12. Prescribed drugs, dentures and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist (Continued)

b. Prescribed Drugs (continued)

(6) Any state supplemental rebate agreements between the state and a drug manufacturer are separate from the drug rebate agreements established under Section 1927 of the Social Security Act. The state reports state supplemental rebates to the Secretary of the Department of Health and Human Services. The state will remit the federal portion of any cash state supplemental rebates collected.

The supplemental rebate program does not establish a drug formulary within the meaning of 1927(d)(4) of the Social Security Act.

The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification, in accordance with Section 1927(b)(3)(D).

(7) When a pharmacist receives a prescription for a brand or trade name drug, and to dispenses an innovator multisource drug that is subject to the Federal Upper Limits (FULs), the innovator multisource drug must be priced at or below the FUL or the prescription hand annotated by the prescriber "Brand Medically Necessary". Only innovator multisource drugs that are subject to the Federal Upper Limit at 42 CFR 447.332(a) and dispensed on or after July 1, 1991, are subject to the provisions of Section 1927(e) of the Social Security Act.

For drugs listed on the Arkansas Medicaid Generic Upper Limit List, the upper limit price will not apply if the prescribing physician certifies in writing that a brand name drug is medically necessary.

The Arkansas Medicaid Generic Upper Limit List is comprised of State generic upper limits on specific multisource drug products and **CMS** identified generic upper limits on multisource drug products.

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OFFICIAL NOTICE

DMS-2004-O-3 DMS-2004-II-3 DMS-2004-Q-2 DMS-2004-OO-3
DMS-2004-E-2 DMS-2004-KK-10 DMS-2004-R-13

TO: **Health Care Provider – Certified Nurse-Midwives, Dental, Federally Qualified Health Centers, Nurse Practitioners, Pharmacy, Physicians and Rural Health Clinics**

DATE: **December 8, 2004**

SUBJECT: **Evidence-Based Preferred Drug List**

I. Purpose

Effective October 15, 2004, the Arkansas Medicaid program will begin development of an evidence-based Preferred Drug List. The Preferred Drug List (PDL) will identify, within a particular class of drugs, which drugs Medicaid will pay for without requiring prior authorization (PA).

The College of Pharmacy will make recommendations to the Medicaid program about which drugs to include on the PDL. Those recommendations will be based on a review by a committee of Arkansas physicians and pharmacists of the scientific evidence regarding which drugs in a class are most effective. The College of Pharmacy will also solicit supplemental rebate bids from pharmaceutical manufacturers in order to reduce the net cost to the Medicaid program for products included on the PDL.

PLEASE NOTE: You do not have to take any action in response to this notice at this time. Prior to the effective date of a Preferred Drug List, you will receive notification specifying which classes are subject to the PDL and which products are on the PDL. That notice will also tell you how to contact the PA Call Center to request a PA.

Until and unless you receive notification otherwise, the PDL will not replace the existing PA requirements for certain drugs or classes of drugs. You should continue to process clinical PA requests or benefit limit extension requests through the Voice Response System.

The Department of Human Services is in compliance with Titles VI and VII of the Civil Rights Act.

II. Development of the Preferred Drug List

As a member of the Drug Effectiveness Review Project, the Arkansas Medicaid program will receive evidence-based reports of drug effectiveness developed by federally-designated Evidence-Based Practice Centers (EPCs). These reports are the result of a systematic, un-biased review of the results of clinical trials and studies regarding the effectiveness of various drugs. For each class reviewed, a report is produced which analyzes and summarizes the results of those trials regarding the relative effectiveness of drugs in terms of efficacy, patient safety, and impact on special populations.

The Arkansas Medicaid program will determine which classes of drugs will be reviewed for potential PDL development; the Medicaid program will also determine whether a previously reviewed class should be re-reviewed in light of additional information. The UAMS College of Pharmacy will convene a Drug Review Committee (DRC) composed of three Arkansas physicians, three Arkansas pharmacists, and the UAMS Project Director. DRC members will be appointed in consultation with the Arkansas Medical Society and Arkansas Pharmacist Association, with final approval by the Department of Human Services (DHS). Meetings of the Drug Review Committee (DRC) will be announced in advance and open to the public. The Drug Review Committee (DRC) will review EPC reports on new drug classes or re-reviewed classes and make recommendations regarding which drugs to consider for the PDL. The DRC will develop key questions to consider in future evidence reviews. The DRC will also develop criteria for approval of PA requests for non-preferred drugs in the class. The DRC will only consider the information in the EPC report or more recent information recommended for consideration by the EPC in its review of the class.

