



November 9, 2015

The Honorable Sylvia M. Burwell
Secretary
U.S. Department of Health and Human Services
Office for Civil Rights
Attention: 1557 NRPM (RIN 0945-AA02)
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: RIN 0945-AA02—Nondiscrimination in Health Programs and Activities

Dear Secretary Burwell:

The Regulatory Education and Action for Patients (REAP) coalition appreciates the opportunity to comment on the Department of Health and Human Services' (HHS) proposed rule, "Nondiscrimination in Health Programs and Activities" (RIN 0945-AA02). REAP strongly supports the proposed rule's intent to both clarify and codify existing nondiscrimination requirements, and set forth new standards to implement Section 1557 of the Affordable Care Act (ACA) with respect to the prohibition of various forms of discrimination in health programs.

Comprised of patient advocacy organizations representing an array of patient issues and conditions, REAP's mission is to ensure that the patient experience is reflected in the federal regulatory and rule-making process. Our coalition convenes the nation's leading patient advocacy and public health organizations to advocate for the implementation of policies that will improve outcomes, affordability and access to health care for patients across the country. By bringing together a broad cross-section of patient-driven organizations, REAP is able to evaluate and build consensus on a wide range of patient concerns and ensure that those concerns are considered in policy development and implemented with a patient-centric focus.

We believe that the provisions regarding grievance procedures and notification requirements provide additional recourses for beneficiaries to ensure they are aware of and able to assert their rights under the law. However, while patients can no longer be denied coverage or charged higher premiums based on their health status, we are concerned that insurers may instead be designing coverage and benefits packages that deter certain patient populations from enrolling in their plan, effectively discriminating against them. Because one of the central aims of the ACA is to expand access to healthcare and health coverage for all individuals, guaranteeing access to necessary medical care for all patients, regardless of their condition, is essential to achieving that goal. REAP believes that expanding on the protections of this proposed rule would bolster the enforcement of Section 1557 and ensure that essential healthcare services are broadly available to individuals throughout the country, irrespective of their current health status. As you work to finalize this proposed rule, we offer the following comments:

Designation of Responsible Employee and Adoption of Grievance Procedures (§ 92.7)

REAP supports the proposed requirements that covered entities designate at least one responsible employee to coordinate that entity's compliance with the nondiscrimination requirements of Section 1557, and that covered entities adopt grievance procedures to ensure the timely and equitable resolution of complaints of any prohibited discriminatory practices. We believe that the presence of a coordinator and a grievance procedure will help to bring patient concerns to a prompt resolution, and thus lead to more efficient outcomes. However, while the current proposal requires only those covered entities that employ 15 or more persons comply with these requirements, we believe that all covered entities, not just those that employ 15 or more persons, should be required to designate a responsible employee and adopt grievance procedures and appropriate due process standards. Doing so would benefit more patients and consumers by reaching more covered entities and allowing them to address any potential compliance issues and incidents of discrimination experienced by patients at an earlier stage and in a less formal manner than a time-consuming and complex investigation conducted by the Office of Civil Rights, which may place additional burdens and barriers for the patient.

Notice Requirement (§ 92.8)

REAP applauds HHS for proposing notification requirements that take into account the needs of those beneficiaries with limited English proficiency and literacy, as well as those with disabilities who may require additional auxiliary aids or supports, to ensure that individuals are aware of their rights under the law. Failures of communication are often a primary contributor to limitations in access to health programs and activities for individuals with disabilities or limited English proficiency, and as such, covered entities must take reasonable steps to provide meaningful access and information to these individuals in a manner that is clear and understandable to them. We support the proposed rule's requirement that each covered entity take the necessary steps to notify beneficiaries, enrollees, applicants, or members of the public of certain important information. Such notice must include a statement that the covered entity provides auxiliary aids and services to individuals with disabilities and language assistance services to individuals with limited English proficiency, free of charge and in a timely manner.

As affordable health insurance becomes more widely available to an increasing number of patients, regardless of their socioeconomic status, background or health condition, it remains critical that HHS and all healthcare stakeholders ensure that all consumer-facing marketing and notification requirements are extended to reach such communities in order to address and eliminate the health disparities among these populations. Doing so will ensure that individuals with a disabilities or limited English proficiency have meaningful access and equal opportunity to benefit from the entity's health programs or activities.

Nondiscrimination in Health-Related Insurance and Other Health-Related Coverage (§ 92.207)

While we appreciate HHS' attempts to define and provide examples of discriminatory practices by insurance plans for certain individuals, REAP is concerned that, as written, the proposed rule lacks sufficient specificity in defining and providing examples of such practices against individuals on the basis of their health status.

We strongly urge HHS to explicitly define and provide additional examples in the final rule of those plan benefit design practices which constitute discrimination against patients, particularly those with serious or

chronic conditions, many of whom are disabled per the definition that applies under Section 1557 and the Americans with Disability Act (ADA). Doing so will serve to demonstrate to insurers how such plan designs can be used to the detriment of those patients.

