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12/27/16

The Honorable Sylvia Matthews Burwell  
Secretary, U.S. Department of Health and Human Services  
200 Independence Ave. SW  
Washington, DC 20201

The Honorable Thomas Perez  
Secretary, U.S. Department of Labor  
200 Constitution Ave., NW  
Washington, DC 20210

The Honorable Jacob J. Lew  
Secretary, U.S. Department of the Treasury  
1500 Pennsylvania Ave. NW  
Washington, DC 20220

Dear Departments of Labor, Health and Human Services, and the Treasury,

We are writing as stakeholders on behalf of the Association for the Treatment of Tobacco Use and Dependence (ATTUD), the leading professional organization for clinicians providing evidence-based interventions to tobacco users. Below please find our comments on tobacco cessation programs and the application of reasonable medical management techniques for tobacco cessation services.

As you know, tobacco cessation services were defined as preventive services under the Affordable Care Act (ACA) and received an A rating by the United States Preventive Services Task Force (USPSTF) (Siu & Force, 2015). As the leading cause of preventable death in the U.S., tobacco use needs to be addressed both as a substance use disorder and as a preventive health intervention. Tobacco use accounts for about 8.7% of all healthcare costs (as of 2010 data), and more than 60% of tobacco use costs were paid by Medicare, Medicaid and other federal programs (Xu, Bishop, Kennedy, Simpson, & Pechacek, 2015). Therefore, tobacco use is one of the biggest drivers of healthcare costs, about **\$170 billion per year**, not to mention costs for lost productivity, which impact the overall US economy.

Tobacco use treatment differs from other preventive services such as mammograms, colonoscopies, or lung cancer screenings, which occur in one visit. The Department of Health

and Human Services (HHS) issued guidance on specific insurance requirements for tobacco treatment coverage under the ACA (5/2014).

In summary, the ACA, states that insurers must cover:

- 1) All 7 FDA-approved medications, a 90-day supply for each medication/year, with no out-of-pocket costs for the patient, and without prior authorizations
- 2) At least 8 visits of counseling/year (individual, group, and telephone counseling), with at least 10 minutes of counseling per visit, with no out-of-pocket costs for the patient, and without prior authorizations.

While this coverage may be sufficient for people who smoke in light or infrequent amounts, when persons evidence chronic, moderate-high levels of addiction and/or difficulty in achieving abstinence, tobacco use disorder needs to be covered as a substance use disorder, as defined by the *Diagnostic and Statistical Manual of Mental Disorders, 5<sup>th</sup> ed. (DSM-V)* (APA, 2013). In contrast to the ACA coverage requirements for the treatment for tobacco use disorder, a range of options exist for other substance use disorders (SUDs). For other SUDs, the appropriate level of treatment is based upon the specific and often complex needs of the patient. For example, a patient with problem drinking who has good social support may respond to a brief counseling intervention that can be managed in a primary care setting. Those with more severe alcohol or drug use disorders, who have physical tolerance, heavier use, and more severe psychosocial consequences, often require referral to a specialized treatment facility. At least 2.5 million people with an alcohol or drug problem received treatment in a specialty facility in 2013, which represents about 11% of those in need (SAMHSA, September 4, 2014; Williams, Steinberg, Kenefake, & Burke, 2016). While certainly not all patients with tobacco use disorder will need this level of care, providing the appropriate level of care based upon clinical factors is both appropriate and cost-effective given the costly health consequences of ongoing tobacco use.

In our view, the ACA coverage requirements as currently written are not sufficient; they negatively affect access to and duration of care needed to treat tobacco use disorder effectively. We make the following recommendations to translate evidence-based research and our real-world clinical practice experiences into effective preventive care insurance policy:

- 1) All 7 FDA-approved medications should be covered at 100% (no patient cost-sharing) without any prior authorization requirements by insurance.
- 2) As with treatment for other chronic conditions such as diabetes, there should be no annual or lifetime limits on treatment.
- 3) As with treatment for other chronic conditions, such as hypertension, combinations of medications used at the same time, should also be covered (simultaneously), with no medical management interference by the insurer. Medication combinations will be determined based on clinician judgment and the clinical needs of the patient, not the insurer. Both the PHS Clinical Practice Guideline for the Treatment of Tobacco Dependence (Fiore et al., 2008), and updated USPSTF guidelines (Siu & Force, 2015)

