Kentucky



Kentucky - BR 945

Sponsor: Representative Danny Bentley (R)

Actions: 11/23/2021 Prefiled

Summary: Summary for 11/23/2021 Version

This measure prohibits cost-sharing for a medication from exceeding \$30 for a 30 day supply of each medication, regardless of the amount or type of medication needed to meet a covered person's needs.

This measure requires all health benefit plans to provide coverage for equipment, supplies, outpatient self-management training, and education, including medical nutrition therapy, and all medications prescribed by a health care provider for the treatment of insulin-dependent diabetes, insulin-using diabetes, gestational diabetes, and noninsulin-using diabetes if the health care provider is legally authorized to prescribe the items.

Under this measure, cost-sharing for a medication must not exceed \$30 for a 30 day supply of each medication, regardless of the amount or type of medication needed to meet the covered person's needs and the following equipment and supplies must not exceed \$30 for each piece of equipment or, if applicable, for a 30 day supply: blood glucose monitors, including continuous glucose monitors, monitor supplies, medication injection aids, syringes, medication infusion devices, pharmacological agents for controlling blood sugar, and orthotics.

This measure would take effect on January 1, 2023, and apply to health benefit plans issued or renewed on or after the effective date of this measure.

Bill Links 11/23/2021 Version



Kentucky - HB 343

Sponsor: Representative Kimberly Moser (R)

Actions: 02/23/2022 Referred to the House Committee on Health and Family Services

01/24/2022 Introduced

Summary: Summary for 1/24/2022 Version

This measure exempts health care providers from the requirement of a pre-authorization for certain services and outlines the process by which that exemption can be granted and provides for revocation and denial of exemptions from pre-authorization, as well as an external review of these decisions.

This measure applies to insurers and private review agents.

Exemption Eligibility

This measure provides that if a provider receives approval from an insurer or a private review agent for a particular medical procedure in 90% of prior authorization requests, the provider must qualify for an exemption for that particular health care service. Insurers and private review agents may not require a provider to obtain prior authorization for a specific health care service if, at the time the service was provided, the provider qualified for a prior authorization exemption under this measure. Insurers or private review agents must evaluate whether a health care provider qualifies for an exemption under this measure. Providers may not be required to request an exemption in order to qualify for exemptions under this measure.

Exemption Details

Within five days after qualifying for an exemption, insurers or private review agents must provide a provider with a notice that includes a statement notifying the provider that they have been granted an exemption under this measure, setting forth the health care services and plans to which the exemption applies, and a list of the health care services and plans to which the exemption applies. A provider may be denied an exemption if the provider does not have the exemption at the time of the relevant evaluation period and the insurer or private review agent provides the provider with actual statistics and data for the relevant evaluation period and detailed information sufficient to demonstrate that the provider does not meet the criteria under this measure for the particular health care service. If a provider submits a prior authorization request for a health care service for which the provider qualifies for an exemption, the insurer must provide the provider with a notice that includes, the required information described above, and a notification of the insurer's payment requirements.

Recession

Insurers or private review agents may rescind an exemption during the months of January or July annually if the insurer or private review agent makes a determination on the basis of a retrospective review of a random sample of no fewer than five and no more than 20 claims submitted by the provider for the specific health service during the most recent evaluation period, that less than 90% of the claims met the medical necessity criteria that would have been used during the relevant evaluation period by the insurer or private review agent when conducting a prior authorization review for that health care service, and notifies the provider of the rescission determination. Notifications of rescission must include the sample information used to make the recession determination and a plain language explanation of how the provider may appeal by seeking external review.

Appeals

Within 30 days of receiving a notice of rescission, a provider may submit a request for an external review of the determination or denial to the insurer or its private review agent. An external review must be conducted by an independent review entity. Insurers or private review agents are prohibited from requiring a provider to engage in an internal appeal before requesting an external review. External review requests must be forwarded by the insurer or private review agent to the independent review entity within 24 hours of receipt.

During an external review, a provider may request that the independent review entity consider a different sample of five to twenty claims submitted to the insurer or its private review agent during

the relevant evaluation period. The independent review entity must base its decision based on the information submitted by the insurer or its private review agent and health care provider, findings, studies, research, and other relevant documents of government agencies and nationally recognized organizations, and relevant findings in peer-reviewed medical or scientific literature.

Effective Date

This measure will take effect on January 1, 2023.

Bill Links 1/24/2022 Version



Kentucky - HB 457

Sponsor: Representative Steve Sheldon (R)

Actions: 03/10/2022 Hearing Held; Substituted; Passed Commitee

03/09/2022 Referred to House Health and Family Services Committee

02/07/2022 Introduced

Summary: Summary for 3/10/2022 Version

This measure creates rules and guidelines for contracts between PBMs and pharmacies, as well as contracts between insurers and PBMs, pertaining to cost-sharing amounts for pharmacy and pharmacist services.

