

**CHAPTER 79****( SB 117 )**

AN ACT relating to pharmacy benefit management.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔Section 1. KRS 304.9-020 is amended to read as follows:

As used in this subtitle:

- (1) "Agent" means a person who sells, solicits, or negotiates insurance or annuity contracts;
- (2) "Appointment" means a notification filed with the insurance department that an insurer has established an agency relationship with a producer;
- (3) "Appointment renewal" means continuation of an insurer's existing appointment based on payment of the required fee without submission of an appointment form;
- (4) "Apprentice adjuster" means an individual who meets the qualification requirements to hold a license as an independent, staff, or public adjuster, except for the experience, education, and training requirements;
- (5) "Business entity" means a corporation, association, partnership, limited liability company, limited liability partnership, employer group, professional employer organization, or other legal entity;
- (6) "Catastrophe" means an event that results in a declaration of emergency by the Governor pursuant to KRS 39A.100 and:
  - (a) A large number of deaths or injuries;
  - (b) Extensive damage or destruction of facilities that provide and sustain human needs;
  - (c) An overwhelming demand on state and local response resources and mechanisms;
  - (d) A severe long-term effect on general economic activity; or
  - (e) A severe effect on state, local, and private sector capabilities to begin and sustain response activities;
- (7) "Crop insurance" means insurance providing protection against damage to crops from unfavorable weather conditions, fire or lightning, flood, hail, insect infestation, disease, or other yield-reducing conditions or perils provided by the private insurance market or that is subsidized by the Federal Crop Insurance Corporation, including multi-peril crop insurance;
- (8) "Home state" means the District of Columbia and any state or territory of the United States in which a licensee maintains his or her principal place of residence or principal place of business and is licensed by that state;
- (9) "Independent adjuster" means a person who:
  - (a) Is an independent contractor, an employee of an independent contractor, or for tax purposes is treated as an independent contractor under Subtitle C of the Internal Revenue Code, 26 U.S.C. secs. 3101 et seq.;
  - (b) Is compensated by an insurer or self-insurer; and
  - (c) Investigates, negotiates, or settles property, casualty, or workers' compensation claims for insurers or self-insurers;
- (10) "Insurance producer" means an individual or business entity required to be licensed under the laws of Kentucky to sell, solicit, or negotiate insurance or annuity contracts. "Insurance producer" includes agent, managing general agent, surplus lines broker, reinsurance intermediary broker and manager, rental vehicle agent and rental vehicle agent managing employee, and consultant;
- (11) "Limited line credit insurance" includes credit life, credit disability, credit property, credit unemployment, involuntary unemployment, mortgage life, mortgage guaranty, mortgage disability, guaranteed automobile protection insurance, and any other form of insurance offered in connection with an extension of credit that is limited to partially or wholly extinguishing that credit obligation that the commissioner determines should be designated a form of limited line credit insurance;

