DEPARTMENT OF REGULATORY AGENCIES

Division of Insurance

PRESCRIPTION DRUG AFFORDABILITY BOARD

3 CCR 702-9

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

Part 1 GENERAL PROVISIONS

1.1 Definitions

A. Authority

The statutory authority for this rule includes but is not limited to section 10-16-1403(5), C.R.S.

B. Scope and Purpose

The purpose of this rule is to provide necessary definitions of terms used throughout the rules.

C. Definitions

"Advisory Council" has the same meaning set forth in section 10-16-1401(1), C.R.S.

"Affordability Review" means a review of a as prescription drug performed by the Board pursuant to section 10-16-1406(3)-(7), C.R.S., to determine whether use of the prescription drug consistent with the labeling approved for prescription drug by the FDA or with standard medical practice is unaffordable for Colorado consumers.

"All-Payer Health Claims Database" or "APCD" has the same meaning as set forth in section 10-16-1401(3), C.R.S.

"Authorized Generic Drug" has the same meaning as set forth in section 10-16-1401(4), C.R.S.

"Average Sales Price" has the same meaning as set forth in section 42 U.S.C. § 1395w-3a(c).

"Biological Product" has the same meaning as set forth in section 10-16-1401(5), C.R.S.

"Biosimilar Drug" has the same meaning as set forth in section 10-16-1401(6), C.R.S.

"Board" has the same meaning as set forth in section 10-16-1401(7), C.R.S.

"Board Activity" has the same meaning as set forth in section 10-16-1401(7.5), C.R.S.

"Board Staff" means any individual employed by the Division of Insurance providing support to and/or doing work on behalf of the Board.

"Brand-name Drug" has the same meaning as set forth in section 10-16-1401(8), C.R.S.

"Carrier" has the same meaning as set forth in section 10-16-102(8), C.R.S.

"Days" means calendar days.

"Division" or "Division of Insurance" means the Colorado Division of Insurance or any successor entity.

"FDA" has the same meaning as set forth in section 10-16-102(27.5), C.R.S.

"Generic Drug" has the same meaning as set forth in section 10-16-1401(12), C.R.S.

"HCPF" means the Colorado Department of Health Care, Policy & Financing or any successor entity.

"Health Benefit Plan" has the same meaning as set forth in section 10-16-102(32), C.R.S.

"Initial WAC" means the earliest listed WAC for a prescription drug.

"Manufacturer" has the same meaning as set forth in section 10-16-1401(16), C.R.S.

"Medicare Maximum Fair Price" has the same meaning as determined by section 42 U.S.C. § 1320f(c)(3).

"National Drug Code" or "NDC" means the numeric code associated with a finished drug product or unfinished drug that identifies its labeler, product, and package size and type.

"Off-label usage" means the use of a prescription drug for a disease or medical condition that is outside the FDA-approved indication(s).

"Optional Participating Plan" has the same meaning as set forth in section 10-16-1401(17), C.R.S.

"Out-of-Pocket Costs" means the amount a covered person is required to pay in the form of cost-sharing for covered benefits in a plan year, including deductibles, coinsurance, and copayments.

"Person" includes an individual, limited liability company, partnership, corporation, association, county, and public or private organization of any character other than an agency.

"Pharmacist" has the same meaning as set forth in section 12-280-103(35), C.R.S.

"Pharmacy Benefit Management Firm" or "PBM" has the same meaning as set forth in section 10-16-102(49), C.R.S.

"Plan ID" means the unique health benefit plan identifier, including number and/or name, and, as applicable, the plan identification number used for Centers for Medicare and Medicaid Services' Health Insurance and Oversight System

"Plan Year" means a consecutive 12 month period during which a health plan provides coverage for health benefits. A plan year may be a calendar year or otherwise.

"Prescription Drug" has the same meaning as set forth in section 10-16-1401(19), C.R.S.

"Pricing Information" has the same meaning as set forth in section 10-16-1401(20), C.R.S

"Priority Populations" means people experiencing homelessness; people involved with the criminal justice system; black people, indigenous people, and people of color; American Indians and Alaska natives; veterans; people who are lesbian, gay, bisexual, transgender, queer, or questioning; people of disproportionately affected sexual orientations, gender identities, or sex assigned at birth; people who have AIDS or HIV; older adults; children and families; and people with disabilities, including people who are deaf and hard of hearing, people who are blind and deafblind, people with brain injuries, people with intellectual and developmental disabilities, people with other co-occurring disabilities; and other populations as deemed appropriate by the Prescription Drug Affordability Board.

"Provider" has the same meaning as set forth in section 10-16-102(56), C.R.S.

"State Entity" has the same meaning as set forth in section 10-16-1401(22), C.R.S.

"Therapeutic Alternative" means a drug product that contains a different therapeutic agent than the drug in question, but is the same pharmacological or therapeutic class and has been shown through peer-reviewed studies to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose or has been recommended as consistent with standard medical practice by medical professional association guidelines.

"Therapeutically Equivalent" means approved drug products that are pharmaceutical equivalents for which bioequivalence has been demonstrated, and that can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

"Upper Payment Limit" has the same meaning as set forth in section 10-16-1401(23), C.R.S.

