CABINET FOR HEALTH AND FAMILY SERVICES
Department for Medicaid Services
Division of Health Care Policy
(Amendment)

907 KAR 23:010. Outpatient Pharmacy Program.

RELATES TO: KRS Chapter 13B, 205.510, [~~205.560, 205.561,~~]205.5631-205.5639, 205.564, 205.6316, 205.8451, 205.8453, 217.015, 217.822, 369.101 to 369.120, ~~4~~2 C.F.R. 430.10, 431.54, 440.120, 447.512-447.518, 42 U.S.C. 1396a, 1396b, 1396c, 1396d, 1396r-8

STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 205.560, 205.561, 205.5632, 205.5634, 205.5639(2), 205.564(10), (13)

CERTIFICATION STATEMENT:

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has the responsibility to administer the Medicaid program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed or opportunity presented by federal law for the provision of medical assistance to Kentucky's indigent citizenry. KRS 205.560 provides that the scope of medical care for which Medicaid shall pay is determined by administrative regulations promulgated by the cabinet. This administrative regulation establishes the provisions for coverage of outpatient drugs through the Medicaid outpatient pharmacy program for fee-for-service recipients and managed care enrollees.

Section 1. Covered Drugs. A covered drug shall be:

(1) Medically necessary;
(2) Approved by the FDA;
(3) Prescribed for an indication that has been approved by the FDA or for which there is documentation in official compendia or peer-reviewed medical literature supporting its medical use;
(4) A rebateable drug; and
(5) A covered outpatient drug.

Section 2. Diabetic Supplies. Except if Medicare is the primary payer, the department shall cover the diabetic supplies listed in this section via the department's pharmacy program and not via the department's medical supplies, equipment, and appliances[~~durable medical equipment~~] program established in 907 KAR 1:479:

(1) A syringe with needle (sterile, 1cc or less);
(2) Urine test or reagent strips or tablets;
(3) Blood ketone test or reagent strip;
(4) Blood glucose test or reagent strips;
(5) Calibrating solutions;
(6) Lancet device;
(7) Lancets; or
(8) Home blood glucose monitor.

Section 3. Tamper-Resistant Prescription Pads.

(1) Each covered drug or diabetic supply shall be prescribed on a tamper-resistant prescription pad, except if the prescription is:
   (a) An electronic prescription;
   (b) A faxed prescription; or
   (c) A prescription telephoned by a prescriber or authorized agent.
(2) To qualify as a tamper-resistant prescription, the prescription pad shall contain one (1) or more of each industry-recognized feature designed to prevent:

(a) Unauthorized copying of a completed or blank prescription form;

(b) The erasure or modification of information written by the prescriber on the prescription; and

(c) The use of counterfeit prescription forms.

Section 4. Kentucky Medicaid Fee-for-Service Outpatient Drug List.

(1) The department shall maintain each Outpatient Drug List to include drug coverage and availability information in the following formats:

(a) Kentucky Medicaid Provider Drug Portal Lookup, which shall be an online searchable drug database that functionally affords users the ability to perform a search of the Kentucky specific fee-for-service drug formulary for the purpose of ascertaining formulary status, drug coverage, and other plan limitations (prior authorization, quantity limits, step therapy, and diagnosis) associated with a drug;

(b) Kentucky Preferred Drug Listing (PDL), which shall be a listing of selected drugs available to fee-for-service recipients that have been included based on proven clinical and cost effectiveness and that prescribers are encouraged to prescribe if medically appropriate;

(c) Physician Administered Drug List (PAD), which was formerly known as the Physician Injectable Drug List (PIDL), and which shall indicate the list of physician administered drugs that can be billed to the fee-for-service medical benefit using appropriate Healthcare Common Procedure Coding System codes, National Drug Codes, and appropriate units;

(d) Over-the-Counter (OTC) Drug List, which shall be a list of OTCs that, if prescribed, are eligible for fee-for-service coverage and reimbursement through the pharmacy benefit;

