

## IMMUNE DEFICIENCY FOUNDATION

September 14, 2007

Kerry Weems, Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

**Re: CMS-1392-P; Comments on Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates, Including “OPPS: Nonpass-Through Coded Drugs, Biologicals, and Radiopharmaceuticals” and “IVIG Preadministration-Related Services”**

Dear Administrator Weems,

The Immune Deficiency Foundation (IDF), founded in 1980, is the national patient organization dedicated to improving the diagnosis and treatment of patients with primary immune deficiency diseases (PIDD) through research, education, and advocacy. Thousands of individuals and their families who live with primary immune deficiency diseases count on IDF for (1) education programs and materials that focus on the recognition and diagnosis of primary immune deficiency diseases, important life management, patient care resources, and support for patients and family members, (2) research and medical education programs that improve diagnosis and treatment of primary immune deficiency diseases, and (3) advocacy to promote policies that positively affect the primary immune deficiency community.

We are providing our comments on the July 16, 2007, Proposed Rule, CMS-1392-P, regarding payment for IVIG provided by hospital outpatient departments at ASP+5%, instead of ASP+6%, for CY 2008, and a reduction in the preadministration-related services payment for IVIG in those settings from \$75 to \$38.52.

### ***Background***

Since the change in Medicare’s reimbursement for IVIG beginning in January 2005, IDF has received countless calls from Medicare patients who have primary immune deficiency diseases and for whom IVIG is their only effective treatment. For all of these patients, IVIG is literally life-saving; without it, they would die. With the change to the ASP+6% reimbursement methodology, in both the physician office beginning January 1, 2005, and the hospital outpatient setting beginning a year later, PIDD patients experienced, for the first time, serious problems with finding providers willing to treat them. The result has been for many patients postponed treatments and increased time between treatments and accompanying negative health effects, including more infections generally, pneumonia, bronchitis, and increased use of antibiotics.

### *IDF Surveys on IVIG Issues for Medicare PIDD Patients*

In order to better quantify and understand the effect the ASP+6% reimbursement change has had on PIDD patient access to care, IDF commissioned three national surveys during 2006: a national patient survey of patients from the IDF data base, including an over-sample of Medicare patients, a national survey of hospital pharmacists, and a national survey of immunologists, conducted with the American Academy of Asthma, Allergy, and Immunology (AAAAI). All surveys were conducted in the second half of 2006.

#### *IDF Patient Survey*

The 2006 IDF Patient Survey was a mail-based survey of 1,000 PIDD patients, including individuals insured through Medicare, as well as those insured through private pay insurance. Conducted between August and October 2006, the survey found:

- 32% of Medicare patients have changed site of infusion since the end of 2004, compared to 20% of private pay patients.
- Medicare patients have moved from being treated in doctors' private offices to hospital outpatient settings. This change in treatment setting for the Medicare patient with PIDD means that patients may be exposed to greater numbers of infectious agents in the hospital, they may experience greater inconvenience and more travel time in getting to that setting, and they will have higher out-of-pocket costs in the hospital outpatient setting as well.
- Reimbursement is the primary reason for changes in location for Medicare patients, but not private pay patients.
- Medicare patients are more likely to report having more trouble in getting IVIG treatments since the beginning of 2005 than private pay patients (27% vs. 12%).
- Medicare patients were much more likely than private pay patients to report:
  - Treatments postponed;
  - Treatment intervals increased;
  - Dosage decreased; and
  - Other problems since the beginning of 2005.
- PIDD patients on Medicare are more than two times more likely than private pay patients (26% vs. 10%) to report negative health effects since the beginning of 2005, as a result of problems in obtaining or paying for IVIG.
- These negative health effects experienced by Medicare patients with PIDD and needing IVIG include more infections generally, pneumonia, bronchitis, and increased use of antibiotics, among others.
- The likelihood and number of health problems experienced by PIDD patients on Medicare is directly correlated with their difficulties in obtaining IVIG therapy.

IDF will be surveying patients again later this year to determine whether their access problems have changed. We assume, however, from the number of calls we have received thus far during 2007 that PIDD patients continue to have the same access problems documented in our 2006 patient survey, with patients experiencing difficulties in finding providers who will treat them because of inadequate reimbursement from

Medicare. Patients also continue to experience negative health effects that accompany delayed treatments.

### ***IDF Hospital Pharmacist Surveys***

The IDF survey of hospital pharmacists was conducted by telephone during August-October, 2006, with 310 randomly selected pharmacies in the U.S. serving 100+ bed hospitals which dispense IVIG. The survey's findings include the following:

- Thirty percent (30%) of the pharmacists reported that their hospitals paid more for liquid IVIG than they were reimbursed. The average price paid for liquid IVIG was 4% more than Medicare reimbursement.
- Fifty-seven percent (57%) of the pharmacists reported their hospitals paid more for lyophilized IVIG than they were reimbursed. The average price paid for lyophilized was 15% more than the Medicare reimbursement rate.
- Sixty-two percent (62%) believe Medicare reimbursement is not adequate. A substantial proportion (41%) of hospitals remains uncertain or doubtful about continuing to provide IVIG therapy to patients in the future given current reimbursement policy.

During the second quarter of 2007, IDF resurveyed hospital pharmacists, conducting a telephone survey between June 13, 2007 and July 15, 2007, with 235 randomly selected pharmacies in the U.S. serving 100+ bed hospitals which dispense IVIG. The picture has changed very little:

- Forty-one percent (41%) of the hospitals pay more for the product than they are reimbursed. The average price paid for liquid IVIG was 1% more than Medicare reimbursement, with the amount varying by the size of the hospital.
- Sixty-two percent (62%) of the pharmacists reported their hospitals pay more for lyophilized IVIG than they were reimbursed. The average price paid for lyophilized was 9% more than the Medicare reimbursement rate.
- Sixty-one percent (61%) stated that Medicare does not fully reimburse the hospital for the purchase of IVIG. Almost one-third (30%) of the hospitals are uncertain or doubtful about continuing to provide IVIG therapy to patients in the future, given current reimbursement policy.

