#### Effective 5/12/2020

# Chapter 46 Pharmacy Benefits Act

# Part 1 General Provisions

#### 31A-46-101 Title.

This chapter is known as "Pharmacy Benefits Act."

Amended by Chapter 198, 2020 General Session

#### 31A-46-102 Definitions.

As used in this chapter:

- (1) "340B drug" means a drug purchased through the 340B drug discount program by a 340B entity.
- (2) "340B drug discount program" means the 340B drug discount program described in 42 U.S.C. Sec. 256b.
- (3) "340B entity" means:
  - (a) an entity participating in the 340B drug discount program;
  - (b) a pharmacy of an entity participating in the 340B drug discount program; or
  - (c) a pharmacy contracting with an entity participating in the 340B drug discount program to dispense drugs purchased through the 340B drug discount program.
- (4) "Administrative fee" means any payment, other than a rebate, that a pharmaceutical manufacturer makes directly or indirectly to a pharmacy benefit manager.
- (5) "Allowable claim amount" means the amount paid by an insurer under the customer's health benefit plan.
- (6) "Contracting insurer" means an insurer with whom a pharmacy benefit manager contracts to provide a pharmacy benefit management service.
- (7) "Cost share" means the amount paid by an insured customer under the customer's health benefit plan.
- (8) "Device" means the same as that term is defined in Section 58-17b-102.
- (9) "Direct or indirect remuneration" means any adjustment in the total compensation:
  - (a) received by a pharmacy from a pharmacy benefit manager for the sale of a drug, device, or other product or service; and
  - (b) that is determined after the sale of the product or service.
- (10) "Dispense" means the same as that term is defined in Section 58-17b-102.
- (11) "Drug" means the same as that term is defined in Section 58-17b-102.
- (12) "Insurer" means the same as that term is defined in Section 31A-22-636.
- (13) "Maximum allowable cost" means:
  - (a) a maximum reimbursement amount for a group of pharmaceutically and therapeutically equivalent drugs; or
  - (b) any similar reimbursement amount that is used by a pharmacy benefit manager to reimburse pharmacies for multiple source drugs.
- (14) "Medicaid program" means the same as that term is defined in Section 26B-3-101.
- (15) "Obsolete" means a product that may be listed in national drug pricing compendia but is no longer available to be dispensed based on the expiration date of the last lot manufactured.

- (16) "Patient counseling" means the same as that term is defined in Section 58-17b-102.
- (17) "Pharmaceutical facility" means the same as that term is defined in Section 58-17b-102.
- (18) "Pharmaceutical manufacturer" means a pharmaceutical facility that manufactures prescription drugs.
- (19) "Pharmacist" means the same as that term is defined in Section 58-17b-102.
- (20) "Pharmacy" means the same as that term is defined in Section 58-17b-102.
- (21) "Pharmacy benefits management service" means any of the following services provided to a health benefit plan, or to a participant of a health benefit plan:
  - (a) negotiating the amount to be paid by a health benefit plan for a prescription drug; or
  - (b) administering or managing a prescription drug benefit provided by the health benefit plan for the benefit of a participant of the health benefit plan, including administering or managing:
    - (i) an out-of-state mail service pharmacy;
    - (ii) a specialty pharmacy;
    - (iii) claims processing;
    - (iv) payment of a claim;
    - (v) retail network management;
    - (vi) clinical formulary development;
    - (vii) clinical formulary management services;
    - (viii) rebate contracting;
    - (ix) rebate administration;
    - (x) a participant compliance program;
    - (xi) a therapeutic intervention program;
    - (xii) a disease management program; or
    - (xiii) a service that is similar to, or related to, a service described in Subsection (21)(a) or (21) (b)(i) through (xii).
- (22) "Pharmacy benefit manager" means a person licensed under this chapter to provide a pharmacy benefits management service.
- (23) "Pharmacy service" means a product, good, or service provided to an individual by a pharmacy or pharmacist.
- (24) "Pharmacy services administration organization" means an entity that contracts with a pharmacy to assist with third-party payer interactions and administrative services related to third-party payer interactions, including:
  - (a) contracting with a pharmacy benefit manager on behalf of the pharmacy; and
  - (b) managing a pharmacy's claims payments from third-party payers.
- (25) "Pharmacy service entity" means:
  - (a) a pharmacy services administration organization; or
  - (b) a pharmacy benefit manager.
- (26) "Prescription device" means the same as that term is defined in Section 58-17b-102.
- (27) "Prescription drug" means the same as that term is defined in Section 58-17b-102.

