House Bill 64 - An act relating to pharmacists.

Permits a pharmacist to prescribe a maintenance medication for a greater than seventy-two hour supply without specific authorization from a prescribing practitioner in emergency situations where authorization is not easily obtained. The prescription is permitted when the standard unit of the drug dispensed exceeds a seventy-two hour supply, the standard unit is dispensed, and the drug is used for insulin therapy or another chronic respiratory disease.

House Bill 151 - An act relating to insurance fraud.

Amends the insurance fraud penalties under Subtitle 47 of the Kentucky Insurance Code based on the claim, money, or benefit amount subject to the insurance fraud. The new penalties are as follows:

- Below five hundred dollars ($500) is a Class A misdemeanor;
- Five hundred dollars ($500) to less than $10,000 is a Class D felony;
- $10,000 to less than $1,000,000 is a Class C felony; and
- $1,000,000 or more is a Class B felony.

The punishments for violations include imprisonment for terms as dictated by the level above, a fine, or both.
Multiple Kentucky licensing boards are now required to report suspected fraudulent insurance acts to the Department of Insurance (the “Department”). The boards subject to the reporting requirements include:

- Board of Medical Licensure;
- Board of Chiropractic Examiners;
- Board of Nursing;
- Board of Physical Therapy;
- Board of Occupational Therapy; and
- Board for Massage Therapy.

These boards have also been extended immunity from civil liability for libel, slander, or related cause for fraud reporting in the absence of malice, fraud, or gross negligence.

To combat health care provider fraud exclusively in the context of the Motor Vehicle Reparations Act, the bill includes an entirely new section prohibiting health care provider self-referrals. Health care providers are defined to include those individuals licensed under KRS 309.353, KRS Chapter 311, 311A, 311B, 312, 313, 314, 314A, 315, 319, 319A, 319B, 320, 327, and a medical laboratory under KRS 333.020. This prohibition does not apply to providers under these sections enrolled in the Kentucky Medicaid program. The bill prohibits, subject to specific federal exceptions, a provider from referring an individual to a person or entity for health care services when the provider has an ownership interest, investment interest, or compensation agreement in the person or entity. In the event a provider violates this section, the Department and the appropriate licensure board may assess civil penalties.

The bill also makes changes to the availability of accident reports from the Kentucky State Police.

**HB 156 - An act relating to insurance.**

Creates a limited exception stating a public adjuster or staff adjuster license is not required for employees or agents of an insurer to adjust food spoilage claims under a residential property insurance policy of $1,000 or less. Previously, individuals adjusting insurance claims were required to hold a license unless an exception to the licensure requirement applied. Therefore, HB 156 permits an insurer to use an unlicensed employee or agent to adjust food spoilage claims of $1,000 or less for residential property insurance policies.

The Department recommends insurers take advantage of this exception during times of natural disaster or otherwise to expedite claims processing to those individuals in need.

**HB 218 - AN ACT relating to dialysate solutions and devices.**

Permits manufacturers or the manufacturer’s agents to receive prescriptions from a licensed Kentucky pharmacist and sell and distribute dialysate solutions and devices to end stage renal patients in Kentucky. Multiple requirements must be satisfied to permit the sale and distribution. If these requirements are satisfied, the manufacturer or their agent can ship the items directly to the patients without being licensed as an out of state pharmacy. Health insurers and pharmacy
benefit managers should consider this option for the sale and distribution of dialysate solutions and devices, and ensure policies are updated to conform and permit this option, if necessary.

**HB 220 - An act relating to the supervision of insurance companies.**

Incorporates two NAIC Model law provisions into KRS Chapter 304, Subtitle 3 related to the financial reporting and supervision of insurance companies. First, an insurer is required to submit a corporate governance annual disclosure form by June 1st of each calendar year. If the insurer is a member of an “insurance group,” the insurer may rely on the form submitted to the insurance group’s lead state regulator unless specifically requested by the Commissioner of the Department of Insurance (the “commissioner”). The insurer must include sufficient material to enable the commissioner to understand the corporate governance structure, policies, and practices used by the insurer or group. The bill includes very specific requirements for the form, and all materials submitted with the form are deemed confidential and not subject to open records. The Department intends to promulgate an administrative regulation elaborating on this disclosure requirement.

The bill also permits the commissioner to act as a group-wide supervisor for an internationally active insurance group or recognize another state commissioner as the proper authority to act in such capacity. Most importantly, the standards for determining the proper supervisor are clearly delineated to ensure the most appropriate regulator serves.

