



Center for Medicaid, CHIP and Survey & Certification

SDL # 11-007

ACA # 16

June 24, 2011

RE: New Medicaid Tobacco Cessation Services

Dear State Medicaid Director:

This letter provides information that we hope will be helpful to States as they work to reduce tobacco utilization along with guidance on the 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. In its assessment of this provision, the Congressional Budget Office estimated that its savings from preventable health problems and costs would outweigh its costs, resulting in reduced costs for States and the Federal government. This provision was effective October 1, 2010. This letter also provides guidance on “tobacco telephone quitline” activities which may be provided to Medicaid beneficiaries as an allowable Medicaid administrative cost expenditure.

BACKGROUND

As you know, smoking causes a number of serious diseases, including cancer, heart disease, stroke and chronic obstructive pulmonary disease, as well as complications of pregnancy. The Centers for Disease Control and Prevention (CDC) reports that the cost of these diseases both to individuals and the nation is substantial, resulting in an estimated \$96 billion a year in medical expenses, and an additional \$97 billion a year in lost productivity. The health effects of smoking and its associated economic and social costs can be addressed through increased availability of tobacco cessation services, which have been demonstrated to be both clinically effective and cost effective. Timely, effective tobacco dependence treatment can reduce smokers’ risks of tobacco-related disease and suffering, and reduce overall health care costs. The “Treating Tobacco Use and Dependence: 2008 Update: A Clinical Practice Guideline” published by the Public Health Service in May 2008 (PHS Guideline) notes that insurance coverage of tobacco cessation services significantly increases the likelihood that individual smokers will obtain treatment and successfully quit smoking. Given the low-income population that Medicaid serves, making treatment affordable through insurance coverage is likely to affect access and utilization of tobacco cessation services.

Expanding coverage of tobacco cessation services, which many States already cover, could significantly benefit the Medicaid program by helping beneficiaries access the resources they need to quit smoking. A 2007 study by the American Legacy Foundation estimated that if all smokers enrolled in Medicaid programs stopped smoking, the Medicaid program would save \$9.7 billion after 5 years. As of 2009, the CDC reports that 45 of the 51 Medicaid programs (88 percent) covered some tobacco cessation services for both pregnant and non-pregnant individuals. Among these 45

Medicaid programs, 23 programs (51 percent) covered individual and/or group tobacco cessation counseling for all Medicaid beneficiaries.

For example, Oregon and Massachusetts have successfully implemented the PHS Guideline recommended coverage for all Medicaid populations. Since 1998, Oregon Medicaid has provided a comprehensive tobacco cessation benefit, and in 2009 the State eliminated co-pays on tobacco cessation products and services for all Medicaid fee-for-service beneficiaries.

For all Massachusetts beneficiaries, MassHealth covers both behavioral counseling and all seven medications approved for tobacco cessation treatment by the U.S. Food and Drug Administration (FDA). Quit attempts among MassHealth beneficiaries are further encouraged by a general media campaign and an increased State excise tax on cigarettes. Research has shown that the Massachusetts comprehensive smoking cessation benefit, which had few barriers to access and was actively promoted, contributed to a significant decline in smoking rates among Medicaid-eligible individuals from 38.3 percent during 2003-2006 to 28.3 percent in 2008, a more than 25 percent reduction. Evidence is mounting as to declines in MassHealth paid claims for smoking related health events. When data on inpatient hospitalizations among MassHealth beneficiaries was analyzed, researchers found a 46 percent decreased risk for hospitalizations due to heart attack, and a 49 percent decrease in risk for other acute coronary heart disease diagnoses (Land, T et al., 2010).

Despite these benefits, a 2004 study found that nationally only 36 percent of Medicaid-enrolled smokers, and 60 percent of Medicaid physicians, knew that their State Medicaid program offered any coverage for tobacco-dependence treatments (McMenamin et al., 2004). This research implies that the promotion of beneficiary and provider awareness of tobacco cessation benefits is needed.

PHS GUIDELINE ON TOBACCO USE AND DEPENDENCE TREATMENT

Section 4107 of the Affordable Care Act amends section 1905 of the Act to require coverage of counseling and pharmacotherapy for cessation of tobacco use by pregnant women. Section 1905(bb)(2) of the Act defines the new tobacco cessation coverage for pregnant women as services recommended in the 2008 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.

