

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Medicaid Services

3 Division of Medical Management

4 (Amendment)

5 907 KAR 1:019. Outpatient Pharmacy Program.

6 RELATES TO: KRS Chapter 13B, 205.510, 205.560, 205.561, 205.5631-205.5639,
7 205.564, 205.6316, 205.8451, 205.8453, 217.015, 217.822, 42 C.F.R. 430.10, 431.54,
8 440.120, 447.331, 447.332, 447.333, 447.334, 42 U.S.C. 1396a, 1396b, 1396c, 1396d,
9 1396r-8[, ~~Pub.L. 109-91~~]

10 STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 205.561,
11 205.5632, 205.5634, 205.5639(2), 205.564(10), (13), Part I.G.3.b.(26) of HB 1 of the
12 2010 Extraordinary Session of the General Assembly

13 NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family
14 Services, Department for Medicaid Services, has the responsibility to administer the
15 Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regula-
16 tion, to comply with any requirement that may be imposed or opportunity presented by
17 federal law for the provision of medical assistance to Kentucky's indigent citizenry. KRS
18 205.560 provides that the scope of medical care for which Medicaid shall pay is deter-
19 mined by administrative regulations promulgated by the cabinet. This administrative
20 regulation establishes the provisions for coverage of drugs through the Medicaid outpa-
21 tient pharmacy program including the establishment of prior authorization procedures

1 as authorized by KRS 205.5632, ~~and~~ Pharmacy and Therapeutics Advisory Committee
2 provisions as authorized by KRS 205.564, tamper resistant prescription requirements
3 pursuant o 42 USC 1396b(i), and combats prescription fraud and abuse pursuant to
4 KRS 205.8453.

5 Section 1. Definitions. (1) "Brand name drug" means the registered trade name of a
6 drug which was originally marketed under an original new drug application approved by
7 the Food and Drug Administration.

8 (2) "Commissioner" is defined by KRS 205.5631(1).

9 (3) "Covered drug" means a drug for which the Department for Medicaid Services
10 provides reimbursement if medically necessary and if provided, but not otherwise ex-
11 cluded, in accordance with Sections 2 and 3 of this administrative regulation.

12 (4) "Covered outpatient drug" is defined by 42 USC 1396r-8(k)(2).

13 (5) "Department" means the Department for Medicaid Services or its designated
14 agent.

15 (6)~~(5)~~ "Department's pharmacy Internet web site" or "web site" means the Internet
16 web site maintained by the Department for Medicaid Services and accessible at
17 <http://www.chfs.ky.gov/dms/Pharmacy.htm>~~<http://www.chfs.ky.gov/dms>~~.

18 (7)~~(6)~~ "Dosage form" means the type of physical formulation used to deliver a drug
19 to the intended site of action, including a tablet, an extended release tablet, a capsule,
20 an elixir, a solution, a powder, a spray, a cream, an ointment, or any other distinct phys-
21 ical formulation recognized as a dosage form by the Food and Drug Administration.

22 (8)~~(7)~~ "Drug list" means the Department for Medicaid Services' list which:

23 (a) Specifies:

- 1 1. Drugs, drug categories, and related items not covered by the department; and
2 2. Covered drugs requiring prior authorization or having special prescribing or dis-
3 pensing restrictions or excluded medical uses; and

4 (b) May include information about other drugs, drug categories, or related items and
5 dispensing and prescribing information.

6 (9)[(8)] "Drug Management Review Advisory Board" or "DMRAB" or "board" means
7 the board established pursuant to KRS 205.5636.

8 (10)[(9)] "Effective" or "effectiveness" means a finding that a pharmaceutical agent
9 does or does not have a significant, clinically- meaningful therapeutic advantage in
10 terms of safety, usefulness, or clinical outcome over the other pharmaceutical agents
11 based on pertinent information from a variety of sources determined by the department
12 to be relevant and reliable.

13 (11) "Emergency supply" means a seventy-two (72) hour supply.

14 (12) "Federal financial participation" is defined by 42 CFR 400.203.

15 (13)[(10)] "Food and Drug Administration" means the Food and Drug Administration
16 of the United States Department of Health and Human Services.

17 (14)[(11)] "Generic drug" or "generic form of a brand name drug" means a drug
18 which contains identical amounts of the same active drug ingredients in the same do-
19 sage form and which meets official compendia or other applicable standards of
20 strength, quality, purity, and identity in comparison with the brand name drug.

21 (15)[(12)] "Legend drug" means a drug so defined by the Food and Drug Administra-
22 tion and required to bear the statement: "Caution: Federal law prohibits dispensing
23 without prescription".

1 ~~(16)~~~~(13)~~ "Manufacturer" is defined in 42 U.S.C. 1396r-8(k)(5).

2 ~~(17)~~~~(14)~~ "Medically necessary" or "medical necessity" means that a covered benefit
3 is determined to be needed in accordance with 907 KAR 3:130.

4 ~~(18)~~~~(15)~~ "Official compendia" or "compendia" is defined in 42 U.S.C. 1396r-
5 8(g)(1)(B)(i).

6 ~~(19)~~~~(16)~~ "Over-the-counter drug" or "OTC drug" means a drug approved by the
7 Food and Drug Administration to be sold without bearing the statement "Caution: Fed-
8 eral law prohibits dispensing without prescription".

9 ~~(20)~~~~(17)~~ "Pharmacy and Therapeutics Advisory Committee" or "committee" or "P&T
10 Committee" means the pharmacy advisory committee established by KRS 205.564.

11 ~~(21)~~~~(18)~~ "Prescriber" means a health care professional who:

12 ~~(a)~~~~(1)~~ Within the scope of practice under Kentucky licensing laws, has the legal au-
13 thority to write or order a prescription for the drug that is ordered;

14 ~~(b)~~ Is enrolled in the Medicaid program pursuant to 907 KAR 1:672; and

15 ~~(c)~~ Is currently participating in the Medicaid program pursuant to 907 KAR 1:671.

16 ~~(22)~~~~(19)~~ "Recipient" is defined by KRS 205.8451(9).

17 ~~(23)~~~~(20)~~ "Secretary" means the Secretary of the Cabinet for Health and Family Ser-
18 vices.

19 ~~(24)~~~~(21)~~ "Supplemental rebate" means a cash rebate that offsets a Kentucky Medi-
20 caid expenditure and that supplements the Centers for Medicare and Medicaid Services
21 National Rebate Program.

