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**TITLE 405 OFFICE OF THE SECRETARY OF
FAMILY AND SOCIAL SERVICES**

Proposed Rule
LSA Document #01-372

DIGEST

Amends 405 IAC 5-24-4 and 405 IAC 5-24-6 to revise reimbursement policy for pharmacy services in the Medicaid program. NOTE: 405 IAC 5-24-4 and 405 IAC 5-24-6 were amended by LSA Document 01-22(F), printed at 25 IR 60. However, that final rule was preliminarily enjoined pursuant to an order issued on October 9, 2001, in the Marion Superior Court, Cause No. 49D05-0109-CP-1480, and those changes not implemented. Effective 30 days after filing with the secretary of state.

405 IAC 5-24-4

405 IAC 5-24-6

SECTION 1. 405 IAC 5-24-4, PROPOSED TO BE AMENDED AT 25 IR 847, SECTION 1, IS AMENDED TO READ AS FOLLOWS:

405 IAC 5-24-4 Reimbursement for legend drugs

Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-21-2; IC 12-15-21-3

Affected: IC 12-13-7-3; IC 12-15

Sec. 4. (a) The office shall reimburse pharmacy providers for covered legend drugs at the lowest of the following:

- (1) The estimated acquisition cost (EAC) of the drug as of the date of dispensing, plus any applicable Medicaid dispensing fee.
- (2) The maximum allowable cost (MAC) of the drug as determined by the Health Care Financing Administration under 42 CFR 447.332 as of the date of dispensing, plus any applicable Medicaid dispensing fee.
- (3) The state maximum allowable cost (MAC) of the drug as determined by the office as of the date of dispensing, plus any applicable Medicaid dispensing fee.
- (4) The provider's submitted charge, representing the provider's usual and customary charge for the drug, as of the date of dispensing.

(b) For purposes of this section, the Indiana Medicaid EAC is ~~ninety~~ **eighty-seven** percent (~~90%~~) (**87%**) of the average wholesale price for each National Drug Code according to the Medicaid contractor's drug database file.

(c) The state MAC is equal to the average actual acquisition cost per drug adjusted by a multiplier of at least 1.0. The actual acquisition cost will be determined using pharmacy invoices and other information that the office determines is necessary. The purpose of the multiplier is to ensure that the applicable state MAC rate is sufficient to allow reasonable access by providers to the drug at or below the established state MAC rate.

(d) OMPP will review state MAC rates on an ongoing basis, and adjust the rates as necessary to reflect prevailing market conditions and ensure reasonable access by providers to drugs at or below the applicable state MAC rate.

(e) Pharmacies and providers that are enrolled in the Indiana health coverage programs (IHCP) are required, as a condition of participation, to make available and submit to the OMPP or its designee acquisition cost information, product availability information, or other information deemed necessary by the OMPP for the efficient operation of the pharmacy benefit within the IHCP in the format requested by the OMPP or its designee. Providers will not be

reimbursed for this information and will submit information to the OMPP or its designee within thirty (30) days following a request for such information unless the OMPP or its designee grants an extension upon written request of the pharmacy or provider. (*Office of the Secretary of Family and Social Services; 405 IAC 5-24-4; filed Jul 25, 1997, 4:00 p.m.: 20 IR 3345; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; filed Aug 29, 2001, 9:50 a.m.: 25 IR 60 [NOTE: On October 9, 2001, the Marion Superior Court issued an Order in Cause No. 49D05-0109-CP-1480, enjoining the Family and Social Services Administration from implementing LSA Document #01-22(F), published at 25 IR 60.]*)

SECTION 2. 405 IAC 5-24-6, AS AMENDED AT 25 IR 60, IS AMENDED TO READ AS FOLLOWS:

405 IAC 5-24-6 Dispensing fee

Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-21-2; IC 12-15-21-3

Affected: IC 12-13-7-3; IC 12-15

Sec. 6. (a) For purposes of this rule, the Indiana Medicaid dispensing fee maximum is ~~four~~ **three** dollars (~~\$4~~) (**\$3**) per legend drug.

(b) A maximum of one (1) dispensing fee per month is allowable per recipient per drug order for legend drugs provided to Medicaid recipients residing in Medicaid certified long term care facilities.

(c) The practice of split billing of legend drugs, defined as the dispensing of less than the prescribed amount of drug solely for the purpose of collecting more dispensing fees than would otherwise be allowed, is prohibited. In cases in which the pharmacist's professional judgment dictates that a quantity less than the amount prescribed be dispensed, the pharmacist should contact the prescribing practitioner for authorization to dispense a lesser quantity. The pharmacist must document the result of the contact and the pharmacist's rationale for dispensing less than the amount prescribed on the prescription or in the pharmacist's records. (*Office of the Secretary of Family and Social Services; 405 IAC 5-24-6; filed Jul 25, 1997, 4:00 p.m.: 20 IR 3345; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; filed Aug 29, 2001, 9:50 a.m.: 25 IR 60 [NOTE: On October 9, 2001, the Marion Superior Court issued an Order in Cause No. 49D05-0109-CP-1480, enjoining the Family and Social Services Administration from implementing LSA Document #01-22(F), published at 25 IR 60.]*)

SECTION 3. The amendments proposed by this rule rulemaking action were previously finalized in amendments to 405 IAC 5-24-4 and 405 IAC 5-24-6 by LSA Document #01-22(F), printed at 25 IR 60. However, that final rule was preliminarily enjoined pursuant to an order issued on October 9, 2001, in the Marion Superior Court, Cause No. 49D05-0109-CP-1480, and the changes promulgated by LSA Document #01-22(F) were not implemented.

