

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF MEDICAID AND MEDICAL ASSISTANCE
Statutory Authority: 31 Delaware Code, Section 512 (31 **Del.C.** §512)

FINAL

ORDER

Tobacco Cessation Counseling Services

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services (“Department”) / Division of Medicaid and Medical Assistance (DMMA) initiated proceedings to amend existing rules in the Title XIX Medicaid State Plan regarding *Comprehensive Tobacco Cessation Services*. The Department’s proceedings to amend its regulations were initiated pursuant to 29 **Delaware Code** Section 10114 and its authority as prescribed by 31 **Delaware Code** Section 512.

The Department published its notice of proposed regulation changes pursuant to 29 **Delaware Code** Section 10115 in the September 2011 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by September 30, 2011 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

SUMMARY OF PROPOSAL

The proposed provides notice to the public that the Division of Medicaid and Medical Assistance (DMMA) intends to amend the Title XIX Medicaid State Plan regarding *Medicaid coverage of comprehensive tobacco cessation services for pregnant women and all Medicaid beneficiaries*.

Statutory Authority

- Patient Protection and Affordable Care Act (Pub. L. No. 111-148 as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152)), together known as the Affordable Care Act;
- 42 CFR §434.6, *General requirements for all contracts and subcontracts*;
- 42 CFR §438.6, *Contract requirements*;
- 42 CFR §447.26, *Prohibition on payment for provider-preventable conditions*.

Background

On June 24, 2011, the Centers for Medicare and Medicaid Services (CMS) issued guidance on the mandatory implementation of Section 4107 of the Patient Protection and Affordable Care Act (Affordable Care Act), P.L. 111-148, which amended Title XIX (Medicaid) of the Social Security Act (the Act) to provide for Medicaid coverage of comprehensive tobacco cessation services for pregnant women, including both counseling and pharmacotherapy, without cost sharing. The period for which these services must be covered includes the prenatal period through the postpartum period.

Section 1905(bb)(2) of the Act defines the new tobacco cessation coverage for pregnant women as services recommended in the 2008 Public Health Service (PHS) Guideline, or any subsequent modification of this Guideline, and such other services that the Secretary recognizes to be effective for cessation of tobacco use by pregnant women. This publication can be accessed at www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf.

This new coverage offers States flexibility with respect to how the services shall be provided: 1) by or under the supervision of a physician; 2) by any other health care professional who is legally authorized to furnish such services under State law and who is authorized to provide Medicaid coverable services other than tobacco cessation services; or 3) by any other health care professional legally authorized to provide tobacco cessation services under State law and who is designated by the Secretary to provide these services.

In addition to this new benefit requirement for pregnant women described above, States are required to cover tobacco cessation services for children when medically necessary and may rely on optional Medicaid benefit categories to provide coverage of tobacco cessation services to other Medicaid beneficiaries.

To implement this new benefit requirement, States should submit an amendment to their Medicaid State plans as soon as possible.

This provision was effective October 1, 2010.

Summary of Proposal

In accordance with the requirements and options outlined in Section 4107 of the Affordable Care Act (ACA), the Delaware Medical Assistance Program (DMAP) is proposing to identify comprehensive tobacco cessation services as a covered Medicaid benefit for the Medicaid eligible population effective for dates of service on and after July 1, 2011.

The Medicaid state plan will be amended at Attachment 3.1-A and Attachment 4.19-B to reflect coverage for diagnostic, therapy and counseling services. DMAP already provides, within program limitations, reimbursement for rebated tobacco cessation products and Nicotine Replacement Therapy (NRT) products; as well as, cessation counseling services through the Delaware Tobacco Quitline.

Tobacco cessation services shall be provided by licensed providers practicing within their scope of practice and the recommended pharmacotherapy shall be based on the most current Public Health Service (PHS) guidelines.

