



1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Medicaid Services

3 Division of Medical Management

4 (Amended after Comments)

5 907 KAR 3:215. 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) “Legend drug” means a drug:

2 (a) Defined by the United States Food and Drug Administration as a legend
3 drug; and

4 (b) Required to bear the statement: “Caution: Federal law prohibits dispensing
5 without prescription.”

6 (6) “Medically necessary” means that a covered benefit is determined by the
7 department to be needed in accordance with 907 KAR 3:130.

8 (7)~~(6)~~ “Physician” is defined by KRS 311.550(12).

9 (8)~~(7)~~ “Physician assistant” is defined by KRS 311.840(3).

10 (9)~~(8)~~ “Recipient” is defined by KRS 205.8451(9).

11 (10)~~(9)~~ “Supervising physician” is defined by KRS 311.840(4).

12 (11)~~(10)~~ “Tobacco cessation product” means:

13 (a) Nicotine replacement therapy:

14 1.~~(a)~~ Gum;

15 2.~~(b)~~ Lozenge;

16 3.~~(c)~~ Patch;

17 4.~~(d)~~ Inhaler; or

18 5.~~(e)~~ Spray; or

19 (b) A legend drug approved by the United States Food and Drug Administration
20 for tobacco cessation.

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

23 (1) A physician who is:

- 1 (a) Enrolled in the Medicaid program pursuant to 907 KAR 1:672; and
2 (b) Currently participating in the Medicaid program pursuant to 907 KAR 1:671;
3 (2) A physician assistant working under the supervision of a supervising physician
4 who is:

- 5 (a) Enrolled in the Medicaid program pursuant to 907 KAR 1:672; and
6 (b) Currently participating in the Medicaid program pursuant to 907 KAR 1:671;
7 (3) An APRN who is:
8 (a) Enrolled in the Medicaid program pursuant to 907 KAR 1:672; and
9 (b) Currently participating in the Medicaid program pursuant to 907 KAR 1:671; or
10 (4) Any of the following employed by a local health department:
11 (a) A physician assistant working under the supervision of a supervising physician;
12 (b) A physician; or
13 (c) An APRN.

14 Section 3. Tobacco Cessation Assessment and Referral. (1) The department shall
15 reimburse for a tobacco cessation assessment if:

16 (a) The tobacco cessation assessment is provided:

17 1.[(a)] By a provider listed in Section 2 of this administrative regulation; and

18 2.[(b)] To a recipient; and

19 (b) The department receives, from the provider, the completed Tobacco
20 Cessation Referral Form corresponding to the assessment.

21 (2) A tobacco cessation assessment shall:

22 (a) Be performed over a period of at least ten (10)~~[thirty (30)]~~ minutes;

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

1 (c) Include:

2 1. Asking the recipient about tobacco use;

3 2. Advising the recipient to quit using tobacco;

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

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

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

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

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

10 (3)(a) A provider shall complete a Tobacco Cessation Referral Form with the
11 recipient in accordance with the instructions on the form;

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

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

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

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

21 (4) A provider shall:

22 (a) Submit a completed Tobacco Cessation Referral Form to the department in
23 accordance with the instructions on the form; **[and]**

1 (b) Give a copy of the completed Tobacco Cessation Referral Form to the recipient;

2 **and**

3 **(c) Maintain, for at least six (6) years from the date a Tobacco Cessation**

4 **Referral Form was completed, a:**

5 **1. Paper copy of the Tobacco Cessation Referral Form; or**

6 **2. Readily accessible electronically formatted copy of the Tobacco Cessation**

7 **Referral Form.**

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

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

12 (a) Determine that a hardship exists; and

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

15 Section 4. Tobacco Cessation Medication. (1) If a physician, APRN, or physician
16 assistant working under a supervising physician as specified in Section 2 of this
17 administrative regulation, prescribes a medically necessary tobacco cessation
18 medication for a recipient, the physician, APRN, or physician assistant shall prescribe:

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

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

21 **(2) In order for the department to reimburse for a refill of a medication**
22 **referenced in subsection (2) of this section for a recipient:**

23 **(a) Who is not participating in a tobacco cessation program:**

1 1. The department shall have received, from the provider or the recipient, a
2 completed Tobacco Cessation Referral Form corresponding to the recipient's
3 assessment; and