indicate that combination medications are needed for many patients and have superior efficacy to use of a single medication. There are three different classes of medications: varenicline, bupropion, and nicotine replacement therapy (NRT). While these medications have some overlap in targeting similar parts of the brain, they also have different biological mechanisms that function somewhat differently in treating tobacco use disorder. Additionally, the five NRTs (patch, gum, lozenge, inhaler, and nasal spray) have somewhat different mechanisms of action and therefore are all different categories of medications. The nicotine patch is long-acting, delivering nicotine slowly over 24 hours. The nicotine inhaler has a tactile-oral mechanism that is fast-acting and beneficial from a behavioral aspect. The nicotine nasal spray is absorbed through the nasal passage and is fast-acting, the nicotine gum and nicotine lozenge work through oral absorption, fast-acting, and can be used inconspicuously. In 2013, the FDA changed the labeling requirements for over-the-counter NRTs to remove the instruction that these products should not be used in combination, as there are “no significant safety concerns” associated with using more than one NRT at the same time (<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm345087.htm>). The average person takes about 30 tries before permanently quitting tobacco use (Chaiton et al., 2016), so there is no evidence base for increasing quit rates via insurance stepped care techniques (that require a patient to try and fail one medication first), preferred formularies, or tier systems, since this is a preventive care service. Furthermore, there is no evidence of additional safety concerns or increased burden related to cost-effectiveness (to the whole healthcare system) for implementing these insurance medical management systems. For example, a “no barrier” insurance reimbursement for comprehensive counseling and FDA tobacco medications in Massachusetts (Land et al., 2010) led to significant decreased hospitalizations for cardiac events, or a return-on-investment (ROI) of 2-1 for every dollar spent on comprehensive preventive tobacco treatment interventions, which is an example of achieving population health or triple aim goals (Berwick, Nolan, & Whittington, 2008).

- 4) As a covered preventive service, insurers must cover an intake visit for the purpose of initial evaluation and treatment planning and at least 8 intensive counseling visits (at least 20-60 minutes each) per year, for each counseling modality (individual, group, telephone), without prior authorization. Brief counseling visits of < 20 min each should also be covered at 100%, before any medical management can be done (prior authorizations). Research demonstrates that more or longer sessions improve cessation rates (Fiore et al., 2008). The current USPSTF guidelines (Siu & Force, 2015) indicate intensive visits of at least 20 minutes lead to the highest quit rates. High intensity counseling lasts at least 15-60 minutes/visit for individual counseling and at least 45-90 minutes for group visits. Non-exhaustive examples of intensive individual face-to-face treatment codes/services include 90832, 90834, 90837, 90791, 99401, 99402, 99403, 99404, 96150 (1-5 units), 96151 (1-5 units), 96152 (1-5 units). Examples of intensive face-to-face group treatment codes include 90853, 99411, 99412, 99078, S9453, 96153 (3-6 units). Other codes may be valid and insurers may require modifiers, such as modifier 33 to indicate 100% preventive coverage (no cost sharing to the patient), so long as this is transparent to the clinician and/or healthcare system billing staff where treatment services are rendered.

- 5) As a substance use disorder, insurers also need to be required to reimburse tobacco treatment codes/services that correspond to more intensive counseling.
- 6) Different clinicians may use different codes; the best services/codes are determined by the individual clinician, their training/experience, and professional discipline. Insurers may not limit reimbursement to just brief codes (e.g., 99406, 3-10 minutes; 99407, 10+ minutes). For example, USPTSF (Siu & Force, 2015) indicates that physicians, nurses, psychologists, social workers, and tobacco treatment “cessation” counselors are valid clinicians rendering these services.
- 7) Telehealth or interactive audiovisual telecommunications (HIPAA compliant platform) tobacco treatment counseling is a form (or subtype) of behavioral tobacco treatment counseling and also needs to be explicitly covered. Medicare already covers Telehealth services for a wide range of clinical conditions (Medicare Learning Network, 12/2015, <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/TelehealthSrvcsfctsh.pdf>) and eligible clinicians also need to be reimbursed for these types of behavioral interventions with tobacco users.
- 8) Combinations of interventions that are the “most acceptable and feasible” to the patient are recommended (Siu & Force, 2015) and should be covered, since it was reported that the largest treatment effect was found in interventions that provided 8 or more sessions. For example, group tobacco treatments may work through different biopsychosocial treatment mechanisms than individual face-to-face treatment. Assuming each counseling treatment modality works by different biopsychosocial mechanisms, different patients may need different combinations or formats of counseling modalities simultaneously, within a given quit attempt. A common example could be a moderately-severely dependent patient with multiple comorbidities receives 4 intensive individual face-to-face visits, combined with 6 face-to-face group visits and 3 interactive audiovisual telehealth visits. Finally, as tobacco dependence represents a chronic condition, there should be no lifetime limits and it is not reasonable to have patients and/or clinicians jump through hoops such as precertifications/prior authorization, paperwork, or phone calls. Patient motivation to quit fluctuates dramatically and our clinical experiences show that making a patient wait 1-6 weeks for a counseling visit due to pre-authorization requirements leads to high no-show rates, high drop-outs, and defeats the goal of high population prevention care utilization and high quit rates.
- 9) As health care makes the transition into team-based approach and outcome-based reimbursements, integration of Certified Tobacco Treatment Specialists (CTTS) (<https://attud.org/ttspa.php>) may be an effective and cost-sensible approach (Bohmer, 2016). The health care system in the United Kingdom has found a doubling of quit rates when patients are referred to a “smoking cessation specialist” as compared with physician preventive care visits (Kotz, Brown, & West, 2014), and effective models have been integrated into larger medical systems in the United States (Burke, Ebbert, Schroeder, McFadden, & Hays, 2015). Effective team approaches used in specialty centers with diabetes are another model that might be considered. In this model, the CTTS would be

