June 25, 2015

By Electronic Submission

Mr. Howard Shelanski
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, D.C. 20503

RE: Comments on HHS/OCR Proposed Rule Under Review at OIRA Titled "Nondiscrimination Under the Patient Protection and Affordable Care Act" (RIN 0945-AA02)

Dear Administrator Shelanski:

We write to express our strong interest in the Department of Health and Human Services (HHS) Proposed Rule regarding *Nondiscrimination Under the Patient Protection and Affordable Care Act* (RIN 0945-AA02), currently under review by the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA).

We represent tens of millions of patients with chronic and serious conditions, for whom affordable, nondiscriminatory access to health care and health insurance is vitally important. It is no exaggeration that, for many patients whom our groups collectively represent, appropriate access to available health care treatments means the difference between life and death. For countless others, it means the ability to maintain employment, the ability to function without debilitating pain, or the ability to care for themselves or others without assistance. For these reasons, we have supported the Administration's efforts to implement the nondiscrimination protections under the Affordable Care Act (ACA)—protections that are essential to the success of the law and to achieving its chief aims to expand access to affordable health insurance coverage for people across America, including those with pre-existing conditions and significant health needs.

These core ACA goals simply cannot be realized without strong, clear, and consistently enforced protections against discrimination. We applaud the inclusion of specific provisions in the ACA that mandate such protections, including protections against discrimination based on individuals' health conditions or significant health needs.[1] We are pleased, as well, that the HHS Office for Civil Rights has developed a formal Proposed Rule to implement these critical ACA nondiscrimination requirements.

We have long advocated for increased clarity, improved transparency, and stronger enforcement with respect to the ACA's nondiscrimination protections. Our efforts have included participation in prior HHS rulemakings through public comments, previous communications with OIRA, and

[1] ACA § 1311(c)(1)(A); § 45 C.F.R. § 156.225(b); *see also* ACA § 1302(b)(4);45 C.F.R. § 156.125.

ongoing engagement with both federal agency representatives and congressional offices about the experiences of patients to date and the importance of appropriate implementation of these critical protections. (For reference, we have attached prior correspondence that we sent to your office regarding the Essential Health Benefits (EHB) standards under the ACA, including the nondiscrimination standards required for EHB.)

In our efforts, we have worked to ensure that the ACA's nondiscrimination protections and EHB package are implemented in a manner that truly protects patients with serious and chronic conditions from discrimination based on health status, as the ACA requires. These ACA requirements include the identification of prescription medications as one of the ten categories of benefits that non-grandfathered individual and small group health plans, including qualified health plans offered through the ACA-created exchanges, must provide to enrollees under the EHB package. Through these requirements, the ACA requires plans to cover medicines in an affordable and nondiscriminatory manner.

These requirements make sense clinically as well as fiscally. Real-world data demonstrate that meaningful access to medications is vital when managing serious and chronic conditions, including cancer, HIV/AIDS, epilepsy, mental health disorders, and autoimmune conditions, as well as immune system responses to organ transplantation. The Congressional Budget Office (CBO) and multiple other sources have found that meaningful access to medicines contains costs by reducing spending on other medical services. For example, appropriate management of serious and chronic conditions, including with prescription drugs, leads to reduced costs and decreased societal burdens by reducing emergency room visits and hospitalizations, preventing relapses, slowing the deterioration of conditions, and increasing productivity.

Therefore, before this Proposed Rule is released, we hope you will take into account our high-priority concerns and recommendations with respect to the ACA's nondiscrimination protections.[2] Our key concerns and recommendations, briefly, include the following:

- **Nondiscrimination standards under the ACA must focus on the discriminatory impact of practices, consistent with other civil rights laws.** The Proposed Rule must recognize that a practice is discriminatory if its *effect* is to discourage patients with certain conditions or with significant health needs from enrolling in the plan, regardless of whether there is evidence that the plan had an *intent* to discriminate. The ACA expressly compels this effect-based standard.[3]

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[2] While we understand the Proposed Rule's scope includes numerous types of discrimination in health care, such as discrimination based on race, color, national origin, sex, age, or disability, pursuant to ACA § 1557, we focus here on the ACA nondiscrimination protections that expressly require the Secretary to ensure that plans do not discriminate against individuals based on an individual's significant health needs or health condition. ACA § 1311(c)(1)(A); 45 C.F.R. § 156.225(b); 45 C.F.R. § 156.125.