(e) Covered Prescription Cold, Cough, and Vitamin Product List, which shall indicate the legend drugs that, if prescribed and FDA indicated for the intended use, are eligible for fee-for-service coverage and reimbursement through the pharmacy benefit;

(f) Long Term Care Per Diem List, which shall indicate OTC drugs that, if provided to a Medicaid nursing facility service recipient, are included in the nursing facility's standard price or daily per diem rate, and are not otherwise reimbursed by the department;

(g) Maximum Quantity Limits List, which shall indicate covered drugs that have a quantity limit consistent with the maximum dosage that the FDA has approved to be both safe and effective; and

(h) Kentucky Medicaid Diagnosis Drug List, which shall indicate covered drugs that require a diagnosis code or a prerequisite to therapy, or both.

(2) Each Outpatient Drug List shall be updated by the department at least quarterly or otherwise as needed.

(3) Each Outpatient Drug List shall be accessible through the department's pharmacy webpage.

Section 5. Exclusions to Coverage. The following drugs shall be excluded from coverage and shall not be reimbursed:

(1) A drug that the FDA considers, by way of a final determination, to be:

(a) A less-than-effective drug; or

(b) Identical, related, or similar to a less-than-effective drug;

(2) A drug or its medical use in one (1) of the following categories unless the drug or its medical use is designated as covered by an Outpatient Drug List:

(a) ~~[A drug if used for anorexia, weight loss, or weight gain;]~~

~~[(b)]~~ A drug if used to promote fertility;

(b) ~~[(c)]~~ A drug if used for cosmetic purposes or hair growth;

(c) ~~[(d)]~~ A drug if used for the symptomatic relief of cough and colds;

(d) ~~[(c)]~~ A vitamin or mineral product other than prenatal vitamins and fluoride preparations;

(e) ~~[(f)]~~ An OTC drug provided to a Medicaid nursing facility service recipient and included in the nursing facility's standard price or daily per diem rate;

(f) ~~[(g)]~~ A drug that the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee; or

(g) ~~[(h)]~~ A drug utilized for erectile dysfunction therapy unless the drug is used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the FDA;

(3) A drug that is not rebateable, unless there has been a review and determination by the department that it is in the best interest of a recipient for the department to make payment for the drug and federal financial participation is available for the drug;

(4) A drug dispensed as part of, or incident to and in the same setting as, an inpatient hospital service, an outpatient hospital service, or an ambulatory surgical center service;

(5) A drug for which the department requires prior authorization if prior authorization has not been approved;

(6) A drug that shall no longer be dispensed by a pharmacy provider because it has reached the manufacturer's termination date or is 365 days past the manufacturer's obsolete date; and

(7) Investigational drugs or drugs being used for investigational uses or uses not otherwise supported by documentation found in official compendia or peer-reviewed medical literature.

Section 6. Limitations to Coverage.

(1) All dispensing and administration of covered drugs shall comply with applicable federal and state law.

(2) Refills.

(a) A controlled substance in Schedule II shall not be refilled.

(b) If authorized by a prescriber, a prescription for a:

1. Controlled substance in Schedule III, IV, or V may be refilled up to five (5) times within a six (6) month period from the date the prescription was written or ordered, at which time a new prescription shall be required; or

2. Noncontrolled substance, except as provided in subsection (3)(a) of this section, may be refilled up to eleven (11) times within a twelve (12) month period from the date the prescription was written or ordered, at which time a new prescription shall be required.

(3) Days Supply. For each initial fill or refill of a prescription, a pharmacist shall dispense the drug in the quantity prescribed not to exceed a thirty-two (32) day supply unless:

(a) The drug is indicated as a noncontrolled maintenance drug per the department's nationally recognized comprehensive drug data file as a drug exempt from the thirty-two (32) day dispensing limit, in which case the pharmacist shall dispense the quantity prescribed not to exceed a three (3) month supply or 100 units, whichever is greater;

(b) A prior authorization request has been submitted on a Kentucky Medicaid prior authorization request form and approved by the department because the recipient needs additional medication while traveling or for a valid medical reason, in which case the pharmacist shall dispense the quantity prescribed not to exceed a three (3) month supply or 100 units, whichever is greater; or

(c) The drug is prepackaged by the manufacturer and is intended to be dispensed as an intact unit, and it is not feasible for the pharmacist to dispense only a month's supply because one (1) or more units of the prepackaged drug will provide more than a thirty-two (32) day supply.

