Immune Deficiency Foundation

The National Patient Organization Dedicated to Advocacy, Education and Research for Primary Immunodeficiency Diseases

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**before the**

**COMMITTEE ON ENERGY AND COMMERCE**
**SUBCOMMITTEE ON HEALTH**

**May 17, 2016**

The Immune Deficiency Foundation (IDF), founded in 1980, is the national patient organization dedicated to improving the diagnosis, treatment, and quality of life of persons with primary immunodeficiency diseases through advocacy, education, and research. On behalf of the thousands of patients we represent, we thank the Committee for its scrutiny of the Medicare Part B Drug Payment Model proposed by the Centers for Medicare and Medicaid Services (CMS) and for providing IDF the opportunity to present the patient perspective.

Primary immunodeficiency, or PI, represents a group of more than 250 rare, chronic genetic diseases in which part of the body's immune system is missing or functions improperly, resulting in a decreased ability to fight off infection. Throughout their lives, people with PI are more susceptible to infections, endure frequent health problems, including a number of other comorbidities, and can develop serious and debilitating illnesses.

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Approximately 250,000 people are diagnosed with PI in the U.S. Depending upon the type of PI, treatments can include prophylactic antibiotic therapy, bone marrow transplantation, enzyme replacement, interferon gamma and antifungals. Patients with PI who have a lack of and/or impaired antibody function require lifelong, lifesaving treatment with immunoglobulin replacement therapy (Ig therapy), partly replacing what the body should be making and protecting them from infection. Today, with early diagnosis and appropriate therapies, such as Ig, many patients diagnosed with PI can live healthy, productive lives.

With that background, we provide the comments outlined below.

**PROPOSED PART B DRUG PAYMENT MODEL**

CMS proposes to modify the average sales price plus 6 percent (ASP+6%) add-on amount over the course of a two-phase demonstration. Under Phase I, CMS would create two study cohorts; each representing 50% of all providers administering Part B drugs. One cohort would receive Part B drug payments under the current payment methodology (ASP+6%), whereas the other cohort would receive a reduced add-on payment (ASP+2.5%) plus a flat fee of $16.80. Given that 2% of the add-on payments is already under sequester, the proposed reimbursement is effectively ASP+.5% plus $16.85.

Under Phase II, CMS would create two additional study cohorts using the same payment structures but add value-based purchasing (VBP) tools currently employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization. CMS proposes that Phase I would begin in Summer 2016; Phase II would begin as soon as January 1, 2017. Specific to the VBP strategies, CMS proposes to allow 30 days for public comment and would provide a minimum of 45 days public notice before implementation. Provider inclusion in the demo will be determined by randomly selected zip codes and, with very limited exceptions, all Part B drugs will be subject to the demo – including immunoglobulin (Ig).

IDF has serious concerns about the model and have asked CMS to withdraw it, for the reasons outlined below. We are not the only patient group with concerns: we joined 23 other patient groups representing millions of patients across the country to send a letter to Congress, expressing opposition to the demo. We hope the Committee will consider the serious concerns expressed by patients and prevent this harmful project moving forward.

## SUBSTANTIVE CONCERNS WITH THE MODEL

### PHASE 1

With regard to Phase 1, patients with PI are leery of reimbursement changes because our patient population has experienced severely compromised access to care in the past as a result of Medicare reimbursement changes. Specifically, starting in 2005,

patients with PI saw significant reductions in reimbursement as a result of the 2003 Medicare Modernization Act (MMA), which changed Part B drug reimbursement from the Average Wholesale Price (AWP) to ASP plus 6%. Two studies by the Health and Human Services Office of Inspector General (OIG) (http://oig.hhs.gov/oei/reports/oei-03-05-00404.pdf) and the Assistant Secretary for Planning and Evaluation (ASPE) (https://aspe.hhs.gov/sp/reports/2007/IGIV) reported in 2007 the difficulties physicians and specialty pharmacies had obtaining Ig products at the Medicare reimbursed price and the impact on patients' ability to obtain their infusions. The HHS OIG reported to Congress that, "Sixty-one percent of responding physicians indicated that they had sent patients to hospitals for IVIG treatment because of their inability to acquire adequate amounts of IVIG or problems with Medicare payment.[i]"

