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December 26, 2012

Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C., 20201

Re: CMS-9980-P

Dear Secretary Sebelius:

On behalf of the American Thoracic Society (ATS), thank you for the opportunity to comment on the Department of Health and Human Service's proposed rule on essential health benefits (EHB) for health insurance exchanges. The ATS is an international educational and scientific multi-disciplinary society of 15,000 members focused on respiratory, critical care and sleep medicine. The ATS recognizes the challenge in establishing a comprehensive package of affordable health benefits for individuals receiving health insurance through exchanges while balancing the need to reduce health system costs, however we have concerns about the EHB package as outlined under the proposed rule. We have the following comments:

EHB Standards

We believe that the ten benefit categories are appropriate and have the potential to be adequately inclusive. However, the state benchmark options outlined proposed rule, with the exception of the federal employee health plans, currently have a large degree of variation in covered benefits. The ATS remains concerned that this variation in benefits across states, despite the mandated categories of care, may hinder the promotion of a consistent package of EHB, and instead permit some states to set inadequate benchmark standards that do not include the full range of health care services that patients need access to.

The ATS also remains concerned that the process for "supplementing" EHB benchmarks that do not include adequate coverage standards for some healthcare services will not ensure the inclusion of all needed services. While it is hoped that the mandate to defray costs of state-required benefits that are not included in the benchmark plan would be incentive enough for states to choose a more comprehensive benchmark plan, some states may instead choose benchmark plans that do not provide adequate coverage of medically necessary services.

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In the final rule, we urge you to specify required services including tobacco cessation, asthma management and tuberculosis diagnosis and treatment, in order to promote a consistent EHB package. For services not covered by the EHB, such as diagnosis, evaluation and treatment of sleep disorders, we urge you to set the minimum benefit standard at the benefit provided by Medicaid and Medicare. We have the following additional comments:

Access to specialty care

In order to provide effective management of chronic respiratory diseases such as COPD, asthma and sleep disorders, it is essential that primary care providers can quickly and easily refer patients to specialty care providers including pulmonologists and sleep specialists. The ATS urges the Department to ensure that the final rule on EHB provides adequate and timely patient access to specialty care.

Prescription Drugs Benefit Category

The ATS notes that the proposed rule expands the EHB requirements for prescription drugs beyond what was proposed in the December 2011 EHB guidance to require plans to cover at least the number of drugs covered in state benchmark plans. However, we are concerned that the proposed rule still does not guarantee access to medications that patients with respiratory diseases, critical illnesses and sleep disorders need. One of our key concerns with the prescription drugs benefit as outlined is that access to a specific number of drugs is emphasized, rather than the range of drugs that best fit patient's needs. Under the proposed rule, which relies on the U.S. Pharmacopeia (USP) system, plans can choose to cover a minimum number of drugs in a class or category while excluding some drugs that may have unique therapeutic benefits to patients.

Lung Transplant Medications

The drug treatment regimen following lung transplant requires use of three immune suppressants, which are all in the same class and category. Under the proposed rule, patient access to these medically necessary drugs may be denied by some health plans that only cover two drugs per class, putting patient lives at significant risk.

Drug Resistant TB Treatment

Currently, the standard treatment regimen for single and multi-drug (MDR) tuberculosis (TB) includes use of multiple drugs in the same classes and categories, such as fluoroquinolones and aminoglycosides. Drug susceptibility of a given TB isolate may be restricted to one or 2 drugs within a given class, so others must be available to the physician in order to prevent further drug resistance from emerging. Furthermore, MDR treatment regimens may require use of 6 first and second-line antibiotic drugs; the limited number of effective medications we have at present for use in such cases often is additionally restricted by both drug susceptibility of the mycobacteria and tolerance of the patient to 12 to 24 or more months of treatment. Under the proposed rule, the option for some plans to cover only one drug per class and category would clearly be a significant problem for treatment of drug resistant TB, an already difficult to treat airborne infectious disease with serious public health implications.

Tobacco Cessation Medications

The ATS is also concerned about adequate coverage for tobacco cessation medications, including over-the-counter (OTC) medications, under the proposed rule. People trying to quit smoking may need to try several medications rather than just one. We urge the Department to clarify that OTC tobacco cessation medications will be covered as part of EHB.