This measure applies to pharmacy benefits managers, mail-order pharmaceutical distributors, and health insurers.

This measure applies to pharmacy benefits managers and mail-order pharmaceutical distributors. Under this measure, PBMs are prohibited from requiring an insured to pay a cost-sharing amount for pharmacy or pharmacist services at a higher amount than would be required without coverage, or to use a mail-order pharmaceutical distributor to receive coverage or to furnish a provider a prescription drug to administer to patients.

PBM's are prohibited from imposing cost-sharing conditions for:

- Pharmacy or pharmacist services received from a retail pharmacy greater than would be required if the person used a mail-order pharmaceutical distributor and the retail pharmacy has agreed to accept reimbursement at the same reimbursement rate for a mail-order pharmaceutical distributor.
- Prescription drugs furnished by a provider at a greater rate than would be imposed if furnished by a mail-order pharmaceutical distributor.
- Pharmacy or pharmacist services not equally imposed on all individuals in the same benefit class/category under the same plan.

PBMs utilizing pharmacy networks must ensure the network offers an adequate number of accessible mail-order pharmacies and a provider network that provides convenient access to pharmacies within a reasonable distance from the insured's residence.

All contracts between pharmacies/pharmacists and PBMs must:

- Outline terms and conditions for the provision of services
- Establish procedures for changing the contract
- Provide the pharmacy/pharmacist with a 30-day right to cure any violations of terms, 90-days written notice of nonrenewal, and 30-days prior written notice to insureds that the pharmacy has or will be removed from the network
- Prohibit PBMs from reducing payment for services under a reconciliation process to an
 effective rate of reimbursement, denying or reducing reimbursement for a fraudulent or
 actual overpayment claim, or reimbursing for a prescription drug or service at a lower net
 amount than that applied to a PBM or PBM affiliate
- Require that medication-assisted treatment prescription be exempt from dispensing fee thresholds

PBM's are prohibited from discriminating against any pharmacy, imposing fees without first seeking commissioner approval, rejecting offers or applications to contract for services that have been credentialed unless provided written notice within 15 days of rejection, or failing to issue rejection or acceptance of applications within 30 days.

Conduct that qualifies as discrimination against pharmacies includes discrimination on the basis of the location of the pharmacy, reimbursing or assessing fees at inappropriate amounts, imposing limits on a pharmacy's access to medications, requiring or incentivizing an insured to receive services from a pharmacy affiliate, and not providing equal access and incentives to all pharmacies within the PBM's network.

Insurers contracting with PBMs on behalf of a health plan must require the PBM to disclose any policy, practice, or contract that may present a conflict of interest and monitor all activities to ensure compliance. Every contract must require the use of pass-through pricing and require the PBM to owe a fiduciary to the insurer. Insurers are required to annually report income, payments, and benefits received. Administrators are prohibited from offering any incentive or discount to health plans for the use of a PBM that is associated with the administrator.

This measure prohibits the sale and distribution of health discount plans that utilize the same identifying information used by an insurer or seek the payment of any refunds or fees from a pharmacy or pharmacist in connection with a consumer's transaction after completion of that transaction.

This measure provides that when contracting on behalf of one or more pharmacies or pharmacists with a PBM, insurer, or a third party payor, or providing any other services on behalf of one or more pharmacies, the pharmacy services administration organization will owe a fiduciary duty to the pharmacies or pharmacists.

This measure takes effect on January 1, 2023.

Definitions:

"Insured" means any individual who is enrolled in a health plan and on whose behalf the insurer is obligated to pay for or provide pharmacy or pharmacist services.

"Pharmacy benefit manager" in this measure DOES NOT include a pharmacy benefit manager that is contracted by and acting under the direction of any hospital or health system that provides a self-insured plan if the hospital or health system owns a pharmacy.

"Health plan" Means any policy, certificate, contract, or plan that offers or provides coverage in this state for pharmacy or pharmacist services, whether such coverage is by direct payment, reimbursement, or otherwise. It includes a health benefit plan, but does not include a policy, certificate, contract, or plan that offers or provides Medicaid services.

"Insurer" means any of the following persons or entities that offer or issue a health plan: an insurance company, a health maintenance organization, a limited health service organization, a self-insurer, a provider-sponsored integrated health delivery network, a self-insured employer-organized association, nonprofit hospitals or health service organization, and any other third-party payor authorized to transact insurance. It includes any person or entity that has contracted with a state or federal agency to provide coverage in this state for pharmacy or pharmacist services, except persons or entities that have contracted to provide Medicaid services.