22 Section 2. Covered Benefits and Drug List. (1) A covered outpatient drug, non-
23 outpatient drug, or diabetic supply covered via this administrative regulation~~drug cov-~~

1 ~~ered through the outpatient pharmacy program]~~ shall be:

2 (a) Medically necessary;

3 (b) Approved by the Food and Drug Administration; and

4 (c) Prescribed for an indication that has been approved by the Food and Drug Ad-
5 ministration or for which there is documentation in official compendia or peer-reviewed
6 medical literature supporting its medical use.

7 (2) A covered outpatient drug covered via this administrative regulation shall be pre-
8 scribed on a tamper-resistant pad unless exempt pursuant to subsection (3) of this sec-
9 tion.

10 (3) The tamper-resist pad requirement established in subsection (2) of this section
11 shall not apply to:

12 (a) An electronic prescription;

13 (b) A faxed prescription; or

14 (c) A prescription telephoned by a prescriber.

15 (4) To qualify as a tamper-resistant pad prescription, a prescription shall contain:

16 (a) One (1) or more industry-recognized features designed to prevent unauthorized
17 copying of a completed or blank prescription form;

18 (b) One (1) or more industry-recognized features designed to prevent the erasure or
19 modification of information written on the prescription by the prescriber; and

20 (c) One or more industry-recognized features designed to prevent the use of counter-
21 feit prescription forms.

22 (5) The department shall cover the following diabetic supplies via the outpatient

23 pharmacy program in accordance with this administrative regulation and not via the de-

1 partment's durable medical equipment program:

2 (a) A syringe with needle (sterile, 1cc or less);

3 (b) Urine test or reagent strips or tablets;

4 (c) Blood ketone test or reagent strip;

5 (d) Blood glucose test or reagent strips for home blood glucose monitor;

6 (e) Normal, low, or high calibrator solution, chips;

7 (f) Spring-powered device for lancet;

8 (g) Lancets per box of 100; or

9 (h) Home blood glucose monitor.

10 (6)[(2)] The department shall have a drug list which:

11 (a) Lists:

12 1. Drugs, drug categories, and related items not covered by the department and, if
13 applicable, excluded medical uses for covered drugs; and

14 2. Maintenance drugs covered by the department;

15 (b) Specifies those covered drugs requiring prior authorization or having special pre-
16 scribing or dispensing restrictions;

17 (c) Specifies those covered drugs for which the maximum quantity limit on dispensing
18 may be exceeded;

19 (d) Lists covered over-the-counter drugs;

20 (e) Specifies those legend drugs which are permissible restrictions under 42 U.S.C.
21 1396r-8(d), but for which the department makes reimbursement;

22 (f) [~~Specifies covered vaccines;~~

23 ~~(g)]~~ May include a preferred drug list of selected drugs which have a more favorable

1 cost to the department and which prescribers are encouraged to prescribe, if medically
2 appropriate;

3 ~~(g)~~~~(h)~~ May be updated monthly or more frequently by the department; and

4 ~~(i)~~~~(j)~~ Shall be posted on the department's Internet pharmacy web site.

5 ~~(7)(a)~~~~(3)~~ The department may implement drug treatment protocols requiring the use
6 of medically-appropriate drugs which are available without prior authorization before the
7 use of drugs which require prior authorization.

8 (b) The department may approve a request from the prescriber or a pharmacist for
9 exemption of a specific recipient from the requirement established in paragraph (a) of
10 this subsection.~~[this requirement]~~ based on documentation that drugs available without
11 prior authorization:

12 (a) Were used and were not an effective medical treatment or lost their effective-
13 ness;

14 (b) Are reasonably expected to not be an effective medical treatment;

15 (c) Resulted in, or are reasonably expected to result in, a clinically-significant ad-
16 verse reaction or drug interaction; or

17 (d) Are medically contraindicated.

18 Section 3. Exclusions and Limitations. (1) The following drugs shall be excluded from
19 coverage:

20 (a) A drug which the Food and Drug Administration considers to be:

21 1. A less-than-effective drug; or

22 2. Identical, related, or similar to a less-than-effective drug;

23 (b) A drug or its medical use in one (1) of the following categories unless the drug or

1 its medical use is designated as covered in the drug list:

2 1. A drug if used for anorexia, weight loss, or weight gain;

3 2. A drug if used to promote fertility;

4 3. A drug if used for cosmetic purposes or hair growth;

5 4. A drug if used for the symptomatic relief of cough and colds;

6 5. ~~[A drug if used to promote smoking cessation;~~

7 ~~6.]~~ Vitamin or mineral products other than prenatal vitamins and fluoride prepara-
8 tions;

9 ~~6.~~~~[7.]~~ An over-the-counter drug provided to a Medicaid nursing facility service reci-
10 pient. An over-the-counter drug provided to a Medicaid nursing facility service recipient
11 shall be considered a routine service which is already included in a nursing facility's
12 reimbursement and shall be excluded from coverage via the Medicaid outpatient phar-
13 macy program;

14 ~~7.~~~~[8.]~~ A barbiturate;

15 ~~8.~~~~[9.]~~ A benzodiazepine;

16 ~~9.~~~~[10.]~~ A drug which the manufacturer seeks to require as a condition of sale that as-
17 sociated tests or monitoring services be purchased exclusively from the manufacturer
18 or its designee; or

19 ~~10.~~~~[11.]~~ A drug utilized for erectile dysfunction therapy unless the drug is used to
20 treat a condition, other than sexual or erectile dysfunction, for which the drug has been
21 approved by the United States Food and Drug Administration;

22 (c) A drug for which the manufacturer has not entered into or complied with a rebate
23 agreement in accordance with 42 U.S.C. 1396r-8(a), unless there has been a review

1 and determination by the department that it is in the best interest of a recipient for the
2 department to make payment for the drug and federal financial participation is available
3 for the drug;

4 (d) Except in accordance with subsection (7) of this section, a drug dispensed as part
5 of, or incident to and in the same setting as, an inpatient hospital service, an outpatient
6 hospital service, or an ambulatory surgical center service;

7 (e) A drug for which the department requires prior authorization if prior authorization
8 has not been approved; and

9 (f) A drug that has reached the manufacturer's termination date, indicating that the
10 drug may no longer be dispensed by a pharmacy.

11 (2) If authorized by the prescriber, a prescription for a:

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

15 (b) Except as prohibited in subsection (4), of this section, noncontrolled substance
16 may be refilled up to eleven (11) times within a twelve (12) month period from the date
17 the prescription was written or ordered, at which time a new prescription shall be re-
18 quired.