4 2. The recipient shall have contacted the department and requested the refill;
5 or

6 (b) Who is participating in a tobacco cessation program:

7 1. The department shall have received, from the provider or the recipient, a
8 completed Tobacco Cessation Referral Form corresponding to the recipient's
9 assessment; and

10 2. The recipient shall:

11 a. For the first refill:

12 (i) Have participated in the first month of a tobacco cessation program; and

13 (ii) Contacted the department to request a refill and to express the intent to
14 continue participating in the tobacco cessation program; or

15 b. For the second refill:

16 (i) Have participated in the second month of a tobacco cessation program; and

17 (ii) Contacted the department to request a refill and to express the intent to
18 continue participating in the tobacco cessation program. ~~(a) A recipient who is~~

19 ~~referred to a tobacco cessation program shall, after participating in the first~~
20 ~~month of the tobacco cessation program, contact the department as instructed~~
21 ~~on the Tobacco Cessation Referral Form and indicate the intent to continue~~
22 ~~participation in the tobacco cessation program for another month.~~

23 ~~(b) If the recipient indicates that he or she will continue participation in the~~

1 ~~program in accordance with paragraph (a) of this subsection, the department~~
2 ~~shall reimburse for the first refill of the tobacco cessation medication as~~
3 ~~established in subsection (1)(b) of this section.~~

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

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

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

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

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

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

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

23 (c) The tobacco cessation medication or product shall be prescribed for the recipient

1 in accordance with Section ~~4~~² of this administrative regulation;

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

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

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

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

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

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

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

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

16 or

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

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

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

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

4 (2) A provider shall, upon the department's request, provide information to the
5 department **in accordance with 907 KAR 1:672**~~[regarding the recipient's success
6 or failure at tobacco cessation as a result of receiving a service reimbursed by
7 the department].~~

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

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

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

15 (2) Disapproves the provision.

16 Section 9. Appeal. An appeal of a department decision regarding a Medicaid
17 Recipient based upon an application of this administrative regulation shall be conducted
18 in accordance with 907 KAR 1:563.

19 Section 10. Incorporation by Reference. (1) The "Tobacco Cessation Referral Form",
20 **December**~~[July]~~ 2010 edition is incorporated by reference.

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

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

- 1 (b)The Department for Medicaid Services, 275 East Main Street, Frankfort, Kentucky
- 2 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

907 KAR 3:215
(Amended after Comments)

REVIEWED:

5 JAN 11
Date

Neville J Wise
Neville Wise, Acting Commissioner
Department for Medicaid Services

APPROVED:

1/13/11
Date

Janie Miller
Janie Miller, Secretary
Cabinet for Health and Family Services

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

Administrative Regulation #: 907 KAR 3:215
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; however, it is being amended via the public comment process. The amendments after comments include inserting a definition of legend drug; clarifying that a legend drug approved by the United States Food and Drug Administration for tobacco cessation qualifies as a tobacco cessation product; reducing the mandated assessment duration from at least thirty (30) minutes to at least ten (10) minutes; requiring a Tobacco Cessation Referral Form to have been submitted by the provider or the recipient to DMS in order for DMS to pay for a recipient's refill of tobacco cessation medication; and require that providers must keep copies (paper or electronic) of Tobacco Cessation Referral Forms for at least six years (consistent with federal medical record maintenance requirements).
 - (b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation; however, the assessment reduction [from thirty (30) minutes to ten (10) minutes] is necessary to address a concern expressed by the Kentucky Medical Association (KMA) and the Tobacco Cessation Referral Form requirements are necessary to enable DMS to be able to evaluate the success of the tobacco cessation initiative and to evaluate the various

- components of the program as DMS is being allocated funds by the legislature to implement this program.
- (c) How the amendment conforms to the content of the authorizing statutes: The amendments in response to comments conform to the content of authorizing statutes by establishing policies as authorized by KRS 194A.030(2).
 - (d) How the amendment will assist in the effective administration of the statutes: The amendments in response to comments will assist in the effective administration of the authorizing statutes by establishing policies as authorized by KRS 194A.030(2).
- (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: Providers who perform tobacco cessation assessments will have to perform an assessment, bill DMS for the assessment using CPT code 99407, complete a Tobacco Cessation Referral Form (in conjunction with the recipient) during the assessment and submit the completed Tobacco Cessation Referral Form to DMS. Recipients who want a refill of tobacco cessation medication will be required to participate in a tobacco cessation counseling program (unless exempt) and contact DMS to confirm participation in a tobacco cessation counseling program in order to procure a refill of tobacco cessation medication.
 - (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 and providers will be able to be reimbursed for tobacco cessation assessments.
 - (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 3:215

