
COALITION FOR ACCESSIBLE TREATMENTS

December 21, 2015

The Honorable Sylvia Mathews Burwell
Secretary of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Re: Comments on *Notice of Benefit and Payment Parameters for 2017 Proposed Rule*, CMS-9937-P

Dear Madame Secretary:

On behalf of the Coalition for Accessible Treatments (CAT), the undersigned organizations provide comment on the Notice of Benefit and Payment Parameters for 2017 Proposed Rule (80 FR, Dec. 2, 2015). CAT is a coalition of more than 30 advocacy organizations representing millions of Americans living with chronic and rare diseases and conditions, and the physicians who treat them. Our goal is to ensure all Americans have access to critical life-changing and life-saving medications. Below are our comments on key provisions in the proposed rule that most impact our patients.

Standardized Plans

While CAT appreciates the inclusion of specialty tier drugs in the list of deductible-exempt expenses, we are extremely concerned with the co-insurance levels in the specialty tier categories. Many of our patients rely on specialty drugs to manage their disease, and these high co-insurance levels put these vital drugs out of reach for most patients. The trend towards higher co-insurance levels is troubling and sets a dangerous precedence for not only Exchange plans but other plans as well.

According to recent report from Avalere, more than a quarter of Exchange plans put all drugs in a class for several disease areas on the specialty tier, including oncology and multiple sclerosis (MS). The number of Exchange plans requiring 30% or higher co-insurance is also rising each year, with more than a fifth of all plans requiring at least 30% coinsurance for all drugs in five classes, and more than 15% of Exchange plans requiring more than 40% co-insurance for all drugs in the classes of HIV, MS, oncology and hepatitis. In the example of HIV medications, with annual costs reaching \$20,000 on average, a 30% or 40% co-insurance means that people living with HIV incur very high out-of-pocket costs in the earliest months of the plan year, until

out-of-pocket limits are reached. Unfortunately, these charges can have the effect of keeping patients from accessing medications because they cannot afford the coinsurance.

In addition, the data show that drug availability and accessibility are more difficult in Exchange plans than employer plans for some of the most serious diseases. For example, there is a significant difference in coverage of drugs for rheumatoid arthritis (RA), MS, mental health and oncology drugs with employer plans covering at least 12% more drugs than Exchange plans in all these cases. In addition, the increasing use of utilization management tools is further hindering accessibility. Utilization management rates in Exchange plans rose 13% from 23% to 36% from 2014-2015, which is three times higher than the growth rate in employer plans. Only 47% of drugs were available on open access in Exchange plans in 2015, down from 58% in 2014 and compared to 78% for employer plans.

CAT urges CMS and HHS to consider the historical context of specialty tiers and cost-sharing rates across markets – not just in the Exchanges – in its methodology for setting co-insurance rates in the standardized plans' specialty tiers. That said, finalizing the rates as proposed would establish a dangerous precedent. Furthermore, the proposed rates are not line with other markets and would place an undue financial hardship on many patients who must have access to these drugs in order to control their disease.

Essential Health Benefits

The Coalition seeks clarification on the proposed amendments to the prescription drug non-formulary coverage appeals process that was finalized in the 2016 rule. The proposed rule seeks to allow state appeals laws to supplant the 2016 rule if they are more stringent than or in conflict with the 2016 rule. Given the breadth of state appeals laws, we seek clarification on the parameters of this exception. We are also concerned that a second level of review could result in a longer appeals process, and seek clarification on how this proposal would be implemented if included in the final rule.

