TITLE 405 OFFICE OF THE SECRETARY OF FAMILY AND SOCIAL SERVICES

Final Rule
LSA Document #16-530(F)

DIGEST

Amends 405 IAC 5-24-2 to update the definition of "pharmacy services". Amends 405 IAC 5-24-4 to update the reimbursement methodology for legend drugs. Amends 405 IAC 5-24-5 to remove insulin from the calculation of reimbursement for nonlegend drugs. Amends 405 IAC 5-24-6 to update terminology and modify the calculation of the Medicaid professional dispensing fee. Effective 30 days after filing with the Publisher.

405 IAC 5-24-2; 405 IAC 5-24-4; 405 IAC 5-24-5; 405 IAC 5-24-6

SECTION 1. 405 IAC 5-24-2 IS AMENDED TO READ AS FOLLOWS:

405 IAC 5-24-2 "Pharmacy services" and "usual and customary charge" defined

Authority: IC 12-15-1-10; IC 12-15-21-2
Affected: IC 12-13-7-3; IC 12-15

Sec. 2. (a) As used in this rule, "pharmacy services" means legend drugs, nonlegend drugs included on the Medicaid nonlegend drug formulary developed in coordination with the Indiana Medicaid Drug Utilization Review (DUR) board, ~~insulin,~~ nutritional supplements, food supplements, and infant formulas. Pharmacy services do not include the following:

(1) Nonlegend drugs ~~(except insulin)~~ not included on the Medicaid nonlegend drug formulary.

(2) Any other products offered for sale or rent by a pharmacy provider except legend drugs, nonlegend drugs included on the Medicaid nonlegend drug formulary, ~~insulin,~~ and nutritional supplements, food supplements, and infant formulas.

(b) As used in this rule, "usual and customary charge" means the amount a pharmacy provider offers to charge the general public for a pharmacy service as follows:

(1) For dispensed legend drugs, this shall include the provider's dispensing fee, if any.

(2) For dispensed nonlegend drugs, the price of the drug as it is presented for retail sale.

(3) Discounts shall be considered as follows:

(A) If a pharmacy provider offers a discount on the pharmacy service to the general public, the usual and customary charge shall be the amount that results from the application of the discount.

(B) If a pharmacy provider offers multiple discounts on the pharmacy service to the general public, the usual and customary charge shall be the lowest amount of the multiple discounts.

This subdivision applies regardless of whether the individual takes the steps necessary to receive the discount or even receives the discount.

(4) For purposes of this subsection, the term "general public" means all individuals who are seeking pharmacy services at a given locality except for individuals who:

(A) are enrolled in or a member of an insurance plan that covers pharmacy services; or

(B) receive a discount of pharmacy services through a program with selective criteria that disqualify certain individuals from eligibility in the program.

(Office of the Secretary of Family and Social Services; 405 IAC 5-24-2; filed Jul 25, 1997, 4:00 p.m.: 20 IR 3344; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; readopted filed Sep 19, 2007, 12:16 p.m.: 20071010-IR-405070311RFA; readopted filed Oct 28, 2013, 3:18 p.m.: 20131127-IR-405130241RFA; errata filed Nov 1, 2016, 9:36 a.m.: 20161109-IR-405160493ACA; filed Jan 4, 2017, 1:44 p.m.: 20170201-IR-405160172FRA; filed Mar 2, 2017, 3:39 p.m.: 20170329-IR-405160530FRA)

SECTION 2. 405 IAC 5-24-4 IS AMENDED TO READ AS FOLLOWS:

405 IAC 5-24-4 Reimbursement for legend drugs

Authority: IC 12-15-1-10; IC 12-15-21-2
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, **as applicable:**

(1) The ~~estimated acquisition cost (EAC)~~ **National Average Drug Acquisition Cost (NADAC)** of the drug **as published by the Centers for Medicare and Medicaid Services (CMS) pursuant to 42 U.S.C. 1396r-8(f),** as of the date of dispensing, plus any applicable Medicaid **professional** dispensing fee.

(2) The state maximum allowable cost (MAC) of the drug as determined by the office as of the date of dispensing, plus any applicable Medicaid **professional** dispensing fee.

(3) The provider's submitted charge, representing the provider's usual and customary charge for the drug, as of the date of dispensing.

(4) The federal upper limit (FUL) of the drug as determined by CMS pursuant to 42 CFR 447.514, as of the date of dispensing, plus any applicable Medicaid professional dispensing fee.

(5) The wholesale acquisition cost (WAC) of the drug according to the office's drug database file contracted from a nationally recognized source such as Medi-Span or First DataBank, adjusted by a percentage as determined by the office through analysis of the dispensing cost survey or other methodology approved by CMS, as of the date of dispensing, plus any applicable Medicaid professional dispensing fee. The purpose of the percentage is to ensure that the applicable WAC rate sufficiently reflects the actual acquisition cost of the provider. The WAC shall only be considered if there is no applicable NADAC, FUL, or state MAC rate.