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

21 (a) The drug is designated in the department's drug list as a drug exempt from the
22 thirty-two (32) day dispensing limit in which case the pharmacist may dispense the
23 quantity prescribed not to exceed a three (3) month supply or 100 units, whichever is

1 greater;

2 (b) A prior authorization request has been submitted on the Drug Prior Authorization
3 Request Form (MAP-82001) and approved by the department because the recipient
4 needs additional medication while traveling or for a valid medical reason, in which case
5 the pharmacist may dispense the quantity prescribed not to exceed a three (3) month
6 supply or 100 units, whichever is greater;

7 (c) The drug is prepackaged by the manufacturer and is intended to be dispensed as
8 an intact unit and it is impractical for the pharmacist to dispense only a month's supply
9 because one (1) or more units of the prepackaged drug will provide more than a thirty-
10 two (32) day supply; or

11 (d) The prescription fill is for an outpatient service recipient, excluding an individual
12 who is receiving supports for community living services in accordance with 907 KAR
13 1:145.

14 (4) A prescription fill for a maintenance drug for an outpatient service recipient who
15 has demonstrated stability on the given maintenance drug, excluding an individual re-
16 ceiving supports for community living services in accordance with 907 KAR 1:145, shall
17 be dispensed in a ninety-two (92) day supply unless:

18 (a) The department determines that it is in the best interest of the recipient to dis-
19 pense a smaller supply; or

20 (b) The recipient is covered under the Medicare Part D benefit in which case the de-
21 partment shall not cover the prescription fill.

22 (5) The department may require prior authorization for a compounded drug that re-
23 quires preparation by mixing two (2) or more individual drugs; however, the department

1 may exempt a compounded drug or compounded drug category from prior authorization
2 if there has been a review and determination by the department that it is in the best in-
3 terest of a recipient for the department to make payment for the compounded drug or
4 compounded drug category.

5 (6) A prescriber shall make his or her national provider identifier (NPI) available to a
6 pharmacist and the prescriber's NPI shall be recorded on a pharmacy claim.

7 ~~(7)(a)[An identification number shall be made available by a prescriber and shall be~~
8 ~~recorded on the pharmacy claim in accordance with the following:~~

9 ~~(a) The medical license number of a physician for the state in which the physician~~
10 ~~practices or, for a physician who does not have a Kentucky state medical license num-~~
11 ~~ber on file and who is enrolled in an approved graduate medical education program, the~~
12 ~~medical license number of the supervising physician;~~

13 ~~(b) The license number, including applicable alpha characters, of a dentist, optometr-~~
14 ~~ist, or podiatrist for the state in which the individual practices;~~

15 ~~(c) The registration number, including applicable alpha characters, of an advanced~~
16 ~~registered nurse practitioner registered in Kentucky or the registration number or li-~~
17 ~~cense number, including applicable alpha characters, of an out-of-state advanced regis-~~
18 ~~tered nurse practitioner for the state in which the individual practices; or~~

19 ~~(d) The certification number, including applicable alpha characters, of a physician~~
20 ~~assistant for the state in which the individual practices.~~

21 ~~(7) If it is determined by the department to be in the best interest of a recipient, the~~
22 ~~department may designate a legend drug that may be provided through prior authoriza-~~
23 ~~tion to a recipient in an inpatient facility that does not bill patients, Medicaid, or other~~

1 ~~third-party payers for health care services.~~

2 ~~(8) A recipient who has been restricted to a single pharmacy in accordance with 907~~
3 ~~KAR 1:677 shall be required to obtain non-emergency pharmacy services from the~~
4 ~~pharmacy to which the recipient has been restricted.~~

5 ~~(9)(a)]~~ Except as provided in paragraph (b), (c), or (d) of this subsection, the depart-
6 ment shall cover no more than a total of four (4) prescriptions, of which no more than
7 three (3) shall be brand name prescriptions per recipient per month.

8 (b) The four (4) prescription limit shall not apply if the recipient:

- 9 1. Is under nineteen (19) years of age;
- 10 2. Uses insulin for the management of diabetes; or
- 11 3. Is a nursing facility resident who does not have Medicare Part D drug coverage.

12 (c) A pharmacist may utilize a four (4) prescription limit override code for a recipient
13 whose prescription will exceed the four (4) prescription limit if the prescription is pre-
14 scribed:

15 1. For any of the following conditions:

- 16 a. Acute infection or infestation;
- 17 b. Bipolar disorder;
- 18 c. Cancer;
- 19 d. Cardiac rhythm disorder;
- 20 e. Chronic pain;
- 21 f. Coronary artery or cerebrovascular disease (advanced atherosclerotic disease);
- 22 g. Cystic fibrosis;
- 23 h. Dementia;

- 1 i. Diabetes;
- 2 j. End stage lung disease;
- 3 k. End stage renal disease;
- 4 l. Epilepsy;
- 5 m. Hemophilia;
- 6 n. HIV or AIDS or immunocompromised;
- 7 o. Hyperlipidemia;
- 8 p. Hypertension;
- 9 q. Major depression;
- 10 r. Metabolic syndrome;
- 11 s. Organ transplant; or
- 12 t. Psychotic disorder;
- 13 ~~[u. Schizophrenic disorder; or~~
- 14 ~~v. Schizotypal personality disorder;]~~ or
- 15 2. As part of:
 - 16 a. Acute therapy for migraine headache or acute pain; or
 - 17 b. Suppressive therapy for thyroid cancer.

18 (d) An additional prescription or prescriptions may be covered if the department de-
19 termines that it is in the best interest of the recipient to cover an additional prescription
20 or prescriptions whether brand name or generic.

21 ~~(8)(10) Until close of business February 28, 2006, but no later than that date, the~~
22 ~~department shall cover unlimited generic prescriptions per member per month in accor-~~
23 ~~dance with the requirements and limitations established in this administrative regulation.~~

1 ~~(11)~~]The department shall cover up to three (3) brand name prescriptions per mem-
2 ber per month unless the department determines that it is in the best interest of the
3 member to cover any additional brand name prescriptions.

4 ~~(9)~~~~(12)~~]A refill of a prescription shall not be covered unless at least ninety
5 ~~(90)~~~~eighty (80)~~ percent of the prescription time period has elapsed.

