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IMMUNE DEFICIENCY FOUNDATION



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Healthcare Crisis Hits Medicare Patients Needing Immune Globulin

Medicare Modernization Act has unintended but devastating repercussions for seriously ill beneficiaries

TOWSON, Md., TEMECULA, Calif. and NEW YORK, N.Y., May 16, 2005—Patient advocacy organizations are joining with the healthcare industry to alert the public and legislators to an emerging healthcare crisis that is likely to cost lives if Congress and the Centers for Medicare and Medicaid Services (CMS) do not act quickly.

The Immune Deficiency Foundation and The Neuropathy Association, two national patient advocacy groups, and FFF Enterprises Inc., a biopharmaceuticals distributor, have joined forces to send an emergency alert to Medicare policy makers and the public that new reimbursement rates for intravenous immune globulin (IVIG) are putting patients' lives at risk and increasing healthcare costs for taxpayers.

The January 1 congressionally-mandated reduction in Medicare Part B reimbursement rates and the April 1 two-tier rates for liquid and lyophilized (powdered) IVIG established two rates for administering IVIG to patients, depending on where they receive treatment: in the physician office and at home, or in hospital outpatient settings. The new reimbursement methodology significantly lowers the rate paid to physician offices and homecare companies for IVIG infusions – at a time when IVIG prices are rising and supplies of some IVIG products are tightening.

The combination of reduced reimbursement, rising prices and tightening supply has created a dangerous situation in which seriously ill, low-income patients with primary immune deficiencies or neuropathies are struggling to maintain access to care – and in some cases are unable to obtain care, causing their health to deteriorate. Because private insurers typically follow Medicare's lead, the problem will likely expand to include private-pay patients who depend on IVIG infusions.

Patients At Risk

“This is a healthcare crisis for patients whose health – whose lives – depend on regular IVIG treatments,” said Michelle Vogel of the Immune Deficiency Foundation, based in Towson, Md. “We have received over 300 phone calls from Medicare patients who can no longer receive their IVIG treatments in their physicians' offices, infusion suites or homecare settings (see attached testimonials). Many of these patients were referred to hospitals that cannot or will not provide their treatment, or that have waiting periods of up to six months. In six months these patients could be dead – essentially because of an inadequately informed decision to lower Medicare reimbursement rates!

“We are hoping that we can draw enough attention to this crisis,” Vogel continued, “that CMS, with congressional support, will take immediate action and save these patients' lives.”

Patients across the country are calling and writing their representatives, attempting to seek assistance on an individual basis to obtain treatment. Marsha Bond, who lives in Irving, Texas, is an immunodeficiency patient. She has missed her monthly IVIG infusion, and her physician has been unable to convince any of the local hospitals to treat her.

“I'm now two weeks late for my treatment,” Bond said, “and I am definitely seeing and feeling the difference. I'm having a lot of symptoms. ... I need the IVIG treatments; I'll just continue becoming more ill without them. On the other hand, we're exposed to lots of opportunistic germs in a hospital, more so than we'd encounter in the community, and many hospitals aren't equipped to administer infusions with the same level of expertise that we receive in the doctor's office. So, by going into the hospital to get our treatments, we're taking on a lot more risks at the same time that we're trying to get better. Of course, I can't get treated in any hospital right now, and I'm not sure what I'm going to do. But I can't believe people will sit by, knowing that people will die, before they fix this problem. I pray that not a single one does, but I don't know.”

The new reimbursement rate is so low, that physicians cannot continue to provide patient care without putting their practices at financial risk (see attached testimonials). Across the country, physicians are now referring their patients to hospitals, where outpatient reimbursement is higher.

According to Dr. Mark Stein, an immunologist practicing in Palm Beach County, Florida, the reduction in IVIG reimbursement rates for physician offices is not resulting in

reduced Medicare costs. “I have one immunodeficiency patient whose IVIG cost about \$1,700 in my office,” Dr. Stein said. “She just received a hospital bill pricing her IVIG at over \$13,000! Any suggestion that Medicare reform is saving tax dollars is a fallacy.”

Additionally, if primary immune deficient patients do not receive their IVIG, the secondary infections they will inevitably acquire result in additional healthcare costs, often including expensive hospitalizations.

