Dear Senators HEIDER, Souza, Jordan, and Representatives WOOD, Packer, Chew:

The Legislative Services Office, Research and Legislation, has received the enclosed rules of the Department of Health and Welfare: IDAPA 16.03.09 - Medicaid Basic Plan Benefits - Proposed Rule (Docket No. 16-0309-1801); IDAPA 16.03.09 - Medicaid Basic Plan Benefits - Proposed Rule (Docket No. 16-0309-1804); IDAPA 16.03.09 - Medicaid Basic Plan Benefits - Proposed Rule (Docket No. 16-0309-1805); IDAPA 16.03.09 - Medicaid Basic Plan Benefits - Proposed Rule (Docket No. 16-0309-1805);

Pursuant to Section 67-454, Idaho Code, a meeting on the enclosed rules may be called by the cochairmen or by two (2) or more members of the subcommittee giving oral or written notice to Research and Legislation no later than fourteen (14) days after receipt of the rules' analysis from Legislative Services. The final date to call a meeting on the enclosed rules is no later than 11/13/2018. If a meeting is called, the subcommittee must hold the meeting within forty-two (42) days of receipt of the rules' analysis from Legislative Services. The final date to hold a meeting on the enclosed rules is 12/12/2018.

The germane joint subcommittee may request a statement of economic impact with respect to a proposed rule by notifying Research and Legislation. There is no time limit on requesting this statement, and it may be requested whether or not a meeting on the proposed rule is called or after a meeting has been held.

To notify Research and Legislation, call 334-4854, or send a written request to the address on the memorandum attached below.



# Legislative Services Office Idaho State Legislature

Eric Milstead Director Serving klaho's Citizen Legislature

# MEMORANDUM

# **TO:** Rules Review Subcommittee of the Senate Health & Welfare Committee and the House Health & Welfare Committee

**FROM:** Principal Legislative Drafting Attorney - Elizabeth Bowen

**DATE:** October 24, 2018

SUBJECT: Department of Health and Welfare

IDAPA 16.03.09 - Medicaid Basic Plan Benefits - Proposed Rule (Docket No. 16-0309-1801)

IDAPA 16.03.09 - Medicaid Basic Plan Benefits - Proposed Rule (Docket No. 16-0309-1804)

IDAPA 16.03.09 - Medicaid Basic Plan Benefits - Proposed Rule (Docket No. 16-0309-1805)

IDAPA 16.03.09 - Medicaid Basic Plan Benefits - Proposed Rule (Docket No. 16-0309-1806)

# Summary and Stated Reasons for the Rule

Docket No. 16-0309-1801: This rule allows critical access hospitals to provide necessary care for individuals on Medicaid who require skilled nursing services but do not live near a skilled nursing facility. Enabling such individuals to receive care closer to home will keep them near their families and social support networks, helping them to maintain a greater quality of life and recover more quickly.

Docket No. 16-0309-1804: This rule modernizes rules regarding laboratory and radiology services for Medicaid recipients, which have not been updated since 2007. Clarification regarding coverage of such services is included in the new language.

Docket No. 16-0309-1805: This rule establishes an open enrollment process during which Medicaid recipients in the Healthy Connections Program may change their primary care provider at will. Currently, recipients may change their primary care provider at any time. The purpose for the rule change is to encourage the establishment of a medical home by the recipient.

Docket No. 16-0309-1806: This rule concerns medication pharmacy coverage under Idaho's Medicaid pharmacy program. The rule clarifies that drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not covered by Medicaid. Investigational drugs are also not covered. The rule updates other coverage rules as well.

# **Negotiated Rulemaking / Fiscal Impact**

Docket No. 16-0309-1801 (critical access hospitals): Negotiated rulemaking was conducted. There is no anticipated negative fiscal impact on the state general fund.

Docket No. 16-0309-1804 (laboratory and radiology services): Negotiated rulemaking was conducted. There is no anticipated negative fiscal impact on the state general fund.

Kristin Ford, Manager	Paul Headlee, Manager	April Renfro, Manager	Glenn Harris, Manager
Research & Legislation	Budget & Policy Analysis	Legislative Audits	Information Technology
Statehouse, P.O. Box 83720 Boise, Idaho 83720–0054			Tel: 208–334–2475 www.legislature.idaho.gov

Docket No. 16-0309-1805 (open enrollment): Negotiated rulemaking was conducted. There is no anticipated negative fiscal impact on the state general fund.

Docket No. 16-0309-1806 (pharmacy coverage): Negotiated rulemaking was conducted. There is no anticipated negative fiscal impact on the state general fund.

# **Statutory Authority**

Docket No. 16-0309-1801 (critical access hospitals): I.C. 56-202.

Docket No. 16-0309-1804 (laboratory and radiology services): I.C. 56-202.

Docket No. 16-0309-1805 (open enrollment): I.C. 56-202.

Docket No. 16-0309-1806 (pharmacy coverage): I.C. 56-202.

cc: Department of Health and Welfare

Frank Powell and Trinette Middlebrook

# \*\*\* PLEASE NOTE \*\*\*

Per the Idaho Constitution, all administrative rules must be reviewed by the Legislature during the next legislative session. The Legislature has 3 options with this rulemaking docket: 1) Approve the docket in its entirety; 2) Reject the docket in its entirety; or 3) Reject the docket in part.

# IDAPA 16 – DEPARTMENT OF HEALTH AND WELFARE

# 16.03.09 – MEDICAID BASIC PLAN BENEFITS

# DOCKET NO. 16-0309-1801

# NOTICE OF RULEMAKING - PROPOSED RULE

**AUTHORITY:** In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 56-202(b), Idaho Code.

PUBLIC HEARING SCHEDULE: A public hearing concerning this rulemaking will be held as follows:

PUBLIC HEARING
Friday, October 26, 2018 - 9:00 a.m. (MDT)
Department of Health & Welfare
Medicaid Central Office
3232 Elder Street
Conference Room D-East
<b>Boise, ID 83705</b>
TELECONFERENCE CALL-IN
Toll Free: 1-877-820-7831
Participant Code: 701700

The hearing site 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 a nontechnical explanation of the substance and purpose of the proposed rulemaking:

Some rural communities in Idaho do not have local skilled nursing facilities. When individuals from those communities need skilled nursing services, they are placed in skilled nursing facilities that are up to 50 miles away from where they and their families live, limiting access to support networks that significantly contribute to their recovery and quality of life. These rule changes will allow eligible Critical Access Hospitals to designate additional acute care beds as swings beds to provide necessary care for individuals, without having to place them in facilities outside of their community and away from their support system. These rules would only apply to those Critical Access Hospitals, who do not have a skilled nursing facility within 35 miles of their facility, and have been approved by Medicare to offer swing-beds.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: N/A

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

The fiscal impact in SFY2020 of allowing Critical Access Hospitals who meet the special requirements to request additional swing-bed days from the Department would be a savings of \$87 per person, per day. The savings to the state general fund would be \$25 per person, per day, and the Federal savings would be \$62 per person, per day. This rule change would only allow those Critical Access Hospitals who do not have nursing facilities in their communities to provide additional hospital swing beds that provide the level of care that individuals need to receive care in their local communities.

**NEGOTIATED RULEMAKING:** Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules – Negotiated Rulemaking was published in the June 6, 2018, Idaho Administrative Bulletin, Vol. 18-6, pages 55 and 56.

**INCORPORATION BY REFERENCE:** No materials are being incorporated by reference in this rulemaking.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact William Deseron at (208) 287-1179.

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 October 26, 2018.

Dated this 31st day of August, 2018.

Tamara Prisock DHW – Administrative Rules Unit 450 W. State Street – 10th Floor P.O. Box 83720 Boise, ID 83720-0036 Phone: (208) 334-5500 Fax: (208) 334-6558 **dhwrules@dhw.idaho.gov** 

#### THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 16-0309-1801 (Only Those Sections With Amendments Are Shown.)

#### 405. INPATIENT HOSPITAL SERVICES: PROVIDER REIMBURSEMENT.

Under the Medicaid provisions of the Social Security Act, in reimbursing hospitals, the Department will pay the lesser of customary hospital charges or the reasonable cost of inpatient services in accordance with the procedures detailed under this Section of rule. The upper limits observed by the Department in reimbursing each individual hospital must not exceed the payment that would be determined as a reasonable cost under the policies, definitions and procedures observed under Medicare (Title XVIII) principles of cost reimbursement. (3-30-07)

**01. Exemption of New Hospitals.** A hospital that has operated as the type of facility for which it is certified (or the equivalent thereof) under present and previous ownership for less than three (3) full years will be paid in accordance with the Title XVIII principles of reasonable cost reimbursement, including those provisions applicable to new providers for the carryover and recovery of unreimbursed costs, in accordance with 42 CFR Section 413.64.

(3-30-07)

02. Medicaid Inpatient Operating Cost Limits. The following describe the determination of inpatient operating cost limits. (3-30-07)

**a.** Medicaid Cost Limits for Dates of Service Prior to a Current Year. The reimbursable reasonable costs for services rendered prior to the beginning of the principal year, but included as prior period claims in a subsequent period's cost report, will be subject to the same operating cost limits as the claims under settlement.