The PHS Guideline is intended to inform clinicians' decisions regarding tobacco cessation treatment as well as to provide insurers, purchasers, and health care administrators with strategies to support effective tobacco dependence treatment. The PHS Guideline identifies effective approaches and treatments for the population as a whole, and contains specific recommendations for some subpopulations, such as pregnant women.

For the general population, the PHS Guideline recommends:

- Because tobacco dependence is a chronic disease that often requires repeated intervention, multiple attempts to quit may be required.
- Counseling and medication as effective treatments, and notes that while each is effective alone, they are more effective together.

- Individual, group, and telephone counseling as effective, and notes that their effectiveness increases with treatment intensity.

For pregnant individuals, the PHS Guideline:

- Recommends that because of the serious risk of smoking to the pregnant smoker and the fetus, whenever possible, pregnant smokers should be offered person-to-person counseling that exceeds minimal advice to quit.
- Does not recommend pharmacotherapy for pregnant women because there is insufficient evidence of the specific safety and effectiveness of pharmacotherapy in pregnant women. However, such use may be evaluated on a case-by-case basis as determined by the woman and her physician.

CDC's two-page summary of the PHS Guideline recommendations on cessation coverage for pregnant women and other populations is attached to this letter as Appendix A.

COVERAGE OF COMPREHENSIVE TOBACCO CESSATION SERVICES FOR PREGNANT WOMEN IN MEDICAID

Under section 4107 of the Affordable Care Act, section 1905(a)(4) of the Act is amended to add a new subsection (D) to require counseling and pharmacotherapy for cessation of tobacco use by pregnant women, as defined above. This coverage is defined in section 1905(bb)(1) of the Act as diagnostic, therapy, counseling services, and pharmacotherapy for cessation of tobacco use by pregnant women who use tobacco products or who are being treated for tobacco use. It 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.

Medicaid regulations at 42 CFR 440.230(b) offer States flexibility in designing their benefits, as long as each covered benefit is "sufficient in amount, duration, and scope to reasonably achieve its purpose." The PHS Guideline's emphasis on the effectiveness of counseling and the need to accommodate multiple attempts to quit should inform States' decisions as they design their smoking cessation benefit. The guidelines suggest that benefit packages ought to include coverage of at least four face-to-face counseling sessions per quit attempt, with a minimum of two quit attempts per year. Some prominent insurers have developed benefits that reflect these recommendations. For example, the Federal Employees Health Benefit Program (FEHBP) and Medicare have established similar tobacco cessation benefit packages in their programs with no cost sharing required. In addition, counseling sessions administered by telephone through evidence-based quitlines, though not a medical service under 1905(a)(4), may be considered in supplementing each beneficiary's counseling sessions. The State may receive Federal financial participation (FFP) for the evidence-based quitlines as an administrative expenditure, as described in the relevant section below. The counseling regimen may vary between beneficiaries.

The period for which these services must be covered includes the prenatal period through the postpartum period (the 60-day period following termination of pregnancy; see 42 CFR 440.210(a)(3)). Questions about the PHS Guideline, or any of the recommended services in the PHS Guideline, should be directed to the Center for Medicaid, CHIP, and Survey & Certification (CMCS).

Cost Sharing Prohibited for Tobacco Cessation Services for Pregnant Women

Section 1916(a)(2)(B) and section 1916A(b)(3)(B)(iii) of the Act 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. Section 4107 of the Affordable Care Act amended section 1916A(b)(3)(B)(iii) of the Act to clarify 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)).” A State must provide assurance of this exemption when submitting a State plan amendment related to cost-sharing for such services under section 1916 or 1916A of the Act.

Submission of State Plan Amendments

To implement this new 1905(a)(4)(D) benefit requirement, States should submit an amendment to their Medicaid State plans as soon as possible but not later than the end of the next calendar quarter following the date of this guidance. We encourage States with questions to contact CMCS. CMCS also encourages States to promote the availability of this new tobacco cessation benefit to beneficiaries and providers.

COVERAGE FOR TOBACCO CESSATION SERVICES FOR INDIVIDUALS WHO ARE NOT PREGNANT

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.

