COMMONWEALTH OF KENTUCKY
DEPARTMENT OF INSURANCE
Frankfort, Kentucky

BULLETIN 2016-02

INSURANCE LEGISLATION ADOPTED BY THE 2016 KENTUCKY GENERAL ASSEMBLY (REGULAR SESSION)

July 5, 2016

THIS BULLETIN IS FOR INFORMATION PURPOSES ONLY. IT DOES NOT AMEND OR INTERPRET PROVISIONS OF THE KENTUCKY REVISED STATUTES OR THE KENTUCKY ADMINISTRATIVE REGULATIONS. THE COMPLETE AND ACCURATE TEXT OF THE LAW CAN BE SECURED WHEN THE 2016 ACTS OF THE KENTUCKY GENERAL ASSEMBLY ARE PUBLISHED IN THE SUMMER OF 2016. UNLESS OTHERWISE NOTED, THE EFFECTIVE DATE OF THE LEGISLATION IS JULY 15, 2016.

(Bills as enacted are available on the LRC website at http://www.lrc.ky.gov/record/16RS/record.htm)

Senate Bill 18 – An Act relating to medical coverage

SB 18 addresses two specific topics: (1) material changes to provider contracts related to health benefit plans and Medicaid managed care plans, and (2) coverage for therapeutic food, formulas, and supplements for the treatment of genetic conditions.

Material Changes to Provider Contracts

SB 18 amends KRS 304.17A-578 and KRS 304.17C-060 to require insurers offering a health benefit plan or a limited service health benefit plan to establish procedures for changing an existing agreement with a participating provider. (The bill expands the definition of provider within the existing statute.) The procedures must include the following:

- Insurers must provide a participating provider at least ninety (90) days' prior notice of a material change to an existing provider agreement. Material change is a defined term in the bill.
- The notice of a material change shall:
    - Provide the proposed effective date of the change;
    - Include a description of the material change;

- Include a statement that the participating provider has the option to either accept or reject the proposed material change;
- Provide the name, business address, telephone number, and electronic mail address of a representative of the insurer to discuss the material change, if requested by the participating provider;
- Provide notice of the opportunity for a meeting using real-time communication to discuss the proposed changes if requested by the participating provider ("real-time communication" is defined in the bill); and
- Provide notice that upon three (3) material changes in a twelve (12) month period, the provider may request a copy of the contract that includes all material changes.

For material changes that relate to the participating provider's inclusion in any new or modified insurance products or proposed changes to the participating provider's membership networks, the change shall not take effect until accepted through a written signature by the participating provider. Notice of the change must be sent in the following manner to the provider's point of contact, as set forth in the provider agreement or if no point of contact is set forth in the provider agreement, to the provider's place of business addressed to the provider:

- By certified mail, return receipt requested; and
- In an orange envelope marked "ATTENTION! CONTRACT AMENDMENT ENCLOSED!" in at least 14-point, boldface, Times New Roman font printed on the front of the envelope.

For any other material change, the material change will take effect on the date provided in the notice unless the participating provider objects to the change. To object to a material change, the participating provider must deliver a written objection to the insurer within thirty (30) days of the receipt of the proposed material change. Within thirty (30) days following receipt of the notice of objection, the insurer and the participating provider must attempt to reach an agreement regarding the disputed provisions. If an agreement is not reached, the insurer and the provider have thirty (30) days to terminate the contract and provide notice to patients and other affected parties.

<u>Coverage for therapeutic food, formulas, and supplements for the treatment of genetic conditions</u>
Section 4 amends KRS 304.17A-258 to clarify that mitochondrial disease is a genetic condition for which coverage for therapeutic food, formulas, and supplements must be provided. The bill specifies that the use of vitamin and nutritional supplements such as coenzyme Q10, vitamin E, vitamin C, vitamin B1, vitamin B2, vitamin K1, and L-carnitine are included in the definition of therapeutic food, formulas and supplements, even if the supplements are compounded.