(28)

- (a) "Rebate" means a refund, discount, or other price concession that is paid by a pharmaceutical manufacturer to a pharmacy benefit manager based on a prescription drug's utilization or effectiveness.
- (b) "Rebate" does not include an administrative fee.

(29)

- (a) "Reimbursement report" means a report on the adjustment in total compensation for a claim.
- (b) "Reimbursement report" does not include a report on adjustments made pursuant to a pharmacy audit or reprocessing.

- (30) "Retail pharmacy" means the same as that term is defined in Section 58-17b-102.
- (31) "Sale" means a prescription drug or prescription device claim covered by a health benefit plan.
- (32) "Wholesale acquisition cost" means the same as that term is defined in 42 U.S.C. Sec. 1395w-3a.

Amended by Chapter 198, 2020 General Session Amended by Chapter 275, 2020 General Session Amended by Chapter 372, 2020 General Session

## Part 2 Licensure

### 31A-46-201 License required.

- (1) A person may not perform, offer to perform, or advertise any pharmacy benefits management service in the state unless the person is licensed as a pharmacy benefit manager under this chapter.
- (2) A person may not utilize the services of another person as a pharmacy benefit manager if the person knows or has reason to know that the other person does not have a license under this chapter.

Enacted by Chapter 241, 2019 General Session

## 31A-46-202 Application for licensure.

- (1) To obtain or renew a license as a pharmacy benefit manager, a person shall:
  - (a) submit an application to the commissioner on forms and in a manner established by the commissioner by rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act; and
- (b) pay a licensure fee established by the department in accordance with Section 31A-3-103. (2)
  - (a) The commissioner may require an applicant to submit information or documentation regarding the management and ownership of the pharmacy benefit manager in the application described in Subsection (1)(a).
  - (b) Any material change in the information submitted in an application described in Subsection (1)(a) shall be reported to the department within 30 days after the day on which the information changes.
- (3) The term of a license issued under this section is one year.

Enacted by Chapter 241, 2019 General Session

# Part 3 Operating Requirements

#### 31A-46-301 Reporting requirements.

(1) Before April 1 of each year, a pharmacy benefit manager operating in the state shall report to the department, for the previous calendar year:

- (a) any insurer, pharmacy, or pharmacist in the state with which the pharmacy benefit manager had a contract:
- (b) the total value, in the aggregate, of all rebates and administrative fees that are attributable to enrollees of a contracting insurer; and
- (c) if applicable, the percentage of aggregate rebates that the pharmacy benefit manager retained under the pharmacy benefit manager's agreement to provide pharmacy benefits management services to a contracting insurer.
- (2) Records submitted to the commissioner under Subsections (1)(b) and (c) are a protected record under Title 63G, Chapter 2, Government Records Access and Management Act.

(3)

- (a) The department shall publish the information provided by a pharmacy benefit manager under Subsection (1)(c) in the annual report described in Section 31A-2-201.2.
- (b) The department may not publish information submitted under Subsection (1)(b) or (c) in a manner that:
  - (i) makes a specific submission from a contracting insurer or pharmacy benefit manager identifiable; or
  - (ii) is likely to disclose information that is a trade secret as defined in Section 13-24-2.
- (c) At least 30 days before the day on which the department publishes the data, the department shall provide a pharmacy benefit manager that submitted data under Subsection (1)(b) or (c) with:
  - (i) a general description of the data that will be published by the department;
  - (ii) an opportunity to submit to the department, within a reasonable period of time and in a manner established by the department by rule made in accordance with Title 63G, Chapter
    - 3, Utah Administrative Rulemaking Act:
    - (A) any correction of errors, with supporting evidence and comments; and
    - (B) information that demonstrates that the publication of the data will violate Subsection (3) (b), with supporting evidence and comments.

Amended by Chapter 198, 2020 General Session

# 31A-46-302 Direct or indirect remuneration by pharmacy benefit managers -- Disclosure of customer costs -- Limit on customer payment for prescription drugs.

