



March 7, 2017

The Honorable Orrin Hatch  
Chairman  
Committee on Finance  
United States Senate  
219 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Ron Wyden  
Ranking Member  
Committee on Finance  
United States Senate  
219 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Lamar Alexander  
Chairman  
Committee on Health, Education Labor & Pensions  
United States Senate  
428 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Patty Murray  
Ranking Member  
Committee on Health, Education, Labor & Pensions  
United States Senate  
428 Dirksen Senate Office Building  
Washington, DC 20510

Dear Chairmen Hatch and Alexander and Ranking Members Wyden and Murray:

As Congress continues to work on the potential repeal and replacement of the Affordable Care Act (ACA), the American Plasma Users Coalition (APLUS) is writing to express both support and concerns regarding some of the proposals being discussed in this context. APLUS represents people with rare and chronic diseases, whose care entails more complexity and additional costs than most people face with acute care. However, not providing that care will result in increased costs to the system. We appreciate the work that is being done to protect patients and urge Congress to recognize the unique needs of individuals with rare and chronic conditions.

The American Plasma Users Coalition (APLUS) 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 affecting 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.

Treatments for our members include plasma-derived products such as clotting factor and immunoglobulin. All are expensive and life-saving and many are lifelong. For people with a primary immunodeficiency for example, immunoglobulin infusions can be administered intravenously (IVIG) or subcutaneously (SCIG), and must be delivered regularly for the patient to receive and sustain a therapeutic benefit. Such treatments can easily cost between \$50,000 and \$100,000 annually, making access to affordable health insurance coverage essential to the community. Individuals with hemophilia require lifelong infusions of replacement clotting factor therapies manufactured from human plasma or using recombinant technology. Clotting factor therapies are very effective at preventing and treating life-threatening bleeding episodes, but



also are extremely expensive. Annual costs for clotting factor are typically \$250,000 or more for someone with severe hemophilia and development of an inhibitor (immune response to treatment), bleeding from a trauma, surgery or other complications can raise costs in a given year to \$1 million or more. Individuals with Alpha-1 Antitrypsin Deficiency use plasma-derived augmentation therapy to treat the lung effects of their condition, with an annual cost of \$100,000.

The Affordable Care Act (ACA) includes a number of vital protections and policies that have enabled members of our communities to obtain and retain access to affordable insurance coverage as well as provisions that have limited patient out-of-pocket costs and help expand access to health insurance coverage. We are grateful for these protections and seek to have them maintained. At the same time, we are concerned about rising premium costs and recognize that our current health care system is suboptimal. We respectfully request that Congress explore opportunities to correct systematic flaws and strengthen overall health care. Following, please find several specific concerns and recommendations from our communities as you move forward with this work.

**Retain invaluable patient protections** such as:

- Prohibiting insurers from denying insurance coverage to anyone because of a pre-existing medical condition, charging people more based on their health status, and from dropping persons because of such conditions.
- Prohibiting insurers from instituting annual or lifetime caps on coverage
- Retaining a maximum for annual out-of-pocket costs
- Prohibiting insurers from instituting discriminatory benefit designs
- Retaining a requirement that health plans include prescription drug coverage as a covered benefit

We recognize and sincerely appreciate that these policies were not repealed by the 2015 ACA repeal legislation passed under reconciliation, nor would they be repealed by various proposals under consideration in Congress in 2017. We applaud many members of Congress for publicly recognizing the value of these patient protections and stating their desire to ensure such protections remain in any repeal and replace law. At the same time, we understand the complexities of these and related insurance market policies that enabled these protections to be offered. We therefore urge you to ensure that these protections are maintained as the legislative process continues.