(3-30-07)

**b.** Application of the Medicaid Cost Limit. In the determination of a hospital's reasonable costs for inpatient services rendered after the effective date of a principal year, a hospital inflation index, computed for each hospital's fiscal year end, will be applied to the operating costs, excluding capital costs and other allowable costs as defined for the principal year and adjusted on a per diem basis for each subsequent year under the hospital inflation index. (7-1-18)

i. Each inpatient routine service cost center, as reported in the finalized principal year end Medicare

DEPARTMENT OF HEALTH AND WELFARE	
Medicaid Basic Plan Benefits	

cost report, will be segregated in the Medicaid cost limit calculation and assigned a share of total Medicaid inpatient ancillary costs. The prorated ancillary costs will be determined by the ratio of each Medicaid routine cost center's reported costs to total Medicaid inpatient routine service costs in the principal year. (3-30-07)

ii. Each routine cost center's total Medicaid routine service costs plus the assigned share of Medicaid inpatient ancillary costs of the principal year will be divided by the related Medicaid patient days to identify the total costs per diem in the principal year. (3-30-07)

(1) The related inpatient routine service cost center's per diem capital and graduate medical education costs plus the prorated share of inpatient ancillary capital costs will be subtracted from the per diem amount identified in Subsection 405.02.b.ii. of this rule to identify each inpatient routine service cost center per diem cost limit in the principal year. (3-30-07)

(2) If a provider did not have any Medicaid inpatient utilization or render any Medicaid inpatient services in an individual inpatient routine service cost center in the fiscal year serving as the principal year, the principal year for only those routine cost centers without utilization in the provider's principal year will be appropriately calculated using the information available in the next subsequent year in which Medicaid utilization occurred. (3-30-07)

iii. Each routine cost center's cost per diem for the principal year will be multiplied by the hospital inflation index for each subsequent fiscal year. (7-1-18)

iv. The sum of the per diem cost limits for the Medicaid inpatient routine service cost centers of a hospital during the principal year, as adjusted by the hospital inflation index, will be the Medicaid cost limit for operating costs in the current year. (7-1-18)

(1) At the date of final settlement, reimbursement of the Medicaid current year inpatient routine cost centers plus the assigned ancillary costs will be limited to the total per diem operating costs as adjusted for each subsequent fiscal year after the principal year through the current year by the hospital inflation cost index. (7-1-18)

(2) Providers will be notified of the estimated inflation index periodically or hospital inflation index (CMS Market Basket Index) prior to final settlement only upon written request. (7-1-18)

03. Adjustments to the Medicaid Cost Limit. A hospital's request for review by the Department concerning an adjustment to or exemption from the cost limits imposed under the provisions set forth in Section 405 of this chapter of rules, must be granted under the following circumstances: (3-30-07)

a. Adjustments. Because of Extraordinary Circumstances. Where a provider's costs exceed the Medicaid limit due to extraordinary circumstances beyond the control of the provider, the provider can request an adjustment to the cost limit to the extent the provider proves such higher costs result from the extraordinary circumstances including, but not limited to, increased costs attributable to strikes, fires, earthquake, flood, or similar, unusual occurrences with substantial cost effects. (3-30-07)

**b.** Reimbursement to Public Hospitals. A public hospital that provides services free or at a nominal charge, which is less than, or equal to fifty percent (50%) of its total allowable costs, will be reimbursed at the same rate that would be used if the hospital's charges were equal to, or greater than, its costs. (7-1-18)

**c.** Adjustment to Cost Limits. A hospital is entitled to a reasonable increase in its Medicaid cost limits if the hospital shows that its per diem costs of providing services have increased due to increases in case- mix, the adoption of new or changed services, the discontinuation of services or decrease in average length of stay for Medicaid inpatients since the principal year. Any hospital making such showing is entitled to an increase commensurate with the increase in per diem costs. (7-1-18)

i. The Medicaid operating cost limit may be adjusted by multiplying cost limit by the ratio of the current year's case-mix index divided by the principal year's case-mix index. (7-1-18)

ii. The contested case procedure set forth in IDAPA 16.05.03, "Rules Governing Contested Case

Proceedings and Declaratory Rulings," is available to larger hospitals seeking such adjustments to their Medicaid cost limits. (7-1-18)

**d.** Adjustment to the Proration of Ancillary Costs in the principal year. Where the provider asserts that the proration of ancillary costs does not adequately reflect the total Medicaid cost per diem calculated for the inpatient routine service cost centers in the principal year, the provider may submit a detailed analysis of ancillary services provided to each participant for each type of patient day during each participant's stay during the principal year. The provider will be granted this adjustment only once upon appeal for the first cost reporting year that the limits are in effect. (3-30-07)

**04. Payment Procedures**. The following procedures are applicable to in-patient hospitals: (3-30-07)

a. The participant's admission and length of stay is subject to prior authorization, concurrent review, continued stay review, and retrospective review by a Quality Improvement Organization (QIO) designated by the Department. QIO review will be governed by provisions of the QIO Idaho Medicaid Provider Manual as amended. If a review identifies that an admission or continued stay is not medically necessary, then no Medicaid payment will be made. Failure to obtain a timely QIO review as required by Section 402 of this chapter of rules, and as outlined in the QIO Idaho Medicaid Provider Manual as amended, will result in the QIO conducting a late review. After a QIO review has determined that the hospital stay was medically necessary, Medicaid will assess a late review penalty to the hospital as outlined in Section 405 of this rule. (7-1-18)

i. All admissions are subject to QIO review to determine if continued stay in inpatient status is medically necessary. A QIO continued stay review is required when the participant's length of stay exceeds the number of days certified by the QIO. If no initial length of stay certification was issued by the QIO, a QIO continued stay review is required when the admission exceeds a number of days as specified by the Department. (3-30-07)

ii. Reimbursement for services originally identified as not medically necessary by the QIO will be made if such decision is reversed by the appeals process required in IDAPA 16.05.03, "Rules Governing Contested Case Proceedings and Declaratory Rulings." (3-30-07)

iii. Absent the Medicaid participant's informed decision to incur services deemed unnecessary by the QIO, or not authorized by the QIO due to the negligence of the provider, no payment for denied services may be obtained from the participant. (3-30-07)

**b.** In reimbursing licensed hospitals, the Department will pay the lesser of customary hospital charges or the reasonable cost of semi-private rates for in-patient hospital care as set forth in this rule, unless an exception applies as stated in Section 402 of these rules. The upper limits for payment must not exceed the payment which would be determined as reasonable cost using the Title XVIII standards and principles. (3-30-07)

#### 05. Hospital Penalty Schedule.

**a.** A request for a preadmission and/or continued stay QIO review that is one (1) day late will result in a penalty of two hundred and sixty dollars (\$260), from the total Medicaid paid amount of the inpatient hospital stay. (3-30-07)

**b.** A request for a preadmission and/or continued stay QIO review that is two (2) days late will result in a penalty of five hundred and twenty dollars (\$520), from the total Medicaid paid amount of the inpatient hospital stay. (3-30-07)

**c.** A request for a preadmission and/or continued stay QIO review that is three (3) days late will result in a penalty of seven hundred and eighty dollars (\$780), from the total Medicaid paid amount of the inpatient hospital stay. (3-30-07)

**d.** A request for a preadmission and/or continued stay QIO review that is four (4) days late will result in a penalty of one thousand and forty dollars (\$1,040), from the total Medicaid paid amount of the inpatient hospital stay. (3-30-07)

(3-30-07)

e. A request for a preadmission and/or continued stay QIO review that is five (5) days late or greater will result in a penalty of one thousand three hundred dollars (\$1,300), from the total Medicaid paid amount of the inpatient hospital stay. (3-30-07)

**06. AND Reimbursement Rate**. Reimbursement for an AND will be made at the weighted average Medicaid payment rate for all Idaho nursing facilities for routine services, as defined per 42 CFR 447.280(a)(1), furnished during the previous calendar year. ICF/ID rates are excluded from this calculation. (3-30-07)

a. The AND reimbursement rate will be calculated by the Department by March 15 of each calendar year and made effective retroactively for dates of service on or after January 1 of the respective calendar year.

(3-30-07)

**b.** Hospitals with an attached nursing facility will be reimbursed the lesser of their Medicaid per diem routine rate or the established average rate for an AND; and (3-30-07)

**c.** The Department will pay the lesser of the established AND rate or a facility's customary hospital charge to private pay patients for an AND. (3-30-07)

07. Reimbursement for Services. Routine services as addressed in Subsection 405.08 of this rule include all medical care, supplies, and services which are included in the calculation of nursing facility property and non-property costs as described in these rules. Reimbursement of ancillary services will be determined in the same manner as hospital outpatient reasonable costs in accordance with Medicare reasonable cost principles, except that reimbursement for prescription drugs will be in accord with Section 665 of these rules. (3-30-07)

**08. Hospital Swing-Bed Reimbursement**. The Department will pay for nursing facility care in certain rural hospitals. Following approval by the Department, such hospitals may provide service to participants in licensed hospital ("swing-beds") *beds* who require nursing facility level of care. (3-30-07)(\_\_\_\_)

**a.** Facility Requirements. The Department will approve hospitals for nursing facility care provided to eligible participants under the following conditions: (3-30-07)

i. The Department's Licensure and Certification Section finds the hospital in conformance with the requirements of 42 CFR 482.58 "Special Requirements" for hospital providers of long-term care services ("swing-beds"), or 42 CFR 485.645 – Special requirements for CAH providers of long-term services ("swing-beds") as applicable; and (3.30.07)(\_\_\_\_)

ii. The hospital is approved by the Medicare program for the provision of "swing-bed" services; and (3-30-07)

iii. The facility does not have a twenty-four (24) hour nursing waiver granted under 42 CFR 488.54(c); (3-30-07)

iv. The hospital must not have had a swing-bed approval terminated within the two (2) years previous to application for swing-bed participation; and (3-30-07)

v. The hospital must be licensed for less than one hundred (100) beds as defined by 42 CFR 482.58(a)(1) for swing-bed purposes; and (3-30-07)

vi. Nursing facility services in swing-beds must be rendered in beds used interchangeably to furnish hospital or nursing facility-type services. (3-30-07)