(4) A refill of a prescription shall not be covered unless at least ninety (90) percent of the prescription time period has elapsed.

(5) Compounded Drugs. The department may require prior authorization for a compounded drug that requires preparation by mixing two (2) or more individual drugs.

(6) Emergency Fills. In an emergency situation, a pharmacy provider may dispense an emergency supply of a prescribed drug to a recipient in accordance with this subsection.

(a) An emergency situation shall exist if, based on the clinical judgment of the dispensing pharmacist, it would reasonably be expected that a delay in providing the drug to the recipient would place the recipient's health in serious jeopardy or the recipient would experience substantial pain and suffering.

(b) At the time of dispensing the emergency supply, the pharmacist shall:

1. Submit a prior authorization request form to the department using the urgent fax number or the department's pharmacy webpage; or

2. Notify the prescriber as soon as possible that an emergency supply was dispensed and that the prescriber is required to obtain prior authorization for the requested drug from the department.

(c) An emergency supply shall not be provided for:

1. An OTC drug;

2. A controlled substance; or

3. A drug excluded from coverage by this administrative regulation.

(d) The quantity of an emergency supply shall be:

1. The lesser of a seventy-two (72) hour supply of the drug or the amount prescribed; or

2. The amount prescribed if the drug is prepackaged by the manufacturer and is intended to be dispensed as an intact unit and it is not feasible for the pharmacist to dispense in a smaller quantity.

Section 7. Confirming Receipt of Prescription.

(1) A recipient, or a designee of the recipient, shall sign his or her name in a format that allows the signature to be reproduced or preserved by the pharmacy provider confirming that the recipient received the prescription.

(2) A pharmacy provider shall maintain, or be able to produce a copy of, the recipient's signature referenced in subsection (1) of this section for six (6) years.

Section 8. Exemptions to Kentucky Enrolled Prescriber Requirements. The department shall reimburse for a full prescription or an emergency supply of a prescription, prescribed by a provider who is not enrolled in the Kentucky Medicaid Program, if the department determines it is in the best interest of the recipient to receive the prescription.

Section 9. Utilization Management. Utilization management techniques shall be applied by the department to support medically appropriate and cost effective access to covered drugs and shall include prior authorization, step therapy, quantity limitations, generic substitution, therapeutic substitution protocols, and clinical edits.

(1) Step therapy.

(a) The department may implement step therapy drug treatment protocols by requiring the use of a medically-appropriate drug that is available without prior authorization before the use of a drug that requires prior authorization.

(b) The department may approve a request from the prescriber or a pharmacist for exemption of a specific recipient from step therapy based on documentation that a drug available without prior authorization:

1. Was used and was not an effective medical treatment or lost its effectiveness;

2. Is reasonably expected to not be an effective medical treatment;

3. Resulted in, or is reasonably expected to result in, a clinically-significant adverse reaction or drug interaction; or

4. Is medically contraindicated.

(2) Prior authorization.

(a)

1. If prior authorization is required for a drug, the applicable prior authorization request form shall be completed and submitted to the department by fax, mail service, telephone, or the department's pharmacy web portal.

2. The applicable prior authorization request form shall be the:

a. Kentucky Medicaid Substance Use Treatment Pharmacy Prior Authorization Form for Buprenorphine Products if prior authorization is being requested for buprenorphine products for substance use treatment; or

b. Kentucky Medicaid Pharmacy Prior Authorization Form if the prior authorization is being requested for a drug that is not a buprenorphine product for substance use treatment.

