Comment of Marian J. Furst
File Code CMS-1670-P

To Whom It May Concern:

This comment is being submitted in response to the proposed Medicare Program: Part B Drug Payment Model, File Code CMS-1670-P. It provides my perspective of a primary immune deficiency patient who is a Medicare beneficiary and receives infusions of immune globulin under Medicare Part B.

My remarks focus on three areas:
- CMS lacks authority to enact the Payment Model;
- The proposed cost-cutting incentives target the wrong parties; and
- The proposed Payment Model would have serious adverse impacts on the quality of patient care.

Introduction

Leading up to my diagnosis with common variable immunodeficiency (CVID) in 2010, I was becoming sick with infections increasingly often and having increasing trouble recovering from these illnesses. During one six-week period at the end of 2009/beginning of 2010, I had 2 rounds of bronchitis, a sinus infection, and a flare of Epstein-Barr virus. Initially I was treated with IVIG at a clinic and then at home. It rapidly became apparent that IV infusions were not a good option for me for several reasons, including recurrent vein inflammation which is apparently due to the IV procedure and not the particular product that was administered. I switched to subcutaneous (subq) infusions of the only immune globulin product which was FDA approved at that time for subcutaneous administration, and that approval was for weekly infusions. Also, like many primary immune deficiency patients, I deal with several other medical conditions and am what is termed a “complex patient.”

The subq infusions of this product cause no significant side effects for me, and they have allowed me to move from being almost constantly sick with one infection or another to being almost constantly well enough to function as a productive member of society. Without infusions, I would likely have continued to spiral downward in my pattern of increasingly frequent and increasingly severe infections and been unable to continue working. That would have led me to apply for social security disability benefits. If I had qualified for social security disability benefits, I would have also received Medicare benefits prior to reaching the age of 65.

Over the last few years more products and additional dosing schedules have been approved by the FDA, and I’ve had several discussions with my prescribing immunologist about changing products and changing the frequency of administration. Each time, we agreed that I’m doing very well with my current product and regimen, and there is no reason to “rock the boat” and risk developing new side effects.
Like many other Medicare beneficiaries who receive immune globulin for subq administration and Medicare beneficiaries participating in the IVIG Demonstration Project, I receive the product and supplies for administration from a specialty pharmacy (DME supplier). My doctor determined which product I use, and the specialty pharmacy is obligated to provide that product, without substitutions, since there are no FDA-approved generic or bioequivalent immune globulin products.

**CMS lacks authority to implement the Payment Model.**

*Authority of the Center for Medicare and Medicaid Innovation (CMI)*

The proposed Model would be under the authority of the Center for Medicare and Medicaid Innovation, Section 1115A (42 U.S.C. 1315A). This authority appears to allow testing of payment and service delivery models without subjecting them to administrative or judicial review.

Section 1115A (a)(3) requires CMI to use open door forums or other mechanisms to seek input from interested parties. It appears that this requirement was not met; representatives of a patient organization and a plasma product distributor, both of whom make concerted efforts to stay informed about issues relating to the availability of immune globulin products, told me that they were caught by complete surprise when the proposed Model was published. Thus, the proposed Model was apparently generated without significant input from numerous interested parties, including patient organizations and provider organizations. The comment submitted by the Immune Deficiency Foundation addresses this issue and how the procedure followed with this rule is not in accordance with the requirements of Executive Order 13563 (January 11, 2011).

Section 1115A(c) addresses the expansion of models in Phase II, *after testing in Phase I*, and provides that the Secretary “...may, through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested ...” Thus, Section 1115A does not contemplate the initial nationwide broad-scope implementation of a model as proposed for this Payment Mode.

It is doubtful that Congress intended to grant CMS and/or the Center for Medicare and Medicaid Innovation (CMI) broad authority to completely re-write provisions of Medicare on a national scale without the revisions being subject to any reasonable form of review, as stated in Section 1115A(c)(2). Yet, this is exactly what the proposed Model does, with the limited exceptions of excluding the state of Maryland and excluding drugs used for end stage renal disease.

*Authority of CMS to Undermine the Medicare Intravenous Immune Globulin (IVIG) Demonstration Project*

The proposed Model contradicts and undermines the Medicare Intravenous Immune Globulin
(IVIG) Demonstration Project, approved by Congress in December of 2012 and signed by President Obama in early 2013. Thus, CMS lacks the authority to enact this rule.