6 Section 4. Prior Authorization Process. (1)(a) To request prior authorization for a
7 drug:

8 1. The applicable form shall be completed and submitted to the department:

9 a. By fax, mail, express delivery service, or messenger service to the department; or

10 b. Via the department's pharmacy Internet web site; or

11 2. A requester may provide the information required on the applicable form to the

12 department verbally via the telephone number published on the department's pharmacy
13 Internet web site.

14 ~~(b)~~, ~~the applicable Drug Prior Authorization Request Form, PPI and H2 Blocker Re-~~

15 ~~quest Form, or the Brand Name Drug Request Form shall be completed and sent by fax~~

16 ~~or, if necessary, via the web-based application located at the web site of~~

17 ~~<http://kentucky.fhsc.com/providers/documents>, by mail, express delivery service, or~~

18 ~~messenger service to the department.~~

19 If drug therapy needs to be started on an urgent basis to avoid jeopardizing the

20 health of a~~the~~ recipient or to avoid causing substantial pain and suffering, the com-

21 pleted request form may be sent to the department's urgent fax number or submitted to

22 the department via the department's pharmacy Internet web site.

23 (2) A Drug Prior Authorization Request Form:

1 (a) Shall be used by a prescriber or pharmacist to request prior authorization for a
2 drug except for a PPI/H2 blocker, a brand name drug, or an atypical antipsychotic
3 agent;

4 (b) Shall be used by a pharmacist to request an early refill of a prescription; or

5 (c) May be used by a pharmacist~~[web-based application located at the web site of~~
6 ~~http://kentucky.fhsc.com/providers/documents. A request shall be submitted in accor-~~
7 ~~dance with the following:~~

8 ~~(a) Drug Prior Authorization Request Form. This form shall be used by the prescriber~~
9 ~~or the pharmacist to request prior authorization for a drug other than a drug classified~~
10 ~~as a proton pump inhibitor or a H2 receptor blocker or for a brand name only request if~~
11 ~~the generic form of the drug is available. This form may also be used by the pharmacist]~~
12 to obtain prior authorization for special dispensing requests involving exceptions to the
13 thirty-two (32) day maximum quantity limit including additional drugs needed for travel
14 or other valid medical reasons.

15 (3)(a) A Brand Name Drug Request Form, except as established in paragraph (c) of
16 this subsection, shall be used by a prescriber to request prior authorization for a brand
17 name drug if a generic form of the drug is available.

18 (b)Regarding a Brand Name Drug Request Form, a prescriber shall:

19 1. Complete the form;

20 2. Include on the form:

21 a. The handwritten phrase “brand medically necessary” or “brand necessary”; and

22 b. The provider’s signature for each specific drug requested; and

23 3. Indicate:

1 a. Whether the recipient has received treatment with available generic forms of the
2 brand name drug and the length of therapy; and

3 b. Why the recipient's medical condition is unable to be adequately treated with the
4 generic forms of the drug.

5 (c) Submission of a Brand Name Drug Request Form shall not be required if:

6 1. The department has specifically exempted the drug, via the drug list, from this re-
7 quirement; or

8 2.a. It has been determined by the department to be in the best interest of a recipient
9 not to require submission of a Brand Name Drug Request Form; or

10 b. The prescriber certifies that the brand name drug is medically necessary in accor-
11 dance with subsection (9) of this section.

12 (d) In addition to the requirements established in paragraphs (a) through (c) of this
13 subsection, the prescriber certify a brand name only request by including for each
14 brand name drug requested, the prescriber's signature and the phrase "Brand Medically
15 Necessary" or "Brand Necessary" handwritten directly on:

16 1. The prescription;

17 2. The nursing facility order sheet; or

18 3. A separate sheet of paper which includes the name of the recipient and the brand
19 name drug requested and is attached to the original prescription or nursing facility order
20 sheet.

21 (4) A Mental Health Drug Authorization Request Form for Atypical Antipsychotic
22 Agents shall be:

23 (a) Used to request prior authorization for an atypical antipsychotic drug; and

1 (b) Completed and submitted as directed on the form.

2 (5) A Suboxone® and Subutex® Prior Authorization Request Form shall be:

3 (a) Used to request prior authorization for suboxone® or subutex®; and

4 (b) Completed and submitted as directed on the form.

5 (6) A Zyvox® (linezolid) Drug Authorization Request Form shall be:

6 (a) Used to request prior authorization for Zyvox®; and

7 (b) Completed and submitted as directed on the form.

8 (7) A Synagis® Prior Authorization Request Form shall be:

9 (a) Used to request prior authorization for Synagis®; and

10 (b) Completed and submitted as directed on the form.

11 ~~(8)(b) Brand Name Drug Request Form. Except as provided in paragraphs (c) and~~
12 ~~(d) of this subsection, this form shall be used by the prescriber to request prior authori-~~
13 ~~zation for a brand name only request if the generic form of the drug is available, unless~~
14 ~~the department has specifically exempted the drug from the requirement to use this~~
15 ~~form. The prescriber shall:~~

16 ~~1. Complete a Brand Name Drug Request Form;~~

17 ~~2. Include on the Brand Name Drug Request Form the handwritten phrase "brand~~
18 ~~medically necessary" or "brand necessary" and the prescriber's signature for each spe-~~
19 ~~cific drug requested; and~~

20 ~~3. Indicate on the Brand Name Drug Request Form:~~

21 ~~a. Whether the recipient has received treatment with available generic forms of the~~
22 ~~brand name drug and the length of therapy; and~~

23 ~~b. Why the recipient's medical condition is unable to be adequately treated with the~~

1 ~~generic forms of the drug.~~

2 ~~(c) A Brand Name Drug Request Form shall not be required if:~~

3 ~~1. It has been determined by the department to be in the best interest of a recipient~~
4 ~~not to require completion of a Brand Name Drug Request Form; and~~

5 ~~2. The prescriber certifies that the brand name is medically necessary in accordance~~
6 ~~with subsection (3) of this section.~~

7 ~~(d) PPI and H2-Blocker Request Form. This form shall be used to request prior au-~~
8 ~~thorization for a drug classified as a proton pump inhibitor or a H2 receptor blocker.~~

9 ~~This form may also be used for a brand name only request if the generic form of the~~
10 ~~proton pump inhibitor or H2 receptor is available and the prescriber completes the ap-~~
11 ~~plicable section of the form and:~~

12 ~~1. Includes on the form the handwritten phrase "brand medically necessary" or~~
13 ~~"brand necessary" and the prescriber's signature for each specific drug requested;~~

14 ~~2. Indicates whether the recipient has received treatment with available generic~~
15 ~~forms of the brand name drug and the length of therapy; and~~