Providing infusions in the hospital setting also poses additional challenges. Some hospitals are refusing patients, reportedly due to lack of adequate treatment facilities or inadequate IVIG supply. Most hospitals only purchase one type of IVIG (whatever is least expensive when the order is placed), resulting in patients being treated with an alternate product to that recommended by their physicians – and suffering the consequent dangerous adverse effects. And, expensive hospital co-pays are causing some patients to forego their IVIG treatments because they can’t afford the higher payments.

One Florida patient, who prefers to use only her first name, Christina, is permanently disabled and on a very limited income. She is now facing hospital co-pays as high as \$649, so she has gone without treatment since February, and her health continues to decline.

“At this point,” Christina said, “I’m not going to the hospital for infusions because I can’t afford to. If I won the lottery, I would, but I can’t afford to waste money playing the lottery!”

The Source of the Problem

The unexpected consequences of the Medicare Modernization Act and the Part B rate reduction are due to the unique nature of the human plasma products market and a lack of policy makers’ understanding of product supply dynamics, according to Patrick M. Schmidt, president and CEO of FFF Enterprises, the nation’s largest distributor of IVIG. He equates current market conditions to the onset of an IVIG supply tightening. “Rising demand coupled with a stable production output is creating a tightened supply market,” Schmidt explained. “We are seeing escalating prices in conjunction with tightening supplies against a backdrop of reduced reimbursement that, together, are creating this healthcare crisis. This means that physician offices and homecare companies have access only to products that are significantly higher in price than what Medicare now reimburses. The math is simple: It does not equate. And the human toll is just as simple, but wholly unacceptable: We will begin to lose patients if we do not act swiftly.

“The Medicare Modernization Act created two-tier pricing for the same treatment provided in different care settings,” Schmidt continued, “and this is having a severe impact on patient care. Additionally, opportunistic distributors are taking advantage of the tightening supply by raising prices above the reimbursement rate for any healthcare

setting. This is diverting the once-responsibly priced supply from where it is needed most.”

Don Jacob, executive director of The Neuropathy Association, estimates about 5,000 neuropathy patients are treated with IVIG. He believes that the reimbursement problem reflects a lack of understanding about the diseases that are treated with IVIG and the settings in which treatment is delivered.

“Medicare’s artificially created disparity in reimbursement rates for IVIG, based on the treatment setting, serves no purpose,” Jacob declared. “Paying one kind of provider more than another does a disservice to the patients. It victimizes people who are already victimized by a disease. I know of one man who, without his IVIG, can’t get out of bed. This is not like getting mumps. This disease determines if you can lift your arms and legs or not. We know that IVIG enables people, and then to deny them their treatment or make it difficult to obtain, I just don’t get it. I cannot imagine that anyone who actually knows anything about this illness and the necessity for treatment would even consider doing what Medicare has done.”

The Solutions

Dr. Daniel Suez is an immunologist, practicing in Irving, Texas. He has been treating primary immune deficient patients for 28 years. He wants a solution to the reimbursement problem that is realistic and best serves his patients. “I think the legislation needs to be rewritten,” Dr. Suez explained, “to make it feasible for the reimbursement formula to reflect reality: the vacillating cost of the IVIG, the cost of the specialized equipment for administering it and the cost of the specialized nursing and physician skills needed.”

Wanda Mench, a Medicare recipient with a chronic immunodeficiency, has been relying on charitable contributions to fund her hospital co-pay so she can continue to be treated. For her, the solution is a matter of making the patients’ lives the priority. “All we can do is take it month to month, and try to get the legislation changed. We have to impress people we can’t vote for, and that’s hard to do. You feel like your hands are tied. They don’t understand the consequences of the bills they are passing. The system just doesn’t work right. When you have a committee that’s making these decisions, it shouldn’t matter where you live, whether you’re a Democrat or a Republican. What should matter is that people’s lives are at risk.”

The Immune Deficiency Foundation (IDF) offers several solutions that would result in realistic Medicare rates, including encouraging CMS to declare a public health crisis or reimburse IVIG as a blood product so that IVIG pricing can revert to the traditional Average Wholesale Price (AWP) methodology. According to IDF’s Michelle Vogel, “Patients need access to all brands of IVIG in all sites of care, and reimbursement should never dictate where or if a patient receives their lifesaving therapy.”