Tobacco Cessation Telephone Quitlines as Allowable Medicaid Administrative Activities

The Delaware Division of Public Health works to prevent the use of tobacco products through its Tobacco Prevention and Control Program (TPCP). The Tobacco Program offers the Delaware Tobacco Quitline and is available to any Delaware resident to help smokers quit and is not limited to Medicaid beneficiaries. The Quitline program is a free comprehensive tobacco treatment service that follows the evidence-based protocols set forth in the PHS Guideline. This State plan amendment will also allow the State to claim expenditures related to Quitlines as administration at the 50 percent Federal Medicaid matching rate, as specified in 42 CFR §433.15(b)(7).

The provisions of this state plan amendment are subject to approval by the Centers for Medicare and Medicaid Services (CMS).

Fiscal Impact Statement

Delaware currently has a smoking cessation program that covers all of its citizens; so, there is no increase in costs on the General Fund. In addition, telephone "quitlines" will be coverable for the first time as an optional administrative activity in Medicaid and the State will be eligible for the 50 percent federal matching rate.

SUMMARY OF COMMENTS RECEIVED WITH AGENCY RESPONSE

The American Heart Association (AHA), the Governor's Advisory Council for Exceptional Citizens (GACEC) and, the State Council for Persons with Disabilities (SCPD) offered the following observations and recommendations summarized below. The Division of Medicaid and Medical Assistance (DMMA) has considered each comment and responds as follows.

AHA

On behalf of the American Heart Association, the following comments are submitted regarding the proposed new regulations regarding smoking cessation services for pregnant women and for the general Medicaid population in Delaware. Unfortunately, cigarette smoking continues to be the leading cause of preventable disease and death in the United States claiming approximately 443,000 lives prematurely every year. Across the nation the adult smoking rate among Medicaid recipients is 36.6%, compared to 22.6% of the general population. Smoking cessation treatments and services are highly cost effective despite how difficult it is for the smoker to successfully quit.

The American Heart Association recommends that **at a minimum** coverage for Medicaid tobacco cessation services in Delaware should:

- Include both pregnant women and the general Medicaid population;
- Follow recommendations in the Public Health Service sponsored 2008 clinical practice guideline, "Treating Tobacco Use and Dependence: 2008 Update," or its successors;
- Include at least two courses of treatment in a 12-month period including personal counseling, which may be telephone, group or individual counseling, and all medications approved by the FDA for the purpose of tobacco cessation, including all prescription and over-the-counter medications; and
- Be provided to this population without any or with very minimal cost sharing.

Additionally, to remove barriers to quitting for this population, we would recommend that these services and benefits be offered under the following provisions:

- No prior authorization requirements
- No annual or lifetime limits on quit attempts or costs
- No limits on treatment duration
- No requirements to pair counseling with medications
- No stepped care therapy
- Require plans to promote services and benefits to members & clinicians.

Comprehensive coverage for smoking cessation within the Medicaid program has the potential to save even more lives and reduce the overall, long-term cost burdens of smoking related disease on public health insurance programs. Significant progress has been made in this area in Massachusetts, and I am attaching a copy of an abstract detailing that study. We at the American Heart Association look forward to working with the Division of Medicaid and Medical Assistance to reduce the human and financial toll on Delaware attributable to tobacco use.

Agency Response: DMMA agrees that the Medicaid program should follow the U. S. Public Health Service-sponsored clinical practice guideline, "Treating Tobacco Use and Dependence: 2008 Update" (PHS Guideline). The Medicaid program expects utilization of tobacco cessation services will be in accordance with medical necessity, medical standards of practice, the evidence-based protocols set forth in the PHS guideline, Food and Drug Administration (FDA) guidelines and

manufacturers' recommendations for dosage and duration.

No change was made to the regulation as a result of this comment.

