

August 24, 2016

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

Re: 2017 Qualified Health Plan Review and 2018 *Notice of Benefit and Payment Parameters* Rule & Letter to Issuers

Dear Madame Secretary:

On behalf of I Am Essential, a coalition of patient and community organizations representing millions of patients and their families dedicated to successful implementation of the Affordable Care Act (ACA), we write today to express our support for your Administration's leadership and to ask for your continued commitment to implementing the strong patient protections contained in the ACA. We believe more can be done to improve access to Essential Health Benefits and address discrimination against beneficiaries with chronic and serious health conditions enrolled in Qualified Health Plans (QHPs). In particular, we want to call your attention to our ongoing concerns about prescription benefit coverage and discriminatory benefit design as you conduct the final review of 2017 QHPs and prepare your Administration's last *Notice of Benefit and Payment Parameters* (NBPP) Rule and Letter to Issuers.

2017 QHP Review & Certification

With the final ACA Section 1557 nondiscrimination rule in place, we urge the Center for Consumer Information & Insurance Oversight (CCIIO) to critically examine proposed 2017 QHPs prior to certifying them for potentially discriminatory benefit designs in compliance with the final rule. As we have noted before, too many enrollees have faced discriminatory benefit design by some insurers. Examples include failing to cover certain medications or placing all medications to treat a condition on the highest cost-sharing tier; failing to follow widely accepted treatment guidelines; imposing excessive medication management tools such as unreasonable prior authorizations and/or step therapy; charging excessively high cost-sharing; mid-year formulary changes; requiring patients to switch medications for non-medical reasons; and having narrow provider networks that fail to include sufficient specialists to treat certain conditions. While we have previously voiced our concern that the Section 1557 rule does not go far enough in defining these discriminatory plan benefit design practices, your Administration has repeatedly stated that through rigorous enforcement, you will protect beneficiaries with serious and chronic health conditions from discriminatory plan design.

We support the positive guidance in prior years' Letters to Issuers and NBPP rules and acknowledge resulting coverage improvements. However, new data and analyses from Avalere Health¹, the National Alliance of State & Territorial AIDS Directors (NASTAD)² and others show that medication coverage gaps still exist and some plans continue to use high co-insurance, adverse tiering, excessive medical management and other practices that restrict access to necessary treatments.

For example, many QHPs do not include drugs commonly used to treat certain types of epilepsy, and many do not cover the drugs that are recommended in a condition's treatment guidelines (e.g., 20% of QHPs cover only one single-tablet HIV regimen). Furthermore, many QHPs still place medications to treat chronic and serious conditions on the highest cost-sharing tier or specialty tier, limiting access. In fact, some plans engage in adverse tiering by placing all medicines, including generics, for some conditions on the specialty tier. Even more common, some QHPs place all branded drugs to treat a condition on the specialty tier, which harms patients because these drugs are often not interchangeable.

Specific examples from the Avalere analysis of Silver QHPs show that, in 2016:

- Plans place single-source drugs to treat multiple sclerosis (50% of plans) and cystic fibrosis (44%) on specialty tiers, and much more frequently than employer plans do.
- As many as 15% of all Silver QHPs nationwide require 40% or higher beneficiary coinsurance for all covered drugs in certain classes used to treat cancer (10-15% of plans); multiple sclerosis (11%); and HIV (9%).
- More plans required greater than 40% co-insurance for all covered single-source antidepressants (12%), atypicals (12%), and bipolar (13%) drugs than in 2015.
- 35% use prior authorization and step-therapy for single-source drugs, a 5% increase in utilization management from 2015.
- QHPs increased utilization management of hepatitis and mental health medications by more than 15% and oncology and immune medications by more than 10% from 2015.

