions. Prices in the drug pricing file are changed according to the effective date advised by the companies. The EAC prices in the Medicaid Program may not correlate exactly with the list price from all wholesalers due to variances among wholesale dealers. The approved methodology used to determine the EAC for a drug is based on the AWP as reported to the states by First DataBank.

251.300 Generic Upper Limit Cost

The generic upper limit (GUL) price is the maximum drug cost used to compute reimbursement for multiple-source drugs unless the provisions for a generic upper limit override have been met. (See section 251.301 for GUL override.)

For several multiple-source drugs, the federal government requires that payment under the Medicaid Program be based on a generic upper limit cost that is established by CMS. For other multiple-source drugs, the state agency has determined which drugs will be on the Arkansas generic upper limit list and is responsible for setting the maximum price the provider may use as his cost for that drug. The generic upper limit is listed in the Arkansas Medicaid Multisource Drugs listing (Section V-A) of this manual.

Generic upper limit is based on price per unit (ml, gm, tablet, capsule, etc.) in the commonly available quantity.

The generic upper limit price is a maximum for a drug. The EAC price or the provider's usual and customary charge for a specific drug will be used in price calculation if it is lower than the generic upper limit.

251.301 Generic Upper Limit Override

The following criteria must be met to override the generic upper limit cost when computing the allowable amount of reimbursement:

A. Pharmacy providers must receive a written prescription from the physician. The prescription must also include the physician's signature.

B. The prescriber must write "Brand Medically Necessary" in his or her own handwriting on the face of the prescription. A rubber stamp is not acceptable. Also, the phrases "Do Not Substitute" or "Dispense as Written" are not sufficient. The prescription must be on file for review by auditors from the Division of Medical Services or their designated agents.

C. For prescriptions received by telephone, providers must also receive the written prescription from the physician with the required phrase "Brand Medically Necessary".

D. Pharmacy providers are required to obtain a prior authorization (PA) for a "Brand Medically Necessary" override. Once the pharmacy provider obtains a written prescription that meets the above criteria, the Voice Response System (VRS) must be accessed to obtain the prior authorization necessary to override the generic upper limit. The physician is not required to fill out a prior authorization request form for a "Brand Medically Necessary" override.

The PA is given for up to a six-month period. If no refills are indicated on the prescription, a new prescription is required with "Brand Medically Necessary" written on the face of the prescription in the prescriber's own handwriting. *Refills by telephone are unacceptable on "Brand Medically Necessary" prescriptions.*

251.301 Generic Upper Limit Override (Continued)

If the criteria stated above are met, the prescription will be priced using the EAC price for the specific product dispensed rather than using the generic upper limit price. Claims inappropriately billed as "Brand Medically Necessary" will be recouped.

252 Dispensing Fee Reimbursement for Long-Term Care Recipients

Only one dispensing fee per month per drug strength will be reimbursed by the Medicaid Program for certified long-term care recipients. This applies even if various brands of the same generic drug or chemical entity are dispensed during the month. The provider must bill the National Drug Code number for the generic drug or chemical entity actually dispensed.

253 Compound Drug Prescriptions

When a pharmacy provider receives a prescription for a compounded prescription, and one or more of the drugs required are covered by the Medicaid Program, the pharmacy may bill each covered National Drug Code (NDC) as a separate claim. Each claim must reflect only the quantity of that drug (NDC) actually used to compound the prescription, not the total quantity of the compound. Each NDC billed will count toward the Medicaid recipient's prescription drug benefit limit. Recipients under age 21 and in the Child Health Services (EPSDT) Program, and long-term care facility residents who do not receive hospice services are exempt from the prescription drug benefit limit. If a pharmacist opts to compound a prescription, the recipient is not responsible for the cost of any noncoverable NDCs, ingredients, etc., used to compound the prescription, but only the applicable copayment.

Due to provisions set forth in the Omnibus Budget Reconciliation Act (OBRA 90), only the NDC that is dispensed and the quantity of that NDC that is dispensed can be submitted to Medicaid. If a pharmacy provider is unable to bill according to these guidelines due to software limitations, the vendor should be notified of these requirements immediately. Any pharmacy that continues to bill compounded prescription claims improperly will be subject to recoupment of the **total paid amount** of those claims.

254 Claims with Incorrect National Drug Code (NDC) Numbers

On each claim submitted for payment, the pharmacy provider must accurately record the NDC number for the drug product. The NDC number must be for the drug and package size actually dispensed. The entire eleven (11) digit NDC number must be billed properly for the NDC to be correct. **When an audit determines that the incorrect NDC number was billed, providers are not allowed to reverse and rebill the claim.** Instead, the state will recoup 20% of the paid amount for claims with incorrect NDC numbers. For example, a pharmacy has claims with misbilled NDCs in the amount of $464.33. The following amount will be recouped: $464.33 X 20% = $92.87.

255 Rate Appeal Process

A provider may request reconsideration of a Program decision by writing to the Assistant Director, Division of Medical Services. This request must be received within 20 calendar days following the application of policy and/or procedure or the notification of the provider of its rate. Upon receipt of the request for review, the Assistant Director will determine the need for a Program/Provider conference and will contact the provider to arrange a conference if needed. Regardless of the Program decision, the provider will be afforded the opportunity for a conference, if he/she so wishes, for a full explanation of the factors involved and the Program decision. Following review of the matter, the Assistant Director will notify the provider of the action to be taken by the Division within 20 calendar days of receipt of the request for review or the date of the Program/Provider conference.

If the decision of the Assistant Director, Division of Medical Services is unsatisfactory, the provider may then appeal the question to a standing Rate Review Panel established by the Director of the Division of Medical Services which will include one member of the Division of Medical Services, a representative of the provider association and a member of the Department of Human Services (DHS) Management Staff who will serve as chairman.

The request for review by the Rate Review Panel must be postmarked within 15 calendar days following the notification of the initial decision by the Assistant Director, Division of Medical Services. The Rate Review Panel will meet to consider the question(s) within 15 calendar days after receipt of a request for such appeal. The question(s) will be heard by the panel and a recommendation will be submitted to the Director of the Division of Medical Services.