

FILED WITH LRC TIME: 3pm
OCT 01 2010
Emily B Caudill REGULATIONS COMPILER

STATEMENT OF EMERGENCY

907 KAR 3:215E

(1) This emergency administrative regulation is being promulgated to establish the Medicaid program's tobacco cessation program.

(2) This action must be implemented on an emergency basis as mandated by the Kentucky legislature pursuant to KRS 205.560(1)(j) and as funding for the program has been provided in the 2010-2012 biennium budget.

(3) This emergency administrative regulation shall be replaced by an ordinary administrative regulation filed with the Regulations Compiler.

(4) The ordinary administrative regulation is identical to this emergency administrative regulation.



Steven L. Beshear
Governor


Janie Miller, Secretary
Cabinet for Health and Family Services

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Medicaid Services

3 Division of Medical Management

4 (New Emergency Administrative Regulation)

5 907 KAR 3:215E. Tobacco cessation coverage and reimbursement.

6 RELATES TO:

7 STATUTORY AUTHORITY: KRS 194A.010(1), 194A.030(2), 194A.050(1),

8 205.520(3), 205.560(1)(j), 42 USC 1396r-8(d).

9 NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family
10 Services, Department for Medicaid Services has responsibility to administer the
11 Medicaid program. KRS 205.520(3) authorizes the cabinet, by administrative regulation,
12 to comply with a requirement that may be imposed, or opportunity presented by federal
13 law for the provision of medical assistance to Kentucky's indigent citizenry. This
14 administrative regulation establishes the department's coverage and reimbursement of
15 tobacco cessation services.

16 Section 1. Definitions. (1) "Advanced practice registered nurse" or "APRN" is defined
17 by KRS 314.011(7).

18 (2) "Department" means the Department for Medicaid Services or its designee.

19 (3) "FDA" means the United States Food and Drug Administration.

20 (4) "Federal financial participation" is defined by 42 CFR 400.203.

1 (5) "Medically necessary" means that a covered benefit is determined by the
2 department to be needed in accordance with 907 KAR 3:130.

3 (6) "Physician" is defined by KRS 311.550(12).

4 (7) "Physician assistant" is defined by KRS 311.840(3).

5 (8) "Recipient" is defined by KRS 205.8451(9).

6 (9) "Supervising physician" is defined by KRS 311.840(4).

7 (10) "Tobacco cessation product" means nicotine replacement therapy:

8 (a) Gum;

9 (b) Lozenge;

10 (c) Patch;

11 (d) Inhaler; or

12 (e) Spray.

13 Section 2. Provider Requirements for a Tobacco Cessation Assessment. A tobacco
14 cessation assessment provider shall be:

15 (1) A physician who is:

16 (a) Enrolled in the Medicaid program pursuant to 907 KAR 1:672; and

17 (b) Currently participating in the Medicaid program pursuant to 907 KAR 1:671;

18 (2) A physician assistant working under the supervision of a supervising physician

19 who is:

20 (a) Enrolled in the Medicaid program pursuant to 907 KAR 1:672; and

21 (b) Currently participating in the Medicaid program pursuant to 907 KAR 1:671;

22 (3) An APRN who is:

23 (a) Enrolled in the Medicaid program pursuant to 907 KAR 1:672; and

1 (b) Currently participating in the Medicaid program pursuant to 907 KAR 1:671; or

2 (4) Any of the following employed by a local health department:

3 (a) A physician assistant working under the supervision of a supervising physician;

4 (b) A physician; or

5 (c) An APRN.

6 Section 3. Tobacco Cessation Assessment and Referral. (1) The department shall
7 reimburse for a tobacco cessation assessment if the tobacco cessation assessment is
8 provided:

9 (a) By a provider listed in Section 2 of this administrative regulation; and

10 (b) To a recipient.

11 (2) A tobacco cessation assessment shall:

12 (a) Be performed over a period of at least thirty (30) minutes;

13 (b) Be performed face-to-face with the recipient;

14 (c) Include:

15 1. Asking the recipient about tobacco use;

16 2. Advising the recipient to quit using tobacco;

17 3. Assessing the recipient's readiness to quit using tobacco;

18 4. Compiling a tobacco usage, medical, and psychosocial history of the recipient;

19 5. Incorporating a review of the recipient's coping skills and barriers to quitting; and

20 6. The provider's obtaining of a signed and dated Tobacco Cessation Referral Form
21 from the recipient declaring the recipient's intent to quit using tobacco; and

22 (d) Be conducted once per course of treatment.