Combination Therapies

Patients with lung disease such as cystic fibrosis, bronchiectasis, asthma, pulmonary arterial hypertension and tuberculosis may require various medications as part of combination therapy. Under the proposed rule, the USP system would be used, however this system does not recognize combination therapies. We urge the Department to issue specific guidance to health plans ensuring that patients have continued access to combination therapies.

Drug Substitutions

A common problem for patients with respiratory diseases including pneumonia and asthma is intolerance to some drugs, or a shortage of a drug, which requires an expeditious prescription change to another drug, often within the same class. We note that the proposed rule includes a requirement that EHB's have "procedures in place to ensure that enrollees have access to clinically appropriate drugs that are prescribed by a provider but are not included on the plan's drug list." However, the ATS urges the Department to modify this requirement to require approvals within 24 hours for alternate drugs not on an EHB's list to ensure that this process does not put patients and the public at risk.

EHB Prescription Drug Coverage Must be Expanded

Under the proposed rule, the "fall back" option for some states to have an EHB requirement of only drug per class if their benchmark plan does not cover a required class of drugs, clearly presents an access barrier to patients with certain lung diseases and conditions, including MDR-TB and patients in need of lung transplants, as well as people trying to quit smoking. These treatment barriers will put patient lives at risk. In the final rule, the ATS urges the Department to require that EHB prescription drug benefits be equivalent to Medicare Part D drug coverage.

New Drugs

The proposed rule does not appear to address how health plans will incorporate new drugs coming into the market during the course of a plan year. Specifically, the rule ties EHB formulary requirements for 2014 and 2015 to the number of drugs covered in the benchmark plan in 201, without offering guidance for drugs approved after 2012. The ATS recommends that plans be required to use the Medicare Part D system for incorporation of new drugs into formularies. Additionally, patients must be able to remain on older drugs after a new drug has been added.

EHB Tobacco Cessation Benefits

Cigarette smoking is the leading cause of death in the U.S., responsible for one in five deaths. As a society representing healthcare specialists who diagnose and treat patients with tobacco-related diseases and illnesses, the ATS is pleased with the Department's strong focus on preventing and reducing tobacco use.

EHB Tobacco Cessation Benefits

In order to reach the goal of reducing tobacco use in the U.S., the Department must ensure open access to a full range of tobacco cessation services, ranging from pharmacological therapies to counseling services through specific inclusion of these services in the EHB. Open access to preventive tobacco cessation services will reduce the incidence and severity of chronic diseases associated with smoking, such as COPD and lung cancer and significantly reduces future health system costs.

The ATS urges the Department to base the EHB for comprehensive tobacco cessation services on model benefit coverage provided by the Federal Employees Health Benefits Program (FEHB) and to clearly define all tobacco cessation benefits, including duration of therapy, in accordance with the 2008 U.S. Public Health Service guideline, *Treating Tobacco Use and Dependence*.ⁱ The definition should include all tobacco cessation medications approved by the FDA, and individual, group and telephone counseling. To ensure full access for low-income enrollees, tobacco cessation benefits must be provided without copays, deductibles or limits.

The ATS notes that under the proposed rule, tobacco cessation services should be guaranteed under the preventive services benefit category's requirement for coverage of all preventive services recommend by the U.S. Preventive Services Task Force. However, despite this standard, there is wide variation of tobacco cessation coverage in private health plans across states. According to the information released by HHS with this proposed rule, 18 benchmark plans currently do not cover any tobacco cessation medications and do not mention coverage of counseling or quit smoking programs in their summary plan document. The ATS urges the Department to require that these plans supplement coverage from another plan that does cover tobacco cessation treatment, or provide other guidance on what the EHB standard for that state includes for tobacco cessation.

Rehabilitative Services

Under the proposed rule, rehabilitative services are not defined and flexibility is left to states and plans. The ATS is concerned about how durable medical equipment (DME) that is essential to patients with respiratory disease, including ventilators, nebulizers and continuous positive airway pressure machines will be covered to ensure patient access. Although we understand that the Department will further define habilitative services in future guidance, the ATS urges the Department to specify coverage of DME in the final rule.

Access to Sleep Medicine

Research has shown that sleep-disordered breathing and sleep-related illnesses affect an estimated 50-70 million Americans.ⁱⁱ The public health impact of sleep illnesses and sleep disordered breathing is still being determined, but is known to include increased mortality, traffic accidents, lost work and school productivity, cardiovascular disease, obesity, mental health disorders, and other sleep-related comorbidities.ⁱⁱⁱ Coverage of treatment for sleep disorders varies across private health plans. In order for people with sleep disorders to be appropriately identified and referred to a sleep specialist for evaluation, physicians, including primary care practitioners, must screen patients.