Non-Discrimination

The Coalition is disappointed that the propose rule omitted further guidance or enforcement of Section 1557 of the Affordable Care Act. Many disease states represented by CAT members face discriminatory practices such as adverse tiering and the extraneous use of utilization management tools like prior authorization, non-medical switching and step therapy. Some state officials have recognized and taken action against discriminatory benefit designs. For instance, the Florida Office of Insurance Regulation curbed discriminatory practices with respect to HIV medications offered by Marketplace plans.¹ While welcome, this oversight action unfortunately applies only to HIV medications in one state. Adverse tiering and widespread prior authorization requirements for other drugs, such as hepatitis treatments, are found in Florida and other states. Strong patient protections against insurance discrimination should be

¹ Florida Office of Insurance Regulation, Informational guidance on Florida's form and rate filing process for Patient Protection and Affordable Care Act (PPACA) compliant products in the small group and individual markets, <http://floir.com/siteDocuments/PPACANoticeToIndustry03242015.pdf>

uniform across the states and applicable to all benefits. Therefore, HHS should use its authority to set out specific federal guidelines and prohibitions on discriminatory insurance practices, and set in place a robust monitoring and enforcement process.

Transparency

Transparency is critically important to ensure patients have a clear understanding of their health coverage. The Coalition supports proposed language strengthening the Navigator program, and the attention to post-enrollment assistance, including appealing an adverse coverage decision. Navigators are an important source of information for consumers. A recent Health Affairs study noted that consumers who received in-person support were twice more likely to enroll in an Exchange plan than those enrolling online without this assistance.² Effective participation in the Exchange Marketplace typically required a sustained relationship between the consumer and the assister, and consumers required help with many aspects of health coverage from basic education about the ACA and health insurance to how to receive health care once covered. The study highlights the fact that a quarter of consumers required help post-enrollment on a number of coverage issues, including getting access to off-formulary drugs and communicating with their insurers. Further, the frequency of consumers needing assistance in understanding basic insurance terms was 75%. Navigators and assisters should help enrollees understand the core elements of insurance design, including the difference between co-insurance, co-payment and deductibles, drug tiers and formularies, provider networks and the difference between in-network and out-of-network, and appeals. The study also detailed uneven implementation of assistance programs across states, so it is important that the requirements listed in the proposed rule apply to consumer assisters in addition to Navigators. Assisters surveyed noted a need for more training, with 39% in the first year and 29% in the second year reporting a need for further training on how to better select an insurance plan.

It is also important that insurance coverage is fully transparent to prospective and current enrollees. Because many of our patients rely on specialty drugs and may be subject to co-payments, deductibles and co-insurance, they need to know exactly how much they will be paying out-of-pocket for their health care *before* they purchase an insurance plan. Plan disclosure should include at a minimum drug formulary and tier placement for each drug; co-payment, co-insurance and deductible levels; and up-to-date provider directories. The inclusion of the out-of-pocket cost calculator this enrollment season is a positive step towards ensuring consumers have an easy tool to estimate their out-of-pocket costs. However, there have been reports that the cost calculator and other aspects of healthcare.gov are not always accurate and easy to use. We urge HHS to continue to make transparency a priority and continue to refine these tools in the coming months and years.

² Grob, Rachel; Schlesinger, Mark. "Educating, Enrolling, and Engaging: The State of Marketplace Consumer Assistance Under the Affordable Care Act." *Health Affairs*. Vol 34, No. 12: 2052-2060

We appreciate the opportunity to engage with HHS on access to treatment issues for the millions of patients that our groups represent. Should you have questions or if we can be of assistance, please contact Anna Hyde, Director of Health Policy and Federal Affairs with the Arthritis Foundation at ahyde@arthritis.org or 202-887-2917.

Sincerely,

The AIDS Institute
Alpha-1 Foundation
American College of Rheumatology
American Autoimmune Related Diseases Association
Arthritis Foundation
GBS|CIDP Foundation International
Hemophilia Federation of America
Hepatitis Foundation International
Immune Deficiency Foundation
Lupus and Allied Diseases Association
Lupus Foundation of America
National Eczema Association
National Hemophilia Foundation
National Organization for Rare Disorders
National Psoriasis Foundation
Patient Services Incorporated
Pulmonary Hypertension Association
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