Although I was not a primary immune deficiency patient in 2003, I have learned from the Immune Deficiency Foundation and other patients that the 2003 Medicare Modernization Act provided for reimbursement to providers for IV immune globulin under Medicare Part B but did not include reimbursement for supplies and nurses to administer the infusions. As a result, home and doctor’s office IVIG infusions became unavailable for Medicare beneficiaries because providers could not profitably provide product along with supplies and nursing care with the reimbursement rate provided for the infusion products. Medicare patients could only receive IVIG infusions in hospitals or associated outpatient settings, generally only in larger metropolitan areas. After years of effort, which I participated in, the Medicare IVIG Access Act was passed in 2012 and provides for the Medicare Intravenous Immune Globulin (IVIG) Demonstration Project to determine whether it is cost-effective to provide IVIG infusions in beneficiaries’ homes. This pilot project is under way, and a few months ago I received an invitation to participate. If reimbursements to the specialty pharmacies that provide the products for home infusions in this demonstration project are decreased significantly, as proposed for the three non-control arms in the Model, it is likely that product availability will decrease as specialty pharmacies and physicians offering treatment at their offices withdraw from the market due to unprofitability.

The proposed Model, with implementation of different reimbursements for different geographic areas and with overall decreased reimbursements to providers of home IVIG infusion supplies and nursing care, could effectively halt the IVIG Demonstration Project. Even if the IVIG Demonstration Project is not completely halted, it would likely be hindered on a geographic basis, due to the use of ZIP codes to select participants in the four arms of the Proposed Reimbursement Model.

The Medicare IVIG Act requires the Secretary of Health and Human Services to evaluate the benefits of providing payment for items and services needed for the in-home administration of intravenous immune globulin for the treatment of primary immune deficiency diseases. Because the true costs attributable to the Demonstration Project would be difficult or impossible to determine, it is likely that the Secretary would be unable to make the required interim and final reports with evaluations of the impact of the demonstration project on Medicare beneficiaries’ access to items and services needed for the in-home administration of immune globulin, and the Secretary will be unable to provide the required analysis of the appropriateness of implementing a new methodology for payment for intravenous immune globulins in all care settings.

Thus, use of the proposed Model would prohibit fulfillment of the requirements of the Medicare IVIG Access Act and therefore exceeds the Secretary’s authority.

Possible Constitutional Issue
It also appears that different reimbursement rates for products delivered to beneficiaries residing
in different geographic areas and the resulting differing access to products and care could create Constitutional issues of equal protection for providers and beneficiaries.

*The proposed cost-cutting incentives target the wrong parties.*
The Medicare Part B Payment Model relies on the assumption that the amount of reimbursement to care providers can provide an incentive for the providers to select products based on the most favorable reimbursement available to the provider and/or deter providers from selecting more expensive products. For Phase 1 of the Model, the incentive would be provided by lowering the reimbursement rate for essentially all medications covered under Part B, which would allegedly make providers less likely to supply more expensive products because their reimbursement wouldn’t increase much for more expensive products. For Phase 2, Value-Based Pricing tools like the ones used by insurance companies would provide other cost-cutting incentives.

Many or most of the drugs covered under Part B are likely administered in clinical settings. I also have some experience with receiving treatment in an hospital outpatient setting, although it was prior to being old enough to qualify for Medicare benefits.

The assumption that the proposed Payment Model measures would provide incentives to providers presumes that the reimbursed provider has control over which product is provided to each patient. In the case of medications provided for home infusions, the incentives created under the Payment Model would be misplaced, and they also may be misplaced for other care settings. My personal experience with the selection of chemotherapy medications was that I asked to choose between multiple treatment regimens, all in accordance with what appears to be the national standard of care. This suggests that neither the prescribing oncologist nor the outpatient hospital facility was incentivized by potential insurance reimbursements.

As explained above, immune globulin is often administered at a patient’s home, and, in the case of subq infusions, is generally self-administered without a paid care provider present. The doctors who prescribe the medications have no financial stake in product selection, and the reimbursed DME providers (specialty pharmacies) have no control over product selection for any patient.

Thus, any attempt to penalize the parties who provide less favored immune globulin products will not directly affect the doctors ordering the medications and will not provide an incentive for the doctors to prescribe preferred products. Instead, it will provide incentives for the pharmacies to stop handling less favored products, at least in the ZIP codes selected for the Model arms in which reimbursements are decreased or “incentivized.”