Contact: *Health & Life Division*
(502) 564-6088

Senate Bill 58 – An Act relating to automobile service contract insurance

This bill amends KRS 304.5-070 to state that a service contract by a service contract provider that has obtained a reimbursement insurance policy is not a contract of insurance.

If a service contract provider is a manufacturer or distributor of motor vehicles or a wholly owned subsidiary of a manufacturer or distributor, the service contract provider is not required to obtain a reimbursement insurance policy in order for the service contract not to be considered a contract of insurance.

"Reimbursement insurance policy" is defined as a policy or insurance which:

- Provides reimbursement to the service contract provider under the terms of the service contracts issued or sold by the service contract provider or, in the event of the service contract provider's nonperformance, pays on behalf of the service contract provider all covered contractual obligations incurred by the service contract provider under the terms of the service contracts issued or sold by the service contract provider; and
- Is issued by an admitted or authorized registered insurer, or properly exported to a nonadmitted insurer by a licensed surplus lines broker, to a service contract provider.

"Service contract" is defined as a contract or agreement given for a separately stated consideration for a specific duration to perform or to provide reimbursement for:

- The repair, replacement, or maintenance of a motor vehicle for the operational or structural failure of the motor vehicle due to a defect in materials, workmanship, or normal wear and tear, with or without additional provisions for incidental payment of indemnity under limited circumstances including but not limited to towing, rental, and emergency road service;
- The repair or replacement of tires or wheels on a motor vehicle damaged as a result of coming into contact with road hazards including but not limited to potholes, rocks, wood debris, metal parts, glass, plastic, curbs, or composite scraps;
- The removal of dents, dings, or creases on a motor vehicle that can be repaired using the process of paintless dent removal without affecting the existing paint finish and without replacing vehicle body panels, sanding, bonding, or painting;
- The repair of chips or cracks in or the replacement of motor vehicle windshields as a result of damage caused by road hazards including but not limited to potholes, rocks, wood debris, metal parts, glass, plastic, curbs, or composite scraps; or
- The replacement of a motor vehicle key or key-fob if the key or key-fob becomes inoperable or is lost or stolen.

The bill specifically excludes from the definition of "service contract" a contract for regular maintenance only or a product warranty provided under the Magnuson-Moss Warranty Act.

"Service contract provider" is defined as a person who is contractually obligated to the purchaser of a service contract under the terms of the service contract.

Section 2 of the bill amends KRS 190.090 to conform to the definition in KRS 304.5-070.

Contact: *Property & Casualty Division*
(502) 564-6046

SB 117 – An Act relating to pharmacy benefit management

This bill (1) creates a specific license for pharmacy benefit managers (PBM); and (2) sets forth a statutory appeals process for prescription drug claims reimbursed based on maximum allowable cost (MAC) pricing.

PBM License
Section 1 of the bill defines a pharmacy benefit manager as 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:

- Contracts directly or indirectly with pharmacies to provide prescription drugs to individuals;
- Administers a prescription drug benefit;
- Processes or pays pharmacy claims;
- Creates or updates prescription drug formularies;
- Makes or assists in making prior authorization determinations on prescription drugs;
- Administers rebates on prescription drugs; or
- Establishes a pharmacy network.

Section 2 requires an entity acting as a PBM to obtain a license from the commissioner. The license is in lieu of an administrator's license as required by KRS 304.9-052. However, if the PBM is performing utilization review as defined in KRS 304.17A-600, the PBM also must be registered as a private review agent.

To apply for a license as a PBM, the applicant must submit:

- An application;
- A nonrefundable fee of $1,000; and
- Evidence of financial responsibility in the amount of $1,000,000.

If an entity is acting as a PBM on the effective date of this Act, the entity has until January 1, 2017, to obtain a license in order to continue doing business. A $500 penalty must be paid if the license fee is submitted after January 1, 2017.