- (12) "Limited line credit insurance agent" means an individual or business entity who sells, solicits, or negotiates one (1) or more forms of limited line credit insurance coverage to individuals through a master, corporate, group, or individual policy;
- (13) "Limited lines insurance" means the lines of insurance defined in subsections (7), (11), ~~(22), (27), and (29)~~~~(21), (26), and (28)~~ of this section and any other line of insurance that the commissioner identifies in accordance with KRS 304.9-230(1)(g) or recognizes for the purpose of complying with KRS 304.9-140(5);
- (14) "Negotiate" means the act of conferring directly with, or offering advice directly to, a purchaser or prospective purchaser of a particular contract of insurance concerning any of the substantive benefits, terms, or conditions of the contract, provided that the person engaged in that act either sells insurance or obtains insurance from insurers for purchasers. "Negotiate" does not include negotiating a claims settlement;
- (15) ***"Pharmacy benefit manager" means an entity that, on behalf of a health benefit plan, state agency, insurer, managed care organization providing services under KRS Chapter 205, or other third-party payor:***
- (a) Contracts directly or indirectly with pharmacies to provide prescription drugs to individuals;***
  - (b) Administers a prescription drug benefit;***
  - (c) Processes or pays pharmacy claims;***
  - (d) Creates or updates prescription drug formularies;***
  - (e) Makes or assists in making prior authorization determinations on prescription drugs;***
  - (f) Administers rebates on prescription drugs; or***
  - (g) Establishes a pharmacy network;***
- (16) "Portable electronics" means electronic devices that are portable and the accessories and services related to the use of the device;
- ~~(17)~~~~(16)~~ (a) "Portable electronics insurance" means insurance providing coverage for the repair or replacement of portable electronics for any one (1) or more of the following:
- 1. Loss;
  - 2. Theft;
  - 3. Inoperability due to mechanical failure;
  - 4. Malfunction;
  - 5. Damage; or
  - 6. Other similar causes of loss.
- (b) "Portable electronics insurance" does not mean:
- 1. A service contract governed by KRS 304.5-070;
  - 2. A policy of insurance covering a seller's or manufacturer's obligations under a warranty; or
  - 3. A homeowner's, renter's, private passenger automobile, commercial multi-peril, or similar policy;
- ~~(18)~~~~(17)~~ "Portable electronics insurance supervising entity" means a business entity that is a licensed insurer or insurance agent that is appointed by an insurer to supervise the administration of a portable electronics insurance program;
- ~~(19)~~~~(18)~~ "Portable electronics retailer" means a licensed business entity that offers and sells portable electronic devices and offers and disseminates portable electronics insurance on behalf and under the direction of a portable electronics insurance supervising entity;
- ~~(20)~~~~(19)~~ "Public adjuster" means any person who, for compensation or anything of value:
- (a) Acts on behalf of an insured or aids an insured, solely in relation to first-party claims arising under insurance contracts that insure the real or personal property of the insured, in negotiating for, or effecting the settlement of, a claim for loss or damage covered by an insurance contract;

- (b) Advertises for employment as a public adjuster of insurance claims, solicits business or represents himself, herself, or itself to the public as a public adjuster of first-party insurance claims for losses or damages arising out of policies of insurance that insure real or personal property; or
  - (c) Directly or indirectly solicits business, investigates or adjusts losses, advises an insured about first-party claims for losses or damages arising out of policies of insurance that insure real or personal property for another person, or engages in the business of adjusting losses or damages covered by an insurance policy for the insured;
- ~~(21)~~~~(20)~~ "Rental vehicle agent" means a business entity with a rental vehicle agent managing employee that is licensed to sell, solicit, or negotiate insurance offered, sold, or solicited in connection with, and incidental to, the rental of rental vehicles, whether at the rental office or by preselection of coverage in master, corporate, or group agreements that:
- (a) Are nontransferable;
  - (b) Apply only to the rental vehicle that is the subject of the rental agreement; and
  - (c) Are limited to the following kinds of insurance:
    - 1. Personal accident insurance for renters and other rental vehicle occupants for accidental death or dismemberment and for medical expenses resulting from an accident that occurs with the rental vehicle during the rental period;
    - 2. Liability insurance that provides protection to the renters and other authorized drivers of a rental vehicle for liability arising from the operation or use of the rental vehicle during the rental period;
    - 3. Personal effects insurance that provides coverage to renters and other vehicle occupants for loss of or damage to personal effects in the rental vehicle during the rental period;
    - 4. Roadside assistance insurance;
    - 5. Emergency sickness protection insurance; or
    - 6. Any other coverage designated by the commissioner;
- ~~(22)~~~~(21)~~ "Rental vehicle insurance" means insurance underwritten by an insurer authorized to transact business in Kentucky that is sold in connection with, and incidental to, a rental vehicle agreement;
- ~~(23)~~~~(22)~~ "Rental vehicle agent managing employee" means an individual who:
- (a) Is a salaried full-time employee of a licensed rental vehicle agent business entity that holds a license under KRS 304.9-505; and
  - (b) Is responsible for the supervision of the other employees engaged in the placement of insurance;
- ~~(24)~~~~(23)~~ "Sell" means to exchange a contract of insurance by any means, for money or other valuable consideration, on behalf of an insurer;
- ~~(25)~~~~(24)~~ "Solicit" means attempting to sell insurance or asking or urging a person to apply for a particular kind of insurance from a particular insurer;
- ~~(26)~~~~(25)~~ "Staff adjuster" means an individual who is an employee of an insurer who investigates, negotiates, or settles property, casualty, or workers' compensation claims on behalf of his or her employer;
- ~~(27)~~~~(26)~~ "Surety" means insurance or bond that covers obligation to pay the debts of, or answer for the default of another, including faithlessness in a position of public or private trust. Surety also includes surety insurance as defined in KRS 304.5-060;
- ~~(28)~~~~(27)~~ "Terminate" means the cancellation of the relationship between an insurance producer and the insurer or the termination of an insurance producer's authority to transact insurance;
- ~~(29)~~~~(28)~~ (a) "Travel insurance" means insurance coverage for personal risks incident to planned travel, including but not limited to:
- 1. Interruption or cancellation of a trip or event;
  - 2. Loss of baggage or personal effects;
  - 3. Damages to accommodations or rental vehicles; and