*Loss of patient access to and choice of treatments*
DME providers, such as specialty pharmacies, could decide that the reimbursement rate is too low for one or more ZIP code areas defined for the study arms and stop providing some or all
products to beneficiaries in those areas, or to beneficiaries in all areas they serve. This could be catastrophic for smaller local and regional suppliers, and it would be very undesirable for patients who would lose local access to the products prescribed by their physicians. My understanding is that this scenario is exactly what occurred after enactment of the 2003 Medicare Modernization Act, which made the reimbursement rate for immune globulin so low that many providers withdrew from the market for home IVIG infusions because they could not profitably provide the supplies and nursing care along with the infusion products. This left hospitals and outpatient clinics as the only providers available to many Medicare patients with primary immune deficiencies.

*Increased administrative burden*

In discussing the selection of geographic areas for the different arms, the proposed Payment Model states:

> ...the areas need to be sufficiently large so that most practice locations and suppliers do not have practice locations in multiple areas. A provider or supplier with practice locations in multiple areas may be subject to multiple payment changes. This situation could create an unnecessary administrative burden for the provider or supplier. It may also create an opportunity for a provider or supplier to attempt to influence a patient to receive a medically appropriate drug paid under Part B at the practice location that provides higher payment to the provider or supplier. (Federal Register, Vol. 81, No. 48, Friday, March 11, 2016, page 13236, middle of the third column)

Just as predicted in the description of the Model, the use of four arms with reimbursements to providers based on the geographic locations of the beneficiary would create a lot of administrative problems with respect to home-administered medications such as immune globulin. There would likely be a huge number of inquiries, reprocessed claims, and appeals questioning whether the reimbursements were calculated correctly, creating burdens for both CMS and the providers. My specialty pharmacy is one of several that operate nationally.

*Cost sharing*

It is likely that most recipients of immune globulin and similarly expensive Part B medications have Medicare supplement coverage, since the 20 percent coinsurance for these medications is unaffordable for most individuals and families. Any reduction in cost sharing that results from reimbursement incentives, as proposed in the Model, would be received by insurance companies that provide Medicare supplement coverage. Most likely, any insurance company savings would not be passed on to Medicare beneficiaries in the form of reduced premiums, and the insurance companies would reap the rewards of incentives provided by the proposed Model.
The proposed Payment Model would have serious adverse impacts on the quality of patient care.

Product Selection
There are no generic or biosimilar immune globulin products. Each of the FDA-approved products has unique characteristics, with different processes for isolation from human plasma, different additional components such as stabilizers, and different concentrations. They are not interchangeable, and many patients tolerate some products better than others. Some patients have medical reasons why one or several products are inappropriate, such as diabetics needing to avoid high-sugar products and cardiac patients needing to avoid high-sodium preparations. Anaphylactic allergic reactions, aseptic meningitis, and other severe reactions are known and have occurred when patients started with a product, including when they switched products. Home infusion patients routinely receive Epi-pens® or similar medications to keep on hand in case of an anaphylactic reaction from an infusion, even when there is no history of prior anaphylaxis. Anecdotally, I know personally several patients who have had adverse reactions significant enough that they changed products and/or dosing regimens, such as switching from IVIG to subq administration and/or infusing lower doses more frequently. Anecdotally, I know of several patients who are allergic to a stabilizer used in one immune globulin product. In many cases, patients who have unacceptable reactions to one product can find another product that is satisfactory for them. It is important that choices of all FDA-approved products and administration routes remain available so Medicare beneficiary patients can receive the treatment that is suitable for their personal needs.

Location and mode of administration
It is well known that hospitals and clinical facilities pose a risk of infection to patients, particularly patients who are immune deficient. Thus, for patients who don’t have a high risk of major adverse reactions to infusions, home infusions are often preferable to avoid the risk of a hospital-acquired infection.

One factor in “quality of care” is comfort and convenience for the patient. If it is necessary for patients to travel to receive infusions, what could be a relatively minor interruption of the patient’s life can become a major hassle. As an example, when I received IVIG infusions, my doctor ordered pre-treatment with an antihistamine to try to prevent vein inflammation, and the antihistamine made me too sleepy to drive anywhere and useless for any productive activity for the entire day. Travel to a hospital or infusion facility would have meant arranging for someone to transport me there and back home; public transportation is not a viable option even in the suburban setting where I live. Receiving infusions at home eliminates the hassles and expense of arranging transportation. Receiving subq infusions eliminates the need for premedications and allows a minimal intrusion into my life. While home infusions are not the first choice for all patients, I appreciate having that option.