23 (3)(a) A provider shall complete a Tobacco Cessation Referral Form with the

1 recipient in accordance with the instructions on the form;

2 (b) Via the Tobacco Cessation Referral Form, a provider and recipient shall choose a
3 tobacco cessation program for the recipient unless:

4 1. The provider recommends that the recipient should not have to participate in a
5 tobacco cessation program; or

6 2. A hardship which prevents the recipient from accessing a tobacco cessation
7 program exists; and

8 (c) If a tobacco cessation program is not selected for a recipient due to subparagraph
9 1. or 2. of this paragraph, the provider shall denote this on the tobacco cessation
10 referral form.

11 (4) A provider shall:

12 (a) Submit a completed Tobacco Cessation Referral Form to the department in
13 accordance with the instructions on the form; and

14 (b) Give a copy of the completed Tobacco Cessation Referral Form to the recipient.

15 (5) The department shall reimburse for no more than two (2) tobacco cessation
16 assessments per recipient per calendar year.

17 (6) If a recipient has a hardship which is not revealed or denoted during an
18 assessment, the department may:

19 (a) Determine that a hardship exists; and

20 (b) Exempt the recipient from the requirement to participate in a tobacco cessation
21 program.

22 Section 4. Tobacco Cessation Medication. (1) If a physician, APRN, or physician
23 assistant working under a supervising physician as specified in Section 2 of this

1 administrative regulation, prescribes a medically necessary tobacco cessation
2 medication for a recipient, the physician, APRN, or physician assistant shall prescribe:

3 (a) An initial one (1) month supply of the medication; and

4 (b) Up to two (2) refills of the medication.

5 (2)(a) A recipient who is referred to a tobacco cessation program shall, after
6 participating in the first month of the tobacco cessation program, contact the department
7 as instructed on the Tobacco Cessation Referral Form and indicate the intent to
8 continue participation in the tobacco cessation program for another month.

9 (b) If the recipient indicates that he or she will continue participation in the program in
10 accordance with paragraph (a) of this subsection, the department shall reimburse for
11 the first refill of the tobacco cessation medication as established in subsection (1)(b) of
12 this section.

13 (c) If the department does not receive confirmation that a recipient intends to
14 continue participation in the tobacco cessation program, the department shall not
15 reimburse for a refill as established in subsection (1)(b) of this section.

16 (3)(a) A recipient who is referred to a tobacco cessation program shall, after
17 participating in the second month of the program, contact the department as instructed
18 on the Tobacco Cessation Referral Form and indicate the intent to continue participating
19 in the tobacco cessation program for another month.

20 (b) If the recipient indicates that he or she will continue participation in the program in
21 accordance with paragraph (a) of this subsection, the department shall provide
22 reimbursement for the second refill of the tobacco cessation medication as established
23 in subsection (1)(b) of this section.

1 (c) If the department does not receive confirmation that the recipient intends to
2 continue participation in the tobacco cessation program, the department shall not
3 reimburse for a refill as established in subsection (1)(b) of this section.

4 Section 5. Tobacco Cessation Reimbursement. (1) For the department to reimburse
5 for a tobacco cessation medication or product provided to a recipient:

6 (a) The tobacco cessation medication or product shall be medically necessary;

7 (b) The tobacco cessation medication or product shall be approved by the FDA for
8 tobacco cessation;

9 (c) The tobacco cessation medication or product shall be prescribed for the recipient
10 in accordance with Section 2 of this administrative regulation;

11 (d) If the tobacco cessation medication or product is a refill, the recipient shall have
12 met the requirements established in Section 4(2) or (3) unless the recipient is exempt
13 from the requirements pursuant to Section 3(3)(b) or Section 3(6); and

14 (e) If subject to prior authorization, the tobacco cessation medication or product shall
15 have been prior authorized by the department.

16 (2) The department shall reimburse for a combination of nicotine replacement therapy
17 that consists of no more than two (2) tobacco cessation medications or products.

18 (3) The department shall reimburse for a tobacco cessation medication in accordance
19 with 907 KAR 1:018.

20 (4) Reimbursement for a tobacco cessation medication shall be limited to two (2)
21 courses of treatment per recipient per calendar year.

22 (5) The department shall reimburse for a tobacco cessation assessment provided by:

23 (a) A physician, in accordance with 907 KAR 3:010, Section 2(2)(b);

1 (b) A physician assistant, in accordance with 907 KAR 3:010, Section 3(6) and (7)(a);

2 or

3 (c) An APRN, in accordance with 907 KAR 1:104, Section 2(1)(b).

4 Section 6. Reporting Requirements. (1) A recipient shall:

5 (a) Upon the department's request, provide information to the department regarding
6 the recipient's success or failure at tobacco cessation as a result of receiving
7 a service reimbursed by the department; or

8 (b) Upon the provider's request, provide information to the provider regarding the
9 recipient's success or failure at tobacco cessation as a result of receiving a service
10 reimbursed by the department.