Access to Sleep Medicine

But currently, a very small number of primary care practitioners screen patients for sleep disorders. The National Sleep Foundation's *Sleep in America Survey 2008* found that 86% of general practitioners had never discussed sleep with patients.^{iv} The ATS urges the Department to require a sleep disorder screening as part of the prevention and wellness and chronic disease management EHB category. An appropriate sleep screening can consist of three simple questions to determine adequateness of nightly sleep and if a patient snores, a primary indicator of a sleep disorder. Further, we urge the Department to ensure patient access to treatment for sleep disorders by requiring EHB coverage of sleep disorder evaluations and treatment at the benefit provided by Medicaid and Medicare.

Asthma

According to the CDC, the burden of asthma among adults and children is growing in the U.S. Asthma is the third leading cause of hospitalization among children under the age of 15 and is a leading cause of school absences.^v Comprehensive asthma management and education is critical to controlling asthma and preventing dangerous and costly asthma exacerbations. The ATS urges the Department to provide specific EHB guidance to states to ensure patient access to asthma therapies and medications and to require EHB coverage of asthma management strategies and education, including in-home asthma trigger assessments and case management under the prevention, wellness and chronic disease management benefits category. Comprehensive treatment and chronic disease management of asthma will reduce overall health system costs.

COPD

COPD is the third leading cause of death in the United States and the third leading cause of death worldwide, yet the disease remains relatively unknown to most Americans. CDC estimates that 12 million patients have COPD; an additional 12 million Americans are unaware that they have this life threatening disease. The ATS urges the Department to ensure that the EHB ensures appropriate diagnosis and treatment for this disease through the chronic disease management category.

Infectious Diseases

The control and prevention of infectious diseases such as influenza, HIV and tuberculosis are vitally important to protecting public health. In accordance with the Department's strategic objective to reduce the occurrence of infectious diseases in the U.S., the ATS urges the Department to ensure open access to immunizations against influenza and ensure appropriate prevention, diagnosis and treatment services for tuberculosis with no co-pays in order to protect public health from these airborne diseases.

At-home care for chronic respiratory disease management

Home-care management of patients with chronic respiratory diseases such as COPD and cystic fibrosis holds significant potential for improving patient care, patient satisfaction with care and reduced health system costs. However, this is an area with great variation of coverage among health care plans across the U.S.

At-home care for chronic respiratory disease management

The Independence at Home pilot program for Medicare, enacted under the Affordable Care Act and scheduled to start in 2012 is one such federally-supported model for these services. The ATS urges the Department to provide specific guidance for EHB coverage of at-home care for patients with chronic diseases under the ambulatory patient services care category.

End of life and palliative care

When patients and families have early and effective communication about end-of-life care options, the result is higher quality care that minimizes ineffective treatments, reduces health system costs, and improves patient and family satisfaction with end-of-life care. Yet this is another area with significant variation in inclusion of specific benefits that cover patient-physician counseling on end-of-life care and palliative care options that patients need. In the final rule, the ATS urges the Department to specify that end of life care consultations and a full range of palliative care are covered under the EHB standards.

Thank you for the opportunity to comment on this important aspect of healthcare system reform.

Sincerely,



Monica Kraft, M.D.
President
The American Thoracic Society

ⁱ Fiore MC, Jaen CR, Baker TB, et al. Treating Tobacco Use and Dependence: 2008 Update. Rickville, MD: U.S. Department of Health and Human Services, U.S. Public Health Service; 2008.

ⁱⁱ Wickwire EM, Collop NA. Insomnia and sleep-related breathing disorders. Chest 2010;137:1449-63.

ⁱⁱⁱ Tregear S, Reston J, Schoelles K, Phillips B. Obstructive sleep apnea and risk of motor vehicle crash: systematic review and meta-analysis. J Clin Sleep Med 2009;5:573-81

^{iv} Sleep in America National Sleep Foundation. Washington: National Sleep Foundation;2008. Sleep in America Poll. Available at: <http://www.sleepfoundation.org/site/c.huIXKjM0Ix/b.3933533/>.

^v Centers for Disease Control and Prevention: National Center for Health Statistics, National Hospital Discharge Survey, 1995-2010.