[3] ACA § 1311(c)(1)(A) (requiring the Secretary to establish, by regulation, criteria for the certification of health plans, and specifying that such criteria "shall require that, to be certified, a plan shall, at a minimum . . . not marketing practices or benefit designs that *have the effect* of discouraging the enrollment in such plan by individuals with significant health needs." ACA § 1311(c)(1)(A) (emphasis added); 45 C.F.R. § 156.225(b).

- **Robust formularies are needed for medications in therapeutic classes where the available treatments are not interchangeable.** The Proposed Rule must ensure that HHS establishes minimum, uniform standards for formulary design that prevent discriminatory benefit designs or implementation. A part of these standards, we believe that patients must have access to "all or substantially all drugs" in certain drug classes for which the available treatments are not interchangeable. Protecting patients' access and choice to their physician-directed drug therapy is important not only to maintain the health of vulnerable populations, but also to ensure the efficient use of health care dollars. A similar policy is in place under Medicare Part D's nondiscrimination protections.
- **Physicians, not plans, should define medical necessity.** Physicians, not plans, should determine in their clinical judgment whether chronically ill patients need access to clinically appropriate drugs not on a health plan's formulary.
- **Parameters for medical management techniques are needed.** Current EHB rules include protections against discrimination, but undermine those protections by permitting plans to use "reasonable medical management techniques" to restrict access. 45 C.F.R. § 156.125(c). The regulations at present do not define or provide parameters for what types of practices are and are not "reasonable" medical management techniques. Such parameters should be included in the Proposed Rule. For example, prior authorization policies and "fail first" or step therapy requirements should not be permitted for classes of medications that treat serious and chronic conditions.
- **Cost-sharing policies must be reasonable and transparent.** Cost-sharing structures that rely on "coinsurance" policies, for example, often impose unreasonable burdens on enrollees and, in most cases, are both excessive and opaque. Plans must be required to ensure that patients' cost-sharing obligations are affordable and clearly disclosed.
- **Specific parameters for formulary tiering structures and for "specialty" drug categories are needed.** Discrimination based on health status results when most or all medicines in a particular category or class are placed on the highest formulary tier(s). We also are concerned that a number of plans have sought to classify certain therapeutic categories of medicines as "specialty" drugs and then use the "specialty" label as a basis for imposing onerous access restrictions and prohibitively high cost sharing. Regulations should expressly prohibit these and other formulary tiering designs that discourage enrollment based on an individual's health condition or significant health needs, which the statute prohibits.
- **Plans should be required to attest to their compliance with the ACA nondiscrimination standards.** As one model, the Florida Office of Insurance Regulation requires an attestation by individual and small group plans, which, among other standards, requires plans to attest to their satisfaction of several specific requirements with respect to prescription drug coverage. This attestation, available at http://www.floir.com/siteDocuments/FormularyAttestation.pdf, is consistent with federal law and guidance issued to date, and provides a model approach for the implementation of the ACA's nondiscrimination requirements going forward.

- **Clear and consistent oversight and enforcement at the federal level is essential to meaningful nondiscrimination protections.** Strong and consistent enforcement at the federal level is essential to the successful implementation of these provisions. Even if states retain some responsibilities with respect to monitoring and enforcing these requirements, strong federal oversight is imperative to ensure appropriate and consistent enforcement.

In light of the critical importance of these issues, we urge OIRA to ensure that this Proposed Rule is not publicly released unless and until it appropriately addresses these areas of concern. In addition, we would like to meet with you or appropriate OIRA staff to discuss in more detail the issues outlined in this letter, and will submit a request to that end.