GACEC and SCPD

As background, CMS recently issued a June 24, 2011 guidance implementing Section 4107 of the Patient Protection and Affordable Care Act. States are now required to provide for Medicaid coverage of comprehensive tobacco cessation services to pregnant women which include the prenatal period through the postpartum period. The new standards are based on recommendations included in a 2008 Public Health Service (PHS) Guideline. DMMA proposes to implement this requirement through Medicaid Plan amendments. DHSS already offers a "Delaware Tobacco Quitline" through the Division of Public Health. Delaware will now be able to claim a 50% Federal Medicaid match for this service. Otherwise, the Plan amendments authorize Medicaid coverage of tobacco dependence assessment, face-to-face counseling, and pharmacotherapy such as nicotine patches. The Councils have the following observations.

First, DMMA interprets the CMA guidance as requiring coverage of tobacco cessation services for children. At 279. The Plan amendments do not address children. It would be preferable for DMMA to clarify whether tobacco cessation services for children is already covered in the State Plan or to develop a conforming State Plan amendment.

Agency Response: As indicated in the "Summary of Proposal" the plan amendment identifies comprehensive tobacco cessation services as a covered Medicaid benefit for the Medicaid eligible population. This statement implies all Medicaid eligible beneficiaries and is inclusive. Coverage of medically necessary tobacco cessation services for children under age 21 is already mandatory under Medicaid's Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit.

No change was made to the regulation as a result of this comment.

Second, the Plan amendments require reimbursable counseling to be "face-to-face". The Councils suspect that "in-person" counseling is generally more effective than telephone-based counseling. Cf. the attached 2008 Guideline at 166. However, the Guideline also describes a study involving an initial in-person counseling session followed by 12 telephone counseling sessions. DMMA may wish to assess whether covering telephone counseling sessions may be appropriate. For example, there may be pregnant women who would prefer telephone-based counseling since it obviates transportation time and inconvenience (e.g. finding babysitter for existing children). Perhaps DMMA could consider a lower reimbursement rate for telephone-based counseling to provide an incentive for "in-person" counseling while not precluding reimbursement for telephone-based counseling altogether.

Agency Response: The Medicaid program expects utilization of tobacco cessation services will be in accordance with medical necessity, medical standards of practice, the evidence-based protocols set forth in the PHS guideline, FDA guidelines and manufacturers' recommendations for dosage and duration.

No change was made to the regulation as a result of this comment.

FINDINGS OF FACT:

The Department finds that the proposed changes as set forth in the September 2011 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend the Title XIX Medicaid State Plan regarding *Comprehensive Tobacco Cessation Services* and is adopted and shall be final effective November 10, 2011.

Rita M. Landgraf, Secretary, DHSS

DMMA FINAL ORDER REGULATION #11-51

REVISION:

NOTE: Since publication of the Proposed Regulation, CMS has issued an additional Medicaid State plan amendment preprint template, as indicated by bracketed bold type)

[Revision:

ATTACHMENT 3.1-A

Page 2.1

OMB No.:

State/Territory: Delaware

AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

4. d. 1) Face-to-Face Tobacco Cessation Counseling Services provided (by):

(i) **By or under supervision of a physician;**

(ii) By any other health care professional who is legally authorized to furnish such services under State law and who is authorized to provide Medicaid coverable services *other* than tobacco cessation services; * or

(iii) Any other health care professional legally authorized to provide tobacco cessation services under State law *and* who is specifically *designated* by the Secretary in regulations. (None are designated at this time; this item is reserved for future use.)

*Describe if there are any limits on who can provide these counseling services

2) Face-to-Face Tobacco Cessation Counseling Services Benefit Package for Pregnant Women
Provided: No limitations With limitations*

*Any benefit package that consists of *less* than four (4) counseling sessions per quit attempt, with a minimum of two (2) quit attempts per 12 month period (eight (8) per year) should be explained below.