The PBM is required to be renewed annually. The renewal fee is $1,000. A $500 penalty must be paid if the renewal fee is received after the renewal date.

Section 3 sets forth the following responsibilities of the department regarding the enforcement of the bill:

- The commissioner is required to review each PBM application and issue a license to qualified applicants. The commissioner may require additional information reasonably necessary to verify the information contained in the application.
- A PBM license may be suspended, revoked, or denied in accordance with KRS 304.9-440. A suspension of a PBM license may be issued for twenty-four (24) months or less. However, if approved by the commissioner, a licensee may pay in lieu of part or all of the suspension period, a penalty of $1,000 per day not to exceed $250,000.
- If the denial or revocation of a PBM license is sustained after an administrative hearing, an applicant must wait at least one year before submitting a new application.
- The department may impose a fee upon PBMs in addition to the license fee to cover the costs of implementation and enforcement of the bill.

Section 4 of the bill clarifies that PBMs are subject to provisions within the following subtitles of the Insurance Code:

- Subtitle 1;
- Subtitle 2;
- Subtitle 3;
- Subtitle 4;
- Subtitle 12;
- Subtitle 14;
- Subtitle 17;
- Subtitle 17A;
- Subtitle 17C;
- Subtitle 18;
- Subtitle 25;
- Subtitle 32;
- Subtitle 38;
- Subtitle 47; and
- Subtitle 99.

<u>Appeals Process Related to Maximum Allowable Cost (MAC) Pricing</u>

The bill amends KRS 304.17A-162 to create within the statute, rather than within the contract between a PBM and a contracted pharmacy, a process to resolve disputes about MAC pricing. The process must include the following provisions:

- An appeal must be made within sixty (60) days following the initial claim;
- The appeal must be investigated and resolved by the PBM within ten (10) calendar days;
- The PBM must respond to all appeals in a manner approved by the department; and
- If the appeal is denied, the PBM must provide:
    - The reason for the denial;
    - The national drug code of a drug product; and

    - The source where the drug may be purchased from a licensed wholesaler by contracted pharmacies at or below the MAC price.

If the appeal results in a price update, the PBM must take the following action as of the initial date of service that the appealed drug was dispensed:

- Make the change in the MAC pricing;
- Adjust the MAC price of the drug from the appealing pharmacy and for all other contracted pharmacies in the network of that PBM that filled a prescription for patients covered under the same health benefit plan;
- Individually notify all other contracted pharmacies in the network of that PBM that a retroactive MAC adjustment has been made as a result of an appeal;
- Adjust the drug product reimbursement for contracted pharmacies that resubmit claims to reflect the adjusted MAC price if applicable to their contract;
- 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 MAC price; and
- Make retroactive price adjustments in the next payment cycle.

With regard to drugs for which the PBM establishes a MAC price, the PBM must:

- Make available to all contracted pharmacies in a manner established through administrative regulation by the department:
    - information identifying the national drug pricing compendia or sources used to obtain the drug price data in a manner established through administrative regulation by the department;
    - a comprehensive list of drugs subject to MAC pricing and the actual MAC price for each drug; and
    - weekly updates to the list of drugs subject to MAC pricing and the actual MAC price for each drug;

- Make available to the department, upon request, information needed to resolve an appeal;
- Review and make necessary adjustments to the MAC pricing every seven (7) calendar days and immediately use the updated pricing in calculating payments to all contracted pharmacies;
- Ensure that drugs subject to MAC pricing are:
    - 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;
    - Not obsolete, temporarily unavailable, or listed on a drug shortage list; and
    - Have an “A” or “B” rating in the Orange Book; or an “NR” or “NA” or a similar rating by a nationally recognized reference; and
- Ensure that reimbursement:
    - Is based solely on that drug and drugs that are therapeutically equivalent if the therapeutically equivalent drug is listed in the Orange Book;

- Is not based on a drug that is obsolete, temporarily unavailable, listed on a drug shortage list, or that cannot be lawfully substituted;
- For a "B" rated drug is based solely on that drug and drugs that are not therapeutically equivalent to a "B" rating in the Orange Book;
- For a "NR" or "NA" drug or a similar rating by a national recognized reference is based solely on that drug and other drugs with a "NR" or "NA" rating or a similar rating; and
- For drugs with no other therapeutically equivalent drug, is based solely on that drug.