(b) If a recipient presents a prescription to a pharmacy provider for a drug that requires prior authorization, the pharmacist shall:

1. Complete and submit a prior authorization request form in accordance with this subsection; or

2. Notify the prescriber or the prescriber's authorized representative that the drug requires prior authorization.

a. If the prescriber indicates that an alternative available without prior authorization is acceptable and provides a new prescription, the pharmacist shall dispense the alternative.

b. If the prescriber indicates that an alternative available without prior authorization has been tried and failed or is clinically inappropriate or if the prescriber is unwilling to consider an alternative, the pharmacist shall request that the prescriber obtain prior authorization from the department.

(c) The department's notification of a decision on a request for prior authorization shall be made in accordance with this paragraph.

1. If the department approves a prior authorization request, notification of the approval shall be provided by telephone, fax, or the department's pharmacy web portal to the party requesting the prior authorization and, if known, to the pharmacist.

2. If the department denies a prior authorization request, the department shall provide a denial notice:

a. By mail to the recipient and in accordance with 907 KAR 1:563; and

b. By fax, telephone, or, if notification cannot be made by fax or telephone, by mail to the party who requested the prior authorization.

(d) Prior authorization time limits.

1. The department may grant approval of a prior authorization request for a drug for a specific recipient for a period of time not to exceed 365 calendar days.

2. Approval of a new prior authorization request shall be required for continuation of therapy subsequent to the expiration of a time-limited prior authorization request.

Section 10. Drug Review Process. The drug review process to determine if a drug requires prior authorization or other utilization management, or is otherwise restricted or excluded by the department, shall be in accordance with this section.

(1) Drug review considerations. Drug review shall be based upon available and relevant clinical information to assess appropriate use of medications and include:

(a) A review of clinically-significant adverse side effects, drug interactions and contraindications, and an assessment of the likelihood of significant abuse of the drug;

and

(b) An assessment of the cost of the drug compared to other drugs used for the same therapeutic indication and if the drug offers a substantial clinically-meaningful advantage in terms of safety, effectiveness, or clinical outcome over other available drugs used for the same therapeutic indication. Cost shall be based on the net cost of the drug after federal rebate and supplemental rebates have been subtracted.

(2) New drugs. Except as provided by subsections (3) and (4) of this section, upon initial coverage by the Kentucky Medicaid Program, a drug that is newly approved for marketing by the FDA under a product licensing application, new drug application, or a supplement to a new drug application and that is a new chemical or molecular entity and not otherwise excluded shall be subject to prior authorization in accordance with KRS 205.5632.

(3) Product line. If a drug, which has been determined to require prior authorization, becomes available on the market in a new strength, package size, or other form that does not meet the definition of a new drug, the new strength, package size, or other form shall require prior authorization.

(4) Generic equivalency for prescribed brands. A brand name drug for which there is a generic form that contains identical amounts of the same active drug ingredients in the same dosage form and that meets compendia or other applicable standards of strength, quality, purity, and identity in comparison with the brand name drug shall require prior authorization, unless there has been a review and determination by the department that it is in the best interest of a recipient for the department to cover the drug without prior authorization.

(5) Advisory recommendation. Drugs subject to review by the Pharmacy and Therapeutics Advisory Committee (P&T Committee) shall be reviewed in accordance with KRS 205.564 and this administrative regulation. Upon review, the P&T Committee shall make a recommendation to the department regarding utilization management of the drug including prior authorization and the recommendation shall be advisory to the commissioner in making the final determination.

(6) The department may exclude from coverage or require prior authorization for a drug that is subject to coverage limitations in accordance with 42 U.S.C. 1396r-8(d).

Section 11. Pharmacy and Therapeutics Advisory Committee (P&T Committee) Meeting Procedures. P&T Committee meetings, processes, and procedures shall be in accordance with KRS 205.564 and this administrative regulation.

(1) Drug review considerations. The P&T Committee shall consider the drug review information specified in Section 10(1) of this administrative regulation when developing recommendations.

(2) Meeting processes and procedures.

(a) Public presentations. A public presentation at a P&T Committee meeting shall comply with this paragraph.