- (1) If a pharmacy service entity engages in direct or indirect remuneration with a pharmacy, the pharmacy service entity shall make a reimbursement report available to the pharmacy upon the pharmacy's request.
- (2) For the reimbursement report described in Subsection (1), the pharmacy service entity shall:
  - (a) include the adjusted compensation amount related to a claim and the reason for the adjusted compensation; and
  - (b) provide the reimbursement report:
    - (i) in accordance with the contract between the pharmacy and the pharmacy service entity;
    - (ii) in an electronic format that is easily accessible; and
    - (iii) within 120 days after the day on which the pharmacy benefit manager receives a report of a sale of a product or service by the pharmacy.
- (3) A pharmacy service entity shall, upon a pharmacy's request, provide the pharmacy with:
  - (a) the reasons for any adjustments contained in a reimbursement report; and
  - (b) an explanation of the reasons provided in Subsection (3)(a).

(4)

(a) A pharmacy benefit manager may not prohibit or penalize the disclosure by a pharmacist of:

- (i) an insured customer's cost share for a covered prescription drug or prescription device;
- (ii) the availability of any therapeutically equivalent alternative medications; or
- (iii) alternative methods of paying for the prescription medication or prescription device, including paying the cash price, that are less expensive than the cost share of the prescription drug.
- (b) Penalties that are prohibited under Subsection (4)(a) include increased utilization review, reduced payments, and other financial disincentives.
- (5) A pharmacy benefit manager may not require an insured customer to pay, for a covered prescription drug or prescription device, more than the lesser of:
  - (a) the applicable cost share of the prescription drug or prescription device being dispensed;
  - (b) the applicable allowable claim amount of the prescription drug or prescription device being dispensed;
  - (c) the applicable pharmacy reimbursement of the prescription drug or prescription device being dispensed; or
  - (d) the retail price of the prescription drug or prescription device without prescription drug coverage.
- (6) For a contract entered into or renewed on or after May 12, 2020, a pharmacy benefit manager may not engage in direct or indirect remuneration that results in a reduction in total compensation received by a pharmacy from the pharmacy benefit manager for the sale of a drug, device, or other product or service unless the pharmacy benefit manager provides the pharmacy with at least 30 days notice of the direct or indirect remuneration.

Amended by Chapter 198, 2020 General Session, (Coordination Clause) Amended by Chapter 198, 2020 General Session Amended by Chapter 275, 2020 General Session

## 31A-46-303 Insurer and pharmacy benefit management services -- Registration -- Maximum allowable cost -- Audit restrictions.

- (1) An insurer and an insurer's pharmacy benefit manager is subject to the pharmacy audit provisions of Section 58-17b-622.
- (2) A pharmacy benefit manager shall not use maximum allowable cost as a basis for reimbursement to a pharmacy unless:
  - (a) the drug is listed as "A" or "B" rated in the most recent version of the United States Food and Drug Administration's approved drug products with therapeutic equivalent evaluations, also known as the "Orange Book," or has an "NR" or "NA" rating or similar rating by a nationally recognized reference; and
  - (b) the drug is:
    - (i) generally available for purchase in this state from a national or regional wholesaler; and (ii) not obsolete.
- (3) The maximum allowable cost may be determined using comparable and current data on drug prices obtained from multiple nationally recognized, comprehensive data sources, including wholesalers, drug file vendors, and pharmaceutical manufacturers for drugs that are available for purchase by pharmacies in the state.
- (4) For every drug for which the pharmacy benefit manager uses maximum allowable cost to reimburse a contracted pharmacy, the pharmacy benefit manager shall:
  - (a) include in the contract with the pharmacy information identifying the national drug pricing compendia and other data sources used to obtain the drug price data;

- (b) review and make necessary adjustments to the maximum allowable cost, using the most recent data sources identified in Subsection (4)(a), at least once per week;
- (c) provide a process for the contracted pharmacy to appeal the maximum allowable cost in accordance with Subsection (5); and
- (d) include in each contract with a contracted pharmacy a process to obtain an update to the pharmacy product pricing files used to reimburse the pharmacy in a format that is readily available and accessible.

