1	Public Protection Cabinet
2	Department of Insurance
3	Division of Health and Life Insurance and Managed Care
4	(Amendment)
5	806 KAR 17:230. Requirements regarding medical director's signature on health care benefit
6	denials.
7	RELATES TO: KRS 304.17A-540, 304.17A-545, <u>304.17A-600 – 304.17A-619</u>
8	STATUTORY AUTHORITY: KRS 304.2-110(1)
9	NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110(1) provides that the
10	Commissioner [Executive Director] may promulgate reasonable rules and regulations necessary
11	for or as an aid to the effectuation of any provision of the Kentucky Insurance Code. This
12	administrative regulation establishes the procedure to be followed when a medical director's
13	signature is required on health care benefit denials.
14	Section 1. Definitions. (1) "Adverse determination" is defined by KRS 304.17A-600(1).
15	(2) "Coverage denial" is defined by KRS 304.17A-617(1).
16	(3) "Electronic signature" is defined by KRS 369.102(8).
17	(4) "Enrollee" is defined by KRS 304.17A-500(5).
18	(5) "Managed care plan" is defined by KRS 304.17A-500(9).

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1	(6) "Medical director" means a person meeting the requirements of KRS 304.17A-545(1),
2	and includes a medical director of an entity under contract and delegated to perform utilization
3	review on behalf of a managed care plan.
4	(7) "Notice of coverage denial" means a letter, a notice, or an Explanation of Benefits
5	statement advising of a coverage denial as defined by KRS 304.17A-617(1).
6	(8) "Signature" means name, title, state of licensure and license number.
7	(9) "Utilization review" is defined by <u>KRS 304.17A-600(17)</u> [KRS 304.17A-600(18)].
8	Section 2. Application. This administrative regulation shall apply to all managed care
9	plans authorized by law to engage in managed care in the state of Kentucky and any utilization
10	review entities registered in Kentucky.
11	Section 3. Appointment of Medical Director. (1) A managed care plan shall submit to the
12	department [office] a:
13	(a) Completed form HIPMC-MD-1, incorporated by reference in this Administrative
14	regulation; and
15	(b) Biographical resume of each individual who shall serve as the medical director [of the
16	managed care plan].
17	(2) A managed care plan shall furnish the <u>department [office</u>] with any change in medical
18	director within thirty (30) days of the change.
19	(3) A managed care plan shall provide for an alternative medical director to serve in the
20	event of the medical director's absence and furnish the <u>department [office</u>] with information as
21	required in subsection (1) of this section.

1	Section 4. Letters of Denial for Adverse Determination or Notices of Coverage Denial (1)
2	Letters of denial for adverse determination or notices of coverage denial shall be sent to an
3	enrollee's last known address with a copy of same sent to the provider.
4	(2) Letters of denial requiring signature of the medical director [of a managed care plan]
5	pursuant to KRS 304.17A-545(1)(d) and KRS 304.17A-607(1) shall include:
6	(a) Letters of adverse determination, including denials, limitations, reductions and
7	terminations of services, based on lack of medical necessity; and
8	(b) Letters of adverse determination, including denials, limitations, reductions and
9	terminations or services, based on lack of medical appropriateness.
10	(3) Notices of coverage denial shall not require the medical director's signature.
11	Section 5. Signature of the Medical Director. For purposes of this administrative
12	regulation, the signature of the medical director shall include:
13	(1) Handwritten and copies of original signature; or
14	(2) Electronic signature.
15	Section 6. Incorporation by Reference. (1) Medical Director Report Form HIPMC-MD-1,
16	<u>03/2021</u> [(10/2000)] is incorporated by reference.
17	(2) This material may be inspected, copied, or obtained, subject to applicable copyright
18	law, at the Kentucky Department [Office] of Insurance, The Mayo-Underwood Building, 500
19	Mero Street [215 West Main Street], Frankfort, Kentucky 40601, Mon-day through Friday, 8
20	a.m. to 4:30 p.m. This material is also available on the Department's Web site at
21	http://www.insurance.ky.gov.

806 KAR 17:230 READ AND APPROVED:

Sharon P. Clark Commissioner, Department of Insurance

Secretary, Public Protection Cabinet

Kerry B. Harvey

Date

Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall be held at 9:00 AM on July 23rd, 2021 at 500 Mero Street, Frankfort, KY 40602. Individuals interested in being heard at this hearing shall notify this agency in writing by five 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 wishes to be heard 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 the proposed administrative regulation. Written comments shall be accepted through 11:59 PM on July 30th, 2021. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person below.