16 ~~3. Indicates why the recipient's medical condition is unable to be adequately treated~~
17 ~~with the generic forms of the drug.~~

18 ~~(2)] If a recipient presents a prescription to a pharmacist for a drug which requires~~
19 ~~prior authorization, the pharmacist:~~

20 ~~(a) Shall, unless the form is one (1) which has to be completed by the prescriber,~~
21 ~~submit a request for prior authorization in accordance with [subsection (1) of]this sec-~~
22 ~~tion;~~

23 ~~(b) Shall notify the prescriber or the prescriber's authorized representative that the~~

1 drug requires prior authorization and:

2 1. If the prescriber indicates that a drug list alternative available without prior authori-
3 zation is acceptable and provides a new prescription, shall dispense the drug list alter-
4 native; or

5 2. If the prescriber indicates that drug list alternatives available without prior authori-
6 zation have been tried and failed or are clinically inappropriate or if the prescriber is
7 unwilling to consider drug list alternatives, shall:

8 a. Request that the prescriber obtain prior authorization from the department; or

9 b. Unless the form is one (1) which has to be completed by the prescriber, submit a
10 prior authorization request in accordance with ~~[subsection (1) of]~~ this section; or

11 (c) Except as restricted by subparagraphs 3 and 4 of this paragraph, may provide the
12 recipient with an emergency supply of the prescribed drug in an emergency situation in
13 accordance with all of the following:

14 1. The emergency situation shall:

15 a. Occur outside normal business hours of the department's drug prior authorization
16 office, except for medications dispensed to a long term care recipient in which an
17 emergency supply may be dispensed after 5 p.m. EST; and

18 b. Exist if, based on the clinical judgment~~[judgement]~~ of the dispensing pharmacist, it
19 would reasonably be expected that, by a delay in providing the drug to the recipient, the
20 health of the recipient would be placed in serious jeopardy or the recipient would expe-
21 rience substantial pain and suffering;

22 2. At the time of the dispensing of the emergency supply, the pharmacist shall in ac-
23 cordance with ~~[subsection (1) of]~~ this section:

1 a. Submit a prior authorization request to the department's urgent fax number or to
2 the department via the department's pharmacy Internet web site~~[web-based application~~
3 ~~located Web site of~~ <http://kentucky.fhsc.com/providers/documents.asp>]; or

4 b. If applicable, notify the prescriber as soon as possible that an emergency supply
5 was dispensed and that the prescriber is required to obtain prior authorization for the
6 requested drug from the department;

7 3. An emergency supply shall not be provided for an over-the-counter (OTC) drug;

8 4. An emergency supply shall not be provided for a drug excluded from coverage in
9 accordance with Section 3(1) (a), (b) or (c) of this administrative regulation; and

10 5. The quantity of the emergency supply shall be:

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

13 b. The amount prescribed if it is not feasible for the pharmacist to dispense just a se-
14 venty-two (72) hour supply because the drug is packaged in such a way that it is not in-
15 tended to be further divided at the time of dispensing but rather dispensed as originally
16 packaged.

17 (9) If a prescriber submits a prescription to a pharmacy via telephone, the prescriber
18 shall also fax the prescription to the pharmacy within forty-eight (48) hours of submitting
19 it via telephone.

20 ~~(10)(3) In addition to the requirements of subsection (1) of this section, the prescrib-~~
21 ~~er shall be required to certify a brand name only request by including for each brand~~
22 ~~name drug requested the prescriber's signature and the phrase "Brand Medically Ne-~~
23 ~~cessary" or "Brand Necessary" handwritten directly on:~~

- 1 ~~(a) The prescription;~~
2 ~~(b) The nursing facility order sheet; or~~
3 ~~(c) A separate sheet of paper which includes the name of the recipient and the brand~~
4 ~~name drug requested and is attached to the original prescription or nursing facility order~~
5 ~~sheet.~~

6 (4) The department's notification of a decision on a request for prior authorization
7 shall be made in accordance with the following:

8 (a) If the department approves a prior authorization request, notification of the ap-
9 proval shall be provided by telephone, fax or via the department's pharmacy Internet
10 web site~~[web-based application located the Web site of~~
11 <http://kentucky.fhsc.com/providers/documents.asp>] to the party requesting the prior au-
12 thorization and, if known, to the pharmacist.

13 (b) If the department denies a prior authorization request:

14 1. The department shall provide a denial notice:

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

16 b. By fax, telephone, or if necessary by mail to the party who requested the prior au-
17 thorization.

18 ~~(11)(a)(5)~~ (11)(a) The department may grant approval of a prior authorization request for a
19 drug for a specific recipient for a period of time not to exceed 365 days.

20 ~~(b)~~ (b) Approval of a new prior authorization request shall be required for continuation of
21 therapy subsequent to the expiration of a time-limited prior authorization request.

22 ~~(12)(6)~~ (12) Prior authorization of drugs for a Medicaid long-term care recipient in a nurs-
23 ing facility shall be in accordance with the following:

1 (a) The department may specify in its drug list specific drugs or drug classes which
2 shall:

- 3 1. Not be exempted from prior authorization; or
- 4 2. Be exempt from prior authorization for Medicaid recipients in nursing facilities.

5 (b) A brand name drug for which the department requires completion by the pre-
6 scriber of a Brand Name Drug Request Form in accordance with this section shall not
7 be exempted from prior authorization.

8 Section 5. Placement of Drugs on Prior Authorization. (1) Except as excluded by
9 Section 3(1)(a) to (c) of this administrative regulation, upon initial coverage by the Ken-
10 tucky Medicaid program, a drug that is newly approved for marketing by the Food and
11 Drug Administration under a product licensing application, new drug application, or a
12 supplement to a new drug application and that is a new chemical or molecular entity
13 shall be subject to prior authorization in accordance with KRS 205.5632.

14 (2) Upon request by the department, a drug manufacturer shall provide the depart-
15 ment with the drug package insert information.

16 (3) The drug review process to determine if a drug shall require prior authorization
17 shall be in accordance with the following:

18 (a) The determination as to whether a drug is in an excludable category specified in
19 Section 3 (1) of this administrative regulation shall be made by the department.

20 1. If a drug, which has been determined to require prior authorization becomes avail-
21 able on the market in a new strength, package size, or other form that does not meet
22 the definition of a new drug the new strength, package size, or other form shall require
23 prior authorization.