4. Sickness, accident, disability, or death occurring during travel.
- (b) "Travel insurance" does not include insurance coverage that provides comprehensive medical protection for travelers with trips lasting six (6) months or longer, including those working overseas as an expatriate or military personnel being deployed;
- ~~(30)(29)~~ "Uniform business entity application" means the current version of the uniform business entity application for resident and nonresident business entities; and
- ~~(31)(30)~~ "Uniform individual application" means the current version of the uniform individual application for resident and nonresident individuals.

➔SECTION 2. A NEW SECTION OF SUBTITLE 9 OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

- (1) (a) *In order to conduct business in this state, a pharmacy benefit manager shall first obtain a license from the commissioner. The license shall be in lieu of an administrator's license as required by KRS 304.9-052.*
- (b) *A licensed pharmacy benefit manager performing utilization review, as defined in KRS 304.17A-600, shall be registered as a private review agent in accordance with KRS 304.17A-607.*
- (2) *A pharmacy benefit manager seeking a license shall apply to the commissioner in writing on a form provided by the department. The application form shall state the name, address, official position, and professional qualifications of each individual responsible for the conduct of affairs of the pharmacy benefit manager, including all members of the board of directors, board of trustees, executive committee, other governing board or committee, the principal officers in the case of a corporation, the partners or members in the case of a partnership or association, and any other person who exercises control or influence over the affairs of the pharmacy benefit manager, and the name and address of the applicant's agent for service of process in this state.*
- (3) *Each application for a license and subsequent renewal for a license shall be accompanied by a nonrefundable fee of one thousand dollars (\$1,000) and evidence of financial responsibility in an amount of one million dollars (\$1,000,000).*
- (4) *Any person acting as a pharmacy benefit manager on the effective date of this Act and who is required to obtain a license under subsection (1) of this section, shall obtain a license from the commissioner not later than January 1, 2017, in order to continue to do business in this state. If the license fee required in subsection (3) of this section is submitted after January 1, 2017, a penalty fee of five hundred dollars (\$500) shall be paid.*
- (5) *All licenses issued under this section shall be renewed annually in accordance with KRS 304.9-260. If the renewal fee required in subsection (3) of this section is paid after the renewal date, a penalty fee of five hundred dollars (\$500) shall be paid.*

➔SECTION 3. A NEW SECTION OF SUBTITLE 9 OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

- (1) *Upon receipt of a completed application, evidence of financial responsibility, and fee, the commissioner shall make a review of each applicant and shall issue a license if the applicant is qualified in accordance with this section and Section 2 of this Act.*
- (2) *The commissioner may require additional information or submissions from applicants and may obtain any documents or information reasonably necessary to verify the information contained in the application.*
- (3) *The commissioner may suspend, revoke, or refuse to issue or renew any license in accordance with KRS 304.9-440.*
- (4) *The commissioner may make determinations on the length of suspension for an applicant, not to exceed twenty-four (24) months. However, the licensee may have the alternative, subject to the approval of the commissioner, to pay in lieu of part or all of the days of any suspension period a sum of one thousand dollars (\$1,000) per day not to exceed two hundred fifty thousand dollars (\$250,000).*
- (5) *If the commissioner's denial or revocation is sustained after a hearing in accordance with KRS Chapter 13B, an applicant may make a new application not earlier than one (1) full year after the date on which a denial or revocation was sustained.*