The ACA is helpful for those with pre-existing conditions because insurers cannot refuse to cover them or charge them higher premiums. However, when these same QHPs put necessary drugs out of coverage reach or implement excessive utilization management such as step-therapy, they dissuade patients who have an established treatment regimen that is working for them or whose condition demands flexible, easily customizable treatment options, from enrolling. This completely undermines the goal of the ACA. Insurers may do this because they want to avoid an influx of enrollees that they perceive as costly. This is especially discriminatory against people with chronic conditions like cancer, HIV, multiple sclerosis, and other diseases

¹ PlanScape Review of Patient Access to Medicines in Exchange Plans, Avalere Health, April 2016

² Discriminatory Design: HIV Treatment in the Marketplace, NASTAD, July 2016

and disorders.

2018 NBPP & Letter to Issuers

We urge you to take the opportunity in this Administration's final round of QHP guidance and rulemaking to reiterate and expand on the important patient protections already in place. Specifically, to prevent the continuation of the above-mentioned discriminatory practices and to provide clarity to state and federal regulators now and in the future, HHS *must* include provisions in the next NBPP and Letter to Issuers that make it clear that certain benefit designs are discriminatory and QHPs will not be certified for the Marketplace if they employ such designs.

While we support the continued use and development of tools such as the formulary outlier, clinical guideline, and tier placement reviews, we believe more standards and parameters for benefit and plan design should be detailed in the final rule so that all QHPs are affirmatively prohibited from employing discriminatory practices with respect to any condition, not just those that are caught as outliers. In particular, regulatory language should expressly prohibit adverse tiering, excluding coverage of combination or extended release products that are customarily prescribed and/or recommended in treatment guidelines, mid-year formulary changes or forcing beneficiaries to switch medications, and requiring prior authorization, step therapy, and/or quantity limits for most or all medications in drug classes regardless of medical evidence.

Beginning with the 2017 plan year, QHPs are required to implement Pharmacy & Therapeutics Committees. We believe this is a critical step forward in ensuring QHPs use thorough and transparent processes and provide more comprehensive coverage. While the P&T Committee parameters and requirements outlined in the current rule are a good foundation, we encourage the Administration to strengthen these requirements and remind QHPs of their obligations. In particular, we believe that P&T Committees should be required to use advisory committees or expert panels so that specialists with relevant expertise are consulted for all formulary coverage decisions.

In addition to prohibiting discrimination and improving formulary development processes, we believe this rulemaking provides the opportunity to do more to ensure beneficiaries are provided affordable, comprehensive QHP options. We are grateful for the implementation of the "standardized options" in 2017 on a voluntary basis. However, to fully realize the benefits that standardized plans can afford, we believe insurers should be required to offer the standardized options and that none of these options should include co-insurance. Therefore, we encourage HHS to refine the standardized options in the 2018 NBPP to mandate that insurers offer standardized QHP options that provide comprehensive coverage with transparent and minimal beneficiary cost-sharing.

Finally, we look forward to inclusion of prescription drug data in the risk adjustment program as announced in the June 8, 2016 Centers for Medicare and Medicaid Services press release, "Strengthening the Marketplace." An accurate, well-managed risk adjustment program can

benefit all stakeholders. The Administration must do everything in its power to reduce incentives for issuers to design plans that attract a disproportionately healthy risk pool, and we agree that the proposed changes to the risk adjuster is an important step in accomplishing this goal.

Stronger non-discrimination protections and improvements to risk adjustment, along with rigorous enforcement, will go a long way toward ensuring the ACA lives up to its promise for all patients.

We greatly appreciate all you and the rest of the Administration are doing to improve the health of all Americans and we look forward to a successful 2017 enrollment season. Thank you for your continued dedication to improving implementation of the ACA so that it meets the needs of patients across the United States.

Sincerely,

Beatriz Duque Long Senior Director, Government Relations Epilepsy Foundation

Carl Schmid Deputy Executive Director The AIDS Institute

Andrew Sperling Director of Federal Legislative Advocacy National Alliance on Mental Illness

cc: Andy Slavitt Acting Administrator Centers for Medicare & Medicaid Services

> Kevin Counihan Director & Marketplace Chief Executive Officer (CEO) Center for Consumer Information and Insurance Oversight