1. A presentation shall be limited to an agenda item.

2. A verbal presentation by pharmaceutical industry representatives shall not exceed three (3) minutes in aggregate per drug per drug manufacturer with two (2) additional minutes allowed for questions from the P&T Committee. Pharmaceutical industry representatives shall be limited to presenting:

a. Information on a new product; or

b. New information on a previously reviewed current agenda topic (package insert changes, new indications, or peer-reviewed journal articles).

3. A verbal presentation by an individual other than a pharmaceutical industry representative shall not exceed five (5) minutes.

4. A request to make a verbal presentation shall be submitted in writing via fax or e-mail to the department no later than five (5) business days in advance of the P&T Committee meeting date.

(b) Nonverbal comments, documents, or electronic media material (limited to package insert changes, new indications, or peer reviewed journal articles) shall be e-mailed to the department in a Microsoft compatible format or mailed to the department as a package including twenty-five (25) printed copies. All materials shall be received by the department no later than seven (7) business days prior to the P&T Committee meeting date.

(3) Postings. P&T Committee meeting documents shall be published in accordance with KRS 205.564(6), and shall include the:

(a) Meeting agenda;

(b) Options, including any department recommendations, for drug review and drug review placements,

(c) P&T Committee recommendations; and

(d) Commissioner's final determination.

Section 12. Exceptions to P&T Committee Recommendations.

(1)

(a) An interested party who is adversely affected by a recommendation of the P&T Committee may submit a written exception to the commissioner.

(b) The written exception shall be received by the commissioner within seven (7) calendar days of the date of the P&T Committee meeting at which the recommendation was made.

(c) Only information that was not available to be presented at the time of the P&T Committee meeting shall be included in the written exception.

(2) After the time for filing written exceptions has expired, the commissioner shall consider each recommendation of the P&T Committee and all exceptions that were filed in a timely manner prior to making a final determination.

Section 13. Final Determination. The commissioner shall issue and post a final determination in accordance with KRS 205.564(9) and (11).

(1) A decision of the commissioner to remand any recommendation to the P&T Committee shall not constitute a final decision or final determination for purposes of an appeal pursuant to KRS Chapter 13B.

(2) If any recommendation of the P&T Committee is not accepted, the commissioner or commissioner's designee shall inform the P&T Committee of the basis for the final determination in accordance with KRS 205.564(9).

Section 14. Appeals. An appeal request shall:

(1) Be in writing;

(2) Be sent by mail, messenger, carrier service, or express-delivery service to the commissioner in a manner that safeguards the information;

(3) State the specific reasons the final determination of the commissioner is alleged to be erroneous or not based on the facts and law available to the P&T Committee and the commissioner at the time of the decision;

(4) Be received by the commissioner within the deadline established by KRS 205.564(12); and

(5) Be forwarded by the commissioner to the Office of Administrative Hearings within the Department of Law~~[Division of Administrative Hearings of the Cabinet for Health and Family Services]~~ for processing in accordance with the provisions of KRS Chapter 13B.

Section 15. Drug Management Review Advisory Board (DMRAB) Meeting Procedures and Appeals.

(1) A person may address the DMRAB if:

(a) The presentation is directly related to an agenda item; and

(b) The person gives notice to the department by fax or email at least five (5) business days prior to the meeting.

(2) A verbal presentation:

(a) In aggregate per drug per drug manufacturer shall not exceed three (3) minutes with two (2) additional minutes allowed for questions from the DMRAB, if required; or

(b) By an individual on a subject shall not exceed three (3) minutes with two (2) additional minutes allowed for questions from the DMRAB, if required.

(3) The proposed agenda shall be posted on the department's pharmacy webpage, located at: https://www.chfs.ky.gov/agencies/dms/dpo/ppb/Pages/p-tac.aspx at least fourteen (14) calendar days prior to the meeting.

