June 25, 2010

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Dear Dr. Jacques:

We are writing in response to the Centers for Medicare and Medicaid Services (CMS) Proposed Decision Memo for Counseling to Prevent Tobacco Use (CAG-00420N).

We support CMS's decision to use the authority it was given in the Medicare Improvements for Patients and Providers Act (MIPPA) to add coverage of preventive services recommended by the U.S. Preventive Services Task Force (USPSTF) to Medicare and are pleased that CMS is proposing to expand coverage for evidence-based tobacco cessation counseling to all Medicare beneficiaries. More than 3.5 million Medicare beneficiaries are current smokers. By expanding coverage of tobacco cessation counseling services to all Medicare beneficiaries, CMS can greatly improve access to these services, help more seniors to quit and reduce the terrible toll of tobacco.

Today, Medicare coverage of tobacco cessation is limited. Medicare covers counseling services but only if a beneficiary presents with a tobacco-related disease or uses medications that are adversely impacted by tobacco use. Medicare also covers smoking cessation pharmacotherapy prescribed by a physician. We agree with CMS's determination that the evidence clearly shows that all Medicare beneficiaries would benefit from smoking cessation counseling.

While we support expanding Medicare coverage for tobacco cessation counseling to all Medicare beneficiaries, we do not believe that CMS's proposal does enough to ensure that Medicare beneficiaries will have access to the evidence-based services they need to help them quit. In its national coverage analysis, CMS appropriately references the U.S. Public Health Service (PHS) Clinical Practice Guideline *Treating Tobacco Use and Dependence*, updated in May 2008. The PHS Clinical Practice Guideline is the result of a rigorous review of the most recent available scientific literature on tobacco cessation and includes the most comprehensive summary of the evidence with regard to tobacco cessation interventions. The USPSTF recommendation for tobacco cessation services also explicitly refers to the PHS Guideline. Unfortunately, CMS's proposed coverage decision does not adhere to the PHS Guideline in key areas.

Recommendation #1: Cover proactive telephone counseling (quitlines) and group counseling in addition to individual in-person counseling.

Quitting is hard and because of the addictive power of nicotine, most smokers fail when they try to quit smoking on their own. Unfortunately, smoking cessation treatment is not one size fits all, and different treatment approaches may be more or less effective for different people. To ensure that Medicare beneficiaries have access to the services they need to help them quit, it is critical that *all* tobacco cessation counseling formats proven to be effective are covered by CMS.

The PHS Guideline found that proactive telephone counseling (quitlines), group counseling and individual counseling formats are all effective in reducing tobacco use. According to the Guideline, tobacco cessation quitlines significantly increase abstinence rates compared to minimal or no counseling. Among the top ten key guideline recommendations is: "Telephone quitline counseling is effective with diverse populations and has broad reach. Therefore, clinicians and health care delivery systems should both ensure patient access to quitlines and promote quitline use." Quitlines provide easy access to cessation services and are a cost-effective and efficient way to reach a large number of smokers. Quitline services can also be tailored to the needs of specific populations, including senior smokers. In fact, the PHS Guideline indicates that certain issues particular to seniors, such as mobility and the use of medications, may make the use of telephone counseling particularly promising for this population. In addition, a study of the Medicare Stop Smoking Program (MSSP), the first large-scale demonstration of the effectiveness and cost-effectiveness of Medicare coverage of smoking cessation services, found that quitline counseling combined with pharmacotherapy to be the most effective approach that was analyzed.

Tobacco cessation quitlines are also included as a key component in the Centers for Disease Control and Prevention's *Best Practices for Tobacco Control Programs.* The U.S. Department of Health and Human Services currently provides funding for quitline infrastructure and services because it has determined that quitlines are an effective intervention to help tobacco users quit. While all states now provide some level of quitline services, these services are nowhere near the level that the Centers for Disease Control and Prevention (CDC) recommends and are therefore simply not available to the vast majority of smokers. Most state quitlines serve one percent or less of the total tobacco users in each state while the CDC Best Practice Guidelines indicates that a state quitline could serve eight percent of tobacco users.

