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November 27, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Attention CMS-9930-P
P.O. Box 8016
Baltimore, MD 21244-8016
RIN 0938-AT12

Dear Administrator Verma:

On behalf of the American Thoracic Society (ATS), thank you for the opportunity to comment on the Centers for Medicare and Medicaid's Services (CMS) proposed rule, CMS-9930-P, *Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters for 2019*. The ATS is a medical professional organization of over 16,000 members who work to prevent, detect, treat and cure respiratory, sleep and critical care related illnesses through research, clinical care and advocacy. Ours is a population that includes millions of people across the US with respiratory illnesses such as asthma, COPD, pulmonary fibrosis, pneumonia, and obstructive sleep apnea. Our patients need continuous, affordable health coverage, including access to specialty care and comprehensive diagnosis, treatment and prevention services. The ATS is gravely concerned that some of the proposals under this proposed rule will result in some medically necessary treatments and health care services becoming unaffordable for our patients in some states. We have the following concerns with this rule:

Qualified Health Plan Certification Standards – § 155.200
The rule proposes to permit states to set their own standards for network adequacy and essential community providers. Network adequacy is a critical health care access issue, particularly for people with chronic conditions who require specialty care. Access to specialty providers including pulmonologists, pediatric pulmonologists, critical care physicians, sleep specialists and respiratory therapists is essential for patients with chronic respiratory diseases such as COPD, asthma, lung cancer and sleep apnea, all of which have a significant disease burden in the U.S. Without appropriate and timely access to medically necessary services provided by trained specialists, people with chronic conditions such as these will not receive adequate care, which will result in them getting sicker, unable to work and attend school and incur higher health care costs including hospitalizations and prolonged treatment. Ensuring access to specialty care enables system-wide management of these and all other chronic diseases, improving public health and reducing health system costs.

Too many Americans do not have adequate access to needed health care because they live in rural, low-income, urban or geographically isolated and remote areas, including American Indian reservations, under-served by healthcare professionals. In order to ensure access to appropriate care, the ATS urges the Department to mandate that state health insurance exchanges require qualified health plan (QHP) provider networks maintain adequate networks of healthcare providers including pulmonologists, critical care and sleep specialists, for all enrollees, including those in underserved areas, to ensure timely and appropriate care and chronic disease management.

The rule proposes to defer regulatory review and oversight of QHP certification standards to states in 2019. The ATS is concerned by this historic shift in oversight, a key function of the Department of Health and Human Services, to individual states and urges the Department to maintain adequate oversight to ensure adequate network adequacy and appropriate access to care for all Americans.

State Flexibility in Essential Health Benefit Benchmark Plans – § 156.111

The rule proposes to allow states to select other state EHB benchmark plans, or new ones from among a state's three largest small group plans. This means that some states, in an effort to reduce healthcare costs as much as possible, could select an EHB plan from another state that has more limited benefits and imposes more cost-sharing on patients. Permitting such variation in covered benefits, despite mandated categories of EHBs, will promote highly varied and potentially inadequate benchmark standards in states that may not include the full range of health care services that people with chronic respiratory and critical illnesses and sleep disorders need. We are gravely concerned that this proposal to allow broad variation in EHB benchmark plans will significantly affect health care access for the residents of some states, which include people with chronic respiratory conditions and other vulnerable populations who require access to appropriate providers and full insurance coverage of critical diagnosis, treatment and prevention services across all of the Affordable Care Act's 10 essential health benefit categories.

The ATS is similarly deeply concerned by the proposal to permit states to allow insurers to shift benefit value across the 10 EHB categories, with the exception of the prescription drugs category. This proposal could permit insurance plans to cut coverage in one critical EHB category, for instance out-patient services, if it increases coverage benefits in another separate EHB category, such as in-patient services. The shifting of benefit values across EHB benefit categories could leave patients with chronic respiratory conditions such as COPD who need comprehensive coverage across all EHB categories to have unexpected, significant gaps in their insurance coverage and be left with exorbitant out-of-pocket costs for needed treatments, forcing some people to forgo needed care. Skimpier EHB benchmark plans coupled with the shifting of benefit values across EHB service categories proposed in the rule will result in more untreated, exacerbated illness, with more children and adults unable to attend school or work and higher long-term health care costs in states that choose these options.