(4) An appeal of a final decision by the commissioner by a manufacturer of a product shall be in accordance with KRS 205.5639(5). The appeal request shall:

(a) Be in writing;

(b) State the specific reasons the manufacturer believes the final decision to be incorrect;

(c) Provide any supporting documentation; and

(d) Be received by the department within thirty (30) calendar days of the manufacturer's actual notice of the final decision.

Section 16. Medicaid Program Participation Compliance.

(1) A provider shall comply with:

(a) 907 KAR 1:671;

(b) 907 KAR 1:672; and

(c) All applicable state and federal laws.

(2)

(a) If a provider receives any duplicate payment or overpayment from the department, regardless of reason, the provider shall return the payment to the department.

(b) Failure to return a payment to the department in accordance with paragraph (a) of this subsection may be:

1. Interpreted to be fraud or abuse; and

2. Prosecuted in accordance with applicable federal or state law.

Section 17. Use of Electronic Signatures.

(1) The creation, transmission, storage, and other use of electronic signatures and documents shall comply with the requirements established in KRS 369.101 to 369.120.

(2) A provider that chooses to use electronic signatures shall:

(a) Develop and implement a written security policy that shall:

1. Be adhered to by each of the provider's employees, officers, agents, or contractors;

2. Identify each electronic signature for which an individual has access; and

3. Ensure that each electronic signature is created, transmitted, and stored in a secure fashion;

(b) Develop a consent form that shall:

1. Be completed and executed by each individual using an electronic signature;

2. Attest to the signature's authenticity; and

3. Include a statement indicating that the individual has been notified of his or her responsibility in allowing the use of the electronic signature; and

(c) Provide the department, immediately upon request, with:

1. A copy of the provider's electronic signature policy;

2. The signed consent form; and
3. The original filed signature.

Section 18. Auditing Authority. The department shall have the authority to audit any claim, medical record, or documentation associated with any claim or medical record.

Section 19. Federal Approval and Federal Financial Participation. The department's coverage of services pursuant to this administrative regulation shall be contingent upon:
(1) Receipt of federal financial participation for the coverage; and
(2) Centers for Medicare and Medicaid Services' approval for the coverage.

Section 20. Appeal Rights.
(1) An appeal of an adverse action taken by the department regarding a service and a recipient who is not enrolled with a managed care organization shall be in accordance with 907 KAR 1:563.
(2) An appeal of an adverse action by a managed care organization regarding a service and an enrollee shall be in accordance with 907 KAR 17:010.

Section 21. Incorporation by Reference.
(1) The following material is incorporated by reference:
(a) "Kentucky Medicaid Substance Use Treatment Pharmacy Prior Authorization Form for Buprenorphine Products", 1-3-17; and
(b) "Kentucky Medicaid Pharmacy Prior Authorization Form", 1-3-17.
(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at:
(a) The Department for Medicaid Services, 275 East Main Street, Frankfort, Kentucky, Monday through Friday, 8:00 a.m. to 4:30 p.m.; or
(b) Online at the department's website at https://www.chfs.ky.gov/agencies/dms/dpo/ppb/Pages/default.aspx[~~Web site at http://www.chfs.ky.gov/dms/incorporated.htm~~].

COMPILER'S NOTE: 2025 RS HB 6, enacted by the General Assembly on March 27, 2025, altered the information to be provided at the time an administrative regulation is filed. Aside from formatting changes necessary to upload the regulation into the LRC's publication application, this regulation has been published as submitted by the agency.

LISA D. LEE, Commissioner
STEVEN J. STACK, MD, MBA, Secretary

APPROVED BY AGENCY: August 1, 2025
FILED WITH LRC: September 9, 2025 at 10:09 a.m.
PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on November 24, 2025, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by November 17, 2025, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation through November 30, 2025. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of

consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-7476; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Krista Quarles and Jonathan Scott

Subject Headings:Behavioral Health; Health and Medical Services; Medicaid; Mental Health; Pharmacy; Physicians and Practitioners

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes the provisions for coverage of outpatient drugs through the Medicaid outpatient pharmacy program for fee-for-service recipients and managed care enrollees.