Sincerely,

American Autoimmune Related Diseases Association, Inc.
Virginia Ladd, President

Epilepsy Foundation
Angela Ostrom, Chief Operating Officer

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

National Council for Behavioral Health
Rebecca Farley, Director, Policy and Advocacy

National Kidney Foundation
Troy Zimmerman, Vice President for Government Relations

The AIDS Institute
Carl Schmid, Deputy Executive Director

Attachments

cc: Ms. Mabel E. Echols, OIRA

cc: Mr. Kevin Counihan, Deputy Administrator and Director, Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services (CMS)

cc: Mr. Andrew M. Slavitt, Acting Administrator, CMS

cc: Dr. Meena Seshamani, Director, Office of Health Reform, Department of Health and Human Services (HHS)

cc: The Hon. Sylvia Mathews Burwell, Secretary, Department of Health and Human Services

November 20, 2014

Mr. Howard Shelanski
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, D.C. 20503

Dear Administrator Shelanski:

We write to express our strong interest in the Department of Health and Human Services' Proposed Rule regarding *CY 2016 Notice of Benefit and Payment Parameters* (CMS-9944-P), currently under review by the Office of Management and Budget (OMB). As representatives of tens of millions of patients with chronic and serious conditions, who strongly supported the passage of the Affordable Care Act (ACA) and are significantly affected by its implementation, we are deeply interested in the Essential Health Benefits (EHB) package, particularly its prescription drug coverage requirements. We are intently focused on helping to ensure that the President's chief aim for the ACA—to achieve access to affordable health insurance coverage for individuals across America—is realized, and that the ACA is implemented in a manner consistent with the letter and spirit of the law.

To that end, before this Proposed Rule is released, we hope you will take into account our high-priority concerns and recommendations in order to ensure that Marketplace plans' prescription drug coverage offers meaningful access to critical medications, especially for those suffering from epilepsy, mental illness, kidney disease, HIV/AIDS, and autoimmune disease. In the spirit of partnership with the Administration on ACA implementation, we met with the Center for Consumer Information & Insurance Oversight (CCIIO) staff on October 16, 2014 to discuss our patients' experiences with Marketplace plans and to provide insights and suggestions for the ongoing implementation efforts. The CCIIO staff encouraged us to continue providing real world examples of the strengths and weaknesses of the Marketplace plans' prescription drug coverage, as well as recommendations for how identified challenges could be resolved.

In follow-up, we recently sent the attached letter to CCIIO staff, outlining our concerns, along with recommendations on how drug coverage may be improved in Marketplace plans. We hope you find this letter helpful in understanding issues facing chronically and seriously ill patients with their Marketplace plans' prescription drug coverage. We encourage OMB not to release

this Proposed Rule publicly until OMB has considered these significant issues and ensured that they are appropriately addressed.

To summarize, our patients' most immediate concerns with respect to implementation of the EHB package are as follows:

- Limited benefits that result from:
  - formulary restrictions
  - reliance on USP categories and classes in benchmark plans
  - lack of processes for adding new drugs to formularies
  - restrictive and onerous utilization management practices
  - limitations in the appeals processes

- High drug cost-sharing that results from:
  - high co-pays and co-insurance rates
  - increasing use of specialty tiers for lifesaving medications
  - increasing placement of entire categories/classes of medications (even generics) for some conditions on the most expensive tiers

- Inadequate transparency in formularies, including:
  - incomplete formulary information
  - limited details on utilization management practices, drug coverage, and cost-sharing requirements

- Discriminatory practices, including:
  - restrictive formularies, onerous utilization management requirements, and high cost-sharing obligations which in many cases are targeted toward treatments for particular health conditions or have a disparate impact on individuals with serious and chronic conditions
  - lack of clear definitions and standards for discriminatory practices, resulting in situations where individuals with certain health conditions are discouraged from enrolling in some Marketplace plans
  - lack of strong and consistent enforcement against such practices

The attached correspondence proposes solutions to these significant issues, including: strengthening the EHB benefit requirements; reducing high cost-sharing; improving the transparency of plan information available to consumers; and clearly defining non-discrimination standards.