Adverse selection in insurance markets

In addition to watering down EHB benefit packages and potentially increasing costs for certain health care services and treatments, an end result of these proposals could be more adverse selection in state insurance markets that could extend more broadly across the U.S, destabilizing all insurance markets. In states where more basic health benchmark plans are available, young, healthy consumers could move to the cheapest plans, while patients with expensive chronic conditions, such as COPD and lung cancer will have to buy much more insurance because they have no other choice.

The end result could be adverse selection and race to the bottom spirals that ultimately cause insurance markets to collapse, leaving people with chronic conditions unable to afford health insurance coverage at all and without access to needed care - an unacceptable situation.

National Prescription Drugs Benefit Standard

The proposed rule notes that the Department is considering creation of a national benchmark plan standard for prescription drugs. The ATS is concerned about this proposal due to historical problems with drug formularies which have included a lack of appropriate consideration of the needs of individual patients, including those with rare diseases, and the absence of mechanisms to enable quick adoption of innovative new drugs. Access to prescription drugs is a critical health benefit for all Americans, but particularly for people with chronic respiratory illnesses. Patients with diseases such as asthma, COPD, cystic fibrosis, sarcoidosis, and pulmonary fibrosis, typically require multiple prescription drugs from within a single drug treatment category (i.e. pulmonary bronchodilator inhalers) to achieve effective disease control. Multiple modalities of mucolytic therapy (i.e. nebulizers, chest percussion devices) are also often necessary.

Prior to enactment of the Affordable Care Act, it was not unusual for ATS members to have patients struggling to prioritize between purchasing needed inhaler medication and buying food for their family. Ensuring access to life-saving medication to control chronic respiratory diseases enables patients to control their disease and attend school and work regularly, avoiding costly emergency department and hospital admissions. If the Department moves to create a national benefit standard for prescription drugs, the ATS urges that ensures open access to medications, guaranteed access to medications that patients with respiratory diseases, critical illnesses and sleep disorders need, including combination therapies. Finally, a national prescription drug benefit must include all medications approved by the Food and Drug Administration for treatment of tobacco use and dependence, including over-the-counter (OTC) medications, with no co-pays, deductibles or plan limits.

Implementation Date - § 156.000

The Department requests comment on whether the EHB policy changes outlined in the proposed rule should be implemented in 2019 or 2020. If the EHB state flexibility policy changes are maintained in the final rule, the ATS urges the Department to delay implementation of the policies until 2020 to give states and insurers adequate time to prepare for these substantial changes in health care coverage standards and policy. We are especially concerned that states have adequate time to draft and finalize standards and policies that will significantly affect health care access for their residents, which include people with chronic respiratory conditions and other vulnerable populations such as children and the elderly.

Medical Loss Ratio - §§ 158.221 – 158.322

The rule proposes to allow insurance companies to report a medical loss ratio (MLR) of 80% rather than “report the issuer’s actual expenditures to improve health care quality”. Without reporting an insurer's actual expenditures, there is no way to verify the 80% MLR. The ATS is concerned that this proposal could result in increased premiums and less healthcare services for patients, as issuers would no longer have an incentive to meet the 80% MLR. The ATS is also concerned that the rule’s proposal to permit state flexibility in establishing lower MLR could create a marketplace where it is challenging for consumers to fully understand the value of their health insurance or to compare competing insurance plans. Although we recognize the importance of giving states flexibility to experiment with models of health care delivery, we believe there should be an MLR floor required of all states to preserve value transparency for consumers. The ATS recommends that the final rule retain the current 80% MLR in the individual market and 85% in the large group market to ensure consumer value in insurance coverage.

Navigator Program - §155.210
The ATS is concerned that the reduction in ACA navigator exchange service in 2017 has impacted access to care for people with chronic conditions who need information about health plan choices. With potentially significant changes in the type of health coverage that will be offered on exchanges following implementation of this rule, it is critical that consumers have access to trained support provided by navigators who have awareness of the communities and consumers in their exchange areas. But the rule proposes to remove the requirement that at least one of the navigators have a physical presence. The ATS believes this proposal may hinder patient access to needed care and urges the Department not to include it in the final rule. The inclusion of navigators from nonprofit groups should remain a part of the Exchange program.