As a group-wide supervisor, the commissioner is empowered to assess the enterprise risks within the group to ensure they are identified by management and reasonable measures to mitigate the risks are in place. The commissioner has broad authority to request documents and other information related to the corporate governance of the group, the capital adequacy, and any material intercompany transactions. Additionally, the commissioner may coordinate with other regulatory on the findings and information provided in connection with group-wide supervisor duties.

**HB 275 - An act relating to insurance.**

Eliminates the requirement for agents to satisfy financial requirements by obtaining liability coverage only through an admitted insurer or a surety bond only from a provider authorized to do business in the Commonwealth. An agent can use the surplus lines to obtain such coverage provided the requirements included within Subtitle 10 are satisfied.

The Department has expanded authority to issue resident licenses to certain agents. In the event an applicant’s home state does not issue a license to sell, solicit, and negotiate travel insurance, and the applicant meets the requirements to obtain a limited license in Kentucky, the applicant may designate Kentucky as their home state and receive a resident license. The option is only available to those applicants whose home state does not offer a specific limited lines travel insurance license. If the applicant’s only choice is to obtain a major line of authority, such as property or casualty to sell, solicit, and negotiate travel insurance, the applicant may designate Kentucky as their home state and be issued a corresponding Kentucky limited lines travel insurance license.

The composition of the Reinsurance Association governing committee is revised due to the merger of two insurance trade organizations previously included on the board. The commissioner will
have greater discretion to determine members of the board through the elimination of specific trade associations. Additionally, the commissioner has one additional discretionary selection. The commissioner may appoint:

- One person representing an insurer chartered under Kentucky law;
- One person representing an insurer chartered outside of Kentucky and not affiliated with one of the national trade associations;
- Three persons from insurance trade organizations;
- One licensed insurance agent; and
- One additional person that meets the requirements above at the discretion of the commissioner.

The bill clarifies that an entity formed as an industrial insured captive insurer that also qualifies as a risk retention group is exempt from the provisions of KRS 417.050.

The bill also includes two red tape reduction provisions. First, licensed agents will no longer be required to surrender the hard copy of their license to the commissioner or provide an affidavit that it was lost, destroyed, or stolen upon expiration, termination, suspension, or revocation of their license. Agent licenses are available for reprint online through the Department’s eServices website. Thus, the surrender of the original license is unnecessary in the current period.

Life insurers will no longer be required to submit information regarding paid up life insurance policies. Previously, the legislature considered the information necessary to inform potential beneficiaries of applicable life insurance policies. Since the enactment of this requirement, the NAIC and state insurance departments, including Kentucky, have created the “Life Insurance Policy Locator” tool. The tool allows anyone to submit a request to determine if they are the beneficiary of a life insurance policy. The tool applies to any policy regardless of its paid-up status. It is broader and more effective than the paid-up reporting included under this repealed statute. Individuals can access the tool at the Department’s website: insurance.ky.gov.

**HB 382 - An act relating to the Kentucky Life and Health Insurance Guaranty Association Act.**

Makes two important and critical changes to the Kentucky Life and Health Guaranty Association. First, health maintenance organizations (“HMOs”) are now added as members of the Kentucky Life and Health Guaranty Association. As members, HMOs will now be responsible for assessments related to member insurer insolvencies covered by the Kentucky Life and Health Guaranty Association.

Second, the assessments related to long-term care insurance written by an impaired or insolvent insurer are to be allocated under a separate methodology. The methodology used by the Kentucky Life and Health Guaranty Association must ensure that 50% of the assessment is allocated to accident and health member insurers (including HMOs) and 50% is allocated to life and annuity member insurers. The equal share of the assessment between these classes of insurers prevents one group (the health insurers) from continuing to shoulder the assessment burden for long-term care insolvencies. The assessments, moving forward, will be equally allocated between the two groups.
with exposure in the long-term insurance market. The Kentucky Life and Health Guaranty Association’s Board of Directors determines the specific assessment methodology. The assessment may be abated or deferred in whole or in part, if, in the opinion of the board, the assessment would endanger the financial condition of a member insurer.

**HB 386 - An act relating to the insurance industry.**

Allows for insurance innovation within the Commonwealth of Kentucky by providing the commissioner with authority to approve innovative conduct outside of specific statutory and regulatory provisions. The goal is to make Kentucky a safe place for meritorious innovation that benefits the public, does not pose an unreasonable risk of harm to consumers, and leads to insurance policy changes benefiting all Kentuckians.

