HEALTH & WELFARE COMMITTEE

ADMINISTRATIVE RULES REVIEW

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2012 Legislative Session

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IDAPA 16 - DEPARTMENT OF HEALTH AND WELFARE 16.03.09 - MEDICAID BASIC PLAN BENEFITS DOCKET NO. 16-0309-1101 NOTICE OF RULEMAKING - TEMPORARY RULE

EFFECTIVE DATE: The effective date of the temporary rule is September 28, 2011.

AUTHORITY: In compliance with Sections 67-5221(1) and 67-5226, Idaho Code, notice is hereby given that this agency has adopted a temporary rule, and proposed regular rulemaking procedures have been initiated. The action is authorized pursuant to Sections 56-202(b), 56-203(7), 56-203(9), 56-209(g), 56-250 through 56-257, and 56-260 through 56-266, Idaho Code, as amended in House Bill 260.

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than December 21, 2011.

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is the required finding and concise statement of its supporting reasons for adopting a temporary rule and a nontechnical explanation of the substance and purpose of the proposed rulemaking:

Under Section 56-209(g), Idaho Code, the Department is required to pay the lesser of the pharmacy provider's lowest charge to the general public for a drug or the estimated acquisition cost (EAC), plus a dispensing fee. These changes provide for the administration and policies needed to implement the reimbursement to pharmacies required in statute. Obsolete language is being removed and the structure for dispensing fees is being added based on a tiered structure.

TEMPORARY RULE JUSTIFICATION: Pursuant to Section 67-5226(1)(b), Idaho Code, the Governor has found that temporary adoption of the rule is appropriate to comply with deadlines in amendments to governing law or federal programs, in particular, House Bill 260 (2011).

FEE SUMMARY: Pursuant to Section 67-5226(2), the Governor has found that the fee or charge being imposed or increased is justified and necessary to avoid immediate danger and the fee is described herein: N/A

FISCAL IMPACT: The following is a specific description, if applicable, of any fiscal impact on the state general fund greater than ten thousand dollars (\$10,000) during the fiscal year:

The state general fund savings associated with this rulemaking are estimated to be \$2,000,000.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220, Idaho Code, negotiated rulemaking was conducted to implement Section 8 of HB 260 regarding pharmacy drug

acquisition costs and dispensing fees. The notice of negotiated rulemaking was published in the May 4, 2011, Idaho Administrative Bulletin, Vol. 11-5, page 62.

INCORPORATION BY REFERENCE: No materials are being incorporated by reference into these rules.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the temporary and proposed rule, contact Robert Kellerman at (208) 364-1994.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before December 28, 2011.

DATED this 8th day of November, 2011.

Tamara Prisock DHW - Administrative Procedures Section 450 W. State Street - 10th Floor P.O. Box 83720 Boise, ID 83720-0036 phone: (208) 334-5564; fax: (208) 334-6558 e-mail: dhwrules@dhw.idaho.gov

THE FOLLOWING IS THE TEXT OF DOCKET NO. 16-0309-1101

665. PRESCRIPTION DRUGS: PROVIDER REIMBURSEMENT.

01. Nonpayment of Prescriptions. Prescriptions not filled in accordance with the provisions of Subsection 664.02 of these rules will be subject to nonpayment or recoupment.

(3-30-07)

 $\theta 2.$ Payment Procedures.The following protocol must be followed for proper
(3-30-07)(9-28-11)T(3-30-07)(9-28-11)T

a<u>01</u>. Filing Claims. Reimbursement is restricted to those drugs supplied from labelers that are participating in the CMS Medicaid Drug Rebate Program.</u> Pharmacists must file claims electronically with Department-approved software or by submitting the appropriate claim form to the fiscal contractor. Upon request, the contractor will provide pharmacies with a supply of claim forms. The form must include information described in the pharmacy guidelines issued by the Department. $\frac{(3-30-07)(9-28-11)T}{(9-28-11)T}$

<u>b02</u>. Claim Form Review. Each claim form may be subject to review by a contract claim examiner, a pharmaceutical consultant, or a medical consultant. (3-30-07)

e03. Billed Charges. A pharmacy's billed charges are not to exceed the usual and customary charges defined as the lowest charge by the provider to the general public for the same service including advertised specials. (3-30-07)

d04. Reimbursement. Reimbursement to pharmacies is limited to the lowest of the (3-30-07)

*i*a. Federal Upper Limit (FUL), as established by the Centers for Medicare and Medicaid Services (CMS) of the U.S. Department of Health and Human Services, plus the dispensing fee assigned by the Department; (3-30-07)