1 2. A brand name drug for which there is a generic form that contains identical
2 amounts of the same active drug ingredients in the same dosage form and that meets
3 compendial or other applicable standards of strength, quality, purity, and identity in
4 comparison with the brand name drug shall require prior authorization in accordance
5 with Section 4 of this administrative regulation, unless there has been a review and de-
6 termination by the department that it is in the best interest of a recipient for the depart-
7 ment to cover the drug without prior authorization.

8 (b) The committee shall make a recommendation to the department regarding prior
9 authorization of a drug based on:

10 1. A review of clinically-significant adverse side effects, drug interactions and con-
11 traindications and an assessment of the likelihood of significant abuse of the drug; and

12 2. An assessment of the cost of the drug compared to other drugs used for the same
13 therapeutic indication and whether the drug offers a substantial clinically-meaningful
14 advantage in terms of safety, effectiveness, or clinical outcome over other available
15 drugs used for the same therapeutic indication. Cost shall be based on the net cost of
16 federal rebate and supplemental rebate dollars.

17 (c)1. Within thirty (30) days of the date the committee's recommendation is posted
18 on the department's pharmacy Internet web site, the secretary, in consultation with the
19 commissioner and the department's pharmacy staff~~[director]~~, shall review the recom-
20 mendations of the committee and make the final determination whether a drug requires
21 prior authorization.

22 2. If the recommendation of the committee is not accepted, the secretary shall inform
23 the committee of~~[present]~~the basis for the final determination in accordance with Sec-

1 tion 8(3) of this administrative regulation.

2 (4) The department may exclude from coverage or require prior authorization for a
3 drug which is a permissible restriction in accordance with 42 U.S.C. 1396r-8(d).

4 Section 6. Drug Management Review Advisory Board Meeting Procedures and Ap-
5 peals. (1) A person may address the DMRAB if:

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

7 (b) The person gives notice to the department (and gives a copy to the DMRAB
8 chairperson) by fax or e-mail at least five (5) business days~~[Written notice has been~~
9 ~~given to the chairperson at least twenty-four (24) hours]~~ prior to the meeting.

10 (2) A verbal presentation:

11 (a) In aggregate per drug per drug manufacturer shall not exceed five (5) minutes; or

12 (b) By an individual on a subject shall not exceed five (5) minutes~~[The DMRAB may~~
13 ~~establish time limits for presentations].~~

14 (3) The proposed agenda shall be posted on the department's pharmacy Internet
15 web site at least five (5) days prior to the meeting.

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

18 (a) Be in writing;

19 (b) State the specific reasons the manufacturer believes the final decision to be in-
20 correct;

21 (c) Provide any supporting documentation; and

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

1 Section 7. Pharmacy and Therapeutics Advisory Committee Meeting Procedures. (1)

2 A P&T Committee meeting agenda shall be posted as required by KRS 205.564(6).

3 (2) A P&T committee meeting shall be conducted in accordance with KRS 205.564.

4 (3) A public presentation at a P&T Committee meeting shall comply with the follow-
5 ing:

6 (a)1. A verbal presentation in aggregate per drug per drug manufacturer shall not ex-
7 ceed five (5) minutes;

8 2. A verbal presentation by an individual on a subject shall not exceed five (5) minu-
9 tes~~[The time limit for a verbal presentation shall not exceed five (5) minutes in aggre-~~
10 ~~gate per drug per manufacturer or five (5) minutes by an individual speaking on a par-~~
11 ~~ticular position];~~

12 3.[2.] A request to make a verbal presentation shall be submitted in writing via fax or
13 e-mail to the department with a copy to the chair of the P&T Committee no later than
14 five (5) business days~~[forty-eight (48) hours]~~ in advance of the P&T Committee meeting;

15 4.[3.] An individual may only present new information (package insert changes, new
16 indication or peer-reviewed journal articles) on a product or information on a new prod-
17 uct; and

18 5.[4.] A presentation shall be limited to an agenda item; or

19 (b) Nonverbal comments, documents, or electronic media material (limited to pack-
20 age insert changes, new indication, or peer reviewed journal articles) shall be:

21 1.a. E-mailed to the department in a Microsoft compatible format (for example, Word,
22 Power Point, Excel or other standard file formats including Adobe Acrobat's pdf format);

23 or

1 b. Mailed to the department with a total of twenty-five (25)~~eighteen (18)~~ copies
2 mailed so that the department may distribute copies to P&T Committee members as
3 well as to any other involved parties; and

4 2. Received by the department no later than seven (7) days prior to the P&T Commit-
5 tee meeting.

6 (4) The department may prepare written recommendations or options for drug review
7 for the committee and shall post them as required by KRS 205.564(6).

8 (5) A recommendation by the committee shall require a majority vote.

9 (6) Recommendations of the committee shall be posted as required by KRS
10 205.564(8).

11 (7) A drug manufacturer may request that its name be placed on the department's
12 distribution list for agendas of committee meetings. Placement of a drug manufacturer's
13 name on the distribution list shall be valid through December 31 of each year, at which
14 time the drug manufacturer shall be required to again request placement on the distri-
15 bution list. To request placement of the drug manufacturer's name on the distribution
16 list, the drug manufacturer shall submit the request in writing to the department and
17 shall provide the following information about the drug manufacturer:

18 (a) Manufacturer's name;

19 (b) Mailing address;

20 (c) Telephone number;

21 (d) Fax number;

22 (e) E-mail address; and

23 (f) Name of a contact person.

1 ~~[(8) A drug manufacturer may be requested to submit a supplemental rebate propos-~~
2 ~~al to the department based on a medication to be discussed at a designated P&T meet-~~
3 ~~ing.~~

4 ~~(9) A supplemental rebate proposal submitted to the department shall be provided to~~
5 ~~P&T members during a closed session.]~~

6 Section 8. Review and Final Determination by the Secretary. (1) An interested party
7 who is adversely affected by a recommendation of the committee may submit a written
8 exception to the secretary in accordance with the following:

9 (a) The written exception shall be received by the secretary within seven (7) calendar
10 days of the date of the committee meeting at which the recommendation was made;
11 and

12 (b) Only information that was not available to be presented at the time of the commit-
13 tee's meeting shall be included in the written exception.

14 (2) After the time for filing written exceptions has expired, the secretary shall consider
15 the recommendation of the committee and all exceptions that were filed in a timely
16 manner prior to making a final determination. The secretary shall issue a final determi-
17 nation, and public notice of the final determination shall be posted on the department's
18 pharmacy Internet web site for six (6) months after which a copy of the final determina-
19 tion may be requested from the department.