It is a concern that a reduction in immune globulin product reimbursements to providers, coupled
with what appears to be a low reimbursement rate for infusion supplies and possibly nursing care, would result in specialty pharmacies and other providers limiting availability of some or all products to patients in some or all geographic areas, possibly depending on which arm of the Model is applied. This could manifest in a variety of ways, such as providers carrying only products with higher reimbursement rates, limitations on the amount of supplies provided (more tubing, needles, and syringes are needed for daily infusions than for biweekly or monthly infusions), or providers simply deciding they don’t want to provide products, supplies, and nurses at all for infusions in some locations, such as homes or doctors’ offices. The same would apply for other providers, infusion centers, and hospitals. The quality of patient care would decrease, and the risk to patients of adverse reactions resulting from “incentivized” dosage and product changes would increase.

*Outcome-based reimbursement*

Outcome-based reimbursement might arguably benefit an insurance company, but it is not a good approach for Medicare. The Medicare beneficiary population differs from the population that receives regular insurance. Medicare beneficiaries meet qualifications of receiving social security disability benefits or age, and they are much more likely to have multiple chronic conditions and/or poorer health than the population as a whole. Tying reimbursements to outcomes provides a strong disincentive for providers to treat patients who have poorer prognoses and patients who have multiple co-existing conditions. Outcome-based reimbursement would decrease access to care for such patients.

In addition, outcome-based reimbursement is impractical in situations where it may take months or years to determine the outcome of treatment. For example, outcomes of breast cancer treatments, i.e., recurrences, may not be apparent for 5-15 years after treatment ends. For primary immune deficiency patients, it would be difficult or impossible to define any reasonable outcome-based criteria for adoption in value-based pricing for immune globulin products. Defining the outcome on the basis of the number of subsequent infections or hospitalizations a patient has would ignore the reality that many antibody-deficient patients also have other immune system defects, such as T cell dysfunction and complement deficiencies. Antibody replacement with immune globulin helps these patients significantly but doesn’t address the defects that don’t involve antibodies. Further, primary immune deficiency patients often have co-existing related chronic health problems, such as lung damage, gastro-intestinal system damage, auto-immune conditions, and increased risk for some forms of cancer. Immune deficiency patients also are not spared other, unrelated, health issues, including conditions that are increasingly likely as patients age and become Medicare beneficiaries, such as cardiovascular disease, diabetes, and osteoarthritis. It would be difficult at best and perhaps impossible to devise a fair and reasonable outcome-based reimbursement scheme for such patients.

*Potential for increased costs to Medicare*

The 2003 Medicare Modernization Act’s non-inclusion of reimbursement for supplies and nursing care for IVIG administration resulted in a lack of availability of IVIG infusions at sites
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other than hospitals and infusion centers because such a reimbursement rate was unprofitable for providers. That same loss of availability is likely to recur, but for subq as well as IVIG infusions. If the patient had to receive his or her infusion at an outpatient care infusion facility instead of at home, Medicare’s cost increase would exceed the savings per infusion.

If the choices decrease for which product a patient receives, how often it is received, and where it is received, some patients will discontinue receiving infusions. This could be due to increased inconvenience for the patient, but more likely because the patient has adverse reactions that make infusions intolerable under the conditions made available with the proposed Model.

It is well known that primary immune deficiency patients who discontinue infusions tend to become ill with new infections that may be severe and require hospitalization. Thus, if the proposed Part B Drug Payment Model goes into effect, it could result in increased costs to Medicare for Part A coverage that would more than offset the savings to Medicare Part B. One hospitalization for an infection resulting from loss of access to immune globulin could eliminate decades worth of savings to Medicare for that patient. In addition, new infections could also cause permanent organ damage to the beneficiaries, contrary to the stated Payment Model goal of “preserving or enhancing the quality of care provided to Medicare beneficiaries.”

Conclusions
CMS should withdraw the Part B Drug Payment Model. CMS lacks the authority to establish a rule of this broad scope and that will interfere with the Congressionally-mandated IVIG Demonstration project. The proposed Model in large part targets the wrong parties with cost-saving incentives, and its implementation would limit options for patient care. It is crucial that patients receiving immune globulin have multiple options for product selection, location of administration, and the mode of administration, based on what is best for their personal situations. The proposed Part B Drug Payment Model would not meet its stated goal of preserving or enhancing the quality of care provided to Medicare beneficiaries, and it would likely increase Medicare costs.

Thank you for your attention. Please do not hesitate to contact me if you require additional information.

Sincerely,

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