**b.** Participant Requirements. The Department will reimburse hospitals for participants under the following conditions: (3-30-07)

i. The participant is determined to be entitled to such services in accordance with IDAPA 16.03.05, "Rules Governing Eligibility for Aid to the Aged, Blind, and Disabled"; and (3-30-07) ii. The participant is authorized for payment in accordance with IDAPA 16.03.10, "Medicaid Enhanced Plan Benefits," Subsection 222.02. (3-30-07)

c. Reimbursement for "Swing-Bed" Patient Days. The Department will reimburse swing-bed hospitals on a per diem basis utilizing a rate established as follows: (3-30-07)

i. Payment rates for routine nursing facility services will be at the weighted average Medicaid rate per patient day paid to hospital-based nursing facility/ICF facilities for routine services furnished during the previous calendar year. ICF/ID facilities' rates are excluded from the calculations. (3-30-07)

ii. The rate will be calculated by the Department by March 15 of each calendar year. The rate will be based on the previous calendar year and effective retroactively for dates of service on or after January 1 of the respective year. (3-30-07)

iii. The weighted average rate for nursing facility swing-bed days will be calculated by dividing total payments for routine services, including patient contribution amounts but excluding miscellaneous financial transactions relating to prior years, by total patient days for each respective level of care occurring in the previous calendar year. (3-30-07)

iv. Routine services include all medical care, supplies, and services which are included in the calculation of nursing facility property and nonproperty costs as described in IDAPA 16.03.10, "Medicaid Enhanced Plan Benefits," Subsection 225.01. (3-30-07)

v. The Department will pay the lesser of the established rate, the facility's charge, or the facility's charge to private pay patients for "swing-bed" services. (3-30-07)

vi. Reimbursement of ancillary services not included in the nursing facility rates furnished for extended care services will be billed and determined in the same manner as hospital outpatient reasonable costs in accordance with Medicare reasonable cost principles, except that reimbursement for prescription drugs will be in accord with Section 665 of these rules. (3-30-07)

vii. The number of swing-bed days that may be reimbursed to a provider in a twelve (12) month period will be limited to the greater of one thousand ninety\_five (1,095) days which may be prorated over a shorter fiscal period or, fifteen percent (15%) of the product of the average number of available licensed beds in the hospital in the period and the number of days in the fiscal period. The Department may authorize additional critical access hospital swing-bed days for participants residing in a community without a nursing facility within thirty-five (35) miles contingent on a review of medical necessity, cost-effectiveness, residency, and quality of care. (3-30-07)(

**d.** Computation of "Swing-Bed" Patient Contribution. The computation of the patient's contribution of swing-bed payment will be in accordance with IDAPA 16.03.10, "Medicaid Enhanced Plan Benefits," Section 224. (3-30-07)

**09.** Adjustment for Disproportionate Share Hospitals (DSH). All Idaho hospitals serving a disproportionate share of low income patients must qualify either as a Mandatory DSH or as Deemed DSH to receive a DSH payment. (3-29-10)

a. DSH Survey Requirements. The Department will send each hospital a DSH survey on or before January 31 of each calendar year. The DSH survey must be returned to the Department on or before May 31 of the same calendar year. A hospital will not receive a DSH payment if the survey is not returned by the deadline, unless good cause is determined by the Department. No later than July 15 of each calendar year, the Department must notify each hospital of their calculated DSH payment and notify each hospital of its preliminary calculated distribution amount. A hospital may file an amended survey to complete, correct, or revise the original DSH survey by submitting the amended survey and supporting documentation to the Department no later than thirty (30) days after the notice of the preliminary DSH calculation is mailed to the hospital. The state's annual DSH allotment payment will be made by September 30 of the same calendar year based on the final DSH surveys and Department data. (3-30-07)

**b.** Mandatory Eligibility. Mandatory Eligibility for DSH status will be provided for hospitals which:

#### (3-30-07)

i. Meet or exceed the disproportionate share threshold as defined in Subsection 400.13 of these rules. (3-30-07)

ii. Have at least two (2) obstetricians with staff privileges at the hospital who have agreed to provide obstetric services. (3-29-10)

(1) Subsection 405.09.b.ii. of this rule does not apply to a hospital in which the inpatients are predominantly individuals under eighteen (18) years of age; or (3-30-07)

(2) Does not offer nonemergency inpatient obstetric services as of December 21, 1987. (3-30-07)

iii. The MUR will not be less than one percent (1%). (3-30-07)

iv. If an Idaho hospital exceeds both disproportionate share thresholds, as described in Subsection 400.13 of these rules, and the criteria of Subsections 405.09.b.ii. and 405.09.b.iii. of this rule are met, the payment adjustment will be the greater of the amounts calculated using the methods identified in Subsections 405.09.b.vi. through 405.09.b.x. of this rule. (3-29-10)

v. Hospitals qualifying for Mandatory DSH eligibility with Medicaid Inpatient Utilization Rates equal to or exceeding one (1) standard deviation and less than one and one-half (1 1/2) standard deviations above the mean of all Idaho hospitals will receive a DSH payment equal to two percent (2%) of the payments related to the Medicaid inpatient days included in the MUR computation. (3-30-07)

vi. Hospitals qualifying for Mandatory DSH eligibility with Medicaid Inpatient Utilization Rates equal to or exceeding one and one-half  $(1 \ 1/2)$  standard deviations and less than two (2) standard deviations of the mean of all Idaho hospitals will receive a DSH payment equal to four percent (4%) of the payments related to the Medicaid inpatient days included in the MUR computation. (3-30-07)

vii. Hospitals qualifying for Mandatory DSH eligibility with Medicaid Inpatient Utilization Rates exceeding two (2) standard deviations of the mean of all Idaho hospitals will receive a DSH payment equal to six percent (6%) of the payments related to the Medicaid inpatient days included in the MUR computation. (3-30-07)

viii. Hospitals qualifying for Mandatory DSH eligibility with Low Income Utilization Rates equal to or exceeding twenty-five percent (25%) will receive a DSH payment equal to four percent (4%) of the payments related to the Medicaid inpatient days included in the MUR computation. (3-30-07)

ix. Hospitals qualifying for Mandatory DSH eligibility with Low Income Utilization Rates equal to, or exceeding, thirty percent (30%) will receive a DSH payment equal to six percent (6%) of the payments related to the Medicaid inpatient days included in the MUR computation. (3-30-07)

**c.** Deemed Disproportionate Share Hospital (DSH). All hospitals in Idaho which have inpatient utilization rates of at least one percent (1%) only in Idaho inpatient days, and meet the requirements unrelated to patient day utilization specified in Subsection 405.09.b. of this rule, will be designated a Deemed Disproportionate Share Hospital. The disproportionate share payment to a Deemed DSH hospital will be the greater of: (3-29-10)

i. Five dollars (\$5) per Idaho Medicaid inpatient day included in the hospital's MUR computation; or (3-30-07)

ii. An amount per Medicaid inpatient day used in the hospital's MUR computation that equals the DSH allotment amount, less the Mandatory DSH payment amount, divided by the number of Medicaid inpatient days used in the MUR computation for all Idaho DSH hospitals. (3-30-07)

**d.** Insufficient DSH Allotment Amounts. When the DSH allotment amount is insufficient to make the aggregate amount of DSH payments to each DSH hospital, payments to each hospital will be reduced by the percentage by which the DSH allotment amount was exceeded. (3-30-07)

e. DSH Payments Will Not Exceed Costs. A DSH payment will not exceed the costs incurred during the year of furnishing services to individuals who are either eligible for medical assistance under the State Plan or were uninsured for health care services provided during the year. (3-30-07)

i. Payments made to a hospital for services provided to indigent patients by a state or a unit of local government within a state will not be considered a source of third party payment. (3-30-07)

ii. Claims of uninsured costs which increase the maximum amount which a hospital may receive as a DSH payment must be documented. (3-30-07)

**f.** DSH Will be Calculated on an Annual Basis. A change in a provider's allowable costs as a result of a reopening or appeal will not result in the recomputation of the provider's annual DSH payment. (3-30-07)

**g.** To the extent that audit findings demonstrate that DSH payments exceed the documented hospital specific cost limits, the Department will collect overpayments and redistribute DSH payments. (4-7-11)

i. If at any time during an audit the Department discovers evidence suggesting fraud or abuse by a provider, that evidence, in addition to the Department's final audit report regarding that provider, will be referred to the Medicaid Fraud Unit of the Idaho Attorney General's Office. (4-7-11)

ii. The Department will submit an independent certified audit to CMS for each completed Medicaid State plan rate year, consistent with 42 CFR Part 455, Subpart D, "Independent Certified Audit of State Disproportionate Share Hospital Payment Adjustments." (4-7-11)

iii. Beginning with FFY 2011, if based on the audit of the DSH allotment distribution, the Department determines that there was an overpayment to a provider, the Department will immediately: (4-7-11)

(1) Recover the overpayment from the provider; and (4-7-11)

(2) Redistribute the amount in overpayment to providers that had not exceeded the hospital-specific upper payment limit during the period in which the DSH payments were determined. The payments will be subject to hospital-specific upper payment limits. (4-7-11)

iv. Disproportionate share payments must not exceed the DSH state allotment, except as otherwise required by the Social Security Act. In no event is the Department obligated to use State Medicaid funds to pay more than the State Medicaid percentage of DSH payments due a provider. (4-7-11)

#### 10. Out-of-State Hospitals.

a. Cost Settlements for Certain Out-of-State Hospitals. Hospitals not located in the state of Idaho will have a cost settlement computed with the state of Idaho if the following conditions are met: (3-30-07)

i. Total inpatient and outpatient covered charges are more than fifty thousand dollars (\$50,000) in the fiscal year; or (3-30-07)

ii. When less than fifty thousand dollars (\$50,000) of covered charges are billed to the state by the provider, and a probable significant underpayment or overpayment is identifiable, and the amount makes it administratively economical and efficient for cost settlement to be requested by either the provider or the state, a cost settlement will be made between the hospital and the Department. (3-30-07)

**b.** Payment for Hospitals Without Cost Settlement. Those out-of-state hospitals not cost settling with the state will have annually adjusted rates of payment no greater than seventy-five percent (75%) for inpatient covered charges and no greater than eighty percent (80%) of outpatient covered charges or, the Department's established fee schedule for certain outpatient services. These rates represent average inpatient and outpatient reimbursement rates paid to Idaho hospitals. (3-30-07)

(3-30-07)