#b.State Maximum Allowable Cost (SMAC), as established by the Department, plusthe assigned dispensing fee;(3-30-07)

*iii***c**. Estimated Acquisition Cost (EAC), *as established by the Department following negotiations with representatives of the Idaho pharmacy profession defined as an approximation of the net cost of the drug defined as the Average Actual Acquisition Cost (AAAC), plus the assigned dispensing fee. In cases where no AAAC is available, reimbursement will be the Wholesale Acquisition Cost (WAC). WAC will mean the price, paid by a wholesaler for the drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug as published by a recognized compendia of drug pricing on the last day of the calendar quarter that corresponds to the calendar quarter; or (4-7-11)(9-28-11)T*

*iv***d**. The pharmacy's *usual and customary charge to the general public* <u>billed charges</u> as defined in Subsection 665.023.e. of this rule. (3-30-07)(9-28-11)T

e<u>05</u>. **Dispensing Fees**. Only one (1) dispensing fee per month will be allowed for the dispensing of each maintenance drug to any participant as an outpatient or a resident in a care facility except: (3-30-07)(9-28-11)T

ia. Multiple dispensing of topical and injectable medication when dispensed in manufacturer's original package sizes, unless evidence exists, as determined by the Department, that the quantity dispensed does not relate to the prescriber's order; (3-30-07)

iib.Multiple dispensing of oral liquid maintenance medication if a reasonable quantity,
as determined by the Department, is dispensed at each filling;(3-30-07)

iiic. Multiple dispensing of tablets or capsules if the quantity needed for a thirty-four (34) day supply is excessively large or unduly expensive, in the judgment of the Department; or (3-30-07)

ivd. When the dose is being titrated for maximum therapeutic response with a minimum of adverse effects. (3-30-07)

06. Claims Volume Survey for Tier-Based Dispensing Fees. The Department will

survey pharmacy providers to establish a dispensing fee for each provider. The dispensing fees will be paid based on the provider's total annual claims volume. The provider must return the claims volume survey to the Department no later than May 31st each year. Pharmacy providers who do not complete the annual claims volume survey will be assigned the lowest dispensing fee starting on July 1st until the next annual survey is completed. Based upon the annual claims volume of the enrolled pharmacy, the dispensing fee is provided online at: http:// healthandwelfare.idaho.govLinkClick.aspx?fileticket=iJDsiQavFLc%3d&tabid=119&mid=1111. (9-28-11)T

<u>f07</u>. **Remittance Advice**. Claims are processed by computer, and payments are made directly to the pharmacy or its designated bank through electronic claims transfer. A remittance advice with detailed information of each claim transaction will accompany each payment made by the Department. (3-30-07)

<u>g08</u>. **Return of Drugs**. Drugs dispensed in unit dose packaging as defined by IDAPA 27.01.01, "Rules of the Idaho State Board of Pharmacy," Subsection 156.05, must be returned to the dispensing pharmacy when the participant no longer uses the medication as follows:(3-30-07)

*i*a. A pharmacy provider using unit dose packaging must comply with IDAPA 27.01.01, "Rules of the Idaho State Board of Pharmacy," Subsection 156.05. (3-30-07)

iib. The pharmacy provider that receives the returned drugs must credit the Department the amount billed for the cost of the drug less the dispensing fee. (3-30-07)

*iii***c**. The pharmacy provider may receive a fee for acceptance of returned unused drugs. The value of the unused drug being returned must be cost effective as determined by the Department. (3-30-07)

032. Periodic State Cost Surveys. The Department will utilize periodic state cost surveys to obtain the most accurate pharmacy drug acquisition costs in establishing a pharmacy reimbursement fee schedule. Pharmacies participating in the Idaho Medicaid program are required to participate in these periodic state cost surveys by disclosing the costs of all drugs net of any special discounts or allowances. A pharmacy that is non-responsive to the periodic state cost surveys can be disenrolled as a Medicaid provider by the Department. (4-7-11)(9-28-11)T

10.Cost Appeal Process.Cost appeals will be determined by the Department's
provided online at: http://healthandwelfare.idaho.gov/
LinkClick.aspx?fileticket=iJDsiQavFLc%3d&tabid=119&mid=1111.

IDAPA 16 - DEPARTMENT OF HEALTH AND WELFARE

16.03.09 - MEDICAID BASIC PLAN BENEFITS

DOCKET NO. 16-0309-1201

NOTICE OF RULEMAKING - ADOPTION OF TEMPORARY RULE

EFFECTIVE DATE: The effective date of the temporary rule is **July 1, 2011**.