"Pharmacy affiliate" means any pharmacy which:

- The PBM shares common ownership, management, or control with.
- Is owned, managed, or controlled by any of the PBM's management companies, parent companies, subsidiary companies, jointly held companies, or companies otherwise affiliated by a common owner, manager, or holding company.
- Shares any common members on its board of directors with the PBM.
- Shares managers in common with the PBM.

"Pharmacy or pharmacist services" means any health care procedures, treatments within the scope of practice of a pharmacist, or services provided by a pharmacy or a pharmacist and includes the provision of prescription drugs and home medical equipment.

"Rebate" means a discount, price concession, or payment that is based on utilization of a prescription drug and paid after a claim for pharmacy or pharmacist services has been adjudicated at a pharmacy. It includes incentives, disbursements, and reasonable estimates of a volume-based discount.

"Actual overpayment" means the portion of any amount paid for pharmacy services that is duplicative or was erroneously paid the services were not rendered in accordance with the prescriber's order.

"Covered entity" means a covered entity participating in the federal 340B drug pricing program.

"Medication-assisted treatment prescription" means a prescription for a medication containing buprenorphine to treat a substance use disorder.

"National drug code number" means the unique national drug code number that identifies a specific approved drug, its manufacturer, and its package presentation.

"Net amount" means the amount paid to the pharmacy or pharmacist by the PBM less any fees, price concessions, and all other revenue passing from the pharmacy or pharmacist to the PBM.

"Other party" means any natural person or entity except a PBM, issuer or administrator, or an insured under a health plan.

"Pharmacy services administration organization" means an entity that provides a pharmacy or pharmacist with administrative, contracting, or payment services relating to the provision of

pharmacy or pharmacist services under any health insurance policy, health plan, or another contract that provides coverage in this state for pharmacy or pharmacist services.

Bill Links 3/10/2022 Substitute

2/7/2022 Version



Kentucky - HB 505

Sponsor: Representative Ken Fleming (R)

Actions: 02/16/2022 Introduced

Summary: Summary for 2/18/2022 Version

This measure creates new membership and licensure requirements for the Kentucky Board of Emergency Medical Services.

This measure establishes membership requirements for the Kentucky Board of Emergency Medical Services. All members must be residents of Kentucky and constitute varying types of physicians, EMS providers, and representatives. The board is required to annually submit by September 1 of each year a report containing information on board expenses and income, data collected, administrative regulations or amendments, and any recommendations for administrative change.

This measure requires the cabinet to license and regulate ambulance providers, inspect ambulance providers, conduct investigations and complaints against ambulance providers, collect and enforce emergency medical service data reporting requirements, review medical protocols, and promulgate any necessary regulations. The cabinet is required to establish minimum data reporting requirements, establish a central repository for all data, analyze the data required to be reported to make relevant recommendations, apply for any available state or federal grants, and develop and monitor projects and programs that may be of benefit to EMS providers.

All EMS providers must be licensed to practice. Anyone whose license is suspended, revoked, or denied, is prohibited from operating ambulatory services.

Personnel employed by the board under the Kentucky Community and Technical College System are required to be transferred to the board.

This measure takes effect 90 days after adjournment.

Bill Links 2/16/2022 Version



Kentucky - HB 90

Sponsor: Representative Danny Bentley (R)

Actions: 01/04/2022 Introduced

11/23/2021 Prefiled

Summary: Summary for 11/23/2021 Version

This measure directs insurers to cover all prescribed diabetes drugs and equipment prescribed by a licensed provider, caps the price of diabetes medication and equipment related to diabetes at \$30, and prohibits insurers from conducting utilization review for equipment, supplies, outpatient self-management training, and education related to diabetes.

This measure mandates all health benefit plans to cover equipment, supplies, outpatient self-management training and education including medical nutrition therapy, and medications prescribed by a health care provider for the treatment of insulin-dependent diabetes, insulin-using diabetes, gestational, diabetes, and non-insulin using diabetes if the health care provider is authorized to prescribe these items.

This measure caps the price of a thirty-day supply of any diabetes medication at \$30. Additionally, this measure caps the price of blood glucose monitors, including continuous glucose monitors; monitor supplies; medication injection aids; syringes; medication infusion devices; pharmacological agents for controlling blood sugar; and orthotics at \$30.

This measure prohibits insurers from conducting utilization review for any equipment, supplies, outpatient self-management training, and education. Outpatient self-management training and education includes medical nutrition therapy, and medications prescribed in accordance with this measure.