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 3:215

Summary of Material Incorporated by Reference

The "Tobacco Cessation Referral Form", December 2010 edition replaces the July 2010 edition. The form contains two (2) pages and is used by providers and recipients to denote which tobacco cessation support program the recipient will participate in if the recipient elects to participate in a tobacco cessation support program.

Amendments to the form include:

(1) Removing the requirement that a tobacco cessation support program that a provider wants to select for a recipient that is not listed on the form, be prior approved by DMS (as tobacco cessation support programs will be voluntarily, the requirement is unnecessary)

(2) Inserting the following statement on the form:

"I understand that my chances of quitting are better if I participate in a support program"

(3) Inserting the requirement that the Department for Medicaid Services must have a copy of the completed form on file for a recipient in order for DMS to reimburse for a refill of tobacco cessation medication for the recipient.

(4) Inserting the following statement on the form:

"I understand that my provider has to submit a copy of this form to Kentucky Medicaid in order for me to be able to get a refill of my medication."

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

Provider Information

Provider National Provider Identifier (NPI): _____

Provider Name: _____

Provider Fax #: _____ Provider Phone #: _____

Provider Email Address (if available): _____

Recipient Information

Recipient Medicaid ID: _____ Date of Birth: _____

Name: _____

Gender: Male Female

Pregnant? Yes No

Street Address: _____

Apt/Bldg#: _____

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

City: _____ County: _____ Zip Code: _____

Primary Telephone#: _____ Secondary Telephone#: _____

Date of Visit: _____

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

Support program recommended for the recipient (to be completed by the provider)

The Cooper/Clayton Method Freedom from Smoking® Online Kentucky's Tobacco Quitline

GetQUIT Plan Other Program: _____

Recipient does not require support program

Support program attendance would create hardship for recipient (provider: please explain): _____

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

I understand that my chances of quitting are better if I participate in a support 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 my provider has to send a copy of this form to Kentucky Medicaid in order for me to be able to get any refills of my medication. If my provider does not do so then I must send a copy of this form to Kentucky Medicaid. Kentucky Medicaid will not pay for any refills of my medication unless they have a copy of this form.

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

Recipient Signature: _____ Date: _____

Provider FAX Instructions

The completed and signed form must be faxed to (502) 564-0223 and a copy of the completed and signed form must be given to the recipient

PROVIDER'S NOTE: A copy of this form must be on file with Kentucky Medicaid before your claim for the tobacco cessation assessment will be paid and in order for the recipient to receive a refill of tobacco cessation medication. If no form is on file with Kentucky Medicaid, Kentucky Medicaid will not reimburse you for the assessment and will not approve a refill of tobacco cessation medication for 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

STATEMENT OF CONSIDERATION RELATING TO
907 KAR 3:215

Department for Medicaid Services
Amended After Comments

(1) A public hearing regarding 907 KAR 3:215 was not requested and, therefore, not held; however, written public comments were submitted regarding 907 KAR 3:215 by the following individual:

<u>NAME and TITLE</u>	<u>AGENCY/ORGANIZATION/ENTITY/OTHER</u>
Gordon R. Tobin, MD President	Kentucky Medical Association

(2) The following individuals from the promulgating administrative body responded to the comments received:

<u>NAME and TITLE</u>	<u>AGENCY/ORGANIZATION/ENTITY/OTHER</u>
Lee Barnard, Assistant Director	Department for Medicaid Services, Division of Medical Management
Brenda Parker,	Department for Medicaid Services, Division of Medical Management
Stuart Owen, Regulation Coordinator	Department for Medicaid Services, Commissioner's Office

SUMMARY OF COMMENTS AND AGENCY'S RESPONSES

(1) Subject: Tobacco Cessation Assessment

(a) Comment: Dr. Tobin indicated that KMA is concerned about the tobacco cessation assessment requirements. He stated, "The AHRQ Guideline reports that nearly 70% of smokers want to quit, but most will not enter a tobacco cessation program. Because most of these smokers who desire to quit visit their physician's office at least once every year, the physician's office is the obvious place to extend tobacco cessation programs to patients. An average office visit lasts 20 minutes, so Medicaid recipients that want to participate in the tobacco cessation program will have to make a separate appointment for a 30-minute assessment. In mandating a 30-minute assessment, Kentucky Medicaid may exclude many patients who want and need help quitting.

