HB0364S03 compared with HB0364S01

~~{deleted text}~~ shows text that was in HB0364S01 but was deleted in HB0364S03.

inserted text shows text that was not in HB0364S01 but was inserted into HB0364S03.

DISCLAIMER: This document is provided to assist you in your comparison of the two bills. Sometimes this automated comparison will NOT be completely accurate. Therefore, you need to read the actual bills. This automatically generated document could contain inaccuracies caused by: limitations of the compare program; bad input data; or other causes.

Representative ~~{Bradley G. Last}~~Paul Ray proposes the following substitute bill:

PHARMACY BENEFIT MANAGER AMENDMENTS

2016 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Bradley G. Last

Senate Sponsor: _____

LONG TITLE

General Description:

This bill creates registration requirements for pharmacy benefit managers.

Highlighted Provisions:

This bill:

- defines terms;
- establishes the Pharmacy Benefit Manager Act;
- requires a person providing pharmacy benefit management services to:
  - register with the Division of Occupational and Professional Licensing (DOPL) instead of the Division of Corporations and Commercial Code; and
  - self-audit and certify compliance with applicable laws and rules;
- establishes certain requirements for the practice of a pharmacy benefit manager;
- requires DOPL to:

- establish a registration process and requirements;
- investigate noncompliance and complaints; and
- provide certain notice to the Insurance Department and insurance carriers regarding registrations;

▸ authorizes administrative rules; and

▸ makes technical changes.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

31A-22-640, as last amended by Laws of Utah 2015, Chapter 258

ENACTS:

58-86-101, Utah Code Annotated 1953

58-86-102, Utah Code Annotated 1953

58-86-103, Utah Code Annotated 1953

58-86-104, Utah Code Annotated 1953

58-86-105, Utah Code Annotated 1953

~~{REPEALS AND REENACTS:~~

~~**31A-22-640**, as last amended by Laws of Utah 2015, Chapter 258~~

~~}~~

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **31A-22-640** is ~~{repealed and reenacted to read:~~

~~**31A-22-640. Insurers using pharmacy benefit management services -- Registration required**~~

~~(1) A person may not perform, offer to perform, or advertise any service as a pharmacy benefit manager in Utah without a valid registration under Title 58, Chapter 86, Pharmacy Benefit Manager Act.~~

~~(2) A person may not use the pharmacy benefit management services of another if the person knows or should know that the other does not have the registration required in~~

~~Subsection (1).}~~amended to read:

31A-22-640. Insurer and pharmacy benefit management services -- Registration -- Maximum allowable cost -- Audit restrictions.

(1) For purposes of this section:

(a) "Maximum allowable cost" means:

(i) a maximum reimbursement amount for a group of pharmaceutically and therapeutically equivalent drugs; or

(ii) any similar reimbursement amount that is used by a pharmacy benefit manager to reimburse pharmacies for multiple source drugs.

(b) "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.

(c) (i) " Pharmacy benefit manager" means a person or entity that provides pharmacy benefit management services as defined in Section 49-20-502 on behalf of an insurer as defined in Subsection 31A-22-636(1) and whose primary state of domicile is Utah.

(ii) "Pharmacy benefit manager" does not mean a person:

(A) that is primarily domiciled in a state other than Utah;

(B) that does not meet the definition of insurer in Section 31A-22-636; or

(C) that is subject to the requirements of Title 58, Chapter 86, Pharmacy Benefit Manager Act.

(2) An insurer and an insurer's pharmacy benefit manager is subject to the pharmacy audit provisions of Section 58-17b-622.

(3) 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.

(4) 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.

(5) 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 (5)(a), at least once per week;

(c) provide a process for the contracted pharmacy to appeal the maximum allowable cost in accordance with Subsection (6); 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.

(6) (a) The right to appeal in Subsection (5)(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.

(7) The contract with each pharmacy shall contain a dispute resolution mechanism in the event either party breaches the terms or conditions of the contract.

(8) (a) To conduct business in the state, a pharmacy benefit manager shall register with the Division of Corporations and Commercial Code within the Department of Commerce and annually renew the registration. To register under this section, the pharmacy benefit manager shall submit an application which shall contain only the following information:

(i) the name of the pharmacy benefit manager;

(ii) the name and contact information for the registered agent for the pharmacy benefit manager; and

(iii) if applicable, the federal employer identification number for the pharmacy benefit manager.

(b) The Department of Commerce may establish a fee in accordance with Title 63J, Chapter 1, Budgetary Procedures Act, for the initial registration and the annual renewal of the registration, which may not exceed $100 per year.

(c) The following entities do not have to register as a pharmacy benefit manager under Subsection (8)(a) when the entity is providing formulary services to its own patients, employees, members, or beneficiaries:

(i) a health care facility licensed under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act;

(ii) a pharmacy licensed under Title 58, Chapter 17b, Pharmacy Practice Act;

(iii) a health care professional licensed under Title 58, Occupations and Professions;

(iv) a health insurer; and

(v) a labor union.

(9) 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 state Medicaid program.

Section 2. Section **58-86-101** is enacted to read:

CHAPTER 86. PHARMACY BENEFIT MANAGER ACT

58-86-101. Title.

This chapter is known as the "Pharmacy Benefit Manager Act."

Section 3. Section **58-86-102** is enacted to read:

58-86-102. Definitions.

As used in this chapter:

(1) "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.

(2) "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.

(3) (a) "Pharmacy benefit manager" means a person or entity that provides pharmacy benefit management services, as defined in Section 49-20-502, on behalf of an insurer, as defined in Subsection 31A-22-636(1).