(b) The necessity of this administrative regulation:

This administrative regulation is necessary to establish the provisions for coverage of outpatient drugs through the Medicaid outpatient pharmacy program for fee-for-service recipients and managed care enrollees.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

This administrative regulation conforms to the content of the authorizing statutes by ensuring coverage of outpatient drugs through the Medicaid outpatient pharmacy program for fee-for-service recipients and managed care enrollees.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This administrative regulation assists in the effective administration of the statutes by establishing the provisions for coverage of outpatient drugs through the Medicaid outpatient pharmacy program for fee-for-service recipients and managed care enrollees.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

This amendment will allow reimbursement for prescription weight loss, anorexia, and weight loss drugs.

(b) The necessity of the amendment to this administrative regulation:

This amendment is necessary to implement reimbursement for weight loss, anorexia, and weight gain drugs as provided by federal law.

(c) How the amendment conforms to the content of the authorizing statutes:

This amendment conforms to the content of authorizing statutes by permitting coverage for medication as permitted by federal law.

(d) How the amendment will assist in the effective administration of the statutes:

This amendment will assist in the effective administrative of the statutes by allowing reimbursement for covered medications.

(3) Does this administrative regulation or amendment implement legislation from the previous five years?No.

(4) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

As many as 350,000 Medicaid members have an obesity related diagnosis. In addition, anorexia is the deadliest behavioral health disorder, and many recipients with a

diagnosis such as cancer may benefit from weight gain drugs.

(5) Provide an analysis of how the entities identified in question (4) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (4) will have to take to comply with this administrative regulation or amendment:

In order to be reimbursed by DMS, participating providers will have to submit claims for covered drugs in accordance with this administrative regulation and applicable billing rules.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4):

There will be no additional costs experienced by affected providers

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4):

Medicaid beneficiaries will be able to access weight loss, anorexia, or weight loss drugs and pharmacies will be able to receive reimbursement for these covered medications.

(6) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

In the Medicaid program, drugs have to be rebateable in order to be covered. DMS therefore would not utilize or offer a GLP-1 weight loss drug if sufficient rebates were not negotiated and available. In addition, any availability of GLP-1 drugs will be mediated through prior authorizations, step therapy, or other ways to ensure that utilization by Medicaid members is responsible and limited to those individuals who will benefit the most. In commercial insurance settings, when available, about 32% of recipients will continue to take GLP-1s over the course of a year. When compared to other states who have introduced GLP-1s, 2.5% of eligible individuals may attempt to take these drugs. Therefore, DMS estimates an actual impact of $1.1 million in state funds.

(b) On a continuing basis:

DMS does not anticipate offering GLP-1 medications without prior authorizations, step therapy, and other utilization management review to ensure appropriate use. DMS further anticipates that cost savings from avoided hospitalizations and other medical interventions. Adherence and persistence (the number of recipients who begin to take a medicine and continue to take it) will drive costs in this area. DMS continues to estimate a lower persistence rate, as consistent with the experience in other states that cover GLP-1 medicines. DMS therefore estimates that about 32% of about 2.5% of the potential population will have sustained use of a GLP-1 medication.

(7) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation or this amendment:

Sources of funding to be used for the implementation and enforcement of this administrative regulation are federal funds authorized under Title XIX and Title XXI of the Social Security Act, and state matching funds of general and agency appropriations.

(8) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an

amendment:

Neither an increase in fees nor funding will be necessary to implement the amendments.

(9) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

The amendment does not establish or increase any fees.

(10) TIERING: Is tiering applied?

Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL IMPACT STATEMENT

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 205.520(3), 42 C.F.R. 447 Subpart I

(2) Identify the promulgating agency and any other affected state units, parts, or divisions:

Cabinet for Health and Family Services, Department for Medicaid Services is the promulgating agency, other agencies have not been identified.