"Wholesale Acquisition Cost" ("WAC") has the same meaning as set forth in section 10-16-1401(24), C.R.S.

"Wholesaler" has the same meaning as set forth in section 12-280-103(55), C.R.S.

1.2 Severability

A. Authority

The statutory authority for this rule is section 10-16-1403(5), C.R.S.

B. Scope and Purpose

The purpose of this rule is to clarify the severability of these rules.

C. Severability

If any portion of these rules is found to be invalid, the remaining portion of the rules shall remain in force and effect.

1.3 Declaratory Orders

A. Authority

The statutory authority for this rule includes but is not limited to section 10-16-1403(5), C.R.S., and section 24-4-105(11), C.R.S.

B. Scope and Purpose

The purpose of this rule is to set forth the declaratory order procedures as required by section 24-4-105(11), C.R.S.

C. Declaratory Orders

1. Who May Request a Petition for Declaratory Order: Any person as defined in section 24-4-102(12), C.R.S., may request the Board to issue a declaratory order to terminate controversies or to remove uncertainties concerning any provision of the Prescription Drug Affordability Act, or any regulation of the Board.

2. Board Response: The Board will determine, in its sound discretion, whether to rule upon the submitted petition. If the Board determines not to rule on the petition, the Board shall issue a written order disposing of the submitted petition, including the reasons for such action. A copy of the order will be provided to the petitioner.

3. Ruling on a Petition for Declaratory Order: In determining whether to rule upon a petition filed pursuant to this rule, the Board may consider the following:

    a. Whether a ruling on the petition will terminate a controversy or remove uncertainties as to the applicability of any statutory provision, rule, or order of the Board to the petitioner;

    b. Whether the petition involves any subject, question, or issue which is the subject of a formal or informal matter or investigation currently pending before the Board, or a court, involving one or more of the petitioners, and which will terminate the controversy or remove the uncertainties as to the applicability or any statutory provision, rule, or order of the Board to the petitioner;

    c. Whether the petition involves any subject, question, or issue which is at-issue in an Affordability Review or Upper Payment Limit currently being conducted by the Board, but does not involve the petitioner, and which will terminate the controversy or remove the uncertainties as to the applicability of any statutory provision, rule, or order of the Board to the petitioner;

    d. Whether the petition seeks a ruling on a moot or hypothetical question, or will result in an advisory ruling or opinion;

    e. Whether the petitioner has other adequate legal remedies, other than an action for declaratory relief pursuant to Rule 57, Colorado Rules of Civil Procedure, which will terminate the controversy or remove any uncertainty as to the applicability of the statute, rule, or order in question to the petitioner; and

    f. Any response to the petition filed by Board Staff. Such response must be filed by the Board Staff within 14 days of the filing of the Petition.

4. Petition for a Declaratory Order: Any petition or request to intervene filed pursuant to this rule shall include the following:

    a. The name and address of the petitioner;

    b. The statute, rule, or order to which the petition relates; and

c. A concise statement of all of the facts necessary to show the nature of the controversy or uncertainty and the manner in which the statute, rule, or order in question applies or potentially applies to the petitioner.

5. Ruling on a Petition: If the Board determines that it will rule on a submitted petition and any response filed by the Board Staff, the following procedures shall apply:

a. The Board may rule solely on the petition and any response filed by the Board Staff. In such a case:

i. Any ruling of the Board will apply only to the extent of the facts and issues presented in the petition and the Board Staff's response to the petition;

ii. The Board may order the petitioner and the Board Staff to submit additional facts, file written briefs, memorandums, or statements of position;

iii. The Board may dispose of the petition on the sole basis of the matters set forth in the petition and the Board Staff's response;

iv. The Board may take notice of facts pursuant to section 24-4-105(8), C.R.S., and may utilize its experience, technical competence, and specialized knowledge in the disposition of the petition; and

v. If the Board rules on the petition without a hearing, the Board shall promptly notify the petitioner and the Board Staff of the decision.

b. The Board may, in its discretion, set a hearing, after appropriate notice, for the purpose of obtaining additional facts or information, to determine the truth of any facts set forth in the petition, or to hear oral argument on the petition. The notice of the hearing may include the factual or other matters to be addressed at the hearing. At the hearing, to the extent necessary, the petitioner shall have the burden of proving all of the facts stated in the petition, all of the facts necessary to show the nature of the controversy, or uncertainty, the manner in which the statute, rule or order in question applies or potentially applies to the petitioner, and shall include any other facts the petitioner desires the Board to consider.

6. Parties: The parties to any proceeding pursuant to this rule shall be the Board Staff and the petitioner. Any other person may request permission to intervene in the proceeding, and leave to intervene will be granted at the sole discretion of the Board. A petition to intervene shall be submitted in accordance with Section C(4) of this rule within 14 days of the filing of the petition for the declaratory order. Any reference to a "petitioner" in this rule also refers to any person who has been granted leave to intervene in a proceeding by the Board.

7. Final Agency Order: Any declaratory order or other order disposing of a petition pursuant to this rule shall constitute a final agency order subject to judicial review pursuant to section 24-4-106, C.R.S.

8. Public Inspection: Files of all petitions and declaratory orders will be maintained by the Board. Except with respect to any material required by law to be kept confidential, such files shall be available for public inspection.