Dr. Tobin also stated, "According to DMS, the assessment will be covered by CPT code 99407 at \$52.03 for physicians (75% for ARNP and PA). As defined by the Current Procedural Terminology (CPT) Guidelines, CPT code 99407 covers "intensive tobacco cessation counseling greater than 10 minutes." However, Kentucky Medicaid mandates the assessment last 'at least 30 minutes.' Older rules for CPT code 99407 did dictate a 30-minute visit, but in 2008 the rules were updated to 'greater than 10 minutes.' According to the AHRQ Guideline, as little as three minutes of a physician's time can double the rate of quitting among patients, and 3 to 10 minutes can increase patients quit rate 60 percent. The Guideline's meta-analysis does find that more than 30 minutes of contact time over 8 or more sessions may increase abstinence rates, but notes that those interventions may have limited reach (affect fewer smokers) and may not be feasible in some medical care settings. The Guideline encourages physicians to refer patients to telephone Quitlines and longer counseling services similar (to the) services provided through the Tobacco Cessation Referral Form in the Kentucky Medicaid program."

Dr. Tobin requested that DMS please consider eliminating "the 30-minute mandate attached to CPT code 99407." He stated, "The 30-minute mandate is impractical for both patients and physicians, and it opposes the CPT definition, potentially causing coding confusion."

(b) Response: In response, the Department for Medicaid Services (DMS) is lowering the mandated assessment length from at least thirty (30) minutes, to at least ten (10) minutes.

(2) Subject: Tobacco Cessation Referral Form

(a) Comment: Dr. Tobin stated, "The regulation states that physicians must complete a two-page Tobacco Cessation Referral Form, submit copies to DMS and the patient, and the form must be on file with Medicaid prior to reimbursement. In addition, KMA proposes an electronic option of the Referral Form and a means of electronic submission for offices using electronic health records. There is further concern about DMS withholding physician reimbursement after services are performed if DMS does not have the Referral Form on file. KMA encourages DMS to reconsider this restriction in an effort to avoid potential payment delays."

Dr. Tobin requested that DMS "Add an electronic format of the Tobacco Cessation Referral Form and a means of electronic submission."

He also requested that DMS "Reconsider withholding physician reimbursement after services are rendered if the Referral Form has not been filed at DMS."

(b) Response: DMS emphasizes that it is receiving limited funding specifically for the tobacco cessation initiative. Tracking the success rate of this initiative is critical as DMS needs to be able to evaluate the impact of miscellaneous components of the program

and also the legislature – who appropriated funding for this initiative- will likely request reports and/or updates from DMS regarding the outcomes of this initiative. If DMS lacks the data to adequately evaluate and analysis the initiative, DMS will be unable to alter the program as needed, if needed, and furthermore funding could cease in the future. The Tobacco Cessation Referral Form is a vital component of DMS's ability to track and evaluate this initiative. Consequently, DMS is preserving the requirement that a Tobacco Cessation Referral Form must be received by the department in order for DMS to reimburse for an assessment.

DMS will explore an electronic option for submitting the Tobacco Cessation Referral Form to DMS.

Additionally, DMS is amending the administrative regulation to establish that providers will have to maintain a copy (paper or electronic format) of the form for at least six (6) years from the date the form was completed.

Lastly, DMS is amending the administrative regulation to establish that it will not reimburse for a refill of a tobacco cessation medication unless the department has received a Tobacco Cessation Referral Form corresponding to the given recipient.

(3) Subject: Limit of Two Assessments Per Year

(a) Comment: Dr. Tobin stated, "Another reimbursement restriction includes a maximum of two assessments per recipient per calendar year."

(b) Response: DMS is preserving the two assessment per recipient per year limit as DMS finds it a very reasonable limit. DMS notes that the limit is on assessments but not counseling as there is no limit on counseling.