(a) Estimate the following for the first year:

Expenditures:In the Medicaid program, drugs have to be rebateable in order to be covered. DMS therefore would not utilize or offer a GLP-1 weight loss drug if sufficient rebates were not negotiated and available. In addition, any availability of GLP-1 drugs will be mediated through prior authorizations, step therapy, or other ways to ensure that utilization by Medicaid members is responsible and limited to those individuals who will benefit the most. In commercial insurance settings, when available, about 32% of recipients will continue to take GLP-1s over the course of a year. When compared to other states who have introduced GLP-1s, 2.5% of eligible individuals may attempt to take these drugs. Therefore, DMS estimates an actual impact of $1.1 million in state funds.

Revenues:The department does not anticipate additional revenues as a result of the amendment.

Cost Savings:The department anticipates that if used appropriately, weight loss (including GLP-1 medications), anorexia, and weight gain drugs will improve the health status of Kentuckians in various ways. This includes a reduction of mortality and morbidity from anorexia, the deadliest behavioral health condition. Weight gaining drugs could improve multiple treatments for conditions including cancer or chronic conditions. Finally, weight loss drugs will reduce costs for treatment of conditions such as diabetes which will lessen the need for other medications and treatments. In addition, hospital admissions and reimbursements could be reduced as a result of fewer cardiac events.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

DMS does not anticipate offering GLP-1 medications without clinical criteria, including use of prior authorizations, step therapy, and other utilization management review in order to ensure appropriate use.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts):

N/A this regulation does not impact local entities.

(a) Estimate the following for the first year:

Expenditures:N/A there is no impact on local entities

Revenues:N/A there is no impact on local entities

Cost Savings:N/A there is no impact on local entities

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

The department does not anticipate that this administrative regulation will have a fiscal impact on local entities.

(4) Identify additional regulated entities not listed in questions (2) or (3):
Providers, pharmacies, and Medicaid recipients.

(a) Estimate the following for the first year:

Expenditures:DMS does not anticipate additional expenditures as a result of this amendment.

Revenues:The department does not anticipate revenues for other regulated entities as a result of this administrative regulation.

Cost Savings:The department does not anticipate cost savings for other regulated entities as a result of this administrative regulation.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?
The department does not anticipate additional expenditures or additional revenues for other regulated entities. Individuals who improve their health status via the use of anorexia medications, weight gaining medications, or GLP-1 medications may experience cost savings.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:
In the Medicaid program, drugs have to be rebateable in order to be covered. DMS therefore would not utilize or offer a GLP-1 weight loss drug if sufficient rebates were not negotiated and available. In addition, any availability of GLP-1 drugs will be mediated through prior authorizations, step therapy, or other ways to ensure that utilization by Medicaid members is responsible and limited to those individuals who will benefit the most. In commercial insurance settings, when available, about 32% of recipients will continue to take GLP-1s over the course of a year. When compared to other states who have introduced GLP-1s, 2.5% of eligible individuals may attempt to take these drugs. Therefore, DMS estimates an actual impact of $1.1 million in state funds.

(b) Methodology and resources used to determine the fiscal impact:
Analysis of addition of GLP-1 medications conducted by the CHFS Office of Data Analytics.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). ($500,000 or more, in aggregate)
This administrative regulation will not have a major economic impact – as defined by KRS 13A.010 – on regulated entities.

(b) The methodology and resources used to reach this conclusion:
The department assessed claims data, studies that have assessed usage of GLP-1 medications across multiple states, and an analysis conducted by the CHFS Office of Data Analytics.

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.
42 C.F.R. 447 Subpart I

(2) State compliance standards.
KRS 205.520(3) states, "Further, it is the policy of the Commonwealth to take advantage of all federal funds that may be available for medical assistance. To qualify for federal funds the secretary for health and family services may by regulation comply with any requirement that may be imposed or opportunity that may be presented by federal law. Nothing in KRS 205.510 to 205.630 is intended to limit the secretary's power in this respect."

(3) Minimum or uniform standards contained in the federal mandate.
42 C.F.R. 447 Subpart I introduces weight-gaining and weight-loss drugs as Medicaid coverable and rebateable services.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?
The amendment will not impose stricter than federal requirements.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.
The amendment will not impose stricter than federal requirements.