9. Posted on Website: The Board shall post a copy of all statements of position and all declaratory orders on the Board's website.

Part 2 REPEALED

Part 3 AFFORDABILITY REVIEWS OF PRESCRIPTION DRUGS

3.1 Affordability Reviews of Eligible Prescription Drugs

A. Authority

The statutory authority for this part 3 is sections 10-16-1403(5) and 10-16-1406, C.R.S.

B. Scope and Purpose

The purpose of this part 3 is to establish a methodology and process for the Board to annually identify and select prescription drugs eligible for affordability review and conduct affordability reviews of prescription drugs to determine whether use of the prescription drug consistent with the labeling approved for the prescription drug by the FDA or with standard medical practice is unaffordable for Colorado consumers pursuant to section 10-16-1406(3), C.R.S.

C. Identifying Prescription Drugs for Affordability Reviews

1. The Board will adopt the list of prescription drugs eligible for an affordability review prior to consideration of which prescription drug(s) to select for an affordability review. The Board will identify eligible prescription drugs in accordance with the statutory criteria set forth in section 10-16-1406(1), C.R.S.

2. Prescription drugs that meet the following requirements qualify for an affordability review.

    a. Any prescription drug that, has:

        i. A wholesale acquisition cost of three thousand dollars or more

        ii.. An increase of three hundred dollars or more above the wholesale acquisition cost for the prescription drug in the preceding twelve months;

        iii. An increase of two hundred percent or more above the wholesale acquisition cost for the prescription drug in the preceding twelve months; or

        iv. A current wholesale acquisition cost for an average course of treatment per person per year of thirty thousand dollars or more; and

    b. Any biosimilar drug that has an initial wholesale acquisition cost that is not at least fifteen percent lower than the wholesale acquisition cost of the corresponding biological product.

D. Selecting Prescription Drugs for Affordability Reviews

After identifying prescription drugs as described in Section C above, the Board will determine whether to conduct an affordability review for an identified prescription drug by considering the following:

1. Class of the Prescription Drug and Therapeutic Equivalents:

    a. Determine the date of FDA approval of the eligible prescription drug and whether the prescription drug was approved through an expedited pathway.

b. For brand-name drugs and biological products, the Board will determine *the* class and whether there are any approved and marketed generic drugs or biosimilar drugs for the specific brand-name drug or biological product.

c. Where there are therapeutic equivalents, the Board may consider for each equivalent the cost and availability by considering utilization data and spending data.

2. Aggregated Data:

a. Historical and current pricing data, including wholesale acquisition cost and average sales price of the prescription drug;

b. Expenditures associated with the prescription drug, including expenditures identified in APCD data, including data collected pursuant to 10-16-1405, C.R.S.;

c. Utilization associated with the prescription drug, including utilization identified in APCD data;

d. Health equity impact, including whether the prescription drug is utilized to treat a condition disproportionately experienced by priority populations; and

e. Information regarding the estimated manufacturer net-cost and net-sales amounts for eligible prescription drugs.

3. Average Patient's Out-Of-Pocket Cost: Consideration of the average patient's out-of-pocket cost for the prescription drug, which may include copayment amounts, cost-sharing amounts, coinsurance amounts, and other information relevant to out-of-pocket costs.

4. Input from Advisory Council:

a. To the extent practicable, information regarding therapeutic alternatives, aggregated data, and the average patient's out-of-pocket cost will be presented to the Advisory Council.

b. The Board will seek input from the Advisory Council regarding which prescription drugs the Advisory Council recommends for the Board to select for an affordability review.

i. The Board may request the Advisory Council provide specific information, data, or its positions concerning a particular prescription drug.

ii. The Advisory Council will provide input in a form and manner determined by the Advisory Council.

c. The Board will consider input provided to it by the Advisory Council before selecting drugs for an affordability review.

5. Input Regarding Orphan Drug Designation: Consideration of whether the prescription drug has an approved orphan drug designation for one or more rare diseases and no other indications. If the prescription drug has an approved orphan drug designation for one or more rare diseases and no other indications, then the Board will consider input from consumers and the Colorado Rare Disease Advisory Council created in section 25-1-1503, C.R.S.

6. The Board may use information from D.1-D.5 to prioritize affordability goals in the selection of prescription drugs for an affordability review.

E. Conducting an Affordability Review

After selecting an eligible prescription drug from the list adopted under D, the Board will conduct an affordability review to determine whether use of the prescription drug consistent with the labeling approved for the prescription drug by the FDA or with standard medical practices is unaffordable for Colorado consumers. The Board will conduct an affordability review by considering, to the extent practicable, all of the factors set forth in section 10-16-1406(4), C.R.S., as discussed in this section E., including the additional factors created by the Board and set forth in section E.2.j. Finally, the Board may consider the factors set forth in section 10-16-1406(6), C.R.S., as discussed in section E.3.

1. To the extent the information submitted to the Board contains confidential information, the Board will consider such information in executive session and will not disclose the information publicly pursuant to section 10-16-1404(3), C.R.S.