We are concerned about one proposal that has recently been floated that could significantly undermine these policies' protection. The ACA eliminated lifetime and annual limits, capped out-of-pocket expenses, and prohibited discrimination based on health status only for those services defined as the Essential Health Benefits (EHBs). Recent Republican proposals circulated in the House would repeal the federal definition of the EHBs and allow states to define EHBs after 2020. We are very concerned that state decisions about EHBs could undermine these protections, even if these provisions of the law are not repealed. This would



also create varied levels of coverage across the country. If a state were to say that prescription drugs were no longer an EHB, for example, then plans could institute lifetime or annual caps on drug costs and any out-of-pocket expenses on drugs would not accrue to the annual out-of-pocket max. We would encourage, a minimum set of EHBs be established nationally, taking the needs of patients with rare and/or chronic conditions into consideration.

We are further concerned that surcharges or penalties for an interruption of coverage will be used to circumvent the pre-existing conditions protection. Someone who becomes unemployed, loses their income and can't afford COBRA, for example, should not be punished because they don't have the income to pay premiums.

**Protect patients with complex rare and/or chronic conditions from significant costs:** We realize that reducing the cost of health care is a driving force in this work. We are supportive of that effort providing there is consideration to all Americans, including people with rare and/or chronic diseases, patients with fixed or limited incomes, and patients with costly treatments. Fixed Healthcare Spending Accounts and deferred tax credits will not meet the needs of this population. We encourage continued conversations to find an economic solution that also meets these people's needs.

**Avoid flawed high risk pools and consider alternative policies regarding insurer risk:** Our organizations and communities are very familiar with present and past proposals to reinstate state-based high-risk pools. While such pools were intended to help patients with serious chronic illnesses obtain access to health insurance coverage, they were largely unsuccessful. Prior to the ACA, state high risk pools charged high premiums and in return offered limited coverage, subjected participants to annual and lifetime caps, as well as pre-existing condition exclusions.. For any such risk pool model to work, adequate and on-going funding (linked to health care inflation) is essential, without which enrolled persons will incur gaps in and caps on care and other limits that will jeopardize their health. We ask that you not reinstitute flawed high risk pools but rather consider new, innovative approaches. For example, State Innovation Grants contemplated in the House proposal could assist with reinsurance. We are open to working with you and your colleagues in exploring alternative models for insurers to balance the costs of having high-cost individuals.

**Preserve coverage gains including Medicaid and the Individual Market:** Despite challenges with the ACA, the law has helped significantly reduce the percentage of the population that is uninsured through individual market reforms and Medicaid expansion. We recognize flaws in the current system relating to premiums and payer participation, but we believe these issues can and should be addressed while preserving the expansion in coverage produced by the law. These coverage gains are critical for our communities, who must have insurance to be able to treat their rare, chronic and expensive conditions.

**Protect Medicaid beneficiaries, especially those with complex chronic conditions:** We ask that you work to protect Medicaid beneficiaries, especially those with complex chronic conditions that are part of the state Medicaid Expansion plans. We recognize that the Medicaid program faces many challenges and that Congress is considering alternative funding mechanisms for the program such as per-capita or block grant models. Such models would change the nature of Medicaid from an entitlement program to a program subject to annual



appropriations at both the federal and state levels. We are very concerned about the impact of such models on people who have rare and/or chronic diseases.

Many in our communities receive coverage via Medicaid. We are concerned that if the program is turned into a block grant or a per-capita model, members of our communities would be placed at a significant disadvantage given the nature of their disease and treatments. We are concerned that such “fixed-dollar” models that depend on appropriations will in a short time lead to the rationing of care as state governments receive less funding. For example, as novel treatments are developed that may carry a higher cost, we would be concerned that severe limits on funding would limit beneficiary access to such products, negatively impacting patient care as well as patient outcomes.

In summary, we know a number of complex questions and challenges remain as this work progresses. APLUS understands that changes will be made and we ask that the needs of the patients our coalition serves be considered going forward. We urge you and your colleagues to ensure that any repeal, replace or repair legislation retains the patient protections we have lifted up in this letter. We stand ready to work with you on these most important issues and thank you for considering these points. If you have any questions or need more information, please contact Larry LaMotte at [llamotte@primaryimmune.org](mailto:llamotte@primaryimmune.org) or 443-632-2552.

Alpha-1 Foundation  
Committee of Ten Thousand  
GBS/CIDP Foundation International  
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  
US Hereditary Angioedema Association