~~(b) For purposes of this section and section 5(c) of this rule, the Medicaid EAC is:~~
~~(1) for brand name drugs, eighty-four percent (84%); or~~
~~(2) for generic drugs, eighty percent (80%);~~
~~of the average wholesale price for each National Drug Code according to the office's drug database file.~~

~~(c)~~ **(b)** 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) The office~~ **(c) OMPP** will review state MAC rates on an ongoing basis and adjust the rates as necessary to:

(1) reflect prevailing market conditions; and

(2) ensure reasonable access by providers to drugs at or below the applicable state MAC rate.

~~(e) Pharmacy~~ **(d) Pharmacies and** providers **that are enrolled in Medicaid** are required, as a condition of participation, to make available and submit to the office acquisition cost information, product availability information, or other information deemed necessary by the office for the efficient operation of the pharmacy benefit in the format requested by the office. Providers will:

(1) not be reimbursed for this information; and

(2) submit information to the office **or its designee** within thirty (30) days following a request for such information unless the office **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.]; filed Apr 30, 2002, 10:59 a.m.: 25 IR 2727; errata filed Aug 22, 2002, 3:11 p.m.: 26 IR 35; filed Nov 23, 2005, 11:30 a.m.: 29 IR 1212; readopted filed Sep 19, 2007, 12:16 p.m.: 20071010-IR-405070311RFA; filed Jan 23, 2008, 1:42 p.m.: 20080220-IR-405070547FRA; readopted filed Oct 28, 2013, 3:18 p.m.: 20131127-IR-405130241RFA; filed Aug 1, 2016, 3:44 p.m.: 20160831-IR-405150418FRA; errata filed Nov 1, 2016, 9:36 a.m.: 20161109-IR-405160493ACA; filed Mar 2, 2017, 3:39 p.m.: 20170329-IR-405160530FRA)

SECTION 3. 405 IAC 5-24-5 IS AMENDED TO READ AS FOLLOWS:

405 IAC 5-24-5 Reimbursement for nonlegend drugs

Authority: IC 12-15-1-10; IC 12-15-1-15; IC 12-15-21-2
Affected: IC 12-13-7-3; IC 12-15

Sec. 5. (a) The office shall reimburse pharmacy providers for the cost and dispensation of nonlegend

(over-the-counter or OTC) drugs included on the Medicaid nonlegend drug formulary as provided for in this section.

(b) The office shall reimburse for nonlegend drugs ~~except insulin,~~ at the lowest of the following rates:
(1) One hundred fifty percent (150%) of the state maximum allowable cost, as set out in the Medicaid Pharmacy Provider Manual and amendments thereto, for the drug in the quantity dispensed, as of the date dispensed.
(2) The provider's submitted charge, representing the provider's usual and customary charge for the drug, as of the date of dispensing.

~~(c) The office shall reimburse for insulin at the estimated acquisition cost (EAC) of the drug, plus any applicable Medicaid dispensing fee. For purposes of this subsection, EAC is defined in section 4(b) of this rule.~~

(Office of the Secretary of Family and Social Services; 405 IAC 5-24-5; filed Jul 25, 1997, 4:00 p.m.: 20 IR 3345; filed Sep 27, 1999, 8:55 a.m.: 23 IR 319; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; filed Nov 23, 2005, 11:30 a.m.: 29 IR 1212; readopted filed Sep 19, 2007, 12:16 p.m.: 20071010-IR-405070311RFA; readopted filed Oct 28, 2013, 3:18 p.m.: 20131127-IR-405130241RFA; errata filed Nov 1, 2016, 9:36 a.m.: 20161109-IR-405160493ACA; filed Mar 2, 2017, 3:39 p.m.: 20170329-IR-405160530FRA)

SECTION 4. 405 IAC 5-24-6 IS AMENDED TO READ AS FOLLOWS:

405 IAC 5-24-6 Dispensing fee

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

Sec. 6. (a) For purposes of this rule, ~~through June 30, 2017,~~ the Medicaid **professional** dispensing fee maximum is ~~three dollars and ninety cents ($3.90)~~ **ten dollars and fifty-seven cents ($10.57)** per legend drug.

(b) A maximum of one (1) **Medicaid professional** dispensing fee per month is allowable per member per drug order for legend drugs provided to members 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 **Medicaid professional** 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.]; filed Apr 30, 2002, 10:59 a.m.: 25 IR 2727; readopted filed Sep 19, 2007, 12:16 p.m.: 20071010-IR-405070311RFA; readopted filed Oct 28, 2013, 3:18 p.m.: 20131127-IR-405130241RFA; filed Nov 8, 2013, 2:56 p.m.: 20131204-IR-405130422FRA; filed Apr 29, 2015, 3:38 p.m.: 20150527-IR-405150034FRA; filed Aug 1, 2016, 3:44 p.m.: 20160831-IR-405150418FRA; filed Mar 2, 2017, 3:39 p.m.: 20170329-IR-405160530FRA)

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