Licensed entities may apply to the commissioner for a safe harbor testing period if they have an innovative proposal that has not been used in Kentucky, is subject to specific statutory or regulatory barriers, and meets specific criteria including whether the innovation poses an unreasonable risk of consumer and benefits the public interest. The entity must complete a detailed application and satisfy necessary financial security requirements. The commissioner, at his or her discretion, may issue, on completion of review of the application, a “notice of acceptance” to the applicant setting forth the terms and conditions that will govern the applicant’s beta test. The applicant can accept the notice or contest it. If accepted, the commissioner shall issue a “limited no-action letter” setting forth the conditions of a beta test and establishing a safe harbor under which the Department will not take any administrative or regulatory action against a participant or client of the participant concerning the compliance of the insurance innovation with Kentucky law so long as the participant or client abides by the terms and conditions established in the limited no-action letter.

The beta test is a one year period, with a potential extension of time to two years, where the applicant may sell or utilize the innovation approved in the application. The commissioner does have oversight during this period including review of specific monthly reporting obligations. The commissioner may also terminate the beta test for various reasons including the violation of the terms and conditions, and a determination that the beta test is harming consumers.

At the conclusion of the beta test, the commissioner has the option to issue an “extended no action letter” informing all entities that they may safely offer the innovation within the Commonwealth. The commissioner may also decline to issue such a letter, at which point the product shall no longer be offered. The extended no action letter may remain in place for up to three years with no provision for an extension. During this time, the barriers to innovation, statutory or regulatory, should be considered for amendment. If the barriers are not removed to accommodate the innovation, then the parties must cease all conduct related to the innovation at the expiration of the extended no action letter.

The Department is required to publish all limited no action letters and extended no action letters on its website. Additionally, the Department is required to report to the legislature on the usage of the innovation provisions, and provide recommendations for statutory changes.
HB 396 - An act relating to the expansion of health insurance options within Kentucky

Expands the availability of association health plans within Kentucky to account for the Department of Labor (“DOL”) changes to the definition of employer under 29 C.F.R. 2510.3-5. The definition of “employer organized association” is amended to allow the continuance of all currently existing association health plans under the “Pathway 1” term from DOL. Associations looking to form under Pathway 1 would need to meet the 2 year existence requirement, and be subject to the rating requirements under KRS 304.17A-0954.

The association health plans formed under the 2018 rule change to 29 C.F.R. 2510.3-5 (“Pathway 2”) increase the potential eligibility of employer members within an association. Specifically, those solo practitioners and working owners who have an ownership interest in the business. These individuals must satisfy minimum requirements including working on average at least 20 hours per week or at least 80 hours per month in the trade or business or earning wages that at least equal the cost of coverage in the association’s health plan.

The new associations are subject to a two year existence requirement under Kentucky law. Additionally, the new associations must comply with the bona fide association, commonality of interest, and nondiscrimination provisions under 29 C.F.R. 2510.3-5. In order to confirm compliance, all fully insured Pathway 2 associations are subject to a registration requirement with the Department of Insurance.

The above requirements apply to those fully insured association health plans. Any self-insured association health plan will need to comply with the requirements beginning at KRS 304.17A-800. The self-insured plans will need to submit a nonrefundable filing fee of $500 to the Department and satisfy all of the requirements included within KRS 304.17A-808, as well as, the financial stability provisions.

On Thursday, March 28, 2019, Judge John Bates issued an opinion that vacated much of the federal rule (29 CFR 2510.3-5) pertaining to “bona fide associations” and “working owners.” This includes the provisions expanding eligibility within an AHP to sole proprietors and working owners, as well as, the permission to form associations on a geographic basis. In essence, Judge Bates found the DOL lacked the authority to issue the rule, casting it as an “end-run around the ACA.” The Opinion and Order sent the rule back to the DOL to determine whether any part of it can be upheld given the specific sections that were vacated. It is unclear how the DOL will respond to this ruling. While the Department continues to study its options, it is unclear when and if association health plans may be formed under Pathway 2.

SB 30 - An act relating to cancer prevention through insurance coverage for screening and appropriate genetic testing.

Accomplishes two objectives related to cancer prevention. First, the bill requires all health benefit plans to cover a genetic test to determine cancer risks as recommended according to the most recent version of the National Comprehensive Cancer Network guidelines. The genetic testing covered in this subsection is not subject to any cost sharing. However, if no in-network providers are
available, the health benefit plan must provide coverage at the in-network rate. Individuals may be balance billed for any additional charges of the out of network provider.

The bill conforms the requirements to provide colorectal cancer examinations and laboratory tests in accordance with the 2018 changes to the American Cancer Society (“ACS”) guidelines. Specifically, the covered individual age is reduced to 45 from 50 to conform to the ACS guidelines.

The 2018 ACS Guidelines confirm the follow-up of positive non-colonoscopy screening tests with a colonoscopy “should not be considered a ‘diagnostic’ colonoscopy but, rather, an integral part of the screening process, which is not complete until the colonoscopy is performed.” Thus, if an individual has a positive FIT test, a follow-up colonoscopy is recommended and should be processed as a screening test. The follow-up colonoscopy would not be subject to cost sharing if performed by a network provider.