2. In accordance with section 10-16-1406(4), C.R.S., in conducting an affordability review, to the extent practicable, the Board shall consider:

    a. Wholesale Acquisition Cost: The Board will consider both the current wholesale acquisition cost of the prescription drug and changes in the prescription drug's wholesale acquisition cost over time.

    b. Therapeutic Alternatives: The Board will consider the cost and availability of therapeutic alternatives to the prescription drug in the state. The Board may review any relevant data regarding costs and expenditures related to the prescription drug and its therapeutic alternatives, as well as any relevant data regarding availability and utilization related to the prescription drug and its therapeutic alternatives.

    c. Price Effect on Colorado Consumer Access: The Board will consider the effect of price on Colorado consumers' access to the prescription drug by reviewing changes in pricing, expenditure, and utilization over time. To the extent the data is available, the Board may consider the impact of the drug's price on insurance premiums and out-of-pocket costs, the impacts of formulary placement on access, and the extent to which rebates are shared with patients purchasing the drug.

    d. Relative Financial Effects of the Prescription Drug on Health, Medical, or Social Services Costs:

        i. To the extent such information can be quantified, the Board may consider the relative financial effects of the prescription drug on broader health, medical, and/or social services costs, compared with therapeutic alternatives and/or no treatment. This may include considering results from external analyses and modeling studies, or impacts on premiums, state expenditures on the drug or disease, and other broader system financial impacts.

        ii. The Board may identify if the literature uses a quality-adjusted life-year analysis or a similar measure that discounts the value of a life because of an individual's disability or age. The Board may use information that uses a quality-adjusted life year analysis to evaluate relative financial effects, but will not use quality adjusted life year analysis to determine an upper payment limit or other appropriate costs of a prescription drug. If quality-adjusted life year analysis is used during affordability review, the Board will acknowledge any health equity impacts to priority populations.

e. Patient Copayment or Other Cost Sharing: The Board will consider the copayment and other cost sharing data, across different health benefit plan designs, to the degree such information is available in the APCD, including:

i. Copayment;

ii. Coinsurance;

iii. Deductible;

iv. Formulary placement; and/or

v. Any other copayment and cost sharing data.

f. Impact on Safety Net Providers: When the prescription drug is available through Section 340B of the Federal "Public Health Service Act", Pub.L. 78-410, the Board will evaluate:

i. The utilization of the prescription drug by the safety net provider's patients;

ii. Whether the safety net provider receives a 340B discount for the prescription drug;

iii. Where the safety net provider does not receive a discount, whether access to the prescription drug is impeded; and

iv. Any other topics identified by safety net provider stakeholders for discussion.

g. Orphan Drug Status: The Board will consider:

i. The Board will identify whether the prescription drug is an orphan drug, as designated by the FDA pursuant to the Orphan Drug Act (Pub.L. 97-414).

ii. The Board may further consider:

(1) The use of the prescription drug for indications with an orphan drug designation as compared to the use of the prescription drug for other indications; and/or

(2) The extent to which the drug addresses an unmet need or treats a rare or serious disease for which limited therapeutic alternatives are available.

h. Input from Specified Stakeholders:

i. Patients and Caregivers

(1) The Board will seek input from patients and caregivers affected by a condition or disease that is treated by the prescription drug by gathering information related to:

(a) The impact of the disease,

(b) Patient treatment preferences,

(c) The availability of therapeutic alternatives,

(d) Patient perspective on the benefits and disadvantages of using the prescription drug,

(e) Caregiver perspective on the benefits and disadvantages of using the prescription drug, and/or

(f) Entities providing patient assistance in purchasing the prescription drug.

(2) In seeking additional information, the Board will attempt to gather a diversity of experience among patients from different socioeconomic backgrounds.

(3) The information gathered from patients and caregivers pursuant to this section will include on-label usage, off-label usage, or usage during a clinical trial.

ii. Individuals with Scientific or Medical Training: The Board will seek input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review by the Board, including:

(1) The impact of the disease,

(2) The availability of therapeutic alternatives,

(3) Perspectives on benefits and disadvantages of the prescription drug, including comparisons with therapeutic alternatives if any exist, and/or

(4) Input regarding the prescription drug utilization in standard medical practice, as well as input regarding off label usage and usage during a clinical trial.

iii. The Rare Disease Advisory Council: The Board will seek input from the Rare Disease Advisory Council with respect to a rare condition or disease treated by the prescription drug that is under review by the Board, including:

(1) The impact of the disease,

(2) Perspectives on benefits and disadvantages of the prescription drug, and

(3) Findings and recommendations concerning the needs of individuals with a rare disease living in Colorado who are affected by the prescription drug.

(4) The Rare Disease Advisory Council may provide the Board with connections to individuals with scientific and medical training who are knowledgeable with regard to the rare condition being treated by the prescription drug under review.

i. Information Voluntarily Submitted from a Manufacturer, Carrier, Pharmacy Benefit Management Firm, or Other Entity:

i. The Board will consider information voluntarily provided by a manufacturer, carrier, pharmacy benefit management firm, or other entity.

ii. Manufacturers, carriers, pharmacy benefit management firms, or other entities shall have 90 days from the commencement of the affordability review to provide such information to the Board for its consideration.

j. Additional Factors, including:

i. Rebates, Discounts, and Price Concessions: To the extent practicable, the Board may consider estimated manufacturer net-sales or net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives; and

ii. Health Equity Factors: The Board will consider whether the pricing of the prescription drug results in or has contributed to health inequities in priority populations.

iii. Information from the Department of Health Care Policy and Financing:

(1) Additional analyses HCPF conducts relevant to the prescription drug or therapeutic alternative under review; and/or

(2) Information regarding safety net providers participating in the 340B, including information to assist with gathering input to assess the impact to safety net providers for a prescription drug under review that is available through Section 340B of the Federal "Public Health Service Act", Pub.L. 78-410.

iv. Non-adherence and Utilization Management Information: The Board may use information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions and prior authorization requirements placed on the prescription drug.

v. Patient Assistance Program Information: The Board may use information regarding eligibility criteria for and the utilization of patient assistance programs.