- Coverage of medically-necessary tobacco cessation services, including both counseling and pharmacotherapy, for children and adolescents, is mandatory under Medicaid’s Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit. The EPSDT benefit includes the provision of anticipatory guidance and risk-reduction counseling with regard to tobacco use during routine well-child visits. In addition to routine visits, additional counseling and tobacco cessation drug therapy must be provided when medically necessary for individuals under age 21.
- States may cover counseling for all other Medicaid beneficiaries through the benefits categories discussed in more detail below. While tobacco cessation drugs for non-pregnant individuals are currently covered outpatient drugs under section 1927(d) of the Act and may be excluded or restricted, States could elect such coverage. Moreover, section 2502 of the Affordable Care Act amended section 1927(d) of the Act so that, effective January 1, 2014, tobacco cessation drugs will no longer be excludable.

Coverage for tobacco cessation services can also be offered by a State as part of a benchmark benefits package under section 1937 of the Act.

States may cover counseling for all other Medicaid beneficiaries through the benefits categories discussed in more detail below. Medicare and FEHBP benefit packages include both tobacco cessation counseling, as described above, and pharmacotherapy for non-pregnant individuals. These programs can be possible models for States. Below are various ways States are able to deliver and receive FFP for tobacco cessation services for individuals who are not pregnant, including counseling and drug therapy.

- **Pharmacotherapy:** States may currently choose to cover prescription and/or non-prescription tobacco cessation drugs for Medicaid beneficiaries who are not pregnant. According to the PHS Guideline, clinicians should encourage all patients attempting to quit to use effective medications for tobacco dependence treatment, except where contraindicated or for specific populations for which there is insufficient evidence of effectiveness (pregnant women, adolescents, light smokers, and smokeless tobacco users). The FDA has currently approved seven medications for smoking cessation.
- **Counseling:** Tobacco cessation counseling services may be covered under a variety of Medicaid benefit categories such as physician services (42 CFR 440.50(a)), other licensed practitioner services (42 CFR 440.60(a)) such as pharmacists, dietitians, mental health counselors, preventive services (42 CFR 440.130(c)) or rehabilitative services (42 CFR 440.130(d)), depending on how States structure their Medicaid programs.
- **Minimizing financial barriers:** Reducing financial barriers, such as cost-sharing, can help encourage the use of effective cessation services. In a review of strategies that are effective in reducing tobacco use, the Task Force on Community Preventive Services, an independent panel of prevention and public health experts, recommended reducing out-of-pocket costs to consumers to increase the use of effective therapy and increase the number of people who use these services. In addition, the PHS Guideline lists the elimination of cost-sharing for tobacco cessation counseling as a key implementation strategy for health systems. Several peer-reviewed studies have found that reductions in patient out-of-pocket costs increase both the use of cessation services and overall tobacco quit rates (Curry SJ, et al 1998, Schauffler HA 2000).

TOBACCO CESSATION TELEPHONE QUITLINES AS ALLOWABLE MEDICAID ADMINISTRATIVE ACTIVITIES

Tobacco telephone quitlines are an effective tool for making intensive, specialist-delivered tobacco cessation support available to smokers in a widespread, easily-accessible manner. The PHS Guideline includes a meta-analysis of nine studies of quitlines, demonstrating an increase of approximately 60 percent in quit rates among smokers who received quitline counseling (See Appendix B). Another meta-analysis in the PHS Guideline found similar improvements in quit rates when quitline counseling and medication were compared to medication alone.

Tobacco quitlines involve specially-trained quit coaches who provide counseling, education and support to quitline callers who smoke or have recently quit smoking. Compared to traditional cessation clinics or classes, using a telephone quitline can offer advantages to smokers. A quitline

enables tobacco users to receive counseling support at a time that is convenient for them, without leaving home. The ease of accessibility of quitlines can be especially beneficial to individuals whose mobility is limited, who live in rural or remote areas, and whose work schedules make obtaining tobacco cessation counseling more challenging. Surveys have indicated that smokers are several times more likely to use such a service than they are to use a face-to-face program (McAfee et al. 1998, Zhu & Anderson 2000).