Patient Marsha Bond believes the solution is self-advocacy, but as she becomes increasingly ill, she doubts her effectiveness. "I've asked everyone I know to write letters to their representatives, but so far, nothing has come of that," Bond said. "I did get a letter back from Representative Kenny Marchant's office, saying they had contacted Medicare on my behalf and that they would let me know when they hear something. But if it takes too much longer, I won't have any energy left to fight. I'm just hoping with all of us pushing in this direction at once, that something good will fall out of the sky."

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Physician testimonial: Dr. Robert Dracker

Dr. Robert Dracker is a pediatrician, hematologist and transfusion medicine specialist, practicing in Syracuse, NY. He treats primary immune deficient patients and neuropathy patients, both of whom receive infusions of immune globulin (IVIG), also known as gamma globulin. The reduced Medicare reimbursement rate for office-based IVIG treatment has severely affected at least eight of Dr. Dracker's Medicare patients. His local hospitals cannot easily treat his patients at their outpatient clinics, and the patients are reluctant to be admitted because of the risk of exposure to infections. Dr. Dracker has taken an active but frustrating role, attempting to advocate for realistic Medicare reimbursement policies with the Centers for Medicare & Medicaid Services (CMS) and his state's elected representatives, to make sure his patients are well served.

"In January, the Medicare reimbursement changed. They took most IVIG products, eliminating the most expensive ones, and considered them to be equal – without considering their availability, pricing or specific indications with regard to patient tolerance or medical requirements – and they came up with a reimbursement

"Of my Medicare patients, I have at least eight who are severely affected. They ended up without treatment for two months – normally they are treated monthly. Three ended up hospitalized, and now I'm treating the other five of them, because they can't wait any longer or their health will further deteriorate."

system that doesn't realistically cover the cost of products. We constantly read about health-care costs going up, but my reimbursement has gone down for four consecutive years in my infusion office.

"I spoke with Dr. Herb Kuhn, at CMS. He said he wished that I, and others like me, had been more involved. They enacted some short-term, interim changes in early February, but with the changes in the reimbursement rates that occurred on April 1st, the situation ended up even worse.

"I'm not sure why we are in this situation, but I do know it appears these decisions have been made in an uninformed way. They didn't include all IVIG products, excluding the higher

priced products and disregarding indication for the individual patient; they spoke with manufacturers, not distributors, so the prices they considered were below market value; and, in excluding the most expensive IVIGs, they excluded the preferred products for some patients.

"I asked Dr. Kuhn what I should do for my patients. He said I could use another product, and see if they can tolerate it. Since I know that some patients will most likely have adverse effects, I could not do that in a medically prudent manner.

"The reimbursement we now receive for giving the gamma globulin averages \$93 total. That's for a six- to eight-hour, labor-intensive treatment, including the disposable equipment required for an infusion; a nurse checking on the patient every half hour; and my checking the patient. It does not cover our costs. And the situation will become worse, as private insurers follow Medicare's lead.

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I'm treating the other five of them, because they can't wait any longer or their health will further deteriorate. What's worse is they don't want to go to the hospital, because they feel it exposes them to even greater health risks.

"It's a horrible position to be in, when we can't even get reimbursed

what we pay for the product, yet we have a duty to our patients, and they want to continue treatments in the safest possible setting. All I want to do is help my patients.

"We are taking a patient group with known high-risk conditions that can be effectively treated by the use of gamma globulin, and

we're allowing their conditions to worsen. Imagine the cost of the additional care as they become increasingly sick and are forced into the hospital, experiencing regression in their general health. I feel we are in a health-care crisis – one that could have been completely prevented."

Patient testimonial: Marsha Bond

After struggling for years with serious illnesses, Marsha Bond was diagnosed in 1997 with autoimmune disease and in 2004, with primary immune deficiency disease. She is now a patient of Dr. Daniel Suez, in Irving, Texas. Prior to her diagnosis and proper treatment, Bond was very ill, unable to care for herself. Then she began monthly treatments in Dr. Suez' office in February 2005, but, with the reduction in reimbursement rates, the doctor sought treatment for her at a local hospital.