Federal Default Definition of EHB
The proposed rule states that the Department is considering a federal default definition of EHB, noting that a federally-defined benefit package was recommended by the Institute of Medicine in its 2011 report. The ATS supports the current federally-defined EHB package rather than this rule's proposals to permit states to create their own EHB standards because these proposed policy changes will promote inconsistent benefits standards across the country, creating significant coverage gaps and barriers to needed care for people in some states. We urge the Department to ensure access to needed diagnosis, treatment and prevention services for all Americans. In the final rule, we urge the Department to require the following services in order to ensure the consistent EHB package of health care services that all Americans need.

EHB Tobacco Cessation Benefits
Cigarette smoking is the leading cause of illness and death in the U.S., responsible for one in five deaths. 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 services for treatment of tobacco dependence, ranging from pharmacological therapies to counseling services through specific inclusion of these services in state EHBs. 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 reduce future health system costs.

Although the Department's regulation on EHB standards indicated that tobacco cessation services should be included as a covered benefit under preventive services, there is variation of coverage in private health plans across states. The ATS urges the Department to require that state EHBs cover tobacco cessation treatment using the Federal Employees Health Benefits Program (FEHB) as the benchmark benefit, including duration of therapy, in accordance with the 2008 U.S. Public Health Service guideline, *Treating Tobacco Use and Dependence* and the U.S. Preventive Services Task Force (USPSTF) 2015 Recommendation.[i] The benefit 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.

Asthma
According to the CDC, about 25 million Americans, including over 6 million children, have asthma.[ii] Comprehensive asthma management and education is critical to controlling asthma and preventing dangerous and costly exacerbations. In the final rule, the ATS urges the Department to provide specific guidance to states based on the cover the National Asthma Education and Prevention Program (NAEPP) guidelines, to ensure patient access to all medically necessary asthma therapies including medications and asthma management strategies and education, including in-home asthma trigger assessments and case management.

Access to Sleep Medicine
Research has shown that sleep-disordered breathing and sleep-related illnesses affect an estimated 50-70 million Americans.[iii] The public health impacts are still being determined, but are known to include increased mortality, traffic accidents, lost work and school productivity, cardiovascular disease, obesity, mental health disorders, and other comorbidities.[iv] Care through sleep physicians is critical to the evaluation and management of patients with sleep disorders. The ATS urges the Department to include specific guidance to states in the final rule to ensure that diagnosis and treatment of sleep disorders is included in state health plan EHBs.

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. The Independence at Home pilot program for Medicare, enacted under the Affordable Care Act, is one such federally-supported model for these services that has been shown to reduce Medicare costs.[v] In the final rule, the ATS urges the Department to provide specific guidance for state EHB coverage of at-home care for patients with chronic diseases under the ambulatory patient services care 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 in the final rule to ensure open access to immunizations against influenza and prevention, diagnosis and treatment services for tuberculosis with no co-pays in order to protect public health from these airborne diseases.[vi]

The ATS appreciates the opportunity to comment on this important rule and welcomes all other opportunities to work with the Department to ensure access to affordable and appropriate health insurance coverage for all Americans.

Sincerely,

Marc Moss, M.D.
President
American Thoracic Society

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[i] https://www.opm.gov/healthcare-insurance/special-initiatives/quit-smoking/
[ii] Centers for Disease Control and Prevention. National Center for Health Statistics. National Health Interview Survey, 2015.
[iii] Wickwire EM, Collop NA. Insomnia and sleep-related breathing disorders. Chest 2010;137:1449-63.
[iv]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.
[v] Affordable Care Act payment model continues to improve care, lower costs. Centers for Medicaid and Medicare Services. 8/9/16.
[vi] Department of Health and Human Services Strategic Plan FY2014 – 2018. https://www.hhs.gov/about/strategic-plan/index.html. Accessed Nov. 16, 2017.