analogous to the diabetes health educator (<http://www.cdc.gov/diabetes/ndep/pdfs/ppod-guide-team-care-approach.pdf>).

- 10) Insurers should not discriminate against reimbursing certain clinician classes (e.g., psychologists, LCSWs, LPCs, ARNPs, APRNs, PAs, respiratory therapists, dentists, pharmacists, CTTS, etc.) whose scope of practice/training permits them to treat people with tobacco use disorder; this is a Harkin Law violation. Also, insurers may not discriminate based on the setting of treatment. For example, tobacco specialist treatment (Kotz et al., 2014) has been shown to yield higher quit rates than brief primary care treatment. Clinicians routinely render tobacco treatment services in oncology departments, primary care, behavioral health settings, specialist settings (e.g., pulmonary medicine practices), inpatient hospital settings, and other healthcare settings.
- 11) Finally, reimbursement rates should be connected to usual and customary rates based on codes identified in [fairhealthconsumer.org](http://fairhealthconsumer.org), so programs are sustainable in most healthcare systems, which currently is not the case.
- 12) The ACA allows for insurers to charge higher premiums for people who use tobacco (“tobacco use surcharge”). We do not charge higher premiums for those with other chronic health and behavioral health conditions, such as diabetes, hypertension, depression, obesity, or alcohol use disorders – why single out tobacco use? Friedman et al. (2016) present evidence that these surcharges reduced take-up of insurance by people who use tobacco, and did not impact tobacco cessation rates. Furthermore, we have evidence from our own practices that some patients often do not admit their tobacco use to avoid paying these surcharges, discouraging them from seeking treatment because they are afraid they will be caught. Therefore, this practice of charging higher premiums to those who use tobacco should be repealed or not allowed, at a minimum, at least until it is studied further and there is solid empirical evidence base for this policy. We believe it constitutes discrimination for a pre-existing condition given that tobacco use disorder is a chronic illness and also causes unnecessary stigma. Additionally, it is a form of cost-shifting from insurer to patient which is not allowed for any other preventive health care service in medicine and sets a dangerous precedent. It should be noted that many ATTUD members commented on this topic in 2009, submitting a letter to Kathleen Sebelius, Secretary of HHS (Richter, December 12, 2009). Since 2009, this problem has significantly worsened. For example, in NJ many people who use tobacco are being charged an extra \$1,300/year for health insurance premiums.
- 13) Health Risk Assessment (HRA) protocols should not be allowed as a precondition or prior to covering counseling or medications, because these present unnecessary regulations that delay treatment and have no evidence base. Clinical experience has shown that many of these involve complicated computerized surveys. Higher rates of tobacco use are found in people with lower education levels and lower socioeconomic status who tend to have less access to computers and/or lower computer literacy. Thus, they be unable to access the HRA, or may take longer to complete (e.g., 1-4 months to get prescriptions in hand, or receive face to face counseling), thereby leading to no shows, high drop-out rates, and/or delaying treatment.

In conclusion, as key clinical and scientific stakeholders, we submit the aforementioned recommendations for these life-saving and medically necessary treatment services, which will improve national quit rates and the overall health of our population.

Sincerely,

/s/ Matthew Bars, MS, CTTS  
ATTUD President & on behalf of the Board of Directors

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