This measure defines "Medication" as any drug that contains insulin and any drug that is approved by the United States Food and Drug Administration to treat diabetes that does not contain insulin.

This measure amends the existing definition of "Utilization review" to include prior authorization, step therapy, drug formulary restrictions, and any other utilization management requirements.

If enacted, this measure will take effect on January 1, 2023.

Bill Links 11/23/2021 Version



Kentucky - SB 140

Sponsor: Senator Max Wise (R)

Actions: 03/02/2022 Hearing Held; Passed Committee

02/24/2022 Referred to House Banking and Insurance Committee

02/17/2022 Passed Senate

02/15/2022 Hearing Held; Substituted; Passed Committee

02/07/2022 Referred to Senate Banking and Insurance Committee

02/03/2022 Introduced

Summary: Summary for 2/15/2022 Version

This measure creates guidelines for establishing step therapy protocols, step therapy exception requests, and an appeals process.

Under this measure, clinical review criteria <u>developed by an insurer, health plan, PBM, or private review agent</u> to establish a step therapy protocol must be based on clinical practice guidelines that recommend prescription drugs be taken in the specific sequence required by the step therapy protocol. The guideless must be developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups. Guidelines must be based on high-quality studies, research, and medical practice and must be created by a transparent process that minimizes conflicts of interest and considers patient subgroups. The guidelines must be continually updated through review of new evidence, research, and newly developed treatments.

In the absence of guidelines, insurers, PBMs, or private review agents may use peer-reviewed publications to establish step therapy protocols. They must take into account the needs of atypical patient populations and diagnoses. They must also take into account if a prescription drug is not in the best medical interest of the patient. Clinical review criteria relating to a particular condition or disease or a step therapy exception determination must be made accessible on a website and to health care professionals by written request. Existing medical exceptions processes may be used to satisfy requirements and must disclose all rules and criteria related to step therapy protocols to all providers to be considered a complete request for a step therapy exception.

Step therapy exception requests must be granted within 48 hours if all necessary information to perform the exception has been provided and if one of the following apply:

- The required prescription drug is contraindicated, expected to be ineffective, or not in the best interest of the insured
- The insured has tried the required prescription drug under another health plan or another drug with the same mechanism of action and the drug was discontinued after inefficacy.
- The insured is stable on the prescription drug while under a current or previous health plan.

If a request for a step therapy exception is incomplete or requires additional information, the insurer, PBM, or private review agent must notify as such within 48 hours of submission. If notice is not received, the appeal is deemed granted.

Nothing under this measure can be construed to prevent insurers, health plans, PBMs, or private review agents from requiring covered individuals to try an AB-rated generic equivalent or interchangeable biological product before providing coverage for the equivalent branded drug, or from requiring a pharmacist to effect substitutions of prescription drugs.

The commissioner is authorized to promulgate any necessary rules. The insurer, PBM, or private review agent must report numerical data annually to the commissioner.

Definitions:

- "Clinical practice guidelines" is defined as a systematically developed statement to assist
 decision making by health care providers and patients about appropriate healthcare for
 specific clinical circumstances and conditions.
- "Clinical review criteria" is defined as the written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by the insurer, health plan, pharmacy benefit manager, or private review agent to determine the medical necessity and appropriateness of health care services.
- "Health plan" means any state-regulated policy, certificate, contract, or plan that offers or
 provides coverage in this state, by direct payment, reimbursement, or otherwise, for
 prescription drugs pursuant to a step therapy protocol, regardless of whether the protocol is
 described as a step therapy protocol.

• "Step therapy protocol" is defined as a protocol, policy, or program that establishes the specific sequence in which prescription drugs that are for a specified medical condition and medically appropriate for a particular insured are covered by an insurer or health plan.

This measure takes effect on January 1, 2023.

Bill Links 2/15/2022 Committee Substitute

2/3/2022 Version



Kentucky - SB 336

Sponsor: Senator Adrienne Southworth (R)

Actions: 03/03/2022 Introduced

Summary: Summary for 3/3/2022 Version

This measure creates disclosure requirements for individuals who administer unapproved drugs.

This measure states that any individual who administers an unapproved drug that the FDA approved for emergency use must inform the patient that:

- The drug is authorized for emergency use.
- The significant known and potential and benefits and risks of such use, and the extent that they are unknown.
- The option to accept or refuse administration of the drug.
- Any medical consequences of refusing administration of the drug.
- Available alternatives and their benefits and risks.

This measure also bans individuals from being required to administer unapproved drugs that are authorized for emergency use.

This measure takes effect immediately upon enactment.

Bill Links 3/3/2022 Version