As your office reviews this important Proposed Rule, we encourage you to consider carefully the points highlighted in the attached letter. We sincerely hope the Proposed Rule, when issued, will address these priority issues appropriately. These issues are critically important to patients across the country and to the overarching goals of the ACA.

If you have any questions, we would be pleased to meet with you to have a more detailed discussion regarding the issues outlined in this letter.

Sincerely,

American Autoimmune Related Diseases Association, Inc.
Virginia Ladd, President

Epilepsy Foundation
Angela Ostrom, Chief Operating Officer

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

National Council for Behavioral Health
Rebecca Farley, Director, Policy and Advocacy

National Kidney Foundation
Troy Zimmerman, Vice President for Government Relations

The AIDS Institute
Carl Schmid, Deputy Executive Director

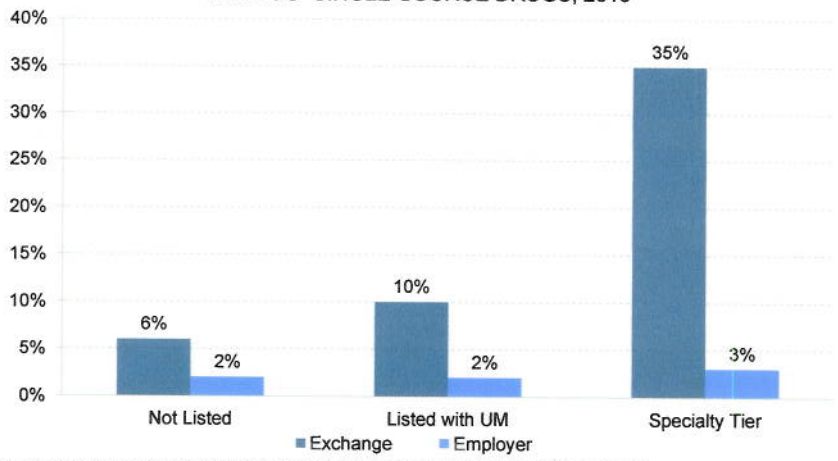
Attachment

cc: The Hon. Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services

cc: The Hon. Sylvia Mathews Burwell, Secretary
Department of Health and Human Services

Exchanges Use Most UM for HIV/AIDS Medicines, Specialty Tier Use Greater than Employer Plans

COVERAGE, UM, AND SPECIALTY TIER PLACEMENT FOR HIV/AIDS[1] SINGLE-SOURCE DRUGS, 2015



1 Includes Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs), Nucleoside and Nucleotide Reverse Transcriptase Inhibitors (NRTIs), Protease Inhibitors (PIs), and HIV-Other
Note: Coverage is weighted according to unique plan-state combinations. Sample includes silver plans in 6 states (FL, GA, IL, NC, PA, and TX) relying on HealthCare.gov, and CA and NY. For the purpose of this analysis, "coverage" means formulary inclusion. Avalere excluded physician-administered drugs from this analysis, except when comparing to state benchmark minimums.
Source: Avalere Health PlanScape®, a proprietary analysis of exchange plan features, February 2015. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.
UM = Utilization Management

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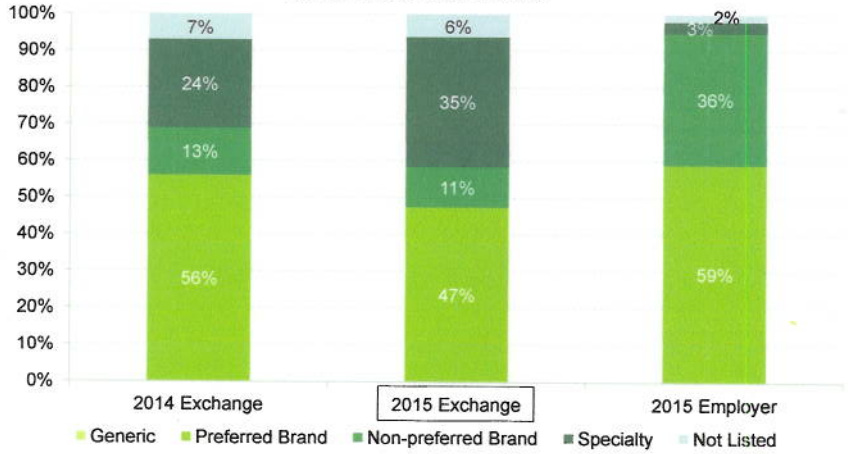
Specialty Tiering for HIV/AIDS Medicines Grew Markedly in 2015