11 (2) A provider shall, upon the department's request, provide information to the
12 department regarding the recipient's success or failure at tobacco cessation as a result
13 of receiving a service reimbursed by the department.

14 Section 7. Cost Sharing Exemption for Tobacco Cessation Medications. The
15 department shall impose no cost sharing for any tobacco cessation medication
16 referenced in this administrative regulation.

17 Section 8. Federal Financial Participation. A provision established in this
18 administrative regulation shall be null and void if the Centers for Medicare and Medicaid
19 Services:

20 (1) Denies federal financial participation for the provision; or

21 (2) Disapproves the provision.

22 Section 9. Appeal. An appeal of a department decision regarding a Medicaid
23 Recipient based upon an application of this administrative regulation shall be conducted

1 in accordance with 907 KAR 1:563.

2 Section 10. Incorporation by Reference. (1) The "Tobacco Cessation Referral Form",
3 July 2010 edition is incorporated by reference.

4 (2) The material referenced in subsection (1) of this section is available at:

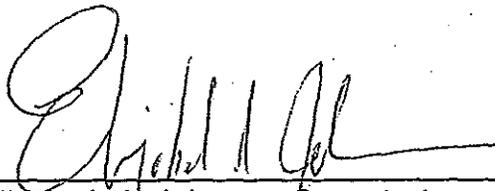
5 (a) <http://www.chfs.ky.gov/dms/incorporated.htm>; or

6 (b) The Department for Medicaid Services, 275 East Main Street, Frankfort, Kentucky
7 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

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REVIEWED:

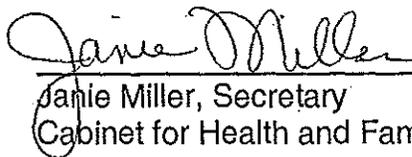
9/30/10
Date



Elizabeth A. Johnson, Commissioner
Department for Medicaid Services

APPROVED:

9/29/10
Date



Janie Miller, Secretary
Cabinet for Health and Family Services

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

Administrative Regulation #: 907 KAR 3:215E
Cabinet for Health and Family Services
Department for Medicaid Services
Agency Contact Person: Lee Barnard (502) 564-4958 or Stuart Owen (502) 564-4321

- (1) Provide a brief summary of:
 - (a) What this administrative regulation does: This is a new administrative regulation which establishes the Department for Medicaid Services' (DMS's) tobacco cessation program provisions.
 - (b) The necessity of this administrative regulation: This administrative regulation is necessary to establish Medicaid tobacco cessation program provisions as mandated by the Kentucky legislature pursuant to KRS 205.560(1)(j) and as funding for the program has been provided in the 2010-2012 biennium budget.
 - (c) How this administrative regulation conforms to the content of the authorizing statutes: The administrative regulation establishes the tobacco cessation program for all Medicaid recipients. Previously, DMS only covered tobacco cessation for pregnant women.
 - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: The administrative regulation establishes the tobacco cessation program for all Medicaid recipients. Previously, DMS only covered tobacco cessation for pregnant women.

- (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 is a new administrative regulation.
 - (b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.
 - (c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.
 - (d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.

- (3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: Medicaid recipients who attempt to quit using tobacco, tobacco cessation programs approved by DMS for Medicaid recipients, and providers who refer Medicaid recipients to a tobacco cessation program will be affected by the administrative regulation.

- (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: Medicaid recipients who wish to receive tobacco cessation program benefits from DMS will have to provide a copy of the Tobacco Cessation Referral Form to the individual performing the tobacco cessation program in which the recipient participates or call DMS (to confirm participation) if the particular tobacco cessation program is an online program rather than an in-person program. Providers who perform assessments will have to complete a Tobacco Cessation Referral Form, in conjunction with the recipient, and give a copy of it to the recipient.

- (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3). No cost is imposed.
 - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3). Medicaid recipients will be able to receive tobacco cessation program benefits.
- (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 implementing this administrative regulation will cost approximately \$ 6.2 million (\$1.5 million commonwealth share/\$4.7 million federal share) for state fiscal year (SFY) 2011.
 - (b) On a continuing basis: DMS estimates that implementing the administrative regulation will cost approximately \$5.2 million ((\$1.5 million commonwealth share/\$3.7 million federal share) for SFY 2012.
- (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 the Social Security Act, Title XIX and matching funds from state general fund appropriations. The Kentucky legislature allocated \$1.5 million in state funds for each of SFY 2011 and 2012 to implement this administrative regulation. Federal matching funds are projected to equal \$4.7 million in SFY 2011 and \$3.7 million in SFY 2012.
- (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: DMS understands that \$1.5 million in general share funds was appropriated for state fiscal year 2011 and state fiscal year 2012 for the amendment via the budget bill HB 1 of the 2010 Extraordinary Session of the General Assembly even though the legislation does not explicitly address smoking cessation appropriation for DMS.
- (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? No, the provisions apply equally to the affected parties.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation Number: 907 KAR 3:215E