20 (3) The secretary shall make a final determination in accordance with KRS
21 205.564(9).

22 (4) A final determination by the secretary may be appealed in accordance with KRS
23 Chapter 13B. A decision of the secretary to remand the recommendation to the commit-

1 tee shall not constitute a final decision for purposes of an appeal pursuant to KRS
2 Chapter 13B. An appeal request shall:

3 (a) Be in writing;

4 (b) Be sent by mail, messenger, carrier service, or express-delivery service to the
5 secretary in a manner that safeguards the information;

6 (c) State the specific reasons the final determination of the secretary is alleged to be
7 erroneous or not based on the facts and law available to the committee and the secre-
8 tary at the time of the decision;

9 (d) Be received by the secretary within thirty (30) days of the date of the posting of
10 the final determination on the department's pharmacy Internet web site; and

11 (e) Be forwarded by the secretary to the Administrative Hearings Branch of the Cabi-
12 net for Health and Family Services for processing in accordance with the provisions of
13 KRS Chapter 13B.

14 Section 9. Confirming Receipt of Prescription. (1) A recipient, or a designee of the
15 recipient, shall sign their name on a log at a pharmacy confirming that the recipient re-
16 ceived the prescription.

17 (2) A pharmacist shall maintain, or be able to produce a copy of, a log of recipient
18 signatures referenced in subsection (1) of this section, for at least six (6) years.

19 Section 10. Exemptions to Prescriber Requirements. The department shall reimburse
20 for:

21 (1) A full prescription prescribed by a provider who is not enrolled in the Kentucky
22 Medicaid program, if the department determines that reimbursing for a full prescription
23 is in the best interest of the recipient; or

1 (2) An emergency supply of a prescription prescribed by a provider who is not
2 enrolled in the Kentucky Medicaid program, if the department determines that reimburs-
3 ing for the emergency supply is in the best interest of the recipient.

4 Section 11. Federal Financial Participation. A provision established in this
5 administrative regulation shall be null and void if the Centers for Medicare and Medicaid
6 Services:

- 7 (1) Denies federal financial participation for the provision; or
- 8 (2) Disapproves the provision.

9 Section 11. Federal Financial Participation. A provision established in this
10 administrative regulation shall be null and void if the Centers for Medicare and Medicaid
11 Services:

- 12 (1) Denies federal financial participation for the provision; or
- 13 (2) Disapproves the provision.

14 Section 12.~~[Section 10.]~~ Appeal Rights. A Medicaid recipient may appeal the de-
15 partment's denial, suspension, reduction, or termination of a covered drug or decision
16 regarding the amount of a drug dispensed based upon an application of this administra-
17 tive regulation in accordance with 907 KAR 1:563.

18 Section 13. Incorporation by Reference. (1) The following material is incorporated by
19 reference:

- 20 (a) "Drug Prior Authorization Request Form", May 15, 2007 edition;
- 21 (b) "Brand Name Drug Request Form", May 15, 2007 edition;
- 22 (c) "Mental Health Drug Authorization Request Form for Atypical Antipsychotic
23 Agents", May 15, 2007 edition;

1 (d) "Subaxone® and Subutex® Prior Authorization Request Form", September 22,
2 2009 edition;

3 (e) ""Zyvox® (linezolid) Drug Authorization Request Form", January 11, 2010 edition;
4 and

5 (f) "Synagis® Prior Authorization Request Form", September 16, 2009 edition.

6 [~~"MAP-82001 Drug Prior Authorization Request Form, October 18, 2004, edition"; and~~

7 ~~(b) "MAP-82101 Brand Name Drug Request Form, October 18, 2004, edition"; and~~

8 ~~(c) "MAP-012802 PPI and H2 Blocker Request Form, October 18, 2004, edition".]~~

9 (2) This material may be inspected, copied, or obtained, subject to applicable copy-
10 right law, at the Department for Medicaid Services, 275 East Main Street, Frankfort,
11 Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

907 KAR 1:019

REVIEWED:

Date

Elizabeth A. Johnson, Commissioner
Department for Medicaid Services

APPROVED:

Date

Janie Miller, Secretary
Cabinet for Health and Family Services

907 KAR 1:019

A public hearing on this administrative regulation shall, if requested, be held on August 23, 2010, at 9:00 a.m. in the Health Services Auditorium, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky, 40621. Individuals interested in attending this hearing shall notify this agency in writing by August 16, 2010, 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. The hearing is open to the public. Any person who attends 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 attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business August 31, 2010. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, (502) 564-7905, Fax: (502) 564-7573.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 907 KAR 1:019

Cabinet for Health and Family Services

Department for Medicaid Services

Agency Contact: Lee Barnard (502) 564-9444, Trista Chapman (502) 564-9444 or
Stuart Owen (502) 564-4321

- (1) Provide a brief summary of:
 - (a) What this administrative regulation does: This administrative regulation establishes the provisions for coverage of drugs through Medicaid's outpatient pharmacy program.
 - (b) The necessity of this administrative regulation: This administrative regulation is necessary to establish the provisions for coverage of drugs through Medicaid's outpatient pharmacy program.
 - (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 establishing the provisions for coverage of drugs through Medicaid's outpatient pharmacy program.
 - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation currently assists and will continue to assist in the effective administration of the authorizing statutes by establishing the provisions for coverage of drugs through Medicaid's outpatient pharmacy program.

- (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 implements various Medicaid pharmacy program efficiencies as mandated by Part I, G.3.b.(26) of HB 1 of the 2010 Extraordinary Session of the General Assembly. The amended regulation requires prescribers to be Kentucky Medicaid program providers; increases the period before a prescription can be refilled from after eighty (80) percent of the prescription period has lapsed to ninety (90) percent; reimburses for diabetic supplies via the pharmacy program rather than the durable medical equipment program in order to procure rebates for the items; updates forms used for prior authorization purposes; establishes that a recipient must sign a log at the pharmacy to confirm receipt of a prescription and requires that requests to present at a Drug Management Review Advisory Board (DMRAB) or Pharmacy and Therapeutics (P&T) Committee meeting must be submitted at least five (5) business days in advance. Additionally, the amendment complies with 42 USC 1396b(i), which contains a provision requiring Medicaid-reimbursed providers to use tamper-resistant prescription drug pads in their prescribing.
 - (b) The necessity of the amendment to this administrative regulation: This