AUTHORITY: In compliance with Sections 67-5226, Idaho Code, notice is hereby given this agency has adopted a temporary rule. The action is authorized by Sections 56-202(b), 56-203(g), 56-203(i), 56-250 through 56-257, Idaho Code; also the Patient Protection and Affordable Care Act (Affordable Care Act), P.L. 111-148 (amended Title XIX (Medicaid) of the Social Security Act).

DESCRIPTIVE SUMMARY: The following is the required finding and concise statement of its supporting reasons for adopting a temporary rule:

The federal Affordable Care Act of 2010 requires all state Medicaid programs to cover smoking cessation products for children and pregnant women. This rulemaking aligns this chapter of rules with federal law by adding exemptions for children and pregnant women to the rule that excludes coverage of smoking cessation products.

TEMPORARY RULE JUSTIFICATION: Pursuant to Section 67-5226(1)(b), Idaho Code, the Governor has found that temporary adoption of the rule is being done to comply with deadlines in amendments to governing law or federal programs, in particular, the federal Affordable Care Act (P.L. 111-148).

FEE SUMMARY: Pursuant to Section 67-5226(2), the Governor has found that the fee or charge being imposed or increased is justified and necessary to avoid immediate danger and the fee is described herein: N/A

FISCAL IMPACT: The following is a specific description, if applicable, of any fiscal impact on the state general fund greater than ten thousand dollars (\$10,000) during the fiscal year.

The total projected budget impact is \$11,114 (\$3,330 in state funds and \$7,784 in federal funds) for SFY 2012. Any savings from reduced health care costs due to a reduction in smoking related illnesses are not incorporated into this fiscal impact statement.

ASSISTANCE ON TECHNICAL QUESTIONS: For assistance on technical questions concerning the temporary rule, contact Matt Wimmer at (208) 364-1989.

DATED this 7th day of December, 2011.

Tamara Prisock DHW - Administrative Procedures Section 450 W. State Street - 10th Floor P.O. Box 83720 Boise, ID 83720-0036 (208) 334-5564 phone; (208) 334-6558 fax dhwrules@dhw.idaho.gov e-mail

HEALTH & WELFARE COMMITTEE

THE FOLLOWING IS THE TEMPORARY TEXT OF DOCKET NO. 16-0309-1201

662. PRESCRIPTION DRUGS: COVERAGE AND LIMITATIONS.

01. General Drug Coverage. The Department will pay for those prescription drugs not excluded by Subsection 662.04 of these rules which are legally obtainable by the order of a licensed prescriber whose licensing allows for the prescribing of legend drugs, as defined under Section 54-1705(28), Idaho Code, and which are deemed medically necessary as defined in Section 011 of these rules. (3-30-07)

02. Dispensing Fee. Dispensing Fee is defined as the cost of filling a prescription including direct pharmacy overhead and is one (1) of two (2) types: (3-30-07)

a. Regular Dose Fee. For services pertaining to the usual practice of pharmacy, including but not limited to: (3-30-07)

i. Interpretation, evaluation, compounding, and dispensing of prescription drug (3-30-07)

ii.	Participation in drug selection;	(3-30-07)
iii.	Drug administration;	(3-30-07)
iv.	Drug regimen and research reviews;	(3-30-07)
v.	Proper storage of drugs;	(3-30-07)
vi.	Maintenance of proper records;	(3-30-07)
vii.	Prescriber interaction; and	(3-30-07)
viii.	Patient counseling.	(3-30-07)

b. Unit Dose Fee. Unit-dose dispensing is defined as a system of providing individually sealed and appropriately labeled unit dose medication that ensures no more than a twenty-four (24) hour supply in any participant's drug tray at any given time. These drug trays, which contain a twenty-four (24) hour supply of medication, must be delivered to the facility at a minimum of five (5) days per week. (3-30-07)

03. Limitations on Payment. Medicaid payment for prescription drugs will be limited (3-30-07)

a. Days' Supply. Medicaid will not cover any days' supply of prescription drugs that

exceeds the quantity or dosage allowed by these rules.

(3-30-07)

b. Brand Name Drugs. Medicaid will not pay for a brand name product that is part of the federal upper limit (FUL) or state maximum allowable cost (SMAC) listing when the physician has not specified the brand name drug to be medically necessary. (3-30-07)

c. Medication for Multiple Persons. When the medication dispensed is for more than one (1) person, Medicaid will only pay for the amount prescribed for the person or persons covered by Medicaid. (3-30-07)

d. No Prior Authorization. Medicaid will not pay for a covered drug or pharmacy item that requires, but has not received, prior authorization for Medicaid payment as required in Section 663 of these rules. (3-30-07)

e. Limitations to Discourage Waste. Medicaid may conduct drug utilization reviews and impose limitations for participants whose drug utilization exceeds the standard participant profile or disease management guidelines determined by the Department. (3-30-07)