11. Audit Function. Under a common audit agreement, the Medicare Intermediary may perform any audit required for both Title XVIII and Medicaid purposes. The Department may elect to perform an audit even though the Medicare Intermediary does not choose to audit the facility. (3-30-07)

12. Adequacy of Cost Information. Cost information as developed by the provider must be current, accurate, and in sufficient detail and in such form as needed to support payments made for services rendered to participants. This includes all ledgers, books, reports, records and original evidences of cost (purchase requisitions, purchase orders, vouchers, requisitions for materials, inventories, labor time cards, payrolls, bases for apportioning costs, etc.), which pertain to the determination of reasonable costs, leaving an audit trail capable of being audited. Financial and statistical records will be maintained in a consistent manner from one (1) settlement period to another. (3-30-07)

13. Availability of Records of Hospital Providers. A participating hospital provider of services must make available to the Department in the state in which the facility is licensed, the provider's fiscal and other necessary records for the purpose of determining its ongoing record keeping capability and to ascertain information pertinent to the determination of the proper amount of program payments due the provider. (3-30-07)

14. Interim Cost Settlements. The Department may initiate or a hospital may request an interim cost settlement based on the Medicare cost report as submitted to the Medicare Intermediary. (3-30-07)

**a.** Cost Report Data. Interim settlement cost report data will be adjusted to reflect Medicaid payments and statistical summary reports sent to providers before the filing deadline. (3-30-07)

**b.** Hard Copy of Cost Report. Hospitals which request to undergo interim cost settlement with Idaho Medicaid must submit a hard copy of the Medicare cost report to the Department upon filing with the Intermediary. (3-30-07)

**c.** Limit or Recovery of Payment. The Department may limit a recovery or payment of an interim settlement amount up to twenty-five percent (25%) of the total settlement amount when the cost report information is in dispute. (3-30-07)

15. Notice of Program Reimbursement. Following receipt of the finalized Medicare cost report and the timely receipt of any other information requested by the Department to fairly cost settle with the provider, a certified letter with the return receipt requested will be sent to the provider which sets forth the amounts of underpayment or overpayment made to the provider. The notice of the results of the final retroactive adjustment will be sent even though the provider intends to request a hearing on the determination, or has appealed the Medicare Intermediary's determination of cost settlement. Where the determination shows that the provider is indebted to the Medicaid program because total interim and other payments exceed cost limits, the state will take the necessary action to recover overpayment, including the suspension of interim payments sixty (60) days after the provider's receipt of the notice. Such action of recovery or suspension will continue even after a request for an informal conference or hearing is filed with the state. If the hearing results in a revised determination, appropriate adjustments will be made to the settlement amount. (3-30-07)

**a.** Timing of Notice. The Department will make every effort to issue a notice of program reimbursement within twelve (12) months of receipt of the cost report from the Medicare Intermediary. (3-30-07)

**b.** Reopening of Completed Settlements. A Medicaid completed cost settlement may be reopened by the provider or the state within a three (3) year period from the date of the letter of notice of program reimbursement. The issues must have been raised, appealed and resolved through the reopening of the cost report by the Medicare Intermediary. Issues previously addressed and resolved by the Department's appeal process are not cause for reopening of the finalized cost settlement. (3-30-07)

16. Nonappealable Items. The formula for the determination of the hospital inflation index, the principles of reimbursement which define allowable cost, non-Medicaid program issues, interim rates which are in compliance with state and federal rules, and the preliminary adjustments prior to final cost settlement determinations as supported by properly completed cost reports and audits must not be accepted as appealable items. (7-1-18)

17. Interim Reimbursement Rates. The interim reimbursement rates are reasonable and adequate to meet the necessary costs which must be incurred by economically and efficiently operated providers which provide services in conformity with applicable state and federal laws, rules, and quality and safety standards. (3-30-07)

a. Annual Adjustments. Interim rates will be adjusted at least annually based on the best information available to the Department. The interim rate will reflect the Medicaid Inpatient Operating Cost Limits used to set inpatient rates and the Reimbursement Floor Percentage. (3-30-07)

**b.** Retrospective Adjustments. Interim rates will not be adjusted retrospectively upon request for rate review by the provider. (3-30-07)

c. Basis for Adjustments. The Department may make an adjustment based on the Medicare cost report as submitted and accepted by the Intermediary after the provider's reporting year to bring interim payments made during the period into agreement with the tentative reimbursable amount due the provider at final settlement. If the settlement amount is equal to or greater than ten percent (10%) of the payments received or paid and equal to or greater than one hundred thousand dollars (100,000), the interim rate will be adjusted to account for half (20,000) of the difference. (3-30-07)

**d.** Unadjusted Rate. The Medicaid interim reimbursement rate on file is synonymous with the term unadjusted rate used by other payors. (3-30-07)

**18.** Audits. All financial reports are subject to audit by Departmental representatives in accordance (3-30-07)

# **IDAPA 16 – DEPARTMENT OF HEALTH AND WELFARE**

# 16.03.09 - MEDICAID BASIC PLAN BENEFITS

# DOCKET NO. 16-0309-1804

# NOTICE OF RULEMAKING - PROPOSED RULE

**AUTHORITY:** In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 56-202(b), Idaho Code.

PUBLIC HEARING SCHEDULE: A public hearing concerning this rulemaking will be held as follows:

PUBLIC HEARING	
Friday, October 26, 2018 - 9:00 a.m. (MDT)	
Department of Health & Welfare Medicaid Central Office 3232 Elder Street Conference Room D-East Boise, ID 83705	
TELECONFERENCE CALL-IN	
Toll Free: 1-877-820-7831 Participant Code: 701700	

The hearing site 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 a nontechnical explanation of the substance and purpose of the proposed rulemaking

Laboratory rules in this chapter haven't been updated since 2007. Laboratory tests have rapidly changed in the past 11 years, and a foundation in rule is needed for Department coverage of these services. A minimum standard will be established with the following changes.

- 1. Ensure that Medicaid providers outside of Idaho maintain the same quality of work and documentation as providers within the state;
- 2. Prevent expenditure of tax payer funds for services that are inaccurate, or for genetic services that could be used for elective abortions;
- 3. Establish authority for prior authorizations to be required by the Department so that delivery of services is consistent with the Department's utilization management as required by CFR; and
- 4. Set minimum requirements for testing coverage.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: N/A

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

There is no anticipated fiscal impact to state general funds, or any other funds as a result of this rulemaking.

**NEGOTIATED RULEMAKING:** Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules – Negotiated Rulemaking was published in the July 4, 2018, Idaho Administrative Bulletin, Vol. 18-7, pages 103 through 104.

**INCORPORATION BY REFERENCE:** No materials are being incorporated by reference in this rulemaking.

**ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS:** For assistance on technical questions concerning the proposed rule, contact William Deseron at (208) 287-1179.

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 October 26, 2018.

Dated this 31st day of August, 2018.

Tamara Prisock DHW – Administrative Rules Unit 450 W. State Street – 10th Floor P.O. Box 83720 Boise, ID 83720-0036 Phone: (208) 334-5500 Fax: (208) 334-6558 **dhwrules@dhw.idaho.gov** 

#### THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 16-0309-1804 (Only Those Sections With Amendments Are Shown.)

# SUB AREA: LABORATORY AND RADIOLOGY SERVICES (Sections 650 - 659)

# 650. LABORATORY AND RADIOLOGY SERVICES: DEFINITIONS.

**01. Independent Laboratory**. A laboratory that is not located in a physician's office, and receives specimens from a source other than another laboratory. A physician is not an independent laboratory.

<u>02.</u> <u>Laboratory or Clinical Laboratory</u>. A facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examinations of material derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease, or the impairment or assessment of human health.

03. Proficiency Testing. Evaluation of a laboratory's ability to perform laboratory procedures within acceptable limits of accuracy through analysis of unknown specimens distributed at periodic intervals.

<u>04.</u> <u>Ouality-Control</u>. A day-to-day analysis of reference materials to ensure reproducibility and accuracy of laboratory results, and includes an acceptable system to assure proper functioning of instruments, equipment and reagents.

025. Reference Laboratory. A laboratory that only accepts specimens from other laboratories and does not receive specimens directly from patients. (3-30-07)(\_\_\_\_\_)

# 651. -- 65<u>32</u>. (RESERVED)

# 653. LABORATORY AND RADIOLOGY SERVICES: COVERAGE AND LIMITATIONS.

01.Medical Necessity Criteria. Services must meet the definition of Medical Necessity in Section011 of these rules as detailed in the Idaho Medicaid Provider Handbook.(\_\_\_\_\_)

02.Prior Authorization of Services. The Department may require prior authorization of any<br/>laboratory or radiology service as detailed in the Idaho Medicaid Provider Handbook.

654. LABORATORY AND RADIOLOGY SERVICES: PROVIDER QUALIFICATIONS AND DUTIES.

Laboratories in a physician's office or a physician's group practice association, except when physicians personally perform their own patients' laboratory tests, must be certified by the Idaho Bureau of Laboratories and be eligible for Medicare certification for participation. All other Idaho laboratories must fulfill these requirements. (3-30-07)

01. Laboratory and Radiology Requirements. Providers of laboratory and radiology services must be eligible for Medicare certification for these services.

