



Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9937-P
P.O. Box 8016
Baltimore, MD 21244-8016

December 21, 2015

RE: Comment by the American Plasma Users Coalition (A-PLUS) on “Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017” (CMS-9937-P)

Submitted via www.regulations.gov

To Whom It May Concern:

The American Plasma Users Coalition (A-PLUS) is a coalition of national patient organizations created to address the unique needs of patients with rare diseases that use life-saving plasma protein therapies. The organizations representing these patients share a common desire to ensure that the patient voice is heard when relevant public policies, regulations, directives, guidelines, and recommendations, which have a major impact on their access to safe and effective therapy and treatment are considered. Together, our coalition represents more than 125,000 Americans living with chronic disorders dependent upon plasma protein therapies for their daily living.

With that background, we provide the comments outlined below.

Standardized Option Designs Do Not Protect Patients with Complex, Chronic Needs.

When developing the standardized plan options, HHS must reject co-insurance and institute a copayment on specialty drugs similar to the copayment on non-preferred brands. We further urge that *any* prescription medications should not be subject to a plan’s deductible for *all* metal levels, including bronze.

While the intent to streamline the patient experience in the marketplace with standardized options is noble, we are concerned that the proposed plan designs will harm patients. HHS requests comments on whether the standardized plan designs should be modified, in particular with respect to certain cost-sharing elements such as deductibles or copayments for particular services. Our comment is that there should be major changes, since the out-of-pocket (OOP) burdens on patients, particularly patients with complex needs, have reached prohibitively high levels. The consequence of such high OOP costs is that our patients and families affected by rare and/or chronic diseases frequently have to pay the entire OOP annual max in the first month or two of the year, or even before they can fill the first prescription. These benefit designs are economically discriminatory and pose huge barriers to people accessing the therapies they need to live healthy and productive lives. Moreover, since HHS has highlighted the use of specialty tiers as being a potentially discriminatory benefit design in prior Affordable Care Act regulations, it does not make sense to codify these in the standardized plan options under consideration.

A high-needs patient is unlikely to choose a bronze plan, since, as the NBPP notes, the “2017 bronze standardized option closely resembles a catastrophic plan [.]” However, cost-sharing is excessive on the higher metal levels as well: the silver option “has a \$3,500 deductible, an annual limitation on cost sharing equal to the maximum allowable annual limitation on sharing for 2017, and a 20 percent enrollee coinsurance rate. Primary care visits, mental health/substance use outpatient services, specialist visits, urgent care visits, and all drug benefits are exempt from the deductible, and all of the deductible-exempt benefits have copayments instead of co-insurance, except for specialty drugs, which are subject to a 40 percent coinsurance rate.”

We understand this to mean that all drugs, including specialty drugs, are exempt from the deductible. This is sound policy and we urge HHS to extend this policy to bronze level plans as well. Our concern lies with the 40% specialty drug coinsurance rate. Many of the most complex patients require specialty drugs to manage their conditions, but these drugs can cost thousands of dollars per month, which makes a 40% coinsurance not only an unreasonable burden to bear but also an incentive for patients to forego treatment. Furthermore, specialty drugs are often the only treatment option for patients. This structure often results in the inherently discriminatory practice of forcing one particular group under one payment structure, while most others are afforded other options.

In the case of patients with a primary immunodeficiency (PI) disease, who need the **life-saving and lifelong** immunoglobulin replacement therapy in order to stay alive, to have to stop their monthly infusions for one or two or three months because they can’t afford their share of the cost is tantamount to denial of care. Such a denial of care may lead to death because patients will not have the antibodies that are obtained from infused immunoglobulin to protect them from viruses, bacteria, and fungi.