TIER PLACEMENT FOR HIV/AIDS[1] SINGLE-SOURCE DRUGS



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Source: Avalere Health PlanScape®, a proprietary analysis of exchange plan features, February 2015. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

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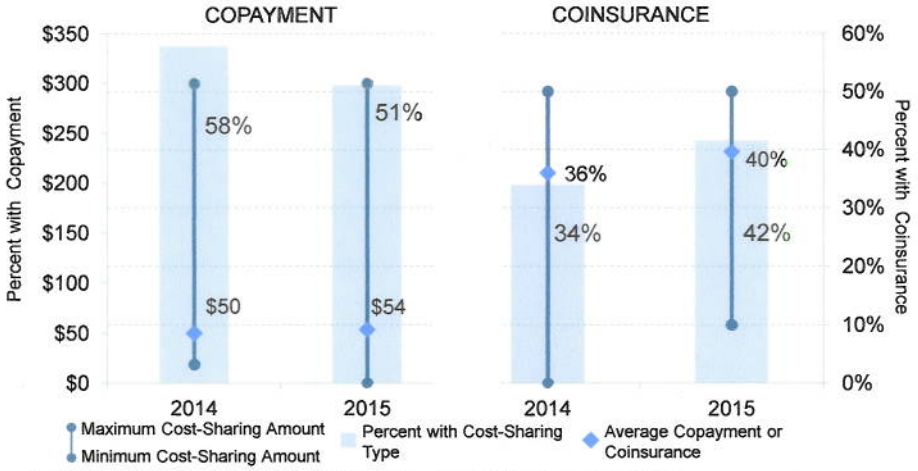
Use of Coinsurance For HIV/AIDS Drugs Increased in 2015, But Copays Still Common Form of Cost Sharing

PERCENT OF EXCHANGE PLANS WITH COST-SHARING TYPE AND RANGE OF AMOUNT, FOR HIV/AIDS[1] SINGLE-SOURCE DRUGS



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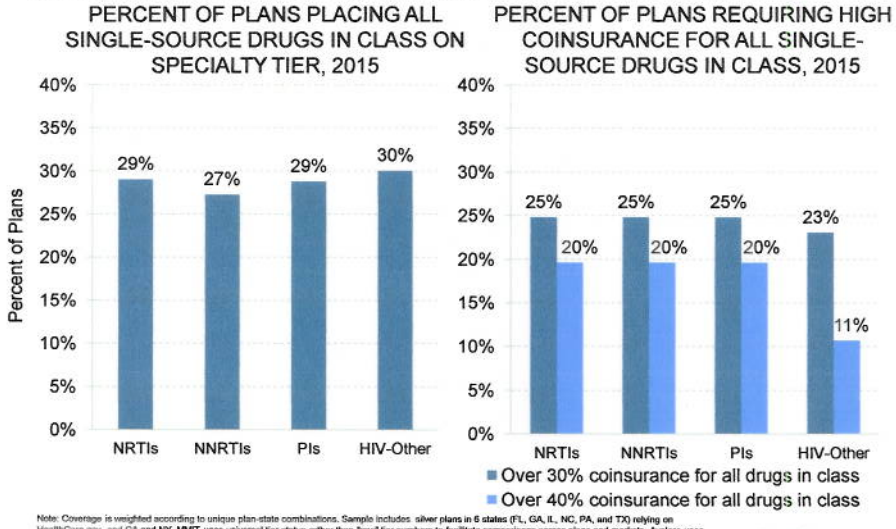
Source: Avalere Health PlanScape®, a proprietary analysis of exchange plan features, February 2015. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

Avalere | 6

Plans Place Single-Source HIV/AIDS Medications the Specialty Tier About 30% of the Time



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