- (6) *The department shall promulgate administrative regulations in accordance with KRS Chapter 13A to implement and enforce the provisions of this section and Sections 2, 4, 6, and 7 of this Act. The administrative regulations shall specify the contents of the application form and any other form or report required.*
- (7) *The department may impose a fee upon pharmacy benefit managers in addition to a license fee to cover the costs of implementation and enforcement of this section and Sections 2, 4, 6, and 7 of this Act, including fees to cover the cost of:*
- (a) *Salaries and benefits paid to the personnel of the department engaged in the enforcement;*
  - (b) *Reasonable technology costs related to the enforcement process. Technology costs shall include the actual cost of software and hardware utilized in the enforcement process and the cost of training personnel in the proper use of the software or hardware; and*
  - (c) *Reasonable education and training costs incurred by the state to maintain the proficiency and competence of the enforcing personnel.*

➔SECTION 4. A NEW SECTION OF SUBTITLE 9 OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

*Pharmacy benefit managers shall be subject to this subtitle and to the provisions of Subtitles 1, 2, 3, 4, 12, 14, 17, 17A, 17C, 18, 25, 32, 38, 47, and 99 of KRS Chapter 304 to the extent applicable and not in conflict with the expressed provisions of this subtitle.*

➔Section 5. KRS 304.17A-161 is amended to read as follows:

As used in this section and KRS 304.17A-162, **304.17A-163, and 304.17A.165** unless the context requires otherwise:

- (1) "Contracted pharmacy" or "pharmacy" means a pharmacy located in Kentucky participating in the network of a pharmacy benefit manager through a direct contract or through a contract with a pharmacy services administration organization or group purchasing organization;
- (2) "Drug product reimbursement" means the amount paid by a pharmacy benefit manager to a contracted pharmacy for the cost of the drug dispensed to a patient and does not include a dispensing or professional fee; ~~and~~
- (3) *"Maximum allowable cost" means the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for the cost of a generic drug and does not include a dispensing or professional fee; and*
- (4) "Pharmacy benefit manager" means an entity that, ~~contracts with pharmacies~~ on behalf of a health benefit plan, state agency, insurer, managed care organization *providing services under KRS Chapter 205*, or other third-party payor:
  - (a) *Contracts directly or indirectly with pharmacies to provide prescription drugs to individuals;*
  - (b) *Administers a prescription drug benefit;*
  - (c) *Processes or pays pharmacy claims;*
  - (d) *Creates or updates prescription drug formularies;*
  - (e) *Makes or assists in making prior authorization determinations on prescription drugs;*
  - (f) *Administers rebates on prescription drugs; or*
  - (g) *Establishes a pharmacy network* ~~[to provide pharmacy health benefit services or administration].~~

➔Section 6. KRS 304.17A-162 is amended to read as follows:

- (1) *A pharmacy benefit manager shall* ~~[All contracts between a pharmacy benefit manager and a contracted pharmacy shall include]:~~
  - (a) *Identify to contracted pharmacies* the sources used by the pharmacy benefit manager to calculate the drug product reimbursement paid for covered drugs available under the pharmacy health benefit plan administered by the pharmacy benefit manager; *and*
  - (b) *Establish a process for contracted pharmacies, pharmacy services administration organizations, or group purchasing organizations*, to appeal ~~[, investigate,]~~ and resolve disputes regarding the maximum allowable cost pricing. The process shall include the following provisions:

1. The right to appeal shall be limited to sixty (60) days following the initial claim;
  2. The appeal shall be investigated and resolved **by the pharmacy benefit manager** within ten (10) **calendar** days;~~and~~
  3. **The pharmacy benefit manager shall respond to all appeals in a manner approved by the department;**
  4. If the appeal is denied, the pharmacy benefit manager shall provide the reason for the denial and identify the national drug code of a drug product **and source where it ~~that~~** may be purchased **from a licensed wholesaler** by contracted pharmacies at a price at or below the maximum allowable cost; and
  5. **If an appeal is granted, the provisions of subsection (2) of this section shall apply.**
- ~~{(c) Within one (1) year from June 25, 2013, a process to provide for retroactive reimbursements.}~~
- (2) **If a price update is warranted as a result of an appeal granted under subsection (1) of this section, the pharmacy benefit manager shall:**
    - (a) **Make the change in the maximum allowable cost to the initial date of service the appealed drug was dispensed;**
    - (b) **Adjust the maximum allowable cost of the drug for the appealing pharmacy and for all other contracted pharmacies in the network of that pharmacy benefit manager that filled a prescription for patients covered under the same health benefit plan to the initial date of service the appealed drug was dispensed;**
    - (c) **Individually notify all other contracted pharmacies in the network of that pharmacy benefit manager that a retroactive maximum allowable cost adjustment has been made as a result of a granted appeal effective to the initial date of service the appealed drug was dispensed;**
    - (d) **Adjust the drug product reimbursement for contracted pharmacies that resubmit claims to reflect the adjusted maximum allowable cost if applicable to their contract;**
    - (e) **Allow the appealing pharmacy and all other contracted pharmacies in the network that filled prescriptions for patients covered under the same health benefit plan to reverse and resubmit claims and receive payment based on the adjusted maximum allowable cost from the initial date of service the appealed drug was dispensed; and**
    - (f) **Make retroactive price adjustments in the next payment cycle.**
  - (3) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall ~~;~~
    - ~~(a) make available to all contracted pharmacies~~~~{include in the contract with the pharmacy}~~ information identifying the national drug pricing compendia or sources used to obtain the drug price data **in a manner established by administrative regulations promulgated by the department.**~~;~~
    - ~~(b) (4) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall make available to all contracted pharmacies in a manner established by administrative regulations promulgated by the department~~~~{a contracted pharmacy}~~ **the comprehensive list of drugs subject to maximum allowable cost and the actual maximum allowable cost for each drug.**~~;~~
    - ~~(c) (5) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall make available to the department, upon request, information that is needed to resolve an appeal. If the department is unable to obtain information from the pharmacy benefit manager that is necessary to resolve the appeal, the appeal shall be granted to the appealing pharmacy.~~
  - (6) **For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall review and make necessary adjustments to the maximum allowable cost for every drug at least every seven (7) calendar**~~{fourteen (14)}~~ days **and shall immediately utilize the updated maximum allowable cost in calculating the payments made to all contracted pharmacies.**~~{and}~~

- (7)(4) ~~For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall make available to all contracted pharmacies in a manner established by administrative regulations promulgated by the department~~ ~~[a contracted pharmacy]~~ weekly updates to the list of drugs subject to maximum allowable cost and the actual maximum allowable cost for each drug.
- (8) *For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall ensure that drugs subject to maximum allowable costs are:*
- (a) *Generally available for purchase by pharmacists and pharmacies in Kentucky from a national or regional wholesaler licensed in Kentucky by the Kentucky Board of Pharmacy;*
  - (b) *Not obsolete, temporarily unavailable, or listed on a drug shortage list; and*
  - (c) *1. Drugs that have an "A" or "B" rating in the most recent version of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book; or*  
*2. Drugs rated "NR" or "NA" or have a similar rating by a nationally recognized reference.*
- (9) *For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall ensure that reimbursement for a drug subject to maximum allowable cost is based solely on that drug and drugs that are therapeutically equivalent if the therapeutically equivalent drugs are listed in the most recent version of the United States Food and Drug Administration Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.*
- (10) *For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall ensure that reimbursement for a "B" rated drug subject to maximum allowable cost is based solely on that drug and drugs that are not therapeutically equivalent to a "B" rating in the most recent version of the United States Food and Drug Administration Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.*
- (11) *For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall ensure that reimbursement for a "NR" or "NA" drug with a similar rating by a nationally recognized reference subject to maximum allowable cost is based solely on that drug and other drugs with a "NR" or "NA" rating or similar rating by a nationally recognized reference that meets criteria for therapeutic equivalence used in the United States Food and Drug Administration Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book.*
- (12) *For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall ensure that reimbursement for a drug subject to maximum allowable cost is based solely on that drug if there is no other therapeutically equivalent drug.*
- (13) *For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall ensure that reimbursement for a drug subject to maximum allowable cost is not based on a drug that is obsolete, temporarily unavailable, listed on a drug shortage list, or that cannot be lawfully substituted.*

➔SECTION 7. A NEW SECTION OF KRS CHAPTER 205 IS CREATED TO READ AS FOLLOWS:

- (1) *As used in this section, "pharmacy benefit manager" has the same meaning as in Section 1 of this Act.*
- (2) *A pharmacy benefit manager contracted with a managed care organization that provides Medicaid benefits pursuant to this chapter shall comply with the provisions of this section and Sections 2, 3, 4, and 6 of this Act.*
- (3) *Subsections (10), (11), (12), and (13) of Section 6 of this Act shall not apply to a pharmacy benefit manager contracted directly with the cabinet to provide Medicaid benefits.*

Signed by Governor April 9, 2016.