For these reasons, CMS will regard tobacco quitlines that follow the evidence-based protocols set forth in the PHS Guideline as an allowable Medicaid administrative activity necessary for the “proper and efficient” administration of the State plan under its authority under section 1903(a)(7) of the Act, to the extent that the quitline provides support to Medicaid beneficiaries under the auspices of the State Medicaid agency. Therefore, States can claim FFP for expenditures on such quitlines in accordance with the applicable cost principles under Office of Management and Budget, Circular A-87. In order for States to claim expenditures related to quitlines as administration at the 50 percent Federal Medicaid matching rate specified at 42 CFR 433.15(b)(7), such claims may not duplicate costs that have been, or should have been, paid through another source. Allowable costs must also be allocated in accordance with the relative benefits received by the Medicaid program. We encourage States with questions to contact CMCS.

We encourage States to offer evidence-based telephone quitline services for all Medicaid beneficiaries as they can be an effective means of providing cessation counseling. States may claim the 50 percent administrative match rate for comprehensive quitline services provided to Medicaid beneficiaries even if States do not provide such services to non-Medicaid beneficiaries. We encourage States with questions to contact CMCS.

CONCLUSION

Along with the new provision requiring tobacco cessation services be provided to pregnant women, the law offers States considerable flexibility to provide these services to Medicaid beneficiaries when medically necessary. The availability of FFP for quitline services should also help States provide tobacco cessation services in efficient and effective ways. CMS also encourages States to actively promote the availability of tobacco cessation benefits to Medicaid beneficiaries and to providers. The evidence is clear that these policies can save lives and reduce costs.

We look forward to working with you to facilitate ways for States to learn from each other as well as from the experience in the private sector, on benefit design outreach strategies. We encourage any State that has questions about this guidance to contact Dr. Jerry Zelinger, Technical Director, Disabled and Elderly Health Programs Group, who may be reached at 410-786-5929.

Sincerely,

/s/

Cindy Mann
Director

Enclosures

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cc:

CMS Regional Administrators

CMS Associate Regional Administrators
Division of Medicaid and Children's Health

Matt Salo
President
National Association of Medicaid Directors

Alan R. Weil, J.D., M.P.P.
Executive Director
National Academy for State Health Policy

Director of Health Legislation
National Governors Association

Christine Evans, M.P.H
Director, Government Relations
Association of State and Territorial Health Officials

Joy Wilson
Director, Health Committee
National Conference of State Legislatures

Debra Miller
Director for Health Policy
Council of State Governments

Overview of PHS Clinical Practice Guideline on Tobacco Use and Dependence

The U.S. Public Health Service's Clinical Practice Guideline, Treating Tobacco Use, and Dependence: 2008 Update recommends that all insurers cover evidence-based treatment for nicotine dependence.¹ Each 2008 PHS recommendation was given a Strength of Evidence grading of A (Multiple self-designed randomized clinical trials, directly relevant to the recommendation, yielding a consistent pattern of findings), B (Some evidence from randomized clinical trials supported the recommendation, but the scientific support was not optimal. For instance, few randomized trials existed, the trials that did exist were somewhat inconsistent, or the trials were not directly relevant to the recommendation) or C (Reserved for important clinical situations in which the Panel achieved consensus on the recommendation in the absence of relevant randomized controlled trials.).

General Coverage Recommendations

For the general population, tobacco cessation can be achieved by offering coverage that includes:

- 1) Proactive telephone, group and individual counseling sessions:
 - **PHS Guideline Recommendation:** Proactive telephone counseling, group counseling, and individual counseling formats are effective and should be used in smoking cessation interventions. (Strength of Evidence = A)
 - **PHS Guideline Recommendation:** Counseling by telephone and/or face-to-face delivered for four or more sessions appears especially effective in increasing abstinence rates. (Strength of Evidence = A)
 - **PHS Guideline Recommendation:** There is a strong dose-response relation between the session length of person-to-person contact and successful treatment outcomes. Intensive interventions are more effective than less intensive interventions and should be used whenever possible. (Strength of Evidence = A)