Section 7 of the bill creates a new statute within KRS 205 to require PBMs that contract with Medicaid managed care organizations to comply with the provisions of the bill except for the provisions in Section 6(10), (11), (12), and (13) related to reimbursement for therapeutically equivalent drugs.

Contact: *Agent Licensing Division*
(502) 564-6004

Health & Life Division
(502) 564-6088

Senate Bill 193 – An Act relating to health benefit coverage of amino acid-based elemental formula and declaring an emergency

Section 3 of this bill amends KRS 304.17A-258 to clarify that the following are genetic conditions for which coverage for therapeutic food, formulas, and supplements must be provided:

- Eosinophilic disorders;
- Food protein allergies;
- Food protein-induced enterocolitis syndrome; and
- Short bowel disorders.

The bill defines "amino acid-based elemental formula" as a product intended for the diagnosis and dietary treatment of eosinophilic disorders, food protein allergies, food protein-induced enterocolitis, and short bowel syndrome under the direction of a physician.

Section 4 of this bill requires any health insurance policy provided to state employees or their dependents to include coverage for obtaining amino acid-based elemental formula in accordance with KRS 304.17A-258.

This bill has an emergency clause and was effective upon the Governor's signature on April 1, 2016.

Contact: *Health & Life Division*
(502) 564-6088

House Bill 80 – An Act relating to government operations

Section 9 of this bill includes non-codified language related to the assessment set forth in KRS 304.17B-021. The language allows the Department of Insurance to determine the amount of the assessment to be imposed on insurers who offer qualified health plans on the federal exchange in the individual market segment in the 2017 or 2018 plan year. The amount of the assessment cannot exceed the maximum amount set forth in KRS 304.17B-021.

Contact: *Health & Life Division*
(502) 564-6088

House Bill 100 – An Act relating to insurance coverage of autism spectrum disorders

This bill creates a new statute within KRS 304, Subtitle 17A to require an insurer to have a member liaison to facilitate communication between the member and the insurer regarding benefits for the treatment of autism spectrum disorders. Specifically, the liaison's responsibilities include, but are not limited to, the following:

- Explaining to the member the benefits for the treatment of autism under the member's health benefit plan and the specific process to access those benefits;
- Explaining to the member the process for prior authorization of treatment, including communicating specific documentation needed from the member or provider for the insurer to consider the request;
- Monitoring the adjudication of the member's claims for the treatment of autism services;
- Explaining to the member the proper coding to use when submitting claims for applied behavioral analysis therapy and any supporting documentation required to be attached to the claim;
- Explaining to the member, upon request, how claims for the treatment of autism services were adjudicated, including the application of any deductibles, copayments, coinsurance, and benefit limitations; and
- Explaining to the member, upon request, any appeal rights the member may have regarding coverage for the treatment of autism that has been denied or limited.

Contact: *Health & Life Division*
(502) 564-6088

For Informational Purposes Only

Senate Bill 11 – An Act relating to alcoholic beverages

SB 11 deals primarily with licenses issued by the Department of Alcoholic Beverage Control. Of note to the insurance industry, section 1(16) of SB 11 defines a "commercial quadricycle" as a vehicle equipped with a minimum of ten (10) pairs of fully operative pedals for propulsion by means of human muscular power exclusively and which:

- Has four (4) wheels;
- Is operated in a manner similar to that of a bicycle;
- Is equipped with a minimum of thirteen (13) seats for passengers;
- Has a unibody design;
- Is equipped with a minimum of four (4) hydraulically operated brakes;
- Is used for commercial tour purposes; and
- Is operated by the vehicle owner or an employee of the owner.