02. Use of Reference Laboratories. Laboratories using reference laboratories must ensure that all requirements of Sections 650 through 659 of these rules are met by the reference laboratory. (\_\_\_\_\_)

# 655. LABORATORY AND RADIOLOGY SERVICES: PROVIDER REIMBURSEMENT.

01. Provider of Service. Payment for laboratory tests can only be made to the actual provider of that service. An exception to the preceding is made in the case of:

**a.** *a*<u>A</u>n independent laboratory that can bill for a reference laboratory-: *A physician is not an independent laboratory.* (3-30-07)(\_\_\_\_\_)

**b.** <u>A transplant facility that can bill for histocompatibility testing; and</u> (

**c.** <u>Healthcare professionals acting within the licensure and scope of their practice to comply with</u> IDAPA 16.02.12, "Procedures and Testing to be Performed on Newborn Infants."</u>

042. Tests Performed by or Personally Supervised by a Physician. The payment level for clinical diagnostic laboratory tests performed by or personally supervised by a physician will be at a rate established by the Department that is no higher than Medicare's fee schedule. The payment level for other laboratory tests will be a rate established by the Department. (3-30-07)

023. Tests Performed by an Independent Laboratory. The payment level for clinical diagnostic laboratory tests performed by an independent laboratory will be at a rate established by the Department that is no higher than Medicare's fee schedule. The payment level for other laboratory tests will be at a rate established by the Department. (3-30-07)

034. Tests Performed by a Hospital Laboratory. The payment level for clinical diagnostic laboratory tests performed by a hospital laboratory for anyone who is not an inpatient will be at a rate established by the Department that is no higher than Medicare's fee schedule. The payment level for other laboratory tests will be at a rate established by the Department. (3-30-07)

045. Specimen Collection Fee. Collection fees for specimens drawn by veinipuncture or catheterization are payable only to the physician or laboratory who draws the specimen. If done during an office visit on the same day the service is ordered, specimen collection may be reimbursed even if prior authorization is not approved.

<del>(3-30-07)</del>(\_\_\_\_\_

#### 656. LABORATORY AND RADIOLOGY SERVICES: OUALITY ASSURANCE.

Laboratories, as a condition of payment, must maintain a quality-control program, including proficiency testing consistent with federal requirements, as detailed in the Idaho Medicaid Provider Handbook. The laboratory must provide the results of proficiency testing to the Department or their Quality Improvement Organization vendor upon request.

65<u>67</u>. -- 659. (RESERVED)

# **IDAPA 16 – DEPARTMENT OF HEALTH AND WELFARE**

# 16.03.09 - MEDICAID BASIC PLAN BENEFITS

# DOCKET NO. 16-0309-1805

# NOTICE OF RULEMAKING - PROPOSED RULE

**AUTHORITY:** In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 56-202(b), Idaho Code; also House Bill 128 (2017) codified as Section 56-265(5), Idaho Code, re: Value-Based Care.

PUBLIC HEARING SCHEDULE: A public hearing concerning this rulemaking will be held as follows:

PUBLIC HEARING
Tuesday, October 23, 2018 - 9:30 a.m. (MDT)
Department of Health & Welfare Medicaid Central Office 3232 Elder Street Conference Room D-East and D-West Boise, ID 83705
TELECONFERENCE CALL-IN
Call in number: 1-240-454-0879 Meeting access code: 805 638 537 Meeting password: 4jsvE7p8 (45783778 from phones)

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 a nontechnical explanation of the substance and purpose of the proposed rulemaking

The 2017 Idaho Legislature passed House Bill 128, amending Section 56-265(5), Idaho Code, that provided the Department with the authority to develop a value-based payment model approach to provide Medicaid services to participants. This rulemaking incorporates new procedural requirements needed to implement a fixed participant enrollment process to support the value-based model through the existing Healthy Connections Program.

The existing Healthy Connections enrollment process allows participants to change their primary care provider (PCP) any time they choose. These proposed rule changes implement an enrollment process, (referred to as a "fixed enrollment process"), which designates a set period of time where participants are free to change their PCP at will. Once this time period ends, participants will not be able to change their PCP at will until the next open enrollment period the following year. There are provisions that allow PCP changes outside of the open enrollment period, for cause, which have been added to meet the requirements of federal law. These changes encourage a long-term provider-patient relationship through which a medical home is established. This ensures the participant is receiving a consistent source of care, provides for better patient outcomes, and supports the value-based model of care, as directed by the legislature.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: N/A

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

There is no anticipated fiscal impact to the State General Fund or any other funds for these rule changes. The rule changes are considered to be budget neutral for providers and there are no benefit changes for participants. Programmatic changes needed to implement this rulemaking are possible within existing Medicaid program funding.

**NEGOTIATED RULEMAKING:** Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules – Negotiated Rulemaking was published in the July 4, 2018, Idaho Administrative Bulletin, Vol. 18-7, pages 105 and 106.

**INCORPORATION BY REFERENCE:** No materials are being incorporated by reference in this rulemaking.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Cindy Brock at (208) 364-1983.

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 October 24, 2018.

Dated this 31st day of August, 2018.

Tamara Prisock DHW – Administrative Rules Unit 450 W. State Street – 10th Floor P.O. Box 83720 Boise, ID 83720-0036 Phone: (208) 334-5500 Fax: (208) 334-6558 dhwrules@dhw.idaho.gov

#### THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 16-0309-1805 (Only Those Sections With Amendments Are Shown.)

# 562. HEALTHY CONNECTIONS: PRIMARY CARE SERVICES.

01.	Eligible Services. Participants enrolled with a primary care provider (PCP) are eligible to receive: (3-25-16)	
a.	Basic care management and care coordination;	(3-25-16)
b.	Timely access to routine primary care;	(3-25-16)
c.	A patient-centered health care decision making process;	(3-25-16)
d.	Twenty-four (24) hour, seven (7) days per week access to an on-call medical professional; and (3-25-16)	
e.	Referral to other medically necessary services as specified in Section 210 of these ru	lles, based on

e. Referral to other medically necessary services as specified in Section 210 of these rules, based on the clinical judgment of their primary care provider. (3-25-16)

02. <u>Selection or</u> Change in Primary Care Provider. Participants may <u>select or</u> change their primary care provider *at any time by contacting Healthy Connections staff.* as follows: (3 25 16)(\_\_\_\_\_)

**a.** When they become eligible for Idaho Medicaid benefits, or after a break in their eligibility for Idaho Medicaid benefits;

# Docket No. 16-0309-1805 Proposed Rulemaking

<u>b.</u>	For cause at any time ("for cause" reasons are listed in the Idaho Medicaid Provider Hand	<u>lbook).</u> ()
<u>c.</u>	Without cause:	<u>()</u>
<u>i.</u>	During the ninety (90) days following the effective date of the participants enrollment wi	t <u>h a PCP.</u> ()
<u>ii.</u>	At least once every twelve (12) months thereafter during the open enrollment period.	<u>()</u>
<u>d.</u>	All approved PCP change requests will be effective the first of the following month.	<u>()</u>

# **IDAPA 16 – DEPARTMENT OF HEALTH AND WELFARE**

# 16.03.09 - MEDICAID BASIC PLAN BENEFITS

# DOCKET NO. 16-0309-1806

# NOTICE OF RULEMAKING - PROPOSED RULE

**AUTHORITY:** In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 56-202(b), Idaho Code; also 42 CFR 447.502, 447.512, 447.514, and 447.518.

PUBLIC HEARING SCHEDULE: A public hearing concerning this rulemaking will be held as follows:

PUBLIC HEARING
Wednesday, October 17, 2018 - 9:00 a.m. (MDT)
Department of Health & Welfare Medicaid Central Office 3232 Elder Street Conference Room D-East Boise, ID 83705
TELECONFERENCE CALL-IN
Toll Free: 1-877-820-7831 Participant Code: 701700

The hearing sites 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 a nontechnical explanation of the substance and purpose of the proposed rulemaking:

These rule changes are being made to implement policy (coverage) and reimbursement changes to the Medicaid Pharmacy program rules that are the result of recent changes in federal regulations and corresponding changes that have been made to the Idaho Medicaid State Plan.

Coverage changes include provisions clarifying that:

- 1. Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not covered; and
- 2. Investigational drugs are not covered under Idaho's Medicaid pharmacy program.

Reimbursement changes include replacing one cost measure (Estimated Acquisition Cost, or EAC) with the Average Acquisition Cost (AAC), or Wholesale Acquisition Cost (WAC) in cases where the AAC is not available. In addition, revisions will also update information in rule regarding which drugs are covered and which drugs are excluded.

Also, this docket updates an old list of drugs for which a three-month supply may be prescribed and dispensed and establishes appropriate controls for prescriptions of opioids.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: N/A

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

There is no anticipated fiscal impact to the State General Fund, or any other funds, related to this rulemaking.

**NEGOTIATED RULEMAKING:** Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules – Negotiated Rulemaking was published in the July 4, 2018, Idaho Administrative Bulletin, Vol. 18-7, pages 107 and 108.

**INCORPORATION BY REFERENCE:** No materials are being incorporated by reference in this rulemaking.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Clay Lord at (208) 364-1979.

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 October 24, 2018.

Dated this 31st day of August, 2018.

Tamara Prisock DHW – Administrative Rules Unit 450 W. State Street – 10th Floor P.O. Box 83720 Boise, ID 83720-0036 Phone: (208) 334-5500 Fax: (208) 334-6558 dhwrules@dhw.idaho.gov

#### THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 16-0309-1806 (Only Those Sections With Amendments Are Shown.)

# 662. PRESCRIPTION DRUGS: COVERAGE AND LIMITATIONS.

**01. General Drug Coverage.** The Department will pay for those prescription drugs not excluded by Subsections 662.04<u>6 and 662.07</u> of *thesethis* rules which are legally obtainable by the order of a licensed prescriber whose licensing allows for the prescribing of <u>prescription drugs or</u> legend drugs, as defined under Section 54-1705<del>(37)</del>, Idaho Code, and which are deemed medically necessary as defined in Section 011 of these rules.

<del>(3-30-07)</del>(\_\_\_\_)

02. Dispensing Fee Preferred Drug List (PDL). Dispensing Fee is defined as the cost of filling a prescription including direct pharmacy overhead, and is for all services pertaining to the usual practice of pharmacy, including:
(4-4-13)(\_\_\_\_\_)

**a.** Interpretation, evaluation, compounding, and dispensing of prescription drug orders; The PDL identifies the preferred drugs and non-preferred drugs within a therapeutic class designated by the Department and reviewed by the Idaho Medicaid Pharmacy and Therapeutics Committee.