(4) Subject: CPT Codes

(a) Comment: Dr. Tobin stated, "After the initial smoking cessation assessment, physicians can determine whether or not it's appropriate to prescribe medication to assist patients with quitting tobacco products, but only 30 days of medication initially and 60 days thereafter. However, DMS has not included a reimbursement code in the Medicaid Physicians Fee Schedule for these services. CPT code 99406 is not covered by Medicaid and cannot be used for smoking cessation services. Therefore, any tobacco cessation counseling other than a 30-minute assessment must be covered under a general E/M code, which typically bundles tobacco cessation for 3 minutes or less. With the plan outlined in the regulation, there is a gap of patient care for those who need anywhere between 3 and 30 minutes of tobacco cessation treatment."

Dr. Tobin requested that DMS cover both CPT codes 99406 and 99407. He stated, "Include both CPT codes 99406 and 99407 in the Kentucky Medicaid Physician Fee Schedule to reimburse for tobacco cessation counseling and assessment. By definition, CPT code 99406 is brief tobacco cessation counseling for 3-10 minutes and CPT code

99407 is intensive tobacco cessation counseling greater than 10 minutes. Both CPT codes 99406 and 99407 can be used with an E/M code on the same day. If physicians were permitted to code 99407 for assessments, as defined, then the code serves as a great benefit for Medicaid recipients who may be visiting the doctor for routine care and can begin a tobacco cessation program in the same visit."

(b) Response: DMS notes that tobacco cessation counseling refers to formal, online, telephonic or in-person support programs sponsored by various entities (for example, the Kentucky Quit Line, the Cooper/Clayton Method) rather than on-going counseling from enrolled Medicaid providers. CPT code 99407 is intended for the face-to-face initial assessment of a recipient's readiness and ability to cease using tobacco products and the need for medications and/or support programs. DMS reimburses for an assessment; however, the counseling (tobacco cessation support programs) are free programs available to the public.

DMS believes that the limit of two comprehensive assessments per calendar year is appropriate and is not increasing the limit.

(5) Subject: Patient Reporting Requirement

(a) Comment: Dr. Tobin stated, "Finally, KMA encourages DMS to exclude physicians from the patient reporting requirement. Since participants are required to report to DMS every 30 days to remain in the cessation program, DMS could ask patient directly about their success or failure in the program. If physicians are required to report their patients' success or failure to DMS, patients may feel like their physician "told on them", potentially threatening the trust and support of the patient-physician relationship. Tobacco users quit a minimum of two times and often have three or more unsuccessful attempts before they quit for life. According to the American Lung Association, unsuccessful attempts to quit can leave smokers feeling alienated and discouraged, but support and motivation from their health care provider helps the quitters keep quitting until they succeed."

Dr. Tobin also stated, "Due to potential damage of the patient-physician relationship, eliminate the requirement that health care providers must report their patients' success or failure in the program at the request of DMS."

(b) Response: DMS notes that enrolled Medicaid providers, as established in 907 KAR 1:672 (Provider Enrollment, Disclosure and Documentation for Medicaid Participation), are required to provide, upon request by the department, "all information regarding the nature and extent of services and claims submitted by, or on behalf of the provider, to the:

1. Cabinet;
2. Department;
3. Attorney General;
4. Auditor of Public Accounts;
5. Secretary of the United States Department of Health and Human Services; or

6. Office of the United States Attorney.”

The intent of the tobacco cessation reporting requirement is to enable DMS to evaluate, as well as report to legislators and other government officials, the overall success of the program or specific components of the program. DMS emphasizes that tracking the success rate of this initiative is critical. The legislature allocated funds to DMS for this initiative and DMS, the legislature and public should be able to analyze the success of the initiative as well as the success of given components of the initiative. Without the cooperation of providers and recipients, DMS will be unable to properly evaluate the overall initiative and its components.

(4) Subject: Refill Requirement

(a) Comment and (b) Response: DMS is amending the administrative regulation to establish that it will not reimburse for a refill of a tobacco cessation medication unless the department has received a Tobacco Cessation Referral Form corresponding to the given recipient.