Section 2 includes the licensing requirement for the operation of a commercial quadricycle including the requirement that the applicant maintains general liability insurance of at least two million dollars ($2,000,000). Written documentation of this insurance is required for the issuance or renewal of the license. The applicable local government may adopt additional insurance requirements.

Senate Bill 20 – An Act relating to Medicaid provider appeals

SB 20 creates a new section of KRS 205 to establish an appeals process to review the denial of a health care service or a claim for reimbursement by a Medicaid managed care organization.

The external independent third party review process is available to a provider who has exhausted the written internal appeals process of a Medicaid managed care organization (MCO).

Section 1(3) requires a MCO's final decision of an internal appeal by a provider to include:

- A statement that the provider's internal appeal rights within the MCO have been exhausted;
- A statement that the provider is entitled to an external independent third-party review; and
- The time period and address to request an external independent third-party review.

The bill also gives a provider the right to appeal a final decision of the external independent third-party review to the Cabinet for Health and Family Services' administrative hearings branch. An appeal must be filed within thirty (30) days of the final decision of the external independent third-party review.

The Cabinet for Health and Family Services is required to promulgate administrative regulations to implement the external independent third-party review requirements within 120 days of its effective date (April 8, 2016). The Cabinet will also promulgate an administrative regulation to establish a fee, not to exceed $1,000, to defray the cost of any administrative hearing. The fee will be paid by the party who does not prevail in the hearing.

This appeal process will apply to all contracts between an MCO and the Commonwealth of Kentucky entered into or renewed on or after July 1, 2016.

Senate Bill 56 – An Act relating to driving under the influence and declaring an emergency

The bill amends various statutes related to penalties for driving under the influence to increase the time period for which offenses can be considered from five (5) years to ten (10) years.

Senate Bill 195 – An Act relating to firefighters

This bill specifies that if a firefighter dies as a result of specified types of cancer, the death shall be a direct result of an act in the line of duty if the firefighter:

- Was a firefighter for at least five (5) consecutive years;
- Developed one (1) or more of the specified types of cancer which caused the firefighter's death within ten (10) years of separation from service as a firefighter;
- Did not use tobacco products for a period of ten (10) years prior to the diagnosis of cancer;
- Was under the age of sixty-five (65) at the time of death;
- Was not diagnosed with any cancer prior to employment as a firefighter; and
- Was exposed while in the course of firefighting to a known carcinogen as defined by the International Agency for Research on Cancer of the National Toxicology Program and the carcinogen is reasonably associated with one of the specified types of cancer.

For purposes of this bill, the specified types of cancer include:

- Bladder cancer;
- Brain cancer;
- Colon cancer;
- Non-Hodgkin's lymphoma;
- Kidney cancer;
- Liver cancer;
- Lymphatic or haematopoietic cancer;
- Prostate cancer;
- Testicular cancer;

- Skin cancer;
- Cervical cancer; and
- Breast cancer.

House Bill 40 – An Act relating to criminal records

This bill permits persons convicted of specific Class D felonies to apply to have the judgment vacated and records expunged.

The bill requires the Administrative Office of the Courts to retain an index of expungement orders that only is accessible to persons preparing a certification of eligibility for expungement.

House Bill 382 – An Act relating to transfer of motor vehicles

This bill amends KRS 186A.220 to specify that when a dealer assigns a vehicle to a purchase for use, the transfer and delivery of the vehicle is effective immediately upon the delivery of all necessary legal documents including proof of insurance as mandated by KRS 304.39-080.

/s/ H. Brian Maynard
H. Brian Maynard
Commissioner
Kentucky Department of Insurance

July 5, 2016
Date