December 8, 2014

RE: Health Benefit Plan Network Access and Adequacy Model Act

Submitted via email to: Jolie Matthews (jmatthews@naic.org)

Dear Ms. Matthews:

The Immune Deficiency Foundation (IDF) is the national patient organization, founded in 1980, dedicated to improving the diagnosis, treatment and quality of life of persons with primary immunodeficiency diseases (PI) through advocacy, education, and research. On behalf of the thousands of patients we represent, we are writing to provide feedback on the Health Benefit Plan Network Access and Adequacy Model Act.

Primary Immunodeficiency diseases represent a group of more than 200 related, rare genetic diseases. The defining characteristic throughout each of these conditions is that the immune system is malfunctioning or non-existent, resulting in a decreased ability to fight off infection. Infections can affect organ function. Throughout their lives, people with PI are more susceptible to infections, endure chronic and diverse health problems, and often develop serious and debilitating illnesses.

There are approximately 250,000 people diagnosed with PI in the United States. Treatments are diverse and can include prophylactic antibiotic therapy, bone marrow transplantation, enzyme replacement, interferon gamma and antifungals. Many patients diagnosed with PI require lifelong treatment with immunoglobulin (Ig) replacement therapy to replace missing or improperly functioning antibodies needed to fight infection. Since it only replaces the missing antibodies, and does not correct the defect in antibody production, immunoglobulin replacement is usually necessary for the patient’s whole life. Depending on the route of administration, PI patients require infusions as often as every 2 or 3 days (subcutaneously) or once every 3 or 4 weeks (intravenously).

IDF has a keen interest in the strength of networks because access to specialty providers is critical for our PI patients seeking care. In 2008, we surveyed our patients using Ig therapy and found the following:¹

- While most patients with PI that have used Ig therapy rely on a primary care doctor as their main source of health care, the vast majority report also having a specialist responsible for the management and treatment of their PI condition. Among patients who had another doctor who was responsible for treatment and

management of their PI, over three-quarters (78%) said they saw an immunologist to treat their PI. In addition, 11% saw an allergist, 10% a hematologist, 5% a pulmonologist, 4% an infectious diseases doctor, and 3% saw an ear, nose and throat (ENT) specialist.

- Moreover, in addition to their primary doctor and the doctor most responsible for the treatment of their immunodeficiency disease, more than four out of five patients with PI (82%) saw at least one other specialist during the preceding year. Between one-quarter and one-third of patients with PI saw a hematologist (35%), dermatologist (30%), ENT specialist (28%) pulmonologist (27%), or an immunologist (26%) other than their primary care doctor and the one responsible for the management of their condition. Twenty-two percent saw another allergist or cardiologist. One in seven patients with PI (16%) have seen an endocrinologist in the past year, while others report seeing an infectious diseases specialist (13%), gastroenterologist (12%), rheumatologist (5%), or neurologist (3%) in the past year.

Because PI is a group of rare disorders, our patients often struggle to be appropriately diagnosed and treated. Yet the ability to access the right care is critical. When patients with PI disease receive the treatment they need from a provider with expertise in treating these disorders, they can lead relatively healthy and productive lives. When they do not, the consequences can be severe and even fatal.

**COMMENTS ON NAIC MODEL ACT**

With that background, we offer the following specific comments on NAIC’s Model Act:

- **Section 5. Network Adequacy.**
  - Section 5B(1): We urge NAIC to include subspecialties in the provider-to-person ratios. For people with PI, an immunologist who only treats asthma and allergy patients may not be the appropriate provider. For our patients, the American Academy of Allergy, Asthma, and Immunology has defined a focused immunologist as someone who devotes at least ten percent of his or her clinical practice to patients with primary immunodeficiency. The need to access subspecialty care exists for any patient with a rare disease, and we urge NAIC to recognize this fact in the Model Act.
  - Section 5B(5): With regard to the criteria used to establish adequacy, we strongly support NAIC’s change to measuring waiting times for appointments to waiting times for actual visits.
  - Section 5B(8): We support NAIC adding as a criterion the volume of specialty services available to serve the needs of persons in need of specialty care, but we also urge NAIC to add to this criterion subspecialty services for those with rare disease.
  - Section 5C: We appreciate NAIC’s acknowledgement that, for some patients, obtaining medically necessary services inside the network may not be possible. However, we urge NAIC to include stronger consumer protection language, as we are concerned that the current language
essentially leaves the process for determining when out-of-network services are appropriate entirely up to the carrier. Unfortunately, our patients’ experience informs us that this will leave patients unprotected. Far more often than we would like, we hear stories from our patients who have been subjected to an appeals process so lengthy that it amounts to a de facto denial of care. PI patients may require treatment every 3 or 4 weeks, leaving them with little time for delays in treatment due to lengthy appeals processes. **We urge NAIC to include language that sets time limits on when an appeals process must be concluded, especially for those with life-threatening diseases.** The Patient Bill of Rights considered by Congress in 2001 may serve as an example, as it included language that was helpful to those with diseases that require timely treatment. The Bill would have required expedited authorization decisions to be made within 72 hours if the regular appeals process would seriously jeopardize the life or health of the beneficiary. We urge NAIC to include similar language in the Model Act.

- **Section 6. Requirements for Health Carriers and Participating Providers.**
  - Section 6L(1)(a) Drafting Note. We echo NAIC’s acknowledgement that mid-year tier switching can have serious cost-sharing implications for patients. **We urge states to require that carriers hold harmless covered persons until the end of the plan year, if a tier switch is made after the person has committed to that plan for that year.**
  - Section 6L(2)(a)(ii). We understand the need to exempt routine monitoring of a chronic condition from the definition of “active monitoring,” however, **we request that NAIC include language that excludes active monitoring for a rare disease.** Again, our patients often experience significant difficulty finding a provider who can treat them. Although the monitoring of the disease may be “routine” in that it happens regularly to control the condition, it is anything but routine in that there may be very few providers who can perform such monitoring, which is crucial for our patients’ survival. Simply put: in the event a provider is terminated without cause, carriers should be required to cover treatment for rare diseases until the next plan renewal date, when patients are free to select a different plan that does provide them access to the medical professionals they need. As an example, for purposes of drug development, the Food and Drug Administration defines a “rare disease” as a disease that affects fewer than 200,000 people in the U.S. We are eager to work with NAIC to define “rare disease” in the most appropriate manner for this context.

- **Section 8. Provider Directories.**
  - Section 8B(1). **We urge NAIC to include subspecialty information to the directory.**
  - We support the drafting note at the end of the section requiring carriers to update their directories at least monthly. Indeed, we would urge updates more frequently. Directories for plans offered on the new exchanges have been rife with inaccuracies and outdated information, and are often difficult for
consumers to navigate. The ability to identify an in-network provider has a
direct effect on a patient’s financial burden, due to implementing regulations
from the Department of Health and Human Services that exclude cost-sharing
incurred out-of-network. We find it grossly unfair that a plan is able to
financially penalize a patient for seeking care outside the network when the
plan never equips the patient with a reliable and accurate tool to identify a
provider inside the network. **We urge NAIC to require plans to update
directories nightly and to ensure user-friendliness for the average
consumer.**

We are very appreciative of the hard work that has already been invested by NAIC in
the updating of its Network Adequacy Model Act. The existing draft reflects a thoughtful
process, and we are confident that, with the changes we suggest herein, the final model
will strike the right balance between providing carriers with the ability to contain costs
and enabling patients with rare diseases to access the care their lives depend on.

On behalf of patients with primary immunodeficiency diseases, I want to thank you for
your consideration of our views. Please feel free to contact me or Larry LaMotte, Vice
President, Public Policy, Llamotte@primaryimmune.org, if we can provide additional
information or answer any follow-up questions.

Sincerely,

Marcia Boyle
President and Founder
Immune Deficiency Foundation

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¹ P.L. Yong, et al. “Use of intravenous immunoglobulin and adjunctive therapies in the treatment of
primary immunodeficiencies.” A working group report of and study by the Primary Immunodeficiency
Committee of the American Academy of Allergy, Asthma and Immunology. Clin. Immunolog. (2009),