











August 18, 2010

Donald M. Berwick, M.D. Administrator Centers for Medicare & Medicaid Services 200 Independence Avenue, S.W., Room 445-G Washington, DC 20201

Dear Dr. Berwick,

We are writing to share our views on implementation of Section 4107 of the Patient Protection and Affordable Care Act (PPACA), which requires state Medicaid programs to cover comprehensive tobacco cessation services for pregnant women beginning on October 1, 2010. This enhanced Medicaid coverage will help pregnant women to quit thereby reducing the pregnancy-related health effects attributable to smoking and, at the same time, lowering health care costs.

Section 4107 of the PPACA amends the Social Security Act to require states to cover "counseling and pharmacotherapy for cessation of tobacco use by pregnant women" in their Medicaid programs with no cost-sharing. The PPACA states that this coverage means "diagnostic, therapy, and counseling services and pharmacotherapy (including the coverage of prescription and non-prescription tobacco cessation agents approved by the Food and Drug Administration)" and is limited to services recommended for pregnant women in the Public Health Service's *Treating Tobacco Use and Dependence* clinical practice guideline ("PHS Guideline") and other services the Secretary recognizes to be effective.

We encourage CMS to clarify – whether through a letter to state Medicaid directors or through other means – what states must do to comply with Section 4107. The scope of the cessation coverage should recognize that quitting tobacco is difficult and that tobacco users typically must make multiple attempts before they successfully quit. Medicaid should cover the full range of proven and effective treatment options so that pregnant women can find the particular service or combination of services that will best help them to quit using tobacco and not relapse. In addition, to achieve maximum benefit, pregnant women who are Medicaid beneficiaries should be made aware of the cessation counseling benefits and provided with information about where they can access these services.

## Coverage of all three types of counseling formats and at least four counseling sessions per quit attempt

The PPACA explicitly requires Medicaid coverage of counseling services for pregnant women, but the statute does not specify the type of counseling or the amount and duration of counseling sessions. The PHS Guideline found that proactive telephone counseling (quitlines, call-back counseling), individual counseling, and group counseling formats are all effective in reducing tobacco use. The PHS Guideline also confirmed that there is a strong dose-response relationship between the frequency and length of the counseling sessions and successful quit attempts. The PHS Guideline found that an effective strategy for producing high, long-term abstinence rates is "relatively intense cessation counseling (e.g., four or more sessions that are 10 minutes or more in length each)" and recommends that, if possible, clinicians should strive to meet with individuals four or more times.

To ensure that state Medicaid cessation services adhere to PPACA requirements and the PHS Guideline, CMS should inform states that they are required to cover all three counseling formats: individual, group, and telephone-based. They should cover a minimum of four counseling sessions per quit attempt and should be strongly encouraged to cover more sessions. While the PHS Guideline does not address the number of quit attempts, accumulating evidence suggests that states cover a minimum of two quit attempts per year.

We also encourage CMS to clarify how states can receive federal Medicaid matching funds for all formats of counseling (group, individual, and telephone-based) that the PHS Guideline recommends. Pregnant Medicaid beneficiaries should be able to easily access all PHS-recommended cessation services, which includes being able to find health care professionals who can be reimbursed by Medicaid for providing these services.

## PHS Guideline Currently Does Not Make a Recommendation on Use of Cessation Medications by Pregnant Women

The PPACA states that pharmacotherapy for cessation of tobacco use by pregnant women must be covered, and the PHS Guideline states that all seven FDA-approved cessation medications (which include prescription and non-prescription agents) are effective, "except when contraindicated or with specific populations for which there is insufficient evidence of effectiveness." Based on available data, the PHS Guideline does "not make a recommendation regarding medication use during pregnancy."

CMS should inform states that the current PHS Guideline does not make a recommendation on pregnant women using cessation medications. If a subsequent Guideline recommends use of cessation medications during pregnancy or if new evidence emerges that cessation medications can be used safely and effectively by pregnant women, CMS should inform states that they must cover those medications in their Medicaid programs with no cost-sharing requirement.

Cigarette smoking is the greatest modifiable risk factor for pregnancy-related morbidity and mortality in the United States. This new Medicaid coverage requirement will result in fewer stillbirths, premature births, low birth-weight babies, and cases of SIDS. We believe effective implementation of this new policy will save lives and money.

Sincerely,

Christopher W. Hansen

President

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Network

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