SUMMARY OF STATEMENT OF CONSIDERATION
AND

ACTION TAKEN BY PROMULGATING ADMINISTRATIVE BODY

The Department for Medicaid Services (DMS) has considered the comments it received regarding 907 KAR 3:215 and is amending the administrative regulation as follows:

Page 2

Section 1(5)

Line 1

After “(5)”, insert the following:

“Legend drug” means a drug:

(a) Defined by the United States Food and Drug Administration as a legend drug;

and

(b) Required to bear the statement: “Caution: Federal law prohibits dispensing without prescription.”

(6).

Page 2

Section 1(6)

Line 3

Before “(6)”, insert “(7)”

Delete “(6)”.

Page 2

Section 1(7)

Line 4

Before “(7)”, insert “(8)”

Delete "(7)".

Page 2

Section 1(8)

Line 5

Before "(8)", insert "(9)"

Delete "(8)".

Page 2

Section 1(9)

Line 6

Before "(9)", insert "(10)"

Delete "(9)".

Page 2

Section 1(10)

Line 6

Before "(9)", insert "(10)"

Delete "(9)".

Page 2

Section 1(10)

Line 7

Before "(10)", insert "(11)".

Delete "(10)".

After "means", insert the following:

“
(a)”.

Page 2

Section 1(10)(a)

Line 8

Before "(a)", insert "1."

Delete "(a)".

Page 2

Section 1(10)(b)

Line 9

Before "(b)", insert "2."

Delete "(b)".

Page 2

Section 1(10)(c)

Line 10

Before "(c)", insert "3."

Delete "(c)".

Page 2

Section 1(10)(d)

Line 11

Before "(d)", insert "4."

Delete "(d)".

Page 2

Section 1(10)(e)

Line 12

Before "(e)", insert "5."

Delete "(e)".

Line 12

After "Spray", insert the following:

: or

(b) A legend drug approved by the United States Food and Drug Administration for tobacco cessation.

Page 3

Section 3(1)

Line 7

After "if", insert the following:

“

(a)”.

Page 3

Section 3(1)(a)

Line 9

Before "(a)", insert "1."

Delete "(a)".

Page 3

Section 3(1)(b)

Line 10

Before "(b)", insert "2."

Delete "(b)".

After "recipient", insert the following:

: and

(b) The department receives, from the provider, the completed Tobacco Cessation Referral Form corresponding to the assessment.

Page 3
Section 3(2)(a)
Line 12

After "least", insert "ten (10)".
Delete "thirty (30)".

Page 4
Section 3(4)
Line 13

After "form;", delete "and".

Page 4
Section 3(4)
Line 14

After "recipient:", insert the following:

; and

(c) Maintain, for at least six (6) years from the date a Tobacco Cessation Referral Form was completed, a:

1. Paper copy of the Tobacco Cessation Referral Form; or
2. Readily accessible electronically formatted copy of the Tobacco Cessation Referral Form

Page 5
Section 4(2)(a)
Line 5

After "(2)", insert the following:

In order for the department to reimburse for a refill of a medication referenced in subsection (2) of this section for a recipient:

(a) Who is not participating in a tobacco cessation program:

1. The department shall have received, from the provider or the recipient, a completed Tobacco Cessation Referral Form corresponding to the recipient's assessment; and
2. The recipient shall have contacted the department and requested the refill; or

(b) Who is participating in a tobacco cessation program:

1. The department shall have received, from the provider or the recipient, a completed Tobacco Cessation Referral Form corresponding to the recipient's assessment; and
2. The recipient shall:

a. For the first refill:

- (i) Have participated in the first month of a tobacco cessation program; and
- (ii) Contacted the department to request a refill and to express the intent to continue participating in the tobacco cessation program; or

b. For the second refill:

- (i) Have participated in the second month of a tobacco cessation program; and
- (ii) Contacted the department to request a refill and to express the intent to continue participating in the tobacco cessation program.

Page 5

Section 4(2)(a) through (3)(c)

Line 5 through

Page 6, line 3

Delete paragraphs (a), (b), and (c) and subsections (3)(a), (b), and (c).

Page 6

Section 5(1)(c)

Line 10

After "Section", insert "4".

Delete "2".

Page 7

Section 6(2)

Line 12

After "department", insert the following:

in accordance with 907 KAR 1:672.

Lines 12-13

Delete the following:

regarding the recipient's success or failure at tobacco cessation as a result of receiving a service reimbursed by the department

Page 8

Section 10(1)

Line 3

Before "July", insert "December".

Delete "July".