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on January 24, 2002 at 9:00 a.m., at the Indiana Government Center-South, 402 West Washington Street, Auditorium, Indianapolis, Indiana the Office of the Secretary of Family and Social Services will hold a public hearing on proposed amendments to revise Medicaid reimbursement rates to pharmacy providers.

In accordance with the public notice requirements established at 42 CFR 447.205, the Indiana Family and Social Services Administration, Office of Medicaid Policy and Planning (OMPP) gives notice of proposed changes to methods and standards governing reimbursement policy for pharmacy services under the Indiana Medicaid program.

The Medicaid program biennial budget (State Fiscal Years 02-03) was not fully appropriated by the General Assembly during the 2001 legislative session. The under-appropriation for the Medicaid program was \$141 million over the biennium, therefore, OMPP does not have sufficient funds to cover the growing costs of health care delivered to those who depend on the Medicaid program. Additionally, after the close of the 2001 Session, the State lost a lawsuit that is expected to add thousands more disabled Hoosiers to the Medicaid disability program at a cost estimated to be around \$136 million over the biennium. As a result, OMPP has had no choice but to pursue a number of cost containment initiatives that will reduce overall expenditures to levels that will enable the State to pay all providers for the services delivered, and to ensure access to services for eligible Medicaid recipients.

In response to rapidly escalating expenditures for Medicaid covered legend drugs, the OMPP proposes changes to the following reimbursement elements applicable to legend drugs: decrease dispensing fee from \$4.00 to \$3.00 and increase from ten percent to thirteen percent, the percentage subtracted from published average wholesale price (AWP).

OMPP's research reveals that the current \$4.00 dispensing fee is substantially higher than dispensing fee is substantially higher than dispensing fees of other payors. In early 2000, the National Association of Medicaid Fraud Control Units advised Medicaid agencies that they had determined that inflated AWP's were causing payors to over-reimburse for drugs nationwide. In August 2001, the Office of the Inspector General of the United States Department of Health and Human Services issued a final report entitled "Medicaid Pharmacy—Actual Acquisition Cost of Brand Name Prescription Drug Products" that provided the results of OIG's review of pharmacy acquisition costs for brand name drugs reimbursed under the Medicaid prescription drug program. The review included pricing information from eight states, including Indiana. The OIG estimated that nationally, pharmacy actual acquisition cost was an average of 21.84 percent below AWP. Shortly after release of the OIG's study, claims surfaced that the referenced percentage was incorrect, due to flaws in the OIG's data. Even if the 21.84 percent figure is eventually revised downward somewhat, it clearly remains the case that what providers actually pay as actual acquisition cost for a drug is less than what they are reimbursed for the drug under the current AWP minus 10 percent methodology. Analysis of Indiana-specific data by Myers and Stauffer indicates that a more accurate percentage figure corresponding to the OIG's study would be in the range of 17 percent to 18 percent. In addition, OMPP's research reveals that average commercial pharmacy pricing in Indiana and the midwest entails AWP minus 40 percent for generic drugs and AWP minus 14.5 percent for brand name drugs. For these reasons and in order to bring Medicaid payments more in line with rates paid and accepted in the marketplace, a reduction of the dispensing fee to \$3.00 and AWP minus thirteen percent are proposed.

The policies implemented by these proposals are expected to result in Medicaid program savings (both state and federal dollars) of approximately \$2.7 million in SFY 2002 and approximately \$24.4 million in SFY 2003.

All parties who are interested in the rule are invited to attend that hearing and offer public testimony. Written comments concerning the rule received at or after the hearing are available for public inspection by contacting, Office of Medicaid Policy and Planning, 402 West Washington Street, Room W382, Indianapolis, Indiana 46204.

Copies of these rules are now on file at the Indiana Government Center-South, 402 West Washington Street, Room W451 and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection. Also, copies of these rules and this public notice are now on file and open for public inspection by contacting the Director of the local office of the Division of Family and Children, except in Marion County. The inspection material will be maintained for viewing in Marion County at the Office of Medicaid Policy and Planning, 402 West Washington Street, Room W382, and will be available from 8:30 a.m. to 4:30 p.m., Monday through Friday. Written comments from any source regarding these changes should be sent to the above listed address to the attention of Catherine Rudd in order to be made part of the public record to be considered by the agency. Correspondence should be identified by reference to LSA 01-372.

John Hamilton
Secretary
Office of the Secretary of Family and Social Services