04. Excluded Drug Products. The following categories and specific products are excluded from coverage by Medicaid: (3-30-07)

a. Non-Legend Medications. Federal legend medications that change to non-legend status, as well as their therapeutic equivalents regardless of prescription, status unless: (3-30-07)

i. They are included in Subsection 662.05.b. of these rules; or (3-30-07)

ii. The Director determines that non-legend drug products are covered based upon appropriate criteria including the following: safety, effectiveness, clinical outcomes of the drug in comparison with other therapeutically interchangeable alternative drugs, cost, and the recommendation of the Pharmacy And Therapeutics Committee. Therapeutically interchangeable is defined in Subsection 663.01.e. of these rules. (3-30-07)

b. Legend Drugs. Any legend drugs for which federal financial participation is not (3-30-07)

c. Diet Supplements. Diet supplements and weight loss products, except lipase inhibitors when prior authorized as outlined in Section 663 of these rules. (3-30-07)

d. Amphetamines and Related Products. Amphetamines and related products for cosmetic purposes or weight loss. Amphetamines and related products which are deemed to be medically necessary may be covered if prior authorized as outlined in Section 663 of these rules. (3-30-07)

(3-30-07)

e. Ovulation/Fertility Drugs. Ovulation stimulants, fertility drugs, and similar (3-30-07)

f. Impotency Aids. Impotency aids, either as medication or prosthesis. (3-30-07)

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g. Tobacco Cessation Products. Nicotine chewing gum, sprays, inhalers, transdermal patches and related products, with the exception that both legend and non-legend tobacco cessation products will be covered for children and pregnant women when prescribed by their physician. (3-30-07)(7-1-11)T

h. Medications Utilized for Cosmetic Purposes. Medications utilized for cosmetic purposes or hair growth. Prior authorization may be granted for these medications if the Department finds other medically necessary indications. (3-30-07)

i. Vitamins. Vitamins unless included in Subsection 662.05.a. of these rules.

(3-30-07)

j. Dual Eligibles. Drug classes covered under Medicare, Part D, for Medicaid participants who are also eligible for Medicare. (3-30-07)

05. Additional Covered Drug Products. Additional drug products will be allowed as (3-30-07)

a.	Therapeutic Vitamins.	Therapeutic vitamins may include:	(3-30-07)
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- i. Injectable vitamin B12 (cyanocobalamin and analogues); (3-30-07)
- ii. Vitamin K and analogues; (3-30-07)
- iii. Pediatric legend vitamin-fluoride preparations; (3-30-07)
- iv. Legend prenatal vitamins for pregnant or lactating women; (3-30-07)
- v. Legend folic acid; (3-30-07)

vi. Oral legend drugs containing folic acid in combination with Vitamin B12 and/or iron salts, without additional ingredients; $\frac{and}{(3-30-07)(7-1-11)T}$

vii. Legend vitamin D and analogues-; and (3-30-07)(7-1-11)T viii. Legend smoking cessation products for children and pregnant women. (7-1-11)T Prescriptions for Nonlegend Products. Prescriptions for nonlegend products may b. include: (3-30-07)i. Insulin; (3-30-07)Disposable insulin syringes and needles; ii. (3-30-07)iii. Oral iron salts; and (3-30-07)(7-1-11)T Permethrin-; and (3-30-07)(7-1-11)T iv.

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v. <u>Smoking cessation products for children and pregnant women.</u> (7-1-11)T

06. Limitation of Quantities. Medication refills provided before at least seventy-five percent (75%) of the estimated days' supply has been utilized are not covered, unless an increase in dosage is ordered. Days' supply is the number of days a medication is expected to last when used at the dosage prescribed for the participant. No more than a thirty-four (34) days' supply of continuously required medication is to be purchased in a calendar month as a result of a single prescription with the following exceptions: (3-30-07)

a. Doses of Medication. Up to one hundred (100) doses of medication may be dispensed, not to exceed a one hundred (100) day supply for: (3-30-07)

i.	Cardiac glycosides;	(3-30-07)
ii.	Thyroid replacement hormones;	(3-30-07)
iii.	Prenatal vitamins;	(3-30-07)
iv.	Nitroglycerin products - oral or sublingual;	(3-30-07)
v.	Fluoride and vitamin/fluoride combination products; and	(3-30-07)
vi.	Nonlegend oral iron salts.	(3-30-07)

b. Oral Contraceptive Products. Oral contraceptive products may be dispensed in a quantity sufficient for one (1), two (2), or three (3) cycles. (3-30-07)