"After the first two treatments at Dr. Suez' office, it wasn't really visible that I was better, but I felt stronger inside, and I felt hopeful. I was so sick before, that any improvement was wonderful! I was scheduled for my third treatment in April, at Baylor Irving Hospital, but they cancelled. Then Dr. Suez contacted Baylor Las Colinas Medical Center, but they wouldn't treat me either. Each time they've cancelled, they've cancelled at the last minute. I have to wonder

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why. And, yesterday, I was turned down by a third hospital, Medical City of Dallas.

"I'm now two weeks late for my treatment, and I am definitely seeing and feeling the difference. I'm having a lot of symptoms: sinus and ear drainage, sore throat, chest congestion, chills, high fever, fatigue, severe GI symptoms, swelling, migraines, body rashes and tremors, and believe it or not, my face is broke out in acne!

"I need the IVIG treatments; I'll just continue becoming more ill without them. On the other hand, we're exposed to lots of opportunistic germs in a hospital, more so than we'd

encounter in the community, and many hospitals aren't equipped to administer infusions with the same level of expertise that we receive in the doctor's office. So, by going into the hospital to get our treatments, we're taking on a lot more risks at the same time that we're trying to get better. Of course, I can't get treated in any hospital right now, and I'm not sure what I'm going to do.

"But I can't believe people will sit by, knowing that people will die, before they fix this problem. I pray that not a single one does, but I don't know.

"I thought I was too sick, but I need to fight for myself. I used to be an event manager; I'm a big multi-tasker, a big problem solver; I know how to do this. But, having gone this long being so fatigued and so sick, it has been paralyzing, and I didn't know if I can continue, yet I know I have to. And I'm afraid that I won't have an effect – there are only 50,000 of us with this disease, and I'm afraid we don't make enough noise, we don't

cast enough votes to be heard.

“I’ve asked everyone I know to write letters to their representatives, but so far, nothing has come of that. I did get a letter back from Representative Kenny

Marchant’s office, saying they had contacted Medicare on my behalf and that they would let me know when they hear something. But if it takes too much longer, I won’t have any energy left to fight.

“I’m just hoping with all of us pushing in this direction at once, that something good will fall out of the sky.”

Physician testimonial: Dr. Mark Stein

Dr. Mark Stein, an immunologist practicing in Palm Beach County, Florida, has been caring for patients with immunodeficiencies for over 15 years. He has watched the dramatic decreases in Medicare reimbursement for intravenous gamma globulin and has become concerned about a disturbing trend in this nation’s healthcare.

“We have seen Medicare progressively cut reimbursement for the last four years – to the point that we can no longer continue to infuse our patients in our office. We have about 60 Medicare patients, some without any supplemental insurance. For those patients, finding money to pay the 20 percent co-pay, when they are indigent, is an impossibility. If we were billing the currently authorized \$39 per gram for the least expensive product (which now costs us \$47 per gram to purchase), the patient would pay 20 percent (usual dose is 20 to 40 grams). When the patient goes to the hospital, the hospital is reimbursed \$80 per gram by Medicare. This means the patient will be responsible for 20 percent of \$80 per gram and any other hospital charges for outpatient

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infusion service. This means they will never be able to afford the hospital co-pay. And it is no better for the taxpayers. I have one immunodeficiency patient whose IVIG cost about \$1,700 in my office. She just received a hospital bill pricing her IVIG at over \$13,000! Any suggestion that Medicare reform is saving tax dollars is a fallacy.

“We now have people who have to go to hospitals that are in inconvenient locations. There are more resistant bacteria in the hospital environment. There are more people who are coughing and spreading these resistant bacteria that you don’t usually find in the community. Most hospitals

only carry one brand of intravenous gamma globulin, so many patients have had to switch to a new brand. If the patient cannot tolerate the product at one hospital, they may have to switch doctors so they can be referred to a different hospital that carries the product they need. Some patients can only tolerate one product, so they may have to put up with side effects, or, if that product is not available at any hospital, they won’t be able to get their infusions.

“We know that this is an ongoing problem. We have one patient with no secondary insurance besides Medicare, who has been fortunate enough to attract some of the area TV stations to her plight. People made donations, so she can still temporarily afford to receive care in the hospital. She has osteomyelitis of her ankle and could be at risk of an amputation if her gamma globulin were discontinued.

“But we have another lady who has been in the hospital a number of times. She also does not have secondary insurance. Unless she gets on Medicaid, she cannot afford to get her infusions, and she’ll probably die of pneumonia.