The PHS Guideline is also clear in its recommendation of group counseling as an effective format for cessation counseling, however, the PHS Guideline does not single out a particular format as preferred. The Guideline states that "the provision of intratreatment social support [is] associated with significant increases in abstinence rates" and is one of the most important elements of an effective cessation counseling session. While social support can be addressed in individual counseling, group counseling sessions come with a built-in social support group. In its recommendations specifically for older smokers, the Guideline indicates that social support is an effective method of helping older smokers quit, mentioning that "buddy support programs" are particularly effective.

The PHS Guideline is not the only guiding document that supports the importance of including group cessation counseling in any insurance benefit. CDC's *Best Practices for Tobacco Control Programs* also recommends that tobacco use treatment include group counseling.

Efforts by the business community to define an appropriate tobacco cessation benefit also recognize the importance of covering all counseling formats. The National Business Group on Health has developed a purchaser's guide to help employers design benefits packages for their employees. The Business Group recommends that employers cover multiple counseling formats in their cessation benefits packages. Counseling options include telephone-based programs, individual counseling programs, group programs and Internet self-help programs.

Recommendation #2: Increase the number of counseling sessions covered during each quit attempt from a <u>maximum</u> of four sessions to a greater number of sessions consistent with the PHS Guideline and current practice.

CMS is proposing coverage of a maximum of four counseling sessions per quit attempt. This proposal differs from the PHS Guideline and may unnecessarily limit access to additional counseling sessions that would help Medicare beneficiaries to quit tobacco use.

The PHS Guideline confirms that there is a strong dose-response relationship between the frequency and length of the counseling sessions and successful quit attempts – more or longer sessions improve quit rates. The PHS Guideline finds that an effective strategy for producing high long-term abstinence rates is "relatively intense cessation counseling (e.g., four or more sessions that are each 10 minutes or more in length)." The Guideline recommends that if possible, clinicians should strive to meet with individuals four or more times. The PHS Guideline recommendations regarding the number of sessions is consistent with other groups including the National Business Group on Health which recommends that employers cover two courses of six counseling sessions per calendar year.

CMS's national coverage decision should set a maximum number of counseling sessions per quit attempt at a level that is higher than four. Given the economic burden of tobacco and the dose-response relationship documented in the PHS Guideline, it is critical that CMS not arbitrarily set a maximum number of sessions. CMS appears to have simply proposed covering the minimum number of counseling sessions found to be effective in the PHS Guideline. Instead, CMS should cover the number of sessions that the evidence suggests will assist the greatest number of Medicare beneficiaries to quit. To determine the maximum number of sessions, CMS should look at the PHS Guidelines as well as the current practice of effective cessation counseling programs.

Recommendation #3: Ensure that the tobacco cessation counseling benefit is promoted to all Medicare beneficiaries.

A comprehensive cessation benefit must not only include proven effective services, but must also include efforts to increase demand for cessation services and promote the use of these services. To achieve maximum benefit, CMS should encourage smokers to quit, make all Medicare beneficiaries aware of the cessation counseling benefit as well as the tobacco cessation medications covered through Part D, and provide them with information about where they can access these services. For example, CMS could include information to highlight the new benefit in the "Medicare and You" publication, on Medicare.gov, and as part of the Welcome to Medicare physical examination. CMS should also utilize the Medicare Learning Network and other means to inform physicians and other health

professionals about the expanded counseling coverage and raise awareness of the effectiveness of counseling at increasing the chances of quitting successfully.

Finally, while outside the scope of this coverage determination and the authority under MIPPA that CMS has for adding preventive services, we believe FDA-approved tobacco cessation medications, including over-the-counter medications, should be covered by Medicare, Medicaid and all private health plans, as the USPSTF recommends.

Thank you for the opportunity to provide comment on the CMS proposal. We look forward to your final decision memorandum.

Sincerely,

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