- 2) Prescription and over-the-counter cessation medications, approved by the FDA*:
 - **PHS Guideline Recommendation:** Clinicians should encourage all patients attempting to quit to use effective medications for tobacco dependence treatment, except where contraindicated or for specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents). (Strength of Evidence = A)
 - **PHS Guideline Recommendation:** The combination of counseling and medication is more effective for smoking cessation than either medication or counseling alone. Therefore, whenever feasible and appropriate, both counseling and medication should be provided to patients trying to quit smoking. (Strength of Evidence = A)
 - **PHS Guideline Recommendation:** There is a strong relation between the number of sessions of counseling, when it is combined with medication, and the likelihood of successful smoking cessation. Therefore, to the extent possible, clinicians should

References

¹ Fiore MC, Jaen CR, Baker TB, et. al. *Treating Tobacco Use and Dependence: 2008 Update*. Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Service. Public Health Service. May 2008.

provide multiple counseling sessions, in addition to medication, to their patients who are trying to quit smoking. (Strength of Evidence = A)

*The FDA has currently approved seven medications for smoking cessation, two non-nicotine medications, and five nicotine medications. These medications are: bupropion, varenicline, nicotine patch, nicotine gum, nicotine lozenge, nicotine inhaler, and nicotine nasal spray.

- 3) At least two quit attempts per year
 - Repeated intervention and multiple quit attempts are often necessary to be successful.^{1,2}
- 4) No co-pays or deductibles
 - Small co-pays or deductibles have been proven to reduce utilization of cessation services.^{2,3}

Specific Recommendation for Pregnant Women

In addition to the coverage for smokers in general, the PHS Guideline also makes recommendations specific to pregnant women. The PHS Guideline does not recommend medication for pregnant women. However, such use may be evaluated on a case-by-case basis, as determined by the woman and her physician.

The recommendations specific to pregnant women are:

- **PHS Guideline Recommendation:** Because of the serious risks of smoking to the pregnant smoker and the fetus, whenever possible pregnant smokers should be offered person-to-person psychosocial interventions that exceed minimal advice to quit. (Strength of Evidence = A)
- **PHS Guideline Recommendation:** Although abstinence early in pregnancy will produce the greatest benefits to the fetus and expectant mother, quitting at any point in pregnancy can yield benefits. Therefore, clinicians should offer effective tobacco-dependence interventions to pregnant smokers at the first prenatal visit as well as throughout the course of pregnancy. (Strength of Evidence = B)

The recommended person-to-person psychosocial interventions typically involve intensive counseling that follows usual care treatment components, such as a recommendation to stop smoking, supplemented by self help materials or referral to a cessation program.¹

² Schauffler HH, McMenamin S, Olsen K, Boyce-Smith G, Rideout JA, Kamil J. Variations in treatment benefits influence smoking cessation: results of a randomized controlled trial. *Tobacco Control* 2001;10:175–80

³ Curry SJ, Grothaus MA, McAfee T, Pabiniak C. Use and cost effectiveness of smoking-cessation services under four insurance plans in a health maintenance organization. *New England Journal of Medicine* 1998; 339(10):673–79.

Appendix B

Table 6.16. Meta-analysis (2008): Effectiveness of and estimated abstinence rates for quitline counseling compared to minimal interventions, self-help, or no counseling (n = 9 studies)^a

| Intervention | Number of arms | Estimated odds ratio (95% C.I.) | Estimated abstinence rate (95% C.I.) |
|---------------------------------------|----------------|---------------------------------|--------------------------------------|
| Minimal or no counseling or self-help | 11 | 1.0 | 8.5 |
| Quitline counseling | 11 | 1.6 (1.4–1.8) | 12.7 (11.3–14.2) |

^a Go to www.surgeongeneral.gov/tobacco/gdlnrefs.htm for the articles used in this meta-analysis.

Table 6.17. Meta-analysis (2008): Effectiveness of and estimated abstinence rates for quitline counseling and medication compared to medication alone (n = 6 studies)^a

| Intervention | Number of arms | Estimated odds ratio (95% C.I.) | Estimated abstinence rate (95% C.I.) |
|------------------------------------|----------------|---------------------------------|--------------------------------------|
| Medication alone | 6 | 1.0 | 23.2 |
| Medication and quitline counseling | 6 | 1.3 (1.1–1.6) | 28.1 (24.5–32.0) |

^a Go to www.surgeongeneral.gov/tobacco/gdlnrefs.htm for the articles used in this meta-analysis.