3. Pricing Information

a. The Board may also consider documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug including information related to:

i. Life-cycle management;

ii. Average cost of the prescription drug in Colorado;

iii. Market competition;

iv. Projected revenue;

v. Estimated cost-effectiveness of the prescription drug; and/or

vi. Off-label usage of the prescription drug.

b. Pursuant to section 10-16-1406(7)(a), C.R.S., to the extent practicable, the Board may access pricing information for prescription drugs by:

i. Accessing publicly available pricing information from a state to which manufacturers report pricing information;

ii. Accessing available pricing information from the APCD and from state entities; and/or

iii. Accessing information that is available from other countries.

4. Pursuant to section 10-16-1406(7)(b), C.R.S., to the extent that there is no publicly available information with which to conduct an affordability review, the Board may request that a manufacturer, carrier, or pharmacy benefit management firm provide pricing information for any prescription drug eligible for an affordability review.

a. Such interested parties shall have 30 days from the date of the request of a prescription drug for affordability review to provide such information to the Board for its consideration.

b. Failure of an entity to provide pricing information to the Board for an affordability review does not affect the authority of the Board to conduct the affordability review, as described in this section.

5. Determination of Unaffordable: After consideration of the factors set forth in section E.2. and Section E.3., pricing information pursuant to section 10-16-1406(7)(a), C.R.S., and pricing information collected and received from manufacturers, carriers, and pharmacy benefit management firms pursuant to section 10-16-1406(7)(b), C.R.S., the Board shall determine whether the use of the prescription drug consistent with the labeling approved for the drug by the FDA or with standard medical practice is unaffordable for Colorado consumers. In reaching such a determination, the Board may consider whether the drug is unaffordable for:

a. Colorado consumers using the prescription drug;

b. Colorado consumers with diseases or conditions that the prescription drug is approved to treat;

c. Colorado consumers whose taxes fund health care costs for public employees, including employees of the state, county, and local governments, school districts, and institutions of higher education, and to public retirees whose health care costs are funded by public programs; and

d. Colorado consumers accessing the health care system in Colorado whose health care costs and health insurance premiums may be impacted by the cost of the prescription drug in the state.

6. Summary Report of Affordability Review: The Board will issue a report summarizing information considered by the Board in conducting the affordability review and reaching its determination as to whether a prescription drug is unaffordable. All reports adopted by the Board will be made public on the Board’s website.

7. Confidentiality: A person submitting information for the Board's consideration pursuant to this Part 3 shall clearly designate the specific information it deems to be confidential, trade-secret or proprietary. The Board may also determine that information submitted to it is confidential, trade secret, or proprietary. The Board may seek additional information regarding whether the information is confidential, trade-secret, or proprietary from the person submitting the information or, to the extent the Board is able to determine who created the document or information, the person who created the document or information. The Board will not disclose confidential, trade secret, or proprietary information in an open meeting, its public meeting materials, or its summary report. To the extent the information submitted to the Board contains confidential information, the Board will consider such information in executive session and will not disclose the information publicly pursuant to sections 10-16-1404(3), or to others except as provided by section 10-16-1406(5), C.R.S.

Part 4 UPPER PAYMENT LIMITS

4.1 Upper Payment Limit Methodology

A. Authority

The statutory authority for this part 4.1 is sections 10-16-1407, 10-16-1412(2), and 10-16-1403(5), C.R.S.

B. Scope and Purpose

The purpose of this part 4.1 is to establish the methodology required pursuant to section 10-16-1407, C.R.S., for the Board to establish upper payment limits for prescription drugs it has determined to be unaffordable pursuant to section 10-16-1406, C.R.S., and part 3 of these rules.

C. Methodology to Establish Upper Payment Limits

1. Number of Upper Payment Limits on Prescription Drugs: The Board may establish an upper Payment limit for any prescription drug for which the Board has performed an affordability review pursuant to section 10-16-1406, C.R.S., and part 3 of the Board's rules and determined that the use of the prescription drug is unaffordable for Colorado consumers.

    a. The Board may not establish more than twelve upper payment limits each calendar year from 2022 through 2024. If the Board finds a need to establish upper payment limits for more than twelve prescription drugs in the 2023 and 2024 calendar years, the Board may establish an additional six upper payment limits during that calendar year.

    b. Beginning in 2025, the Board may establish any number of upper payment limits.