(5)

- (a) The right to appeal in Subsection (4)(c) shall be:
  - (i) limited to 21 days following the initial claim adjudication; and
  - (ii) investigated and resolved by the pharmacy benefit manager within 14 business days.
- (b) If an appeal is denied, the pharmacy benefit manager shall provide the contracted pharmacy with the reason for the denial and the identification of the national drug code of the drug that may be purchased by the pharmacy at a price at or below the price determined by the pharmacy benefit manager.
- (6) The contract with each pharmacy shall contain a dispute resolution mechanism in the event either party breaches the terms or conditions of the contract.
- (7) This section does not apply to a pharmacy benefit manager when the pharmacy benefit manager is providing pharmacy benefit management services on behalf of the Medicaid program.

Amended by Chapter 198, 2020 General Session Amended by Chapter 275, 2020 General Session

## 31A-46-304 Claims practices.

- (1) A pharmacy benefit manager shall permit a pharmacy to collect the amount of a customer's cost share from any source.
- (2) A pharmacy benefit manager may not deny or reduce a reimbursement to a pharmacy or a pharmacist after the adjudication of the claim, unless:
  - (a) the pharmacy or pharmacist submitted the original claim fraudulently;
  - (b) the original reimbursement was incorrect because:
    - (i) the pharmacy or pharmacist had already been paid for the pharmacy service; or
    - (ii) an unintentional error resulted in an incorrect reimbursement; or
  - (c) the pharmacy service was not rendered by the pharmacy or pharmacist.
- (3) Subsection (2) does not apply if:
  - (a) any form of an investigation or audit of pharmacy records for fraud, waste, abuse, or other intentional misrepresentation indicates that the pharmacy or pharmacist engaged in criminal wrongdoing, fraud, or other intentional misrepresentation; or
  - (b) the reimbursement is reduced as the result of the reconciliation of a reimbursement amount under a performance contract if:
    - (i) the performance contract lays out clear performance standards under which the reimbursement for a specific drug may be increased or decreased; and
    - (ii) the agreement between the pharmacy benefit manager and the pharmacy or pharmacist explicitly states, in a separate document that is signed by the pharmacy benefit manager and the pharmacy or pharmacist, that the provisions of Subsection (2) do not apply.

Amended by Chapter 198, 2020 General Session

### 31A-46-305 Pharmacy reimbursement.

A pharmacy benefit manager shall reimburse a network pharmacy, in the aggregate, in an amount no less than the amount that the pharmacy benefit manager reimburses an affiliate of the pharmacy benefit manager in the same network, in the aggregate, for providing the same or equivalent pharmacy service.

Enacted by Chapter 198, 2020 General Session

## 31A-46-306 Mailing or delivering prescription drugs.

A pharmacy benefit manager or an insurer may not, directly or indirectly:

- (1) prohibit an in-network retail pharmacy from:
  - (a) mailing or delivering a prescription drug to an enrollee as an ancillary service of the innetwork retail pharmacy;
  - (b) charging a shipping or handling fee to an enrollee who requests that the in-network retail pharmacy mail or deliver a prescription drug to the enrollee, as an ancillary service; or
  - (c) offering or soliciting the ancillary services described in Subsection (1)(a) to an enrollee; or
- (2) charge an enrollee who uses an in-network retail pharmacy that offers to mail or deliver a prescription drug to an enrollee as an ancillary service a fee or copayment that is higher than the fee or copayment the enrollee would pay if the enrollee used an in-network retail pharmacy that does not offer to mail or deliver a prescription drug to an enrollee as an ancillary service.

Enacted by Chapter 198, 2020 General Session

### 31A-46-307 Pharmacy benefit manager reporting.

- (1) A pharmacy benefit manager may not enter into or renew a contract with an insurer on or after January 1, 2021, to administer or manage rebate contracting or rebate administration unless the pharmacy benefit manager agrees to regularly report to the insurer information regarding pharmaceutical manufacturer rebates received by the pharmacy benefit manager under the contract.
- (2) The quality and type of information required under Subsection (1) shall be detailed, claims level information unless the pharmacy benefit manager and insurer agree to waive this requirement in a separate written agreement.