Please describe any limitations:]

Revision:

ATTACHMENT 3.1-A
Page 3 Addendum

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State/Territory: Delaware

LIMITATIONS ON AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES
PROVIDED TO THE CATEGORICALLY NEEDY

6.d. Other Practitioners' Services

6.d.2. Comprehensive Tobacco Cessation Services, as recommended in the 2008 Public Health Service (PHS) Guideline or any subsequent modification of this Guideline, and provided by 1) by or under the supervision of Medicaid-enrolled physician; or 2) by any other Medicaid-enrolled health care professional who is legally authorized to furnish such services under State law and who is authorized to provide Medicaid coverable services other than tobacco cessation services under State law to include the following:

1. Assessment of tobacco dependence, including a written tobacco cessation treatment plan of care;
2. Face-to-face counseling; and,
3. If appropriate, prescribing tobacco cessation pharmacotherapy, as medically necessary.

Vendors that contract with the State may be included in the group of eligible tobacco cessation service providers.

(Break in Continuity of Sections)

Revision:

Attachment 3.1-A
Page 8 Addendum

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State/Territory: DELAWARE

LIMITATIONS ON AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES
PROVIDED TO THE CATEGORICALLY NEEDY

20. a. & b. Extended Services to Pregnant Women

Those services normally covered by Medicaid for all eligibles are available to pregnant women.

~~In addition, the~~ The following extended services ~~are~~ available with prior authorization include:

- Nutrition assessment, counseling and education.
- Nursing assessment, education and referral to needed medical services.
- Social services as medically necessary to assure that home, family, community and environmental issues are not complicating the pregnancy.

Prior authorization will be based on complicating and social problems that would have a negative impact on the

outcome of the pregnancy.

In addition, the following extended services available without prior authorization include:

- Comprehensive tobacco cessation services, as recommended in the 2008 Public Health Service (PHS) Guideline or any subsequent modification of this Guideline, to include the following:

1) Assessing the pregnant and postpartum woman's tobacco dependence, including a written tobacco cessation treatment plan of care;

2) Face-to-face counseling; and,

3) If appropriate, prescribing tobacco cessation pharmacotherapy, as medically necessary.

Extended services to pregnant women will include the above services when given as part of a medical service provided: 1) by agencies organized, and licensed by the State of Delaware, to provide medical care or under the supervision of Medicaid-enrolled physician; or 2) by any other Medicaid-enrolled health care professional who is legally authorized to furnish such services under State law and who is authorized to provide Medicaid coverable services other than tobacco cessation services under State law.

Vendors that contract with the State may be included in the group of eligible tobacco cessation service providers.

(Break in Continuity of Sections)

ATTACHMENT 4.19-B

Page 2 Addendum

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State/Territory: Delaware

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES –
OTHER TYPES OF CARE

Tobacco Cessation Counseling Services

To maximize the effectiveness of tobacco cessation medications, counseling services are available for Medicaid beneficiary use in conjunction with cessation medication.

Counseling services must be prescribed by a licensed practitioner participating in the Delaware Medical Assistance Program (DMAP).

Clinicians and other licensed practitioners must bill their usual and customary charges and must use the appropriate CPT/ CDT Codes to bill for their counseling services. Services supplied by contracted vendors are reimbursable under the terms of the agreement with the State of Delaware.

State developed fee schedule rates and any annual periodic adjustments to the fee schedule and its effective dates are published at <http://www.dmap.state.de.us/downloads/hcpcs.html>

Assurances – Cost Sharing Exemption for Tobacco Cessation Services

The State assures that cost-sharing is prohibited for tobacco cessation services for pregnant women. In accordance with Section 1916(a)(2)(B) and section 1916A(b)(3)(B)(iii) of the Act, the State does not permit cost sharing for services furnished to pregnant women, if such services are related to the pregnancy or to any other medical condition which may complicate the pregnancy. The State assures that the prohibition on cost-sharing for pregnant women specifically includes "counseling and pharmacotherapy for cessation of tobacco use by pregnant women (as defined in section 1905(bb))."

15 DE Reg. 656 (11/01/11) (Final)