Many patients lost access to Ig in the physician's office as well as in the home. As a result of the MMA cuts, intravenous immunoglobulin (IVIG) therapy (the only Ig therapy at the time) in the physician's office was nearly eliminated because physicians could not afford to administer infusions. Even though Medicare covered home infusions, the reimbursement became so low that specialty pharmacies could not afford to provide the items and services necessary for IVIG in the home. Congress responded by passing the Medicare IVIG Access Act (P.L. 112-242) with overwhelming support (401-3 in the House; unanimously in the Senate). This demonstration is currently underway, and IDF anticipates it will lead to a permanent fix in the current Medicare home infusion benefit for IVIG. (See https://innovation.cms.gov/initiatives/IVIG/index.html.) Our fear is that the proposed Part B demonstration, which explicitly includes the current Medicare IVIG

Access demonstration, will undercut the IVIG demo. Specialty pharmacies already complain that they are close to underwater now with ASP+6 and low payment for the items and services needed for infusions in the home.

There have been comments by CMS officials intimating that the demonstration will not jeopardize patient access because patients could travel to a hospital or a practice in a zip code not affected by the demonstration. At best, this is poor stewardship of the Medicare program, given that the hospital is a more expensive setting than the physician's office and the home, and a dangerous place to be for patients with malfunctioning immune systems. At worst, these comments indicate a disregard for the frustrating experiences that patients with PI face in trying to get the treatment necessary to save their lives. Most importantly, these comments have caused great consternation in the patient community, as it indicates an incredibly cavalier and patronizing attitude by the agency towards beneficiaries. No Medicare beneficiary should have to travel farther to a more expensive setting. In addition, there is no guarantee that patients will necessarily find a site of care that they will be able to access, particularly in rural areas. Physician offices and hospitals that administer Ig therapy are few and far between.

PHASE 2

Patients with PI have extensive – and usually negative – experience with the private payer tools that CMS proposes to utilize in Phase 2 of the demo. On a daily basis, IDF is called upon by patients to assist in overcoming insurance barriers associated with affording high out-of-pockets costs as a result of what CMS has termed "value-based"

policies used by commercial payers and pharmacy benefit managers. These are not the policies that should apply to Medicare beneficiaries.

The goals of value-based purchasing (VBP) – lowering health care costs and improving quality and outcomes – are laudable. The literature about VBP consistently discusses the need to look at the correlation between cost of care *and patient outcomes*. Patients, especially those with rare or chronic diseases, must be involved in every step of the value assessment process. Unfortunately, the extent of patient involvement in the proposed demo is nominal at best: CMS states that it expects "to base many of our analyses on secondary data sources such as Medicare FFS claims" but that it "*may* consider a survey of beneficiaries" and other stakeholders "to provide insight on beneficiaries' experience under the model." (Emphasis added.)

CMS' endeavor to emulate the tactics used in the private sector to place barriers to care reflects the "one size fits all" mindset. For patients with PI, that approach is dangerous. One tactic in the private sector used against our patients is to limit Ig replacement therapy to just one Ig product. There are 13 Ig products in the market. Each product is different from the others; additionally, two patients may react differently to the same product. No two products are interchangeable. While each product is derived from donated pooled plasma, the formulation is different. For example, some have higher concentrations of salts or sugars and some lower. It would be medically dangerous to require a person with a heart condition to be forced to use a product with a high concentration of salt for their lifelong infusions. The same would occur with a product

with high concentration of sugars for a diabetic patient. A number of products are developed for intravenous infusion (IVIG). Some are 5% and some are 10% solutions. Some products are designed for subcutaneous infusion (SCIG), which is generally self-infused after sufficient training. Some patients do well on IVIG, and other patients cannot tolerate IVIG, and may have serious venous access issues and reactions. SCIG can be a good choice for these patients but not for other patients who are unable to self-administer.

Forcing a patient stabilized on a particular Ig product to switch to a different product is also dangerous. IDF surveys and other studies indicate that upwards of 30% of patients, when switched to a product they have never used before, will have adverse reactions running from mild headaches to anaphylaxis shock, sepsis, thromboembolic events and even death. Again, creating financial incentives to switch patients for non-medical reasons is not a commercial payer tactic that should be emulated by CMS.