Patients with Hemophilia, Alpha-1 Antitrypsin, Hereditary Angioedema, Idiopathic Thrombocytopenic Purpura (ITP) and other rare and/or chronic disorders find themselves in similar circumstances of high out-of-pocket costs to access lifesaving therapies. These patients hit the annual OOP max every year and must find the money every year to pay for life-saving treatments. The annual “ceiling” limitation for individuals and families, while a good thing, has become a “floor” for people with rare and/or chronic conditions. People should not be penalized because they are sick and not wealthy.

In addition, because there is no clear definition of what is a “specialty” drug, the determination of what is a preferred brand, non-preferred brand, or specialty drug in any given year is usually decided by opaque negotiations between insurers and manufacturers. This allows insurers to place all of the most expensive medicines on the specialty tier, which, as previously noted, has created a loophole in the preexisting condition discrimination protections provided by the Affordable Care Act.¹

Again, we strongly believe that **any prescriptions, whether generic, brand, or specialty, should not be subject to deductibles or unduly high coinsurances – in any of the metal**

¹ *Modern Healthcare*, “Aetna Revises HIV Drug Policy for All Exchange Plans,” by Bob Herman (March 27, 2015). Accessible: <http://www.modernhealthcare.com/article/20150327/NEWS/150329914>.



levels. Such high OOP costs interfere with patients and families' ability to afford needed medical care. We are pleased that HHS has recognized this for some prescription drugs, but are still concerned that specialty drugs fall outside of those protections.

Network Adequacy Must Be a Qualified Health Plan Certification Criterion.

We urge HHS to establish the showing of an adequate network as a prerequisite to QHP certification.

With regard to network adequacy, we thank HHS for, at a minimum, considering time and distance standards at the county level. The NAIC, in its finalized model, opted for a standard based on accessibility "without unreasonable travel or delay." Given the geographic variations within states, "travel" is likely the better term for a standard intended to be applied statewide. However, we support HHS taking a county-based approach and, with that parameter, we support reasonable time and distance standards.

We also encourage HHS to include access to specialized care as part of network adequacy standards, regardless of specialty utilization rates. Patients with chronic and expensive conditions often need treatment at very specialized facilities, and excluding access to these facilities results in inherently discriminatory plan design. For example, many patients with bleeding disorders are treated at hemophilia treatment centers (HTC). A plan that does not include an HTC in its network would be structuring its design in precisely as discriminatory or discouraging a way as those that place bleeding disorder treatments on the highest specialty drug tier.

As the NBPP notes, the National Association of Insurance Commissioners (NAIC) has updated its network adequacy standards after a year-and-a-half long, public, consensus-driven process. The NAIC model has been finalized and includes many positive changes from the patient perspective. However, the NAIC model does not require issuers to submit their plans through a "pre-approval" process with a state's insurance commissioner: such a pre-approval process is optional. This means that any deficits will have to be remedied after the plan is marketed and has potentially already enrolled individuals. We worry that the lack of a pre-approval process has the effect of turning the network requirements into a toothless tiger.

HHS notes that in the first few years of the exchanges, it has generally used an "open market" approach to QHP certification by accepting plans that met the minimum QHP certification criteria. HHS now requests comment on whether product value could be improved if the agency uses its authority to deny certification to QHP applications. We see certification denial as the only meaningful opportunity to ensure that issuers comply with network adequacy standards *before* any patients are enrolled and face access problems.

Restrictions on Surprise Bills Must Hold Harmless Patients.

We support the proposal concerning surprise billing but ask that CMS permit patients to count cost-sharing for out-of-network services towards annual limits even if notified by the plan.

The NBPP offers patients some protection against surprise bills for out-of-network care received



in an in-network setting. The NBPP would count a patient's cost-sharing for out-of-network services provided in connection with an in-network service against the annual limitation on cost-sharing. Alternatively, the plan can provide the individual a notice in advance of receiving care regarding the additional costs associated with an out-of-network service or provider and the fact that these costs will not count against the annual OOP limit. However, even with such notice, patients may not be able to manage their care to avoid these out-of-network services and charges. We recommend that CMS permit the patient to count cost-sharing for out-of-network services toward annual limits even if the patient has received notice of possible out-of-network services.