In advance of the DRC's scheduled review of a class of drugs, the Department of Human Services will send an invitation to bid to manufacturers of products in that class. For each product, manufacturers will be allowed to submit bids for supplemental rebates. The bids will be stated in terms of the net cost of the product, net of all rebates. Bids will be due one week prior to the DRC meeting; however, the bids will not be opened until after the DRC recommendations are developed. After the DRC meeting, the DRC recommendations will be reviewed by a UAMS/DHS Cost Committee along with the net cost bids received from the pharmaceutical manufacturers. Based on the review of the evidence and the supplemental rebated bids, the Cost Committee will develop a recommendation specifying which products should be included on the PDL. The UAMS College of Pharmacy recommendation will be forwarded to the Arkansas Medicaid program for a final decision.

For those products which are included on the PDL, the Arkansas Medicaid program will execute a supplemental rebate agreement with the manufacturer. In the agreement, the manufacturer will commit to pay supplemental rebates, and the State will commit to place the product(s) on the preferred drug list. The state will retain the right to utilize mechanisms to control utilization of preferred products, including, but not limited to quantity limits, day supply limits, or other clinical prior authorization criteria. The supplemental rebate agreement will have a three-year term; however, the agreement will include a provision allowing either party to terminate without cause with 60 days notice.

III. Notification of Additions and Changes to the PDL

At least sixty days prior to any addition or change to the Preferred Drug List, the Arkansas Medicaid program will issue notification detailing the additions or changes. In addition, where feasible, the Medicaid program will provide recipient-specific notifications to prescribers identifying their patients who have received drugs that are not going to be on the PDL. The PDL will also be posted on the Arkansas Medicaid website, along with any upcoming additions or changes. During the 60-day notice period, pharmacy providers will receive system-generated messages when they submit a claim for a drug that is going to be a non-preferred drug in the future. Prescribers and pharmacies should use this notice period to counsel their patients about the potential need to change their prescriptions to products on the PDL.

The Department anticipates that the initial PDL will be effective in early 2005; the provider notice will be issued at least 60 days prior to the effective date. Drug classes will be phased in over the succeeding months, subject to the 60-day notice period for each change. Each provider notice will include information on how to contact the PA Call Center to request a PA.

IV. Implementation of the PDL

At the time a class of drugs is included on the PDL (or changes are made to existing classes), claims for preferred drugs will be processed just as they are today. If a prescriber determines that a non-preferred drug is medically necessary, the prescriber must contact the PA Call Center and request a PA.

If a pharmacy submits a claim for a non-preferred drug, and the prescriber has not obtained a PA approval, a system-generated message will notify the pharmacy that the claim is for a non-preferred drug. The pharmacist should then contact the prescriber to determine whether the prescription can be changed to a preferred product. If the prescriber changes to a preferred drug, the pharmacist should fill the prescription and submit the claim. If the prescriber determines that the non-preferred product is medically necessary, the prescriber must contact the PA Call Center and request a PA. After a PA request is approved and entered into the system, the pharmacy can fill the prescription and submit the claim. PA requests for non-preferred drugs will be approved for up to six months.

In an emergency, a pharmacy may dispense a supply of up to five days of a non-preferred drug (for those drugs for which a five day supply may be calculated). This provision applies only when the PA Call Center is unavailable or the pharmacist is not able to contact the prescribing physician. A pharmacy provider will submit an '03' in the Level of Service (418-DI) field. The software vendor should be consulted to enable the pharmacy provider to access this field.

During the first 30 days of the implementation of a PDL for a class of drugs, a physician who believes that additional time is needed to discuss the change with the patient may request a one-time 30-day PA from the Call Center for a non-preferred drug. This exception will *not* be made for new prescriptions.

V. Operation of the Call Center

The PA Call Center will be operated by the UAMS College of Pharmacy. The Call Center will operate from 9:00 a.m. to 5:00 p.m. Monday through Friday, 11:00 a.m. to 1:00 p.m. on Saturday, and 1:00 p.m. to 3:00 p.m. on Sunday.

Prescribers may submit PA requests to the PA Call Center via telephone or fax or mail. A toll-free number will be established and communicated to all providers in the initial PDL provider notice. The Call Center will respond to all PA requests within 24 hours of receipt. A prescriber who submits a PA request via telephone will speak directly to a pharmacist. The pharmacists will evaluate all requests. If a request is approved the Call Center staff will enter the approval directly into the MMIS. Once that approval is entered into the system, the pharmacist can submit the claim for the prescription. If a PA request is denied by the Call Center pharmacist, the prescriber can request a review by a Call Center physician; the Call Center physician will respond to the request within 24 hours. If the PA is denied after physician review, a denial letter will be sent to the recipient, and the prescriber will be notified. The recipient may appeal the denial utilizing the existing appeal procedures.

Thank you for your participation in the Arkansas Medicaid Program.

Roy Jeffus, Director

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

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

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.**