Agency Contact Person: Lee Barnard (502) 564-4958 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? The Department for Medicaid Services will be affected by this administrative regulation and local health departments, who perform tobacco cessation assessments for Medicaid recipients, will be affected.
3. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. No state or federal regulation, other than this administrative regulation, requires or authorizes this action.
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? DMS projects no revenue to be generated by the administrative regulation.
 - (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? DMS projects no revenue to be generated by the administrative regulation.
 - (c) How much will it cost to administer this program for the first year? The Department for Medicaid Services (DMS) estimates that implementing this administrative regulation will cost approximately \$1.5 million commonwealth share/\$4.7 million federal share) for state fiscal year (SFY) 2011.
 - (d) How much will it cost to administer this program for subsequent years? DMS estimates that implementing this administrative regulation will cost approximately \$5.2 million (\$1.5 million commonwealth share/\$3.7 million federal share) for SFY 2012.

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

907 KAR 3:215E

Summary of Material Incorporated by Reference

The "Tobacco Cessation Referral Form", July 2010 edition is incorporated by reference. The form contains two (2) pages and is used by providers and recipients to denote which tobacco cessation program the recipient will participate in or if the recipient will not participate in a tobacco cessation program.

**Department for Medicaid Services
Tobacco Cessation Referral Form**

Provider Information (to be completed by the provider)

Provider National Provider Identifier (NPI): _____
Provider Name: _____
Provider Fax #: _____ Provider Phone #: _____
Provider Email Address (if available): _____

Recipient Information (to be completed by the recipient)

Recipient ID: _____ Date of Birth: _____
Name: _____ Gender: Male Female
Pregnant? Yes No
Street Address: _____
Apt/Bldg#: _____
City: _____ County: _____ Zip Code: _____
Primary Telephone#: _____ Secondary Telephone#: _____
Date of Visit: _____

Prescriber: Please refer to FDA guidelines regarding the use of Chantix™ in pregnant women.

Tobacco Cessation Medication Choice(s) Prescribed for the Recipient [to be completed by the provider]

Nicotine replacement therapy (NRT) gum _____ NRT patch _____
 NRT lozenge _____ NRT inhaler _____
 NRT spray _____ Bupropion _____ Varenicline _____

Prescription amount must be for a one-month supply with two subsequent one-month refills

Tobacco Cessation Support Program Chosen for the Recipient (to be completed by the provider)

The Cooper/Clayton Method Freedom from Smoking® Online
 Kentucky's Tobacco Quitline Chantix™
 Other Program (Must be Prior Approved by the Department): _____
 Recipient does not require support program
 Support program attendance would create hardship for recipient (provider: please explain: _____)

IMPORTANT: If recommending a program not listed on this form, the provider **MUST** request approval from the Department for Medicaid Services (DMS) **PRIOR** to recommending the program; otherwise, the department shall not reimburse for any tobacco cessation medication prescribed in conjunction with the unapproved program. To request DMS approval, please fax this completed form to (502) 564-0223 and write "tobacco cessation program approval request" at the top of this form or on a separate cover page.

Tobacco Cessation Program Contact Person: _____
Contact Person Phone Number #: _____
Contact Person Email Address (if available): _____
Provider Signature: _____ Date: _____

Recipient Commitment (to be completed by the recipient)

What kind of tobacco do you use? Cigarette Smokeless Tobacco
Cigar Pipe

I am ready to quit using tobacco and want to complete a tobacco cessation program

I understand that to get medication to help me stop using tobacco, I have to participate in the tobacco cessation support program chosen for me by my provider. If my provider has written me a prescription for medication to help me stop using tobacco, I can get the first month's supply by signing this form. Before I can get my medication refilled, I must tell Medicaid that I will continue to go to the support program chosen by my provider. To do this, I can:

- Call Medicaid at 502-564-9444, or
- Write to Tobacco Cessation Program, Kentucky Medicaid, 275 East Main Street, 6C-C, Frankfort, KY 40601 or
- Send a fax to 502-564-0223

I understand that I must, if asked, give an update on my progress or lack of progress in quitting tobacco.

Recipient Signature: _____

Date: _____

Provider FAX Instructions

Please fax the completed and signed form to (502) 564-0223 and give a copy of the completed and signed form to the recipient

If you have any questions, please contact the Department for Medicaid Services, Division of Medical Management at (502) 564-9444 and mention "tobacco cessation referral" as the subject of your call

PROVIDERS NOTE: A copy of this form must be on file with Kentucky Medicaid before your claim for the tobacco cessation assessment will be paid.