(b) "Pharmacy benefit manager" does not mean a person:

(i) that is primarily domiciled in a state other than Utah;

(ii) that does not meet the definition of insurer in Section 31A-22-636; and

(iii) that is subject to the requirements of this chapter.

Section 4. Section **58-86-103** is enacted to read:

58-86-103. Insurer and pharmacy benefit management services -- Registration -- Maximum allowable cost -- Audit restrictions.

(1) An ~~{insurer and an }~~insurer's pharmacy benefit manager ~~{are}~~is subject to the pharmacy audit provisions of Section 58-17b-622.

(2) A pharmacy benefit manager may 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 Utah from a national or regional wholesaler; and

(ii) not obsolete.

(3) A pharmacy benefit manager shall determine maximum allowable cost by 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 Utah.

(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 information identifying the national drug pricing compendia and other data

sources used to obtain the drug price data in the contract with the pharmacy;

(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 a process to obtain an update to the pharmacy product pricing files used to reimburse the pharmacy, in each contract with a contracted pharmacy, in a format that is readily available and accessible.

(5) (a) (i) A contracted pharmacy may appeal the maximum allowable cost, in accordance with Subsection (4)(c), within 21 days following the initial claim adjudication.

(ii) The pharmacy benefit manager shall investigate and resolve the appeal within 14 business days.

(b) If an appeal is denied, the pharmacy benefit manager shall provide the contracted pharmacy with:

(i) the reason for the denial; and

(ii) the identification of the national drug code of the drug for which the pharmacy appealed that may be purchased by the pharmacy at a price at or below the price determined by the pharmacy benefit manager.

(6) The pharmacy benefit manager shall ensure that the contract with each pharmacy contains a dispute resolution mechanism to be used if either party breaches the terms or conditions of the contract.

(7) (a) To conduct business in the state, a pharmacy benefit manager shall register with the division and renew the registration annually.

(b) To register under this chapter, the pharmacy benefit manager shall submit to the division an application containing:

(i) the name of the pharmacy benefit manager;

(ii) the name and contact information for the registered agent for the pharmacy benefit manager; and

(iii) if applicable, the federal employer identification number for the pharmacy benefit manager.

(c) The division may establish a fee, in accordance with Title 63J, Chapter 1,

Budgetary Procedures Act, which may not exceed $100 per year, for the initial registration and the annual renewal of the registration.

(d) The division shall:

(i) make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to establish an application process and an application form for registration under this chapter; and

(ii) retain the registration fees imposed under Subsection (7)(c) as a dedicated credit, as defined in Section 51-5-3, to the division to pay for the cost of administering this chapter.

(e) The following entities are not required to register as a pharmacy benefit manager under Subsection (7)(a) when the entity is providing formulary services to the entity's patients, employees, members, or beneficiaries:

(i) a health care facility licensed under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act;

(ii) a pharmacy licensed under Title 58, Chapter 17b, Pharmacy Practice Act;

(iii) a health care professional licensed under Title 58, Occupations and Professions;

(iv) a health insurer; and

({~~iv~~}v) a labor union.

(8) 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 state Medicaid program.

Section 5. Section **58-86-104** is enacted to read:

58-86-104.{~~ Self-audit and certification~~} Certification to division -- Complaints.

(1) The division shall make rules, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, that:

(a) for the purpose of ensuring compliance with the provisions of {~~this chapter~~}Section 58-86-103(7), require a{~~ self-audit and~~} certification of a person:

(i) registered under {~~this chapter~~}Section 58-86-103(7); or

(ii) who engages in activities that require registration under {~~this chapter~~}Section 58-86-103(7);

(b) create a form on which a person described in Subsection (1)(a){~~:~~

~~(i) ~~} certifies that the person is in full compliance with each requirement of {~~this~~

~~chapter}~~Section 58-86-103(7) and any other applicable laws, rules, regulations, or registration conditions; and

~~{ (ii) names each insurance carrier with which the person engages as a pharmacy benefit manager; and~~

~~}~~ (c) establish procedures to~~{:~~

~~(i) receive, evaluate, and investigate complaints regarding failures to comply with this chapter by a person described in Subsection (1)(a), including, if applicable, adjudicative procedures under Title 63G, Chapter 4, Administrative Procedures Act; and~~

~~(ii) }~~ provide the notice described in Section 58-86-105.

(2) A person described in Subsection (1)(a) shall honestly and in good faith complete the ~~{self-audit and }~~certification process described in Subsections (1)(a) and (b).

Section 6. Section **58-86-105** is enacted to read:

58-86-105. Notification of Insurance Department, insurance carriers.

(1) (a) The division shall give the notice described in Subsection (1)(b) when, through procedures established under Subsection 58-86-104(1)(c), the division:

(i) receives a complaint that a person ~~{who}~~that is not registered in compliance with this ~~{chapter}~~section is conducting business as a pharmacy benefit manager or providing pharmacy benefit management services, as defined in Section 49-20-502; and

(ii) determines that the complaint described in Subsection (1)(a)(i) is true.

(b) The division shall ensure that the notice required in Subsection (1)(a) contains a statement:

(i) that the person is not registered as a pharmacy benefit manager as required by this ~~{chapter}~~section; and

(ii) that the person is prohibited from providing services as a pharmacy benefit manager in Utah, unless the person registers within 60 days of receipt of the notice.

(c) The division shall give the notice required in Subsection (1)(a) to:

(i) the person who is the subject of the complaint described in Subsection (1)(a);

(ii) each insurance carrier with which the division has reason to believe the person engages as a pharmacy benefit manager; and

(iii) the Insurance Department, to promote insurer compliance with Section 31A-22-640.

(2) To promote insurer compliance with Section 31A-22-640, the division shall, at least once every three months, provide the Insurance Department with a list of all current and valid registrations under this chapter.