Contact Person: Abigail Gall Title: Executive Administrative Secretary Address: 500 Mero Street, Frankfort, KY 40601 Phone: +1 (502) 564-6026 Fax: +1 (502) 564-1453 Email: <u>abigail.gall@ky.gov</u>

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Regulation: 806 KAR 17:230 Contact Person: Abigail Gall Phone: +1 (502) 564-6026 Email: abigail.gall@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the procedure to be used when a medical director's signature is required on health care benefit denials.

(b) The necessity of this administrative regulation: This administrative regulation clarifies when and what type of medical director's signature is acceptable for purposes of KRS 304.17A-545.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 304.2-110(1) provides that the Commissioner make reasonable rules and regulations necessary for or as an aid to the effectuation of any provision of the insurance code. This administrative regulation will aid in implementation of KRS 304.17 A-545.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: KRS 304.2-110(1) provides that the Commissioner make reasonable rules and regulations necessary for or as an aid to the effectuation of any provision of the insurance code. This administrative regulation clarifies when and what type of medical director's signature is acceptable for purposes of KRS 304.17A-545.

(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: Several of the amendments to this administrative regulation are technical in nature and are set forth by Chapter 13A's drafting requirements. This administrative regulation was changed to generalized "medical director" instead of solely the "medical director of the managed care plan". The amendments to the form incorporated update the Department's contact information and include 806 KAR 17:280 as an authorizing regulation.

(b) The necessity of the amendment to this administrative regulation: The necessity of these amendments derive from Chapter 13A and to generalize the term medical director, not just applying to the medical director of a managed care plan.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 304.2-110(1) provides that the Commissioner make reasonable rules and regulations necessary for or as an aid to the effectuation of any provision of the insurance code.

(d) How the amendment will assist in the effective administration of the statutes: These amendments help to clarify when and what type of medical director's signature is acceptable for purposes of KRS 304.17A-545.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation will affect all licensed managed care plans in the state of Kentucky. Currently, there are five (5) licensed managed care plans in this state.

(4) Provide an analysis of how the entities identified in the previous question 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 each of the regulated entities have to take to comply with this regulation or amendment: This administrative regulation establishes the procedure to be used when a medical director's signature is required on health care benefit denials. The Department anticipates that this administrative regulation will have minimal effect upon the costs of complying with the statutory requirements.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities: There is no associated cost with this administrative regulation.

(c) As a result of compliance, what benefits will accrue to the entities: If the regulated entities meet the regulatory and statutory guidelines set forth in this administrative regulation, then they will not face potential civil penalty by the Commissioner and the Medical Director will have been properly determined for signature if need be.

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

(a) Initially: Implementation of this amendment is not anticipated to have an initial cost on the Department of Insurance.

(b) On a continuing basis: Implementation of this amendment is not anticipated to have an on-going cost on the Department of Insurance.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Department will use funds from its current operational budget to perform the tasks necessary.

(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:

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees:

(9) TIERING: Is tiering applied? Explain why or why not. Tiering is not applied since this administrative regulation applies to all managed care plans in the state of Kentucky.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation: 806 KAR 17:230 Contact Person: Abigail Gall Phone: +1 (502) 564-6026 Email: abigail.gall@ky.gov

(1) 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? The Department of Insurance as the implementer.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 304.2-110(1)

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

(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? No revenue is expected to be generated.

(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? No revenue is expected to be generated.

(c) How much will it cost to administer this program for the first year? No cost is expected.

(d) How much will it cost to administer this program for subsequent years? No cost is expected.

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

- (4) Revenues (+/-): Neutral
- (5) Expenditures (+/-): Neutral
- (6) Other Explanation:

SUMMARY OF MATERIALS INCORPORATED BY REFERENCE

806 KAR 17:230

(a) HIPMC-MD-1, Medical Director Report Form 03/2021. This form provides the format to be used to report Medical Director information initially and to report any subsequent change in the information within thirty (30) days of the change.

SUMMARY OF CHANGES TO MATERIALS INCORPORATED BY REFERENCE

806 KAR 17:230

(a) HIPMC-MD-1, Medical Director Report Form 03/2021. This form was amended to update the contact information of the Department, thus, requiring electronic submission to the specified Division. The form was also amended to include 806 KAR 17:280 as a cited regulation in the introductory paragraph, as this form will be incorporated into that administrative regulation. Along with these amendments the edition date is being updated.