- amendment is necessary to comply with Part I.G.3.b.(26) of HB 1 of the 2010 Extraordinary Session of the General Assembly by implementing pharmacy program efficiencies.
- (c) How the amendment conforms to the content of the authorizing statutes:
This amendment conforms to Part I.G.3.b.(26) of HB 1 of the 2010 Extraordinary Session of the General Assembly by implementing Medicaid pharmacy program efficiencies.
- (d) How the amendment will assist in the effective administration of the statutes:
This amendment will assist in the effective administration of Part I.G.3.b.(26) of HB 1 of the 2010 Extraordinary Session of the General Assembly by implementing Medicaid pharmacy program efficiencies.
- (3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: All Medicaid-reimbursed prescribing providers are affected by this amendment and recipients are affected as well.
- (4) Provide an analysis of how the entities identified in question (3) 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 (3) will have to take to comply with this administrative regulation or amendment:
Regulated entities will be required to use tamper-resistant prescription drug pads in their prescribing and non-Medicaid providers will have to enroll in Kentucky's Medicaid program in order to prescribe controlled substances for Kentucky Medicaid recipients. Medicaid recipients will have to sign, at the pharmacy, confirming their receipt of prescriptions.
- (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): Medicaid-reimbursed prescribing providers may experience costs associated with purchasing tamper-resistant prescription drug pads.
- (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Providers who comply will receive reimbursement for Medicaid recipient prescriptions and recipients will receive prescriptions.
- (5) Provide an estimate of how much it will cost to implement this administrative regulation:
- (a) Initially: The Department for Medicaid Services (DMS) estimates that the efficiencies, in aggregate, implemented via the amendment will reduce DMS expenditures by approximately \$15.7 million (state and federal share combined) annually.
- (b) On a continuing basis: DMS estimates that the efficiencies, in aggregate, implemented via the amendment will reduce DMS expenditures by approximately \$15.7 million (state and federal share combined) annually.
- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be

used for implementation and enforcement of this administrative regulation are federal funds authorized under Title XIX of the Social Security Act and state matching funds of general fund appropriations.

- (7) 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 is necessary to implement this amendment.
- (8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither establishes nor increases any fees.
- (9) Tiering: Is tiering applied? (Explain why tiering was or was not used)
Tiering was not appropriate in this administrative regulation as the administrative regulation applies equally to all those individuals or entities regulated by it. Disparate treatment of any person or entity subject to this administrative regulation could raise questions of arbitrary action on the part of the agency. The “equal protection” and “due process” clauses of the Fourteenth Amendment of the U.S. Constitution may be implicated as well as Sections 2 and 3 of the Kentucky Constitution.

FEDERAL MANDATE ANALYSIS COMPARISON

Regulation Number: 907 KAR 1:019

Agency Contact: Lee Barnard (502) 564-9444, Trista Chapman (502) 564-9444 or
Stuart Owen (502) 564-4321

1. Federal statute or regulation constituting the federal mandate. 42 USC 1396b(i)(23).
2. State compliance standards. KRS 205.560 establishes “The scope of medical care for which the Cabinet for Health and Family Services undertakes to pay shall be designated and limited by regulations promulgated by the cabinet, pursuant to the provisions in this section.”
3. Minimum or uniform standards contained in the federal mandate. Prescriptions, if not executed electronically, must be executed on a tamper resistant pad.
4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? Federal law or regulation does not require a prescriber to be a provider enrolled in the given state’s Medicaid program, but DMS is implementing this requirement.
5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. DMS is implementing the requirement that a prescriber be an enrolled Medicaid program provider in order to prevent recipient from doctor shopping in order to procure additional drugs.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation Number: 907 KAR 1:019

Agency Contact: Lee Barnard (502) 564-9444, Trista Chapman (502) 564-9444 or
Stuart Owen (502) 564-4321

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments or school districts)?

Yes X No

If yes, complete 2-4.

2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This amendment will affect all Medicaid-reimbursed prescribing providers as well as non-Medicaid providers who are accustomed to prescribing controlled substances for Medicaid recipients.
3. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. This amendment is authorized by Part I.G.3.b.(26) of HB 1 of the 2010 Extraordinary Session of the General Assembly, KRS 194A.010(1), KRS 194A.030(2), KRS 205.520(3), KRS 205.560(1), KRS 205.8453, 42 USC 1396b(i)(23) and 42 USC 1396r-8.
4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
 - (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This amendment will not generate any additional revenue for state or local governments during the first year of implementation.
 - (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This amendment will not generate any additional revenue for state or local governments during subsequent years of implementation.
 - (c) How much will it cost to administer this program for the first year? No additional costs are necessary to implement this amendment during the first year. The Department for Medicaid Services (DMS) estimates that the efficiencies, in aggregate, implemented via the amendment will reduce DMS expenditures by approximately \$15.7 million (state and federal share combined) annually.

(d) How much will it cost to administer this program for subsequent years? No additional costs are necessary to implement this amendment during subsequent years. The Department for Medicaid Services (DMS) estimates that the efficiencies, in aggregate, implemented via the amendment will reduce DMS expenditures by approximately \$15.7 million (state and federal share combined) annually.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): _____

Expenditures (+/-): _____

Other Explanation:

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR MEDICAID SERVICES

907 KAR 1:019

Summary of Material Incorporated by Reference

The following material is incorporated by reference:

(1) The "Drug Prior Authorization Request Form", which is being updated from the October 18, 2004 edition to the May 15, 2007 edition. The form contains one (1) page.

(2) The "Brand Name Drug Request Form", which is being updated from the October 18, 2004 edition to the May 15, 2007 edition. The form contains one (1) page.

(3) The "Mental Health Drug Authorization Request Form for Atypical Antipsychotic Agents", May 15, 2007 edition is a new form used to request prior authorization for atypical antipsychotic drugs. The form consists of one (1) page.

(4) The "Subaxone® and Subutex® Prior Authorization Request Form", September 22, 2009 edition is a new form used to request prior authorization for Subaxone® and Subutex® and contains one (1) page.

(5) The "Zyvox® (linezolid) Drug Authorization Request Form", January 11, 2010 edition is a new form used to request prior authorization for Zyvox® (linezolid) and contains one (1) page.

(6) The "Synagis® Prior Authorization Request Form", September 16, 2009 edition is a new form used to request prior authorization for Synagis® and contains one (1) page. The "MAP-012802 PPI and H2 Blocker Request Form", October 18, 2004, edition is being deleted from the material incorporated by reference as it is no longer used.

The material incorporated by reference encompasses a total of six (6) pages.