**b.** *Participation in drug selection;* A brand name drug may be designated as a preferred drug by the Department if the net cost of the brand name drug after consideration of all rebates is less than the cost of the generic equivalent.

therapeutic prior authorization regardless of preferred or non-preferred designation. (3-30-07)	
e. Proper storage of drugs; (3-30-	<del>97)</del>
f. Maintenance of proper records; (3-30-	<del>97)</del>
g. Prescriber interaction; and (3-30-	<del>97)</del>
h. Patient counseling. (3-30-	<del>97)</del>

03. Limitations on Payment. Medicaid payment for prescription drugs will be limited as follows: (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)

*e. 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)

**043.** Excluded Covered Drug Products. The following categories and specific products are excluded from coverage by Idaho Medicaid provides coverage to Medicaid participants for the following drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Section 1927(d)(2) of the Social Security Act: (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: Agents, when used to promote smoking <u>(3-30-07)(</u>)

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 eriteria 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 available.* <u>Prescription vitamins and mineral products. Covered agents include the following:</u> (3 30 07)(\_\_\_\_)

<u>i.</u>	Injectable vitamin B12 (cyanocobalamin and analogues);	(	)
<u>ii.</u>	Vitamin K and analogues;	(	)
<u>iii.</u>	Prescription vitamin D and analogues;	(	)

# DEPARTMENT OF HEALTH AND WELFARE Docket No. 16-0309-1806 Medicaid Basic Plan Benefits Proposed Rulemaking

Prescription pediatric vitamins, minerals, and fluoride preparations; iv. Prenatal vitamins for pregnant or lactating individuals; and <u>v.</u> vi. Prescription folic acid and oral prescription drugs containing folic acid in combination with vitamin B12 or iron salts, or both, without additional ingredients. c. Diet Supplements. Diet supplements and weight loss products, except lipase inhibitors when prior authorized as outlined in Section 663 of these rules. Certain prescribed non-prescription products, including the <del>(3-30-07)</del>( following: Permethrin; <u>i.</u> ii. Oral iron salts; Disposable insulin syringes and needles; and iii.

<u>iv.</u> <u>Insulin.</u> (\_\_\_\_\_

**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 Barbiturates. (3-30-07)(\_\_\_\_)

e.Ovulation/Fertility Drugs. Ovulation stimulants, fertility drugs, and similar products<br/>(3-30-07)(\_\_\_\_)Benzodiazepines.(3-30-07)(\_\_\_\_\_)f.Impotency Aids. Impotency aids, either as medication or prosthesis.

g. 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)

*h. Vitamins. Vitamins unless included in Subsection 662.05.a. of these rules.* (3-30-07)

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

04. Additional Criteria for Coverage.

**a.** Medical necessity is the primary determinant of whether a therapeutic agent will be covered. The Department will cover generic drugs, and also brand drugs when medically necessary and when that necessity is adequately documented. If case-specific indications of medical necessity are present, the Department may also issue prior authorization for otherwise excluded drugs.

**b.** The Director of the Department of Health and Welfare, acting upon the recommendation of the Pharmacy and Therapeutics Committee, may determine that a non-prescription drug product is covered when the non-prescription product is found to be therapeutically interchangeable with prescription drugs in the same pharmacological class following evidence-based comparisons of efficacy, effectiveness, clinical outcomes, and safety, and the product is deemed by the Department to be a cost-effective alternative. Information regarding the Pharmacy and Therapeutics Committee and covered drug products is posted at http://medicaidpharmacy.idaho.gov.

**05.** Additional Covered Excluded Drug Products. Additional drug products will be allowed as follows Idaho Medicaid excludes from coverage the following drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Section 1927(d)(2) of the Social Security Act:

<del>(3 30 07)</del>(\_\_\_\_

-)

a.	Therapeutic Vitamins. Therapeutic vitamins may include: Agents, when used to p	promote fertility. (3-30-07)()
<del>i.</del>	Injectable vitamin B12 (cyanocobalamin and analogues);	<del>(3-30-07)</del>
<del>ii.</del>	Vitamin K and analogues;	<del>(3-30-07)</del>
<del>iii.</del>	Pediatric legend vitamin fluoride preparations;	<del>(3-30-07)</del>
<del>iv.</del>	Legend prenatal vitamins for pregnant or lactating women;	<del>(3-30-07)</del>
<del>v.</del>	Legend folic acid;	<del>(3-30-07)</del>
<del>vi.</del> additional ingre	<i>Oral legend drugs containing folic acid in combination with Vitamin B12 and/or</i> edients;	<del>iron salts, without</del> <del>(4-4-13)</del>
<del>vii.</del>	Legend vitamin D and analogues; and	<del>(4-4-13)</del>
<del>viii.</del>	Legend tobacco cessation products.	<del>(3-20-14)</del>
<b>b.</b> when used for c	Prescriptions for Nonlegend Products. Prescriptions for nonlegend products ma cosmetic purposes or hair growth.	<del>ty include:</del> <u>Agents,</u> (3-30-07)()
<del>i.</del>	Insulin;	<del>(3-30-07)</del>
<del>ii.</del>	Disposable insulin syringes and needles;	<del>(3-30-07)</del>
<del>iii.</del>	<del>Oral iron salts;</del>	<del>(4-4-13)</del>
<del>iv.</del>	Permethrin; and	<del>(4-4-13)</del>
<del>).</del>	Tobacco cessation products.	<del>(3-20-14)</del>
<u>c.</u>	Agents, when used for the symptomatic relief of cough and colds.	<u>()</u>
d. associated tests	Covered outpatient drugs for which the manufacturer seeks to require as a cor or monitoring services be purchased exclusively from the manufacturer or its design	ndition of sale that gnee. ()
<u>e.</u> to treat a condit and Drug Admi	Agents, when used for the treatment of sexual or erectile dysfunction, unless su tion, other than sexual or erectile dysfunction, for which the agents have been app nistration.	
<u>06.</u> apply:	Additional Excluded Drugs. Drugs are also not covered when any of the follow	ving circumstances ()
<u>a.</u> financial partici	The participant's practitioner has written an order for a prescription drug ipation is not available.	for which federal ()
covered service case-by-case ba	The participant's practitioner has written an order for a prescription drug that r investigational, as defined in Subsection 390.03 of these rules. Investigational under the Idaho Medicaid pharmacy program. The Department may consider Medi asis for life-threatening medical illnesses when no other treatment options are syment, reimbursement will be at actual acquisition cost, plus the assigned profession	al drugs are not a caid coverage on a e available. When
0 <del>6</del> 7. the estimated da	<b>Limitation of Quantities</b> . Medication refills provided before at least seventy-fiv ays' supply has been utilized are not covered, unless an increase in dosage is order	

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: Maintenance Medications. Pharmacy providers may be reimbursed for up to a three (3) month supply of select medications or classes of medications for a participant who has received the same dose of the same select medication or class of medications for two months or longer. The Director of the Department of Health and Welfare, acting upon the recommendation of the Pharmacy and Therapeutics Committee, approves the list of covered maintenance medications, which targets medications that are administered continuously rather than intermittently, are used most commonly to treat a chronic disease state, and have a low probability for dosage changes. The list of covered maintenance medications is available on the Medicaid Pharmacy website at http://medicaidpharmacy.idaho.gov. (3-30-07)(\_\_\_)

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

**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)

#### 663. PRESCRIPTION DRUGS: PROCEDURAL REQUIREMENTS.

In accordance with Section 1927(d)(1)(A) of the Social Security Act, the Idaho Medicaid Pharmacy Program may subject any covered outpatient drug to prior authorization.

01. Items Drugs Requiring Prior Authorization. Pharmaceutical items requiring prior authorization include: No payment for drugs requiring prior authorization will be issued until the prior authorization request has been reviewed and approved by the Department.

<del>a.</del>	Amphetamines and related CNS stimulants;	<del>(3-30-07)</del>
<del>b.</del>	Growth hormones;	<del>(3-30-07)</del>
<del>e.</del>	Retinoids;	<del>(3-30-07)</del>
<del>d.</del>	Brand name drugs when an acceptable generic form exists;	<del>(3-30-07)</del>

e. Medication otherwise covered by the Department for which there is a therapeutically interchangeable alternate medication identified by the Department. Therapeutically interchangeable means a medication that is interchangeable with another medication within the same pharmacologic or therapeutic class and is at least as effective as the medication for which it is being interchanged. The Director may exempt a drug from the prior authorization requirement described in Section 663 of this chapter of rules, 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 (P&T Committee). The Department determines, and will make available to providers, which drugs are therapeutically interchangeable using a number of resources that may include: (3-30-07)

<del>i.</del>	Peer-reviewed medical literature;	<del>(3-30-07)</del>
<del>ii.</del>	Randomized elinical trials;	<del>(3-30-07)</del>

	<del>iii.</del>	Drug comparison studies;	<del>(3-30-07)</del>
	<del>iv.</del>	Pharmacoeconomic studies;	<del>(3-30-07)</del>
	<del>v.</del>	Outcomes research data;	<del>(3-30-07)</del>
	<del>vi.</del>	Idaho practice guidelines; and	<del>(3-30-07)</del>
	<del>vii.</del>	Consultation with practicing physicians, pharmacists, and the Idaho Medicaid Medical I	<del>Director.</del> ( <del>3-30-07)</del>
<del>dosage</del>	<del>f.</del> <del>guideline</del>	Medications prescribed in quantities which exceed the Food and Drug Administrations:	i <del>on (FDA)</del> <del>(3-30-07)</del>
	<del>8.</del>	Lipase inhibitors.	<del>(3-30-07)</del>
	<del>k.</del>	Medications prescribed outside of the Food and Drug Administration approved indication	<del>ms.</del> <del>(3-30-07)</del>
<del>medical</del>	<del>i.</del> l <del>y-appro</del>	Medications excluded in Subsection 662.04 of these rules that the Department accept: ved indications.	<del>s for other</del> <del>(3-30-07)</del>
will be	<u>02.</u> determine	<b>Prior Authorization Criteria</b> . Criteria for prior authorization for individual drugs and de ed by the Department, and will include:	rug classes
	<u>a.</u>	Food and Drug Administration (FDA) indications and labeling, including dosage guideli	<u>nes.()</u>
<u>(CMS),</u>	<u>b.</u> includin	Compendia of drug information recognized by the Centers for Medicare and Medicai g:	d Services
	<u>i.</u>	American Hospital Formulary Service-Drug Information;	<u>()</u>
	<u>ii.</u>	United States Pharmacopeia-Drug Information, or its successor publications; and	<u>()</u>
	<u>iii.</u>	The DrugDex Information System.	<u>()</u>
	<u>c.</u>	Evidence-based, peer-reviewed, published medical literature, including:	()
	<u>i.</u>	Systematic reviews;	<u>()</u>
	<u>ii.</u>	Randomized controlled trials; and	<u>()</u>
	<u>iii.</u>	Meta-analysis studies.	()
controll	<u>d.</u> ed trials :	Guidelines and case-controlled studies may be considered where systematic reviews, ra and meta-analysis studies do not exist.	andomized
	<u>e.</u>	The requested drug's preferred drug status.	<u>()</u>
	0 <del>2</del> 3.	Request for Prior Authorization.	<u>()</u>
	<u>a.</u>	The prior authorization procedure is initiated by the prescriber who must submit the req	uest to the