### ***IDF/AAAI Survey***

The survey of immunologists, conducted in collaboration with the AAAAI, looked at the treatment of patients with PIDD and other conditions with IVIG. This survey was conducted by internet between October 13 and November 17, 2006. A total of 230 immunologists completed the survey. Its findings include the following:

- The average price physicians (immunologists) paid for liquid IVIG was 11% more than Medicare's reimbursement. Forty-four percent (44%) of the physicians paid more for the product than they were reimbursed.
- The average price physicians paid for lyophilized IVIG was 19% higher than the reimbursement at that time. Eight-one percent (81%) of the physicians paid more than they were reimbursed.
- Fifty-one percent (51%) of physicians have had patients change their site of IVIG therapy because of reimbursement.
- Thirty-six percent (36%) of physicians treating PIDD patients with IVIG reported that their IVIG-using patients have experienced additional or more severe health problems since the beginning of 2005 because of reductions in Medicare reimbursement.
- Nearly half of the doctors with IVIG-using PIDD patients believe current Medicare reimbursement rules for IVIG pose an extreme or serious risk to the health of their patients.
- Three-quarters of physicians were of the opinion that current reimbursement poses at least a moderate risk to the health their PIDD patients.

***Similarities between IDF's Survey Findings and the April 2007 Report of the Office of the Inspector General (OIG)***

As summarized above, IDF's surveys have demonstrated that a significant portion of the PIDD patient population needing IVIG has encountered serious problems with continuing access to IVIG since the change to Medicare's ASP+6% reimbursement methodology. Providers have also had difficulty purchasing IVIG at a cost equal to or less than Medicare's reimbursement.

The April 2007 OIG report, *Intravenous Immune Globulin: Medicare Payment and Availability*, validates many of the findings of IDF's surveys. The OIG found that 41% of IVIG sales to physicians and 44% of sales to hospitals by the three largest distributors occurred at prices above the Medicare payment amount during the third quarter of 2006. This finding was for a time during the calendar year when ASP+6% could begin to catch up to price increases that had occurred at the beginning of the year. *The OIG observed that whatever improvement some providers saw in the relationship of Medicare reimbursement for IVIG to prices paid during the first three quarters of 2006 would be eroded if manufacturers were to increase prices for IVIG in the future.*

The OIG also reported that 61% of responding physicians indicated that they had sent patients to hospitals for IVIG treatment, largely because of their inability to purchase IVIG at prices below the Medicare reimbursement amounts, but also because they were unable to provide patients with adequate amounts of IVIG. As noted above, IDF does not believe the hospital is the most appropriate setting for PIDD patients to receive their infusion. In addition, OIG found that some physicians had stopped providing IVIG to Medicare beneficiaries altogether.

### ***Specific Comments on Proposed Rule***

#### ***Payment for IVIG Should Not be Reduced to ASP+5% in Hospital Outpatient Settings***

While IDF believes that the hospital outpatient setting is far from the most ideal setting for infusion of IVIG for patients with PIDD, the reality for many of our patients is that hospital outpatient departments are the only place they can turn to for treatment. Both our patient survey and the OIG report document the dramatic shift from physician office to hospital outpatient settings for treatment. IDF surveys of hospital pharmacists also show that a significant number of hospitals continue to pay more for IVIG than they are reimbursed by Medicare at ASP+6. We fear that a reduction in payment to ASP+5% will create even greater dislocations for patients with PIDD than we have seen in the past, with devastating consequences for their health. Our patients will not be able to return to the physician office for their treatment, since many physicians ceased providing IVIG infusions during 2005 and 2006 because of inadequate reimbursement. Nor is home infusion an option for our patients, because Medicare law does not allow reimbursement for the costs of administration of IVIG. The question is where our patients will be able to go if hospital outpatient departments begin turning them away.

#### ***Payment for Preadministration-Related Services Should Not be Reduced***

IDF's tracking of PIDD patients' access to IVIG through surveys and its patient advocacy help-line have clearly indicated that a significant portion of Medicare beneficiaries with PIDD have experienced—and continue to experience—serious problems in finding providers who will infuse them with life-saving IVIG. The consequences of these access problems are the negative health effects discussed above. We believe that the preadministration-related services add-on has helped hospitals to cover some of the difference between the price they pay for IVIG and Medicare's reimbursement for the product. With a reduction in the amount paid for preadministration-related services, we again fear that patients with PIDD will be turned away from the hospital and no alternative treatment setting will be available to them. We would also ask that you consider the very real possibility that hospital billing errors have led CMS to an erroneous conclusion about the costs hospital incur for preadministration-related services. At the same time, we believe that the amount of the add-on is insufficient to correct the IVIG access problems our patients are having. CMS' action to create separate codes for each of the liquid IVIG products may ameliorate some of our patients' problems, but it is far too early for us to believe that this is the solution we need.

### ***Conclusion***

In the last analysis, we do not believe that the ASP+6% methodology is working for IVIG. Too many hospitals and other providers serving our patients simply can not purchase IVIG for the amount Medicare pays. Patients with PIDD are the ones who suffer the consequences in the end. As the OIG's report notes, IVIG is a unique pharmaceutical product whose production requires substantial time, resources, and

special handling not generally associated with other drug products. We urge that CMS review existing data and collect whatever additional data is necessary for making recommendations on payment reforms appropriate for IVIG.