2. Upper Payment Limit Methodology: In establishing an upper payment limit, the Board shall review the following factors to determine an upper payment limit for a prescription drug, in accordance with section 10-16-1407(2)-(4), C.R.S.

    a. Prescription Drug Costs: To approximate prescription drug costs, the Board may consider one or more price and cost metrics as an estimation of the cost of administering or dispensing the prescription drug, the cost of distributing the prescription drug, and other relevant costs. Price and cost metrics include but are not limited to:

        i. Wholesale Acquisition Cost,

        ii. Average Sales Price,

iii. National Average Drug Acquisition Cost as reported by the Center for Medicare and Medicaid Services,

iv. Out-of-pocket amounts,

v. Carrier paid amounts,

vi. Retail discount amounts,

vii. Public health care program fee schedules,

viii. Estimates of manufacturer net-cost and net-sales amounts,

ix. Medicare's Maximum Fair Price, and

x. Cost information voluntarily provided by a wholesaler, pharmacist, or provider.

b. Drug Shortage List: The Board will consider the status of the prescription drug on the Drug Shortage List published by the Drug Shortage Program within the Food and Drug Administration and the American Society of Health System Pharmacists. The Board's consideration may include:

i. Whether the prescription drug is listed on the Drug Shortage List on the day the Board adopts an upper payment limit for the prescription drug, as well as whether the prescription drug is subject to a resolved or discontinued shortage.

ii. If the prescription drug is listed on the Drug Shortage List, the Board may consider:

(1) Availability and estimated shortage duration,

(2) Shortage reason,

(3) Therapeutic classification, and

(4) Other related information.

c. Impact to Older Adults and Persons with Disabilities: The upper payment limit methodology must consider the impact of the upper payment limit methodology to older adults and persons with disabilities and shall not place a lower value on their lives.

i. Impact to Older Adults - the Board will consider the following metrics for individuals 65 years and older: to the extent such information is readily available in the APCD:

(1) To the extent such information is available in the APCD:

(a) Utilization of the prescription drug,

(b) Cost of the prescription drug, and

(c) Insurance coverage type for individuals utilizing the prescription drug; and

(2) Qualitative or quantitative analyses and information submitted by stakeholders with lived experience or expertise of the prescription drug's impact to older adults. The Board will not consider any analyses or information submitted that utilizes a cost-per-QALY or similar measure that discounts the value of life because of an individual's disability or age.

ii. Impact to Persons with Disabilities: The Board will consider the following metrics for persons with disabilities:

(1) Therapeutic classification of the prescription drug, including the prescription drug's therapeutic purpose and any conditions or diseases the prescription drug may treat,

(2) To the extent it is known that any conditions or diseases the prescription drug may treat are considered disabilities, or to the extent it is known the drug treats a condition or disease causes disabilities, and to the extent such information is available in the APCD, the Board may consider:

(a) Utilization of the prescription drug,

(b) Cost of the prescription drug, and

(c) Insurance coverage type for individuals utilizing the prescription drug; and

(3) Qualitative or quantitative analyses and information submitted by stakeholders with lived experience or expertise of the prescription drug's impact to persons with disabilities. The Board will not consider any analyses or information submitted that utilizes a cost-per-QALY or similar measure that discounts the value of life because of an individual's disability or age.

d. Reasonable Pharmacy Fees: An upper payment limit established by the Board does not preclude a pharmacist or pharmacy (as defined by section 12-280-103(43), C.R.S.) licensed by the State Board of Pharmacy to charge reasonable fees, to be paid by the providing health benefit plan of the consumer, for dispensing or delivering a prescription drug for which the Board has established an upper payment limit.

e. Research and Methods that Employ a Dollars-Per-Quality Adjusted Life Year (QALY): The Board shall not consider research or methods that employ a dollars-per-QALY or similar measure in estimating impact to older adults and persons with disabilities, or in any other upper payment limit methodology considerations.

f. Stakeholder Input: The Board shall receive stakeholder information submitted through an upper payment limit rulemaking, containing information relevant to any of these considerations that the Board may take into account in establishing an upper payment limit.

D. Process for Establishing Upper Payment Limits

1. Process: The Board will establish upper payment limits through rulemaking, as required by section 10-16-1406(1)(a)(II), C.R.S., and in compliance with section 24-4-103, C.R.S. The Board will select drugs for which to establish an upper payment limit and initiate a rulemaking for a rule establishing an upper payment limit for the prescription drug. An upper payment limit may apply to multiple NDCs that are indicated for the prescription drug.

    a. If the Board has determined a prescription drug to be unaffordable pursuant to section 10-16-1406, C.R.S, the Board may choose to establish an upper payment limit for that prescription drug. The Board will select drugs for which to establish an upper payment limit and initiate a rulemaking for a rule establishing an upper payment limit for the prescription drug.

    b. The Board may terminate a rulemaking to establish a specific upper payment limit for a prescription drug.

2. Consumer Notice: The Board's initiation of a public rulemaking pursuant to section 24-4-103, C.R.S., shall constitute notification to consumers of the Board's decision to establish an upper payment limit as required by section 10-16-1407(6), C.R.S.

3. Effective Date: rules establishing upper payment limits promulgated by the Board will identify an effective date for the upper payment limit as required by section 10-16-1407(5), C.R.S.