 Department in the format prescribed by the Department.
 (3-30-07)

 b.
 Whenever possible, the Department will use automated authorization, in which claims are

**b.** Whenever possible, the Department will use automated authorization, in which claims are adjudicated at point of sale using submitted National Council for Prescription Drug Programs (NCPDP) data

(3-30-07)

elements or claims history to verify that the Department's authorization requirements have been satisfied, without the need for the prescriber to submit additional clinical information.

034. Notice of Decision. The Department will determine coverage based on this request, and will notify the participant of a denial. The participant has twenty-eight (28) days from the date the denial letter is mailed to appeal the decision. Hearings will be conducted in accordance with IDAPA 16.05.03, "Rules Governing Contested Case Proceedings and Declaratory Rulings."

045. Emergency Situation. The Department will provide for the dispensing of at least a seventy-two (72) hour supply of a covered outpatient prescription drug in an emergency situation as required in 42 U.S.C. 1396r-8(d)(5)(B). (3-30-07)

**056. Response to Request**. The Department will respond within twenty-four (24) hours to a request for prior authorization of a covered outpatient prescription drug as required in 42 U.S.C. 1396r-8(d)(5)(A). (3-30-07)

07. Prohibition Against Cash Payment for Controlled Substances. Pharmacy providers are prohibited from accepting cash as payment for controlled substances from persons known to be Medicaid participants.

#### 068. Supplemental Rebates.

a. Purpose. The purpose of supplemental rebates is to enable the Department to purchase prescription drugs provided to Medicaid participants in a cost\_effective manner, whether or not these drugs are subject to prior authorization by the Department. The supplemental rebate may be one (1) factor considered in exempting a prescription drug from prior authorization determining a drug's preferred drug status, but it is secondary to considerations of the safety, effectiveness, and clinical outcomes of the drug in comparison with other therapeutically interchangeable alternative drugs.

**b.** Rebate Amount. The Department may negotiate with manufacturers supplemental rebates for prescription drugs that are in addition to those required by Title XIX of the Social Security Act. There is no upper limit on the dollar amounts of the supplemental rebates the Department may negotiate. (3-30-07)

**079. Comparative Costs to be Considered**. Whenever possible, physicians and pharmacists are encouraged to utilize less expensive drugs and drug therapies. (3-30-07)

# 664. PRESCRIPTION DRUGS: PROVIDER QUALIFICATIONS AND DUTIES.

01. Payment for Covered Drugs. Payment will be made, as provided in Section 665 of these rules, only to pharmacies registered with the Department as a provider for the specific location where the service was performed. An out of the state pharmacy shipping or mailing a prescription into Idaho must have a valid mail order license issued by the Idaho Board of Pharmacy and be properly enrolled as a Medicaid provider. (3-30-07)

**02. Dispensing Procedures**. The following protocol must be followed for proper prescription filling. (3-30-07)

**a.** Prescription Drug Refills. Refills of prescription drugs must be authorized by the prescriber on the original or new prescription order on file and each refill must be recorded on the prescription or logbook, or computer print-out, or on the participant's medication profile. (3-30-07)

**b.** <u>Automatic Refills.</u>

i. Automatic refills are not allowed for Idaho Medicaid participants. A request specific to each medication is required.

ii. All prescription refills must be initiated by a request from the participant, the prescriber, or another person, such as a family member, acting as an agent of the participant.

(3-30-07)

iii. Authorization for each prescription refill must be received prior to the beginning of the filling process by the pharmacy.

<u>₽c</u> .	Dispensing Prescription Drugs. Prescriptions must be dispensed according to:	(3-30-07)
i.	21 CFR Section 1300, et seq.;	(3-30-07)
ii.	Title 54, Chapter 17, and Title 37, Chapters 1, 27, and 32, Idaho Code;	<del>(3-30-07)<u>(</u>)</del>
iii.	IDAPA 27.01.0 <del>13</del> , "Rules <del>of the Idaho State Board of</del> Governing Pharmacy Pra	<u>ctice"; and</u> ( <u>3-30-07)(</u> )

iv. Sections 660 through 666 of these rules.

ed. Prescriptions on File. Prescriptions must be maintained on file in pharmacies in such a manner that they are available for immediate review by the Department upon written request. (3-30-07)

**03. Return of Unused Prescription Drugs**. When prescription drugs were dispensed in unit dose packaging, as defined by IDAPA 27.01.013, "Rules of the Idaho State Board of Governing Pharmacy Practice," and the participant for whom the drugs were prescribed no longer uses them:

**a.** A licensed skilled nursing care facility may return unused drugs dispensed in unit dose packaging to the pharmacy provider that dispensed the medication. (3-30-07)

**b.** A residential or assisted living facility may return unused drugs dispensed in unit dose packaging to the pharmacy provider that dispensed the medication. (3-30-07)

**04. Pharmacy Provider Receiving Unused Prescription Drugs**. In order for a pharmacy provider to receive unused prescription drugs that it dispensed in unit dose packaging and that are being returned by a facility identified in Subsection 664.03 of this rule, the pharmacy provider: (3-30-07)

**a.** Must comply with IDAPA 27.01.043, "Rules of the Idaho State Board of Governing Pharmacy Practice," regarding unit dose packaging;

**b.** Must credit the Department the amount billed for the cost of the drug less the <u>professional</u> dispensing fee; and (3-30-07)(

c. May receive a fee for acceptance of returned unused prescription drugs. The value of the unused prescription drug being returned must be such that return of the drug is cost-effective as determined by the Department. (3-30-07)

#### 665. PRESCRIPTION DRUGS: PROVIDER REIMBURSEMENT.

All medications dispensed to With specific exceptions as set forth in Subsections 665.01 through 665.04 of this rule. Idaho Medicaid participants will be pharmacy providers are reimbursed based on actual acquisition costs. All medications administered to participants by physicians or other qualified and licensed providers must be reimbursed based on Medicare rates as directed in Section 56-265, Idaho Code, or if no Medicare rate is available, based on actual acquisition costs. Idaho Medicaid may require providers to supply documentation of their acquisition costs as described in the Medicaid Pharmacy Claims Submission Manual available at: https://idaho.fhsc.com/downloads/providers/IDRx\_Pharmacy\_Claims\_Submission\_Manual.pdf. Reimbursement is restricted to those drugs supplied from labelers that are participating in the CMS Medicaid Drug Rebate Program. (4 I 17)(\_\_\_\_)

**01. Pharmacy Reimbursement**. Prescriptions not filled in accordance with the provisions of Subsection 664.02 of these rules will be subject to nonpayment or recoupment. The following protocol must be followed for proper reimbursement. (4-1-17)

**a.** Filing Claims. Pharmacies 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. (4-1-17)

*b. 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)

**eb.** 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)

**dc.** Reimbursement. Reimbursement to pharmacies is limited to the lowest of the following: (3-30-07)

i. 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 professional dispensing fee assigned by the Department Actual Acquisition Cost (AAC) based on results of the periodic state cost survey as defined in this rule, plus the assigned professional dispensing fee. In cases where no AAC is available, reimbursement will be the Wholesale Acquisition Cost (WAC). WAC will mean the price, for a given calendar quarter, paid by a wholesaler for the drugs purchased from the wholesaler's supplier. The wholesaler's supplier is typically the manufacturer of the drug as published by a recognized compendium of drug pricing for the same calendar quarter; (4-1-17)(

ii. State Maximum Allowable Cost (SMAC), as established by the Department, plus the assigned professional dispensing fee; (4-1-17)

iii. Actual Acquisition Cost (AAC) based on results of the periodic state cost survey as defined in this rule, plus the assigned professional dispensing fee. In cases where no AAC 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 [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 professional dispensing fee assigned by the Department; or (4-1-17)(\_\_\_\_)

iv. The pharmacy's provider's billed charges as defined in Subsection 665.01 of this rule usual and customary charge to the general public. (4-1-17)(

ed. 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 Pharmacy *pP*rogram are required to participate in these periodic state cost surveys by disclosing the costs of all drugs. A pharmacy that is non-responsive to the periodic state cost surveys can be disenrolled as a Medicaid provider by the Department. (4-1-17)(

e. <u>Physician Administered Drugs.</u>

i. Reimbursement to providers that are not 340B covered entities for medications administered to Medicaid participants by physicians or other qualified and licensed providers will be ninety percent (90%) of the published Medicare Average Sales Price plus six percent (6%) rate (ASP+6% rate). If the ASP+6% rate is not available, payment will be at the Wholesale Acquisition Cost (WAC).

ii. Reimbursement to 340B covered entities for medications administered to Medicaid participants by physicians or other qualified and licensed providers will be the actual 340B drug acquisition cost, not to exceed the 340B ceiling price.