There is insufficient detail to even provide feedback on the proposals since it is unclear how some of these could be implemented within Medicare Part B. For example, while IDF has always supported any reduction in cost-sharing for beneficiaries, a large portion of Medicare beneficiaries have supplemental coverage, so that a reduction in cost-sharing would just be a reduction in what the supplemental insurer pays. This would do nothing to actually reduce costs for beneficiaries.

Finally, what the proposal lacks – and what other CMMI demonstrations have included

very explicitly – is outcomes measures. For Ig, such measures are difficult in that the desired outcome is more holistic than that of some other products. For example, if a product treats hemophilia, a simple outcome measure will ask whether the drug is effective at stopping bleeds. For Ig products, a physician and patient will determine together whether the drug has reduced the number of pneumonias and other illnesses, but they must also determine how well the patient tolerates the product overall – and that will vary from person to person. Any VBP proposal must include outcomes measures, but they must be informed by patients and providers who actually experience the disease every day.

**PROCEDURAL CONCERNS WITH THE MODEL**

In early February 2016, CMS posted guidelines to contractors about the Medicare Part B Drug Payment Model, which proposed changes to the Average Sales Price (ASP) methodology for Part B drug reimbursement. This posting appeared to have happened erroneously, as the agency quickly removed the guidelines from its website. The posting and subsequent hasty removal greatly worried the provider, patient, and manufacturer communities, as it indicated a major payment change was well underway, even though CMS had not engaged in any pre-rulemaking dialogue such as town halls or Requests for Information.

Rather than pause to address these concerns, CMS only seemed to accelerate its timeline for beginning this sweeping payment demonstration. Within a month, CMS issued the proposed rule containing the Model. We believe that this retreat, followed by

the hasty rollout, indicates that the Agency knew how concerning the proposed change would be to the community.

Executive Order 13563 (January 11, 2011) explains that, "*Before issuing a notice of proposed rulemaking, each agency, where feasible and appropriate, shall seek the views of those who are likely to be affected, including those who are likely to benefit from and those who are potentially subject to such rulemaking.*" Apart from the erroneous posting for contractors described above, CMS did not engage affected stakeholders in an open, transparent manner to inform, and thus improve, the proposed regulation.

Given that CMS has employed pre-rulemaking engagement strategies in developing the requirements associated with new physician payment programs established under the Medicare Access and CHIP Reauthorization Act (MACRA), we do not understand why CMS failed to utilize this process for the Part B Drug Model, particularly in light of the tremendous impact it will have on patients.

The Affordable Care Act authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures, while preserving or enhancing the quality of care furnished to beneficiaries. However, the scope of the Model far exceeds any reasonable definition of a "test" and is so expansive as to constitute a program change. First, with very limited exceptions, the Model will include all Part B drugs. Second, CMS proposes to mandate participation by all providers who prescribe Part B drugs. The model can no longer be considered a "demonstration" when it is scaled nationwide (excluding Maryland) and will apply to all Part B medicines. Given

that Congress statutorily defined the ASP methodology and add-on in section 303 of the Medicare Modernization Act of 2003, it is an inappropriate overreach of regulatory authority for CMS to force changes to this formula, especially in a way that lacks any transparency or opportunity for meaningful input.

Finally, the ACA explicitly states that no ACA provision, including the provision creating the Innovation Center, can result in a reduction of guaranteed Medicare benefits. As outlined above, we believe that the model will jeopardize beneficiary access – and thus may be a potential violation of ACA section 3601, which provides, in relevant part, that nothing contained in the ACA "shall result in a reduction of guaranteed benefits under title XVIII of the Social Security Act."

## CONCLUSION

**IDF has urged CMS to withdraw the Part B Drug Payment Model and requests that Congress do everything in its power to stop this harmful experiment from moving forward**. It jeopardizes beneficiary access to needed medications, is the result of an opaque and poorly thought out process, and fails to address the actual issue of drug pricing in any way. IDF proposes that CMS engage all stakeholders in a true dialogue to develop pilot projects to demonstrate the relative effectiveness of those pilots in reducing costs AND maintaining or improving outcomes of all beneficiaries.

IDF thanks the Committee for its attempt to create accountability in a CMS process that

has lacked any transparency or patient input whatsoever, and for the opportunity to present the potential implications of the model for patients with PI.

[i] OIG, April 2007, OEI-03-05-00404, p. 13