“Medicare is forcing a reduction in the quality of care for patients with primary immunodeficiency diseases. Medicare is supposed to cut reimbursement to the hospital for intravenous gamma globulin in 2006. If this problem isn’t fixed before then, Medicare patients will probably have nowhere to go to receive gamma globulin.

“Immunodeficient patients are going to be in a class by themselves, the only patients unable to get the care they need in this country. This would be sad; it would suggest that we’ve slipped into a healthcare system that’s worse than what we see in

any other western democracies, where people are denied care based on a specific disease state. Is our government saying, ‘This is it for you; your life expectancy is limited by your disease state’? The country is essentially eliminating a class of patients, those with immunodeficiencies. These people are few in number, but imagine if this were people on dialysis. Could we deny all dialysis patients their treatment?

“There is a lack of understanding of primary immunodeficiency diseases, what these patients require, and how to make it available, convenient and

affordable. Imposing different pricing for different care settings does nothing for patient care. In fact, it is detrimental to the continuity of care. We need Medicare to appropriately price gamma globulin so that it can again be purchased and administered in all locations. And, doesn’t it make more sense to keep people out of the hospital, and allow them to be treated by those who know their cases, who can closely monitor them and provide an environment that protects them from resistant bacteria?”

Patient testimonial: Wanda Mench

Wanda Mench, a Medicare recipient, has a chronic immunodeficiency and began receiving regular IVIG infusions in 2002. Until January 2005, she had no problem obtaining treatment in her physician’s office, and the IVIG helped keep her functioning. When Medicare reimbursement rates were reduced in January and then again in April, Wanda could not afford the hospital co-pay. Her daughter, Heather Mench, attracted television media attention to her mother’s plight and, through the contributions of generous community members, Wanda has been able to obtain treatment in her local hospital.

Wanda: “I’m due for my treatment tomorrow, I’m going to the hospital, but I’m apprehensive. I don’t know how long I’ll be able

“I don’t know how long I’ll be able to afford the treatment, but if I don’t get the treatments, I’m looking, at the very least, at an amputation of my leg, and it could be worse.”

to afford the treatment, but if I don’t get the treatments, I’m looking, at the very least, at an amputation of my leg, and it could be worse.

“It’s absurd for Medicare to think that a doctor could do this in an office without paying for the costs of doing it. Yet they’re paying twice as much to the hospital, where I can’t even get my product, and I don’t know what will happen.

“All we can do is take it month to month, and try to get the legislation changed. We have to impress people we can’t vote for, and that’s hard to do. You feel like your hands are tied. They don’t understand the consequences of the bills they are passing. The system just doesn’t work right. When you have a committee that’s making these decisions, it shouldn’t matter where you live, whether you’re a Democrat or a Republican. What should matter is that people’s lives are at risk.”

Heather: “It’s frustrating. This is my *mom*. And the government is deciding how to classify a drug and how to pay the provider – and whether my mom will live or not. It seems that no one who has the power to change things is willing to change them. We’re

going month to month on the generosity of people who are sending contributions because they saw our story on TV. So we don't know whether she'll be able to continue getting her treatment.

"I don't have any respect for our system. I don't think it values people's lives. If you are ill, then you are a throwaway, you're just

an expense and your life has no value.

"Right now, our only way of getting her treatment is through the donations of others and a whole lot of prayer.

"Fixing this will take a lot of persistence, a lot of people being willing to speak out and say,

'This is a problem and we aren't going to accept it. We aren't getting what we need, but this is our government, and we aren't going to stand for this. It is just unacceptable.'"

Physician testimonial: Dr. Daniel Suez

Dr. Daniel Suez is an immunologist, practicing in Irving, Texas. He has been treating primary immune deficient (PIDD) patients for 28 years. The new Medicare reimbursement rates have damaged his doctor-patient relations and hindered his patients' access to treatment in the most therapeutic setting.

"Primary immune deficiency disease is a rare condition. I have 10 Medicare PIDD patients. I was able to find local solutions for four patients who live outside of the Dallas/Fort Worth area, but we have six patients living in the Dallas/Fort Worth metroplex area who are waiting to be treated.