4. Unit: The Board will identify the unit to which the upper payment limit applies for the prescription drug.

E. Prescription Drug Availability Inquiries and Reporting

1. Withdrawal Information from Manufacturers:

    a. Inquiry process:

        i. For any upper payment limit established, the Board shall inquire of manufacturers:

            (1) Whether the manufacturer is able to make the prescription drug available for sale in the State of Colorado, and

            (2) The rationale for the manufacturer's response.

        ii. Manufacturers shall have 30 days to respond.

    b. Notification to Consumers: If the Board receives notification that a manufacturer intends to withdraw a prescription drug for which the Board has established an upper payment limit from the sale or distribution within Colorado, the Board will notify consumers within ten days, as required by section 10-16-1412(2), C.R.S.

2. Reporting to the General Assembly: The Board shall submit the manufacturer's inquiry response annually to the Health and Human Services Committee of the Senate and the Health and Insurance Committee of the House of Representatives, or to any successor committees.

F. Confidentiality

A person submitting information for the Board's consideration pursuant to this part 4 shall clearly designate the specific information it deems to be confidential, trade secret or proprietary. The Board may also determine that information submitted to it is confidential, trade secret, or proprietary. The Board will not disclose confidential, trade-secret, or proprietary information in an open meeting or its public meeting materials. The Board may seek additional information regarding whether the information is confidential, trade-secret, or proprietary from the person submitting the information or, to the extent the Board is able to determine who created the document or information, the person who created the document or information. To the extent the information submitted to the Board contains confidential information, the Board will consider such information in executive session and will not disclose the information publicly pursuant to sections 10-16-1404(3), and 10-16-1407(7), C.R.S.

4.2 Upper Payment Limit Methodology

A. Authority

The statutory authority for this part 4.2 is sections 10-16-1407 and 10-16-1403(5), C.R.S.

B. Scope and Purpose

The purpose of this part 4.2 is to establish the applicability of all upper payment limits for prescription drugs set by the Board pursuant to section 10-16-1407, C.R.S. and part 4.1 of these rules.

C. Applicability of Upper Payment Limits

1. An upper payment limit established by the Board, plus any reasonable fees charged by the pharmacy or pharmacist for dispensing or delivering a prescription drug, applies to a consumer's purchase from a pharmacy (as defined by section 12-280-103(43), C.R.S.) or provider of a prescription drug that is dispensed or administered to the Colorado consumer in person, by mail, or by other means. If the Colorado consumer is insured, the consumer's portion of the payment together with the reimbursement to the pharmacy and provider by the carrier, state entity, or optional participating plan should not exceed the upper payment limit plus any reasonable fees charged by the pharmacy or pharmacist for dispensing or delivering a prescription drug.

2. An upper payment limit established by the Board also applies to any pharmacy (as defined by section 12-280-103(43), C.R.S.) or provider's purchase of a prescription drug that is dispensed or administered to a Colorado consumer in person, by mail, or by other means.

Part 5 REPORTING REQUIREMENTS FOR USE OF SAVINGS

5.1 Reporting Requirements for Use of Savings

A. Authority

The statutory authority for this part 5 is sections 10-16-1410(3) and 10-16-1403(5), C.R.S.

B. Scope and Purpose

The purpose of this part 5 is to establish a formula and process for carriers issuing health benefit plans to calculate savings attributable to the establishment of an upper payment limit (UPL) by the Prescription Drug Affordability Board (Board) and document their use of savings for the purposes of complying with section 10-16-1410(1), C.R.S., and establish the process by which state entities and carriers that issue a health benefit plan or optional participating plans shall submit reports to the Board describing savings achieved during the preceding plan year pursuant to section 10-16-1410(2), C.R.S.

C. Reporting Requirements for Savings Attributable to Upper Payment Limits

1. On or before March 15, 2023 and each year after, each carrier, state entity, and optional participating plan subject to the requirements of section 10-16-1410, C.R.S., shall submit one report to the Board describing the savings achieved during the preceding plan year for each prescription drug for which the Board has established a UPL. For carriers, this report shall include the elements set forth in subsections C.2 and C.3. For state entities and optional participating plans, the report shall include the elements set forth in section C.3.

    a. If the Board has not established any upper payment limits, a carrier, state entity, and optional participating plan is not required to submit a report.

    b. If the Board has established upper payment limits but a carrier, state entity, or optional participating plan did not make any reimbursements for any of the prescription drugs for which there is a UPL, then a carrier, state entity, or optional participating plan shall not submit a report, but shall notify the Board that they did not reimburse pursuant to a UPL.

2. Carrier Use of Savings Formula

    Carriers shall provide the Board with aggregated claims savings, cost-sharing savings, and premium savings, for each prescription drug with a UPL for each plan ID the carrier offered in the preceding plan year.

    Claims savings are calculated and reported by determining the difference between utilization and cost of a prescription drug with a UPL compared to the estimated utilization and cost of the prescription drug without the UPL.

    Cost-sharing savings and premium savings are calculated and reported in a manner that demonstrates how carriers utilized any savings generated for a health benefit plan from a prescription drug's UPL to reduce costs to consumers, prioritizing the reduction of out-of-pocket costs.