<u>**f.**</u> <u>Clotting Factors.</u>

i. <u>Reimbursement to specialty pharmacies will be at a state-based price equivalent to the published</u> <u>Medicare ASP+6% rate, plus the assigned professional dispensing fee.</u> (\_\_\_\_)

ii. <u>Reimbursement to Hemophilia Treatment Centers will be the 340B actual acquisition cost, not to</u>

#### Docket No. 16-0309-1806 Proposed Rulemaking

#### exceed the 340B ceiling price. Professional Dispensing Fee. Professional Dispensing Fee is defined as a tier-based amount paid on a pharmacy claim, over and above the ingredient cost, to compensate the provider for the pharmacist's professional services related to dispensing a prescription to a Medicaid participant, including: Looking up information about a participant's coverage on the computer; <u>i.</u> Performing drug use reviews and preferred drug list review activities; ii. ( )<u>iii.</u> Measuring or mixing the covered outpatient drug; Filling the container; iv. V. Participant counseling; Physically providing the completed prescription to the Medicaid participant; vi. Special packaging; and vii. Overhead associated with maintaining the facility and equipment necessary to operate the <u>viii.</u> dispensing entity.

**fh**. Limitations on Payment of Professional Dispensing Fee. Only one (1) professional 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:  $(4 \ 1 \ 17)($ 

i. 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)

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

iii. 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)

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

i. <u>Tier-Based Professional Dispensing Fees. A professional dispensing fee for each pharmacy</u> provider will be established in accordance with this rule. (\_\_\_\_\_)

**gj.** Claims Volume Survey for Tier-Based Professional Dispensing Fees. The Department will survey pharmacy providers to establish a professional dispensing fee for each provider. The professional 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 professional dispensing fee starting on July 1st until the next annual survey is completed. Based upon the annual claims volume of the enrolled pharmacy, the professional dispensing fee is provided online at: http://healthandwelfare.idaho.gov/LinkClick.aspx?fileticket=iJDsiQavFLc%3d&tabid=119& mid=1111. (4-1-17)

**hk.** Remittance Advice. Claims are processed by computer, and payments are made directly to the pharmacy or its designated bank through electronic funds transfer. A remittance advice with detailed information of each claim transaction will accompany each payment made by the Department. (4-1-17)

# 02. 340B Covered Entity Reimbursement.

(4 - 1 - 17)

**a.** Participation as a 340B Covered Entity. Medicaid will reimburse 340B covered entities as defined in Section 340B of the Public Health Service Act, codified under 42 U.S.C. 256b(a)(4), when the provider meets the following requirements: (4-1-17)

i. A 340B covered entity may receive reimbursement for drugs provided to Idaho Medicaid participants through the 340B drug pricing program if the 340B covered entity submits its unique 340B identification number issued by the Health Resources and Services Administration (HRSA) and a copy of its completed HRSA 340B registration to Idaho Medicaid. (4-1-17)

ii. A 340B covered entity that elects to provide drugs to Idaho Medicaid participants through the 340B drug pricing program must use 340B covered outpatient drugs for all dispensed or administered drugs, including those dispensed through the 340B covered entity's retail pharmacy or administered in an outpatient clinic. A 340B covered entity must ensure that a contract pharmacy does not dispense drugs, or receive Medicaid reimbursement for drugs, acquired by the 340B covered entity through the 340B drug pricing program. An entity that does not use 340B covered entity's retail pharmacy including those dispensed through the 340B covered entity through the 340B drug pricing program. An entity that does not use 340B covered entity's retail pharmacy or administered drugs, including those dispensed through the 340B drug pricing program and will be reimbursed for brand name and generic drugs as provided in Subsection 665.01 of this rule.

iii. A 340B covered entity must provide Idaho Medicaid with thirty (30) days advance written notice of its intent to discontinue the provision of drugs acquired through the 340B drug pricing program to Idaho Medicaid participants. (4-1-17)

**b.** Filing Claims. A 340B covered entity must file claims electronically with Department-approved software or by submitting the appropriate claim form to the fiscal contractor. The form must include information described in the pharmacy guidelines issued by the Department. (4-1-17)

c. Claim Form Review Reimbursement Exclusions. Each claim form may be subject to review by a contract claim examiner, a pharmaceutical consultant, or a medical consultant Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmaceis are not covered. (4-1-17)(\_\_\_\_\_\_)

*d*: Billed Charges. A 340B covered entity's billed charges are not to exceed the entity's actual 340B drug acquisition cost. (4-1-17)

ed. Reimbursement. Reimbursement to 340B covered entities is limited to their actual 340B drug acquisition cost submitted, not to exceed the 340B ceiling price, plus the assigned professional dispensing fee.  $\frac{(4-1-17)(2-1)}{(2-1)}$ 

**fe.** Professional Dispensing Fee. Only one (1) professional 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: (4-1-17)

i. 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; (4-1-17)

ii. Multiple dispensing of oral liquid maintenance medication if a reasonable quantity, as determined by the Department, is dispensed at each filling; (4-1-17)

iii. 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 (4-1-17)

iv. When the dose is being titrated for maximum therapeutic response with a minimum of adverse effects. (4-1-17)

**gf.** Tier-Based Professional Dispensing Fees. A professional dispensing fee for each 340B covered entity will be established in accordance with this rule. (4-1-17)

**hg.** Remittance Advice. Claims are processed by computer, and payments are made directly to the 340B covered entity or its designated bank through electronic funds transfer. A remittance advice with detailed information of each claim transaction will accompany each payment made by the Department. (4-1-17)

03. <u>Reimbursement for Drugs Dispensed by Other Provider Types.</u>

**a.** Drugs acquired through non-340B Indian Health Service, Tribal, or Urban Indian pharmacies will be reimbursed at the actual acquisition cost to the entity, plus the assigned professional dispensing fee. (\_\_\_\_)

b. Drugs acquired via the Federal Supply Schedule (FSS) will be reimbursed at the FSS actual acquisition cost, plus the assigned professional dispensing fee.

**c.** Drugs acquired at nominal price, which is defined as pricing that is outside of 340B regulations or FSS, will be reimbursed at the actual acquisition cost, plus the assigned professional dispensing fee.

**d.** Specialty drugs not dispensed by retail community pharmacies and dispensed primarily through the mail will be reimbursed at the Idaho actual acquisition cost, if such cost is available, plus the professional dispensing fee. If the actual acquisition cost is not available, drugs will be reimbursed at the lower of the Wholesale Acquisition Cost (WAC) or State Maximum Allowable Cost (SMAC) as established by the Department, plus the assigned professional dispensing fee.

e. Drugs not distributed by a retail community pharmacy, such as drugs dispensed in a long-term care facility or dispensed to participants receiving swing-bed services, as described in Subsection 405.08 of these rules, will be reimbursed at the actual ingredient cost, plus the assigned professional dispensing fee.

04. Limitations on Payment. Medicaid payment for prescription drugs will be limited as follows:

**a.** <u>Medication for Multiple Persons. When the medication dispensed is for more than one (1) person,</u> Medicaid will only pay for the amount prescribed for the person or persons covered by Medicaid. (\_\_\_\_\_\_)

**b.** 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.

<u>c.</u> <u>Limitations to Discourage Waste. Medicaid may conduct drug utilization reviews and impose</u> limitations for participants whose drug utilization exceeds the standard participant profile or disease management guidelines determined by the Department.

**035.** Return of Drugs. Drugs dispensed in unit dose packaging as defined by IDAPA 27.01.01, "*Rules of the Idaho State Board of Pharmacy* General Provisions," *Section 012,* must be returned to the dispensing pharmacy when the participant no longer uses the medication as follows: (4-1-17)(

**a.** A pharmacy provider using unit dose packaging must comply with IDAPA 27.01.04<u>3</u>, "Rules of the Idaho State Board of Governing Pharmacy Practice,." Section 146.

**b.** The pharmacy provider that receives the returned drugs must credit the Department the amount billed for the cost of the drug less the professional dispensing fee. (4-1-17)

**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)

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

(4-4-13)

# 666. PRESCRIPTION DRUGS: QUALITY ASSURANCE.

# 01. Pharmacy And Therapeutics Committee (P&T Committee). (3-30-07)

**a.** Membership. The P&T Committee is appointed by the Director and is composed of practicing pharmacists, physicians and other licensed health care professionals with authority to prescribe medications.

(3-30-07)

**b.** Function. The P&T Committee has the following responsibilities for the prior authorization of drugs under Section 663 of these rules: (3-30-07)

i. To serve in evaluational, educational and advisory capacities to the Idaho Medicaid <u>Pharmacy</u> Program specific to the prior authorization of drugs *with therapeutically interchangeable alternatives*.

<del>(3-30-07)<u>(</u>)</del>

ii. To <u>receive review</u> evidence-based clinical and pharmacov economic data and recommend to the Department <u>the agents to be exempt from prior authorization in selected classes of drugs with therapeutically</u> interchangeable alternatives. The recommendation of items to be exempt from prior authorization will be based primarily on objective evaluations of their relative safety, effectiveness, and clinical outcomes of the drug in comparison with other therapeutically interchangeable alternative drugs, and secondarily on cost preferred and non-preferred drugs in classes designated for the Idaho Medicaid Preferred Drug List. (3-30-07)(\_\_\_\_)

iii. To recommend to the Department the classes of medications to be reviewed through evidencebased evaluation. (3-30-07)

iv. To review drug utilization outcome studies and intervention reports from the Drug Utilization Review Board as part of the process of reviewing and developing recommendations to the Department. (3-30-07)

c. Meetings. The P&T Committee meetings will be open to the public and a portion of each meeting will be set aside to hear and review public comment. The P&T Committee may adjourn to executive session to consider the following: (3-30-07)

i. Relative cost information for prescription drugs that could be used by representatives of pharmaceutical manufacturers or other people to derive the proprietary information of other pharmaceutical manufacturers; or (3-30-07)

ii. Participant-specific or provider-specific information. (3-30-07)