Enacted by Chapter 198, 2020 General Session

## 31A-46-308 Out-of-state mail service pharmacies -- Drugs not readily available in all pharmacies.

- (1) As used in this section, "out-of-state mail service pharmacy" means the same as that term is defined in Section 58-17b-102.
- (2) Except as provided in Subsection (3), a third party payor of pharmaceutical services within the state, or its agent or contractor, may not require a pharmacy patient to obtain prescription drug benefits from one or more out-of-state mail service pharmacies as a condition of obtaining third party payment prescription drug benefit coverage as defined in rule.
- (3) For a prescription drug or device that is not readily available in all pharmacies, including an injectable medication, a third party payor of pharmaceutical services may require a pharmacy patient to obtain prescription drug benefits from certain pharmacies, including one or more out-of-state mail service pharmacies.

(4)

- (a) A violation of this section is a class A misdemeanor.
- (b) Each violation of this section is a separate offense.

Renumbered and Amended by Chapter 198, 2020 General Session Renumbered and Amended by Chapter 372, 2020 General Session

#### 31A-46-309 Reimbursement -- Prohibitions.

- (1) This section applies to a contract entered into or renewed on or after January 1, 2021, between a pharmacy benefit manager and a pharmacy.
- (2) A pharmacy benefit manager may not vary the amount it reimburses a pharmacy for a drug on the basis of whether:
  - (a) the drug is a 340B drug; or
  - (b) the pharmacy is a 340B entity.
- (3) Subsection (2) does not apply to a drug reimbursed, directly or indirectly, by the Medicaid program.
- (4) A pharmacy benefit manager may not:
  - (a) on the basis that a 340B entity participates, directly or indirectly, in the 340B drug discount program:
    - (i) assess a fee, charge-back, or other adjustment on the 340B entity;
    - (ii) restrict access to the pharmacy benefit manager's pharmacy network;
    - (iii) require the 340B entity to enter into a contract with a specific pharmacy to participate in the pharmacy benefit manager's pharmacy network;
    - (iv) create a restriction or an additional charge on a patient who chooses to receive drugs from a 340B entity; or
    - (v) create any additional requirements or restrictions on the 340B entity; or
  - (b) require a claim for a drug to include a modifier to indicate that the drug is a 340B drug unless the claim is for payment, directly or indirectly, by the Medicaid program.

Enacted by Chapter 275, 2020 General Session

## 31A-46-310 Prohibited actions with respect to a federally qualified health center.

- (1) As used in this section, "federally qualified health center":
  - (a) means the same as that term is defined in 42 U.S.C. Sec. 1395x(aa)(4); and
  - (b) includes the pharmacy or pharmacies that are operated by or contract with a federally qualified health center described in Subsection (1)(a) to dispense drugs purchased through the federally qualified health center.
- (2) This section applies to a contract entered into or renewed on or after January 1, 2022, between an insurer and a pharmacy described in Subsection (1)(b).
- (3) An insurer may not vary the amount that the insurer reimburses to a federally qualified health center for a drug on the basis of whether:
  - (a) the drug is a 340B drug; or
  - (b) the pharmacy is a 340B entity.
- (4) Subsection (3) does not apply to a drug reimbursed, directly or indirectly, by the Medicaid program.
- (5) An insurer or an insurer's pharmacy service entity may not:
  - (a) on the basis that a federally qualified health center participates, directly or through a contractual arrangement, in the 340B drug discount program:
    - (i) assess a fee, charge-back, or other adjustment on a federally qualified health center;

- (ii) restrict access to the insurer's pharmacy network;
- (iii) require the federally qualified health center to enter into a contract with a specific pharmacy to participate in the insurer's pharmacy network;
- (iv) create a restriction or an additional charge on a patient who chooses to receive drugs from a federally qualified health center; or
- (v) create any additional requirements or restrictions on the federally qualified health center; or
- (b) require a claim for a drug to include a modifier to indicate that the drug is a 340B drug unless the claim is for payment, directly or indirectly, by the Medicaid program.

Enacted by Chapter 317, 2021 General Session

## Part 4 Miscellaneous

#### 31A-46-401 Penalties.

A person that violates a provision of this chapter is subject to the penalties described in Section 31A-2-308.

Enacted by Chapter 241, 2019 General Session

#### 31A-46-402 Severability.

If any provision of this chapter or the application of any provision of this chapter is found invalid, the remainder of this chapter shall be given effect without the invalid provision or application.

Enacted by Chapter 241, 2019 General Session