    Estimated total claims savings (C.2.a.x) must be approximately equal to the sum of both total estimated total cost-sharing savings (C.2.b.vi.) and estimated total premium savings (C.2.c.vi.). Carriers shall provide a narrative description of any discrepancies between estimated total claims savings and the sum of estimated total cost-sharing savings and estimated total premium savings.

    a. Calculation of Carrier Claims Savings from Upper Payment Limits: Each carrier shall provide to the Board the following information for each prescription drug with a UPL using the "Prescription Drug Affordability Board Carrier Use of Savings Template" spreadsheet located on the Board's website.

        i. The utilization of each prescription drug with a UPL in the preceding plan year, expressed as the total utilization per 1000 members per year and report for each prescription drug with a UPL the reported measurement, such as "per treatment", "per dose", "per 30-day supply";

ii. The estimated utilization of each prescription drug assuming there was no upper payment limit in the preceding plan year, expressed as the total estimated utilization per 1000 members per year and report for each prescription drug with a UPL the reported measurement, such as “per treatment”, “per dose”, “per 30- day supply”. The carrier shall provide the calculations for how the estimated utilization per 1000 members per year were determined along with a narrative description;

iii. The cost per utilization for each prescription drug with a UPL;

iv. The estimated cost per utilization of each prescription drug assuming there was no upper payment limit in the preceding plan year. The carrier shall provide the calculations for how the estimated costs per utilization were determined along with a narrative description, including an explanation of any estimated trend used to determine the estimated cost;

v. Total cost per member per month for each prescription drug with a UPL;

vi. Estimated total cost per member per month without a UPL for each prescription drug with a UPL;

vii. Estimated total savings per member per month for each prescription drug with a UPL;

viii. Estimated total claims savings, per member per month for all prescription drugs with a UPL; and

ix. Estimated total claims savings for all prescription drugs with a UPL.

b. Reduction of Consumer Out-of-Pocket Costs Resulting from Carrier Claims Savings. Each carrier shall provide to the Board the following information for each prescription drug with a UPL using the “Prescription Drug Affordability Board Carrier Use of Savings Template” spreadsheet located on the Board’s website.

i. Whether each prescription drug with a UPL is subject to consumer copay or coinsurance;

ii. Cost-sharing amount for each prescription drug with a UPL that the consumer is responsible for, prior to the consumer satisfying their out-of-pocket maximum;

iii. Estimated cost-sharing amount for the prescription drug assuming there was no upper payment limit in the preceding plan year. The carrier shall provide the calculations for how the estimated cost-sharing was determined along with a narrative description, including if the estimated cost-sharing was based on cost sharing from a previous year, and any trend assumptions, if applicable;

iv. Estimated total cost-sharing savings for each prescription drug with a UPL;

v. Estimated cost-sharing savings, per member per month for all prescription drugs with a UPL; and

vi. Estimated total cost-sharing savings for all prescription drugs with a UPL.

c. Reduction of Consumer Premiums Resulting from Carrier Claims Savings. Each carrier shall provide to the Board the following information for each prescription drug with a UPL using the "Prescription Drug Affordability Board Carrier Use of Savings Template" spreadsheet located on the Board's website.

i. Total allowed paid claims amount for each prescription drug with a UPL;

ii. Estimated total allowed paid claims amount without a UPL for each prescription drug with a UPL;

iii. Premium savings per member per month due to implementation of a UPL for each prescription drug with a UPL;

iv. Total premium impact expressed as a percentage due to implementation of the UPL for each prescription drug with a UPL;

v. Estimated total premium savings, per member per month for all prescription drugs with a UPL; and

vi. Estimated total premium savings for all prescription drugs with a UPL.

3. Savings Description Report

Carriers, state entities, and optional participating plans shall prioritize the reduction of out-of-pocket costs for consumers and provide a detailed analysis and description of the out-of-pocket cost savings achieved during the preceding plan year for each prescription drug for which the Board has established a UPL. The analysis shall include at a minimum:

a. An explanation of how total claims savings were achieved;

b. An explanation of how total claims savings were used to reduce out-of-pocket costs for prescription drugs including prescription drugs subject to an upper payment limit and prescription drugs not subject to an upper payment limit, and, as appropriate, any reductions in premiums; and

c. Any changes made to the plan formulary resulting from the Board establishing a UPL, including removing or adding prescription drugs to the formulary or changing tiering of a prescription drug.

D. Confidentiality

Reports submitted to the Board pursuant to section 10-16-1410(1)-(3), C.R.S., may contain trade secret or confidential commercial or financial information such that the information is not subject to the Colorado

Open Records Act, as determined after review by the Board. A carrier, state entity, and optional participating plan that submits a report pursuant to this part 5 shall clearly identify any such information in its report that it asserts is not public as "confidential" and provide a justification for the assertion of confidentiality. Any information not marked as confidential or otherwise confidential under state law may be disclosed pursuant to the Colorado Open Records Act.

Editor's Notes

History

New rules Parts 1, 2 eff. 03/30/2022.

Part 5 eff. 10/15/2022.

Parts 1, 3 eff. 01/14/2023.

Part 4 eff. 03/17/2023.

Rules 1.1 C, 4.1 C.1.a, 4.1 D.1 eff. 11/14/2023. Part 2 repealed eff. 11/14/2023.

Parts 1, 3 eff. 01/30/2025.