Payments Made to QHP Enrollees on Behalf of third Parties

To help ensure that patients are not being denied care because of economic circumstance, insurers should be required to accept financial help from third parties such as federal and state governments, Indian tribes and not for profit organizations.

The NBPP draft slightly addresses the ability of third-party entities to contribute to patient premiums and cost-sharing, but does not resolve the issue for our patients.

Many of our members have written to CMS in the past expressing concerns about the Interim Final Rule on Third Party Payment for Qualified Health Plan Premiums released by CMS in March 2014. Since this rule excluded non-profit organizations from the list of entities from which plans must accept third-party assistance, the rule has enabled QHPs in 37 states to prohibit health insurance premium assistance from non-profit organizations. Certain plans have taken this one step further by also prohibiting any reimbursement of the premium. Patients with rare and chronic illnesses who need access to life sustaining therapies rely on this assistance from charitable organizations and any barriers to that assistance runs counter to the aims of the Affordable Care Act. These steps by insurance carriers have the potential of unraveling the safety net that patient assistance organizations and patient advocacy groups have created.

We appreciate that HHS is considering requiring plans to accept third-party assistance from non-profits but are concerned about the potential for "guardrails" that might limit this requirement. Many individuals with private health insurance need assistance with their premiums, so restricting this to only be available for people without access to other plans would mean that no one would benefit. We urge HHS to simply require QHPs to accept payments from non-profits without any guardrails.

Moreover, we are very concerned about the discussion in the preamble about cost-sharing assistance. While CMS intends to clarify that its rules surrounding premium assistance also apply to cost-sharing assistance in a positive way – plans must accept cost-sharing assistance from Ryan White programs, for example -- we fear that plans will take this as authority to decline non-profit cost-sharing assistance. While the impact of this prohibition is less clear since any cost-sharing restrictions may be harder to implement, this would be extremely harmful to our patients. We urge CMS to clarify that QHPs should accept cost-sharing assistance from non-profits.



Congress is concerned with this issue and has expressed that concern to CMS through a series of letters and now with the introduction of legislation, H.R. 3742, the Access to Marketplace Insurance Act. APLUS urges the Department of Health and Human Services to correct this problem permanently by adding non-for-profit organizations to the list of entities from which insurance carriers are required to accept third party premium assistance.

Formulary Exceptions

HHS should clarify its intent of the formulary exceptions proposal and ensure that costs incurred for medications accessed through exceptions processes count towards the annual OOP limit.

As discussed elsewhere in the letter, the patients represented by APLUS members rely on expensive, plasma protein and recombinant therapies to treat their conditions. It is critical that people have timely access to the precise therapy prescribed by their physician, since individuals respond differently to these complex, biologic products, even if they are in the same category or class. APLUS supports the efforts in the proposed rule to strengthen and clarify requirements around formulary exceptions, but ask that HHS clarify the intent of the proposed changes. Please codify that costs incurred for medications accessed through exceptions processes count towards the annual OOP limit and furthermore, we support proposals that costs for off-formulary drugs determined by a physician to be the most appropriate treatment would also accrue to the annual OOP max.

Conclusion

APLUS supports both the National Health Council comments on the NBPP as well as the comments of the I Am Essential coalition.

We thank you for your consideration. Should you have any questions or require additional information, please do not hesitate to contact Larry LaMotte, Vice President, Public Policy, Immune Deficiency Foundation, llamotte@primaryimmune.org or 443-632-2552.

Alpha-1 Foundation
GBS/CIDP Foundation International
Committee of Ten Thousand
Hemophilia Federation of America
Immune Deficiency Foundation
Jeffrey Modell Foundation
National Hemophilia Foundation
National Organization for Rare Disorders (NORD)
Patient Services Incorporated
Platelet Disorder Support Association
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