Additionally, the bill further confirms laboratory tests provided in conjunction with a screening test should be considered preventive and provided at no cost sharing. Specifically, the ACS Guidelines, citing the Centers for Medicare and Medicaid Services interpretation, state “that, ‘polyp removal is an integral part of a colonoscopy’ and indicating that commercial plans ‘may not impose cost-sharing with respect to a polyp removal during a colonoscopy performed as a screening procedure.’ Subsequent communications to insurers clarified that anesthesia and pathology services and bowel preparation medications provided in conjunction with a screening colonoscopy must also be covered without cost-sharing.” (See, Centers for Medicare and Medicaid Services. Affordable Care Act Implementation FAQs—Set 12. Baltimore, MD: Centers for Medicare and Medicaid Services; 2015. cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html. See also, Centers for Medicare and Medicaid Services. FAQs About Affordable Care Act Implementation Part 29. Baltimore, MD: Centers for Medicare and Medicaid Services; 2015. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXIX.pdf.)

**SB 54 – An act relating to prior authorization.**

Alters the prior authorization processes used by insurers and the disclosures that must be provided to members.

Health benefit plans must develop, coordinate, or adopt a process satisfying the most recent National Council for Prescription Drug Programs SCRIPT standards for electronically requesting and transmitting prior authorizations for a drug by providers.

Prior authorizations of drugs for individuals requiring an ongoing medication therapy for which the provider continues to prescribe the drug in a manner approved by the FDA or proven safe and effective shall be valid for one year or the last day of coverage under the plan, whichever is less. The authorization applies to any change in dosage of the medication during the authorization. Thus, if a provider continues to prescribe the same medication, but simply changes the dosage, the previous prior authorization applies to provide approval for the prescribed medication.

The prescription prior authorization mandate does not apply to:
• Medications prescribed for non-maintenance conditions;
• Medications with a typical treatment period of fewer than 12 months;
• Medications where there is medical or scientific evidence that doesn’t support 12 month approval; or
• Opioid analgesic or benzodiazepines.

Health benefit plans will be required to update plan and member documents to address these prescription prior authorization changes, and file the forms with the Department for approval.

The bill includes a definition for “medically necessary health care services.” It includes those services rendered to prevent, diagnose, or treat an illness, injury, disease, or symptoms that are:

• In accordance with generally accepted standards of medical practice; and
• Clinically appropriate in terms of type, frequency, extent, and duration.

Certified utilization review or private review agents when determining the medical necessity of services should utilize the definition of medically necessary health care services.

All health benefit plans, to the extent they do not already, must publish the prior authorization procedures on their website. This includes a list of the services and codes, and the corresponding dates of inclusion or removal, for which prior authorization is required. Insurers are prohibited from denying claims for a lack of prior authorization if the service or code is not listed on their website.

Prior authorization is not required for births or the inception of neonatal intensive care services. Additionally, insurers must cover supplies routinely used during preauthorized procedures or those procedures not requiring preauthorization unless their provider contract requires otherwise.

All entities performing utilization review must ensure, when possible, that licensed physicians in the same specialty or subspecialty of the ordering physician are used to make utilization review decisions. The requirement includes an important “when possible” caveat. The Department will review the utilization review entity and private review agent filings for compliance with this requirement.

Utilization review entities and private review agents are required to render a utilization review determination for “urgent health care services” and provide notification within twenty-four (24) hours after obtaining all necessary information. For “non-urgent health care services”, reviewing entities must make a decision and notify the individual within five (5) days of obtaining all necessary information. If the reviewing entity fails to decide within the applicable timeframe, the service requested is deemed authorized.

The timeframes do not begin to run until the entity receives “all necessary information” from the individual or provider. The statute describes “all necessary information” as:

• The results of any face to face clinical evaluation;
• Any second opinion that may be required; and
• Any other information determined by the department to be necessary to make a utilization review determination.

The Department has not yet issued guidance on the necessary information to be submitted with a prior authorization request. However, 806 KAR 17:370 details standardized health claim attachments that an insurer may request to determine the compensability of claims submitted. At this point, the Department recommends interested parties look to the attachments referred to in 806 KAR 17:370 for important documentation necessary to determine compensability.

Insurers, utilization review entities, and private review agents must comply with all sections of the bill by January 1, 2020.

The Department is available by telephone at 502-564-3630 to answer any questions regarding the information included within this bulletin. The bulletin is not intended to convey legal advice and all parties are encouraged to consult with an attorney, as needed, for compliance.