As you well know, half of all Americans struggle with at least one chronic condition—conditions which require many of the patients whom they afflict to rely on prescription medications to remain healthy and alive. Ensuring that patients with chronic and other serious conditions can access the medication they need to prevent the progression of their condition and manage their overall health is paramount not only to the patient, but also to improving the health of our society and, in the long-term, delivering healthcare at a lower cost.

As such, coverage of prescription medications and formulary design must be addressed in the final rule. One example of a potentially discriminatory plan design that must be explicitly prohibited is the practice of placing all or nearly all medications that treat a certain condition on the highest cost-sharing tier of a formulary, leaving patients with no lower-cost alternatives and thus rendering the necessary medication inaccessible to many of the patients who need them. Indeed, when designed in this manner, formularies can be a particularly effective tool for discouraging individuals with chronic and other serious conditions from enrolling in a particular plan, which is tantamount to discrimination based on a specific health condition. It is therefore critical that HHS clearly define it as such to ensure that plans do not design formularies that result, intentionally or unintentionally, in discrimination against patients.

Moreover, in addition to discriminatory formulary tiering, patients are often faced with other barriers to accessing the care they need as a result of benefit design. For example, plans that do not include coverage for certain medications also deter plan enrollment for such patient populations. Many patients are basing their enrollment decision entirely on cost of premiums, because that information is most widely available, rather than on level of coverage, and thus leaving many patients underinsured when their health plan does not enable them to access the medication or treatment they need to treat their conditions. When a patient enrolls in a plan only to subsequently learn that a medication they need is not covered by the plan they purchased, they are responsible for the entirety of the cost of the medication. This scenario often renders the medication inaccessible.

Imposing excessive medication management tools such as unreasonable prior authorizations and/or step therapy can also discriminate against patients with serious or chronic conditions. In a system that varies widely in terms of cost and quality, prior authorization requirements are intended to serve as a tool for the proper use and management of medical procedures and treatments for the purposes of standardizing care. However, the prior authorization process—typically only required of more expensive therapies rather than generics—is often lengthy and burdensome for patients and providers alike, and creates tremendous problems for patients by delaying their access to life-saving medications. Similarly, step therapy, which is applied to treat a wide range of diseases and chronic conditions, has also been shown to hinder a patient's ability to access their medications, and can lead to adverse outcomes for patients if the duration and effectiveness of required step therapy protocols are not carefully managed. By requiring a patient to try one or more drugs selected by their health plan, primarily based on financial considerations, before coverage is granted for the desired prescribed drug—if granted at all—step therapy has caused delays in optimal treatment for patients. The consequences for patients include increased risk factors and disease progression and can also prevent patients from receiving any treatment at all.

Narrow provider networks represent yet another type of discriminatory benefit design against patients with certain conditions. Such narrow networks create barriers to access for patients in need of specialty or chronic care, many of whom are unable to afford the cost-sharing requirements to see out-of-network providers who are able to treat their specific condition. Due to the access barriers that narrow provider networks and higher cost-sharing create for patients in need of specialty care, in particular for those who may be lower-income, we urge HHS to include in the final rule detailed standards and parameters for benefit design, specifically address formulary design and medication management tools, so that insurers have a clear understanding of what types of practices constitute discrimination. Such clarity will promote understanding of covered entities' obligations and compliance with Section 1557, and the ability of individuals to assert and protect their rights under the law.

Finally, while the inclusion of persons with disabilities as a protected group under Section 1557 appears to offer protections to patients with certain chronic and other serious health conditions under the ADA's definition, it does not protect all patients with chronic health conditions or serious illness. We implore HHS to clarify and expand the definition of who is protected under Section 1557 to encompass such patients and ensure all patients have equal access to healthcare and health coverage provided by the ACA.

Conclusion

REAP appreciates the opportunity to provide comments on this proposed rule. We hope that as you review and finalize the proposed rule, you continue to ensure that all patients are able to access the affordable and comprehensive health coverage they need. We look forward to working with HHS in the future to advance a regulatory framework capable of supporting such a role. REAP members stand ready to answer questions and provide any additional information about the patient groups for whom we advocate.

Sincerely,

Adult Congenital Heart Association
The AIDS Institute
Alpha-1 Foundation
American Autoimmune Related Diseases Association
Arthritis Foundation
Cancer Support Community
COPD Foundation
Cutaneous Lymphoma Foundation
Epilepsy Foundation
Fight Colorectal Cancer
Global Healthy Living Foundation
Hypertrophic Cardiomyopathy Association
International Myeloma Foundation
Kidney Cancer Association
Lung Cancer Alliance
Lymphoma Research Foundation
Men's Health Network

National Alliance on Mental Illness
National Hemophilia Foundation
National Organization for Rare Disorders
National Patient Advocate Foundation
National Viral Hepatitis Roundtable
Ovarian Cancer National Alliance
RetireSafe
State Pain Policy Advocacy Network
Susan G. Komen
US Pain Foundation
Zero - The Project to End Prostate Cancer