"I have privileges at four hospitals, and I'm fighting to get these six patients treated, but the hospitals' administrators are refusing to allow me to treat these patients in their respective hospitals. I think it has to do with a lack of experience with PIDD patients, and the feeling that this is too much of a responsibility. One

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hospital administrator said that the patients must be treated in an intensive care unit and that they do not have the personnel to deal with it. This is absolutely not necessary. PIDD patients can be treated in an outpatient department. I also think that there is some financial concern and that the hospital administrators may believe that the patients would be using too much of the hospital resources. Hospital pharmacies normally keep a low IVIG supply, as it is not commonly used. The concern may be that as more PIDD patients require treatment in the hospital, it will potentially drain their cash flow.

"The purpose of IVIG therapy is preventative. It's been five weeks since their last treatment. They require treatments an average of every three or four weeks, so by now my patients are exposed to potentially life-threatening infections, and the longer they wait for treatment, the lower their antibody levels and the greater the risk of serious infection. If they develop a severe infection, then they'll be hospitalized, but then it could be too late. Normally, PIDD patients should not be treated in the hospital, because there is a higher risk of exposure to germs in a hospital. Yet according to the new legislation, Medicare doesn't cover the cost of treating them in my office, and the hospitals don't have the experience to treat these patients. What is the logic of this?

"If these patients don't receive their treatments, it is a life-threatening condition. This disease is so debilitating without treatment, frequently leading to disabilities

and chronic mental depression. I would not be surprised, if they are not treated, that PIDD patients may develop serious complications with potentially fatal outcomes.

“Somebody didn’t think it through. In determining reimbursement, CMS disregarded the various related factors reflecting real costs. In the last six months alone, there has been a dramatic

surge in the cost of the IVIG, which is not reflected by the new formula, and, hence, the patients cannot receive their treatment.

“I think the legislation needs to be rewritten to make it feasible for the reimbursement formula to reflect reality: the vacillating cost of the IVIG, the cost of the specialized equipment for administering it and the cost of

the specialized nursing and physician skills needed. This, in order to re-establish physician-patient relations that have been seriously damaged and to allow PIDD patients to receive their treatments at specialty clinics and avoid potential adverse outcomes.”

Patient testimonial: Linda Swim

Linda Swim, who lives in Irving, Texas, has common variable immune deficiency. She began IVIG therapy in 1996, and has been a patient of Dr. Suez for two or three years. Swim normally receives monthly infusions of IVIG to boost her immune system and keep her healthy and independent. Swim explained what has happened to her since the Medicare reimbursement rate for IVIG was reduced on April 1.

“My last treatment was March 29th, and now I’m being denied treatment: The doctor’s office can’t treat me because Medicare doesn’t pay enough for my IVIG, and the hospitals, Baylor Irving and Baylor Las Colinas, won’t treat me. My doctor told me they said they didn’t want to take the responsibility for it. Las Colinas sent a fax stating that they would not take on the responsibility.

“It ought to be against the law! If the doctor orders the treatment,

“I’m afraid I will end up back in the same condition I was in before I started my IVIG treatments. I’ll get infections and not be able to fight them. I won’t be able to care for myself or provide for myself. I don’t know what I’m going to do.”

and if the patient has Medicare, the hospital should have to give you the treatment.

“Before I began my IVIG treatments, my condition was so severe that I was in bed all the time. I was so weak, that I could not get out of bed except to go to the bathroom. I had to stop working. I could not do anything for myself. It was terrible. They sent me to a specialist and I was finally diagnosed. Then I started treatment, and it still took a long time, months – almost a year, for the treatment to begin to work, because I had been so sick.

“I need my treatments to stay healthy, and I would go to the hospital, but I’m also fearful of going to the hospital, because of the exposure to infections. But now they won’t even take me. It’s not fair to us. We are very sick people, and they are denying us lifesaving treatment. It would be like taking insulin away from a diabetes patient or taking chemotherapy away from a cancer patient, though they wouldn’t do this to a cancer patient. But they can get away with taking away our treatments, because so few people know anything about our disease.

“We should be able to continue to get the treatment in our doctor’s office. He monitors us and makes sure we don’t have side effects – you can have life-threatening side effects. They know what to look for, and they keep us away from other patients with infections that can make us sick. They know how to mix the IVIG, how to infuse it.

Whereas, at the hospital, they think it's just another IV treatment, which it is not. So, I can understand why the hospitals don't want to treat us.

"Now, I'm afraid I will end up back in the same condition I was

in before I started my IVIG treatments. I'll get infections and not be able to fight them. I won't be able to care for myself or provide for myself. I don't know what I'm going to do.

"And I'm too young to end up in

a nursing home," Swim managed to chuckle. "But without the IVIG, I'll only get worse. And, if I end up in a nursing home, it'll cost the government even more than if they'd just let me continue getting my treatment at my doctor's office!"

Physician testimonial: Dr. Robert Hostoffer

Dr. Robert Hostoffer is an immunologist in private practice in Cleveland, Ohio. He currently has 20 Medicare patients, whom he has continued to treat, despite the Medicare reimbursement rate reduction for office-based infusions of IVIG.

"We still are caring for the patients here in the office. It's at breakeven to a loss. I don't know how much longer we can – maybe another month or two.

"If the situation does not improve, we're going to try to get them treated in the hospital setting, that's our only option – homecare companies don't want Medicare patients. But what will end up happening is, we can slip them under the hospitals' radar for a couple infusions – but once the hospitals start feeling the financial crunch, they won't want to continue treating them. They don't want the risk.

"The patients are very worried. They've asked me to be their representative, but they're all worried. At the hospital, they may not get the right IVIG product and there won't be a doctor there to attend them. They're at high risk for other problems, but

"If you move the patients away from the doctor to a hospital, if the doctor doesn't get to see them regularly, serious problems will be missed. For instance, patients with common variable immune deficiency have a 600% chance of developing lymphoma or leukemia."

they won't be able to see me on a regular basis.

"If you move the patients away from the doctor to a hospital, if the doctor doesn't get to see them regularly, serious problems will be missed. For instance, patients with common variable immune deficiency have a 600% chance of developing lymphoma or leukemia. If I don't see them for six months, that could be missed, but I would still be liable.

"There are a number of forces creating this problem. First, Medicare created different prices for different care settings – I've never seen that before. It doesn't take into consideration quality of care.

"Some of the problem is caused by secondary distributors – they are going off the wall with this. If we had a secure purchase place, a portal for PIDD only, something approved by Medicare that didn't over-inflate the prices, we could purchase there at reasonable prices. Or if doctors could buy directly from the manufacturer, that would also be a partial solution.

"Third, we've been hearing about an IVIG shortage, but I'm not sure there is one. If manufacturers are holding back product, Congress needs to look into it. Or, if there really is a shortage, we should bring another product into the country and get it approved as quickly as possible.

"The long-term impacts of this situation are very serious. We have so few immunologists now, and, if inadequate reimbursement eliminates the doctor's office as a treatment component, you'll end up with no immunologists. If you damage the profession, that damages the patients' quality of care. And, in ten years, there won't be any patients."

Patient testimonial: Christina

Christina, who asked that only her first name be used, has common variable immune deficiency, and she has been treated with gamma globulin for about eight years. She received her first hospital infusion at the end of December and her second one was the beginning of February.

“I asked the hospital if they could forgive the co-pay, but I didn’t get much of an answer. Then the first bill came for about \$320, and then I got a bill for \$649. I can’t afford it. I’m on disability. I just don’t have the energy to work, because I’m so sick. So I haven’t had an infusion since very early February.

“In the past couple of months I’ve had two bugs, one I’m still getting over. I’m very vulnerable to everything. If I’d had my

“I’ve only seen my doctor once since February, but he can’t do too much, because his hands are tied. Things were so much better before; they could be so much better now, but I feel helpless to change it.”

infusion, I wouldn’t be coping with this. The little energy I have is taken away when I come down with something.

“Now I am trying not to go out into public too much. I avoid crowds. If someone sounds as though they’re sick, I apologize and back away. There’s a tendency not to be as social as much as one might want anyway, because of the memory impairment associated with this disease.

“I’ve only seen my doctor once since February, but he can’t do too much, because his hands are tied. Things were so much better before; they could be so much better now, but I feel helpless to change it. I would ask Medicare to please consider people who need care and can’t afford it. Please have some kind of plan to help us. Please don’t make such drastic changes without considering all the ramifications on us.

“At this point, I’m not going to the hospital for infusions because I can’t afford to. If I won the lottery, I would, but I can’t afford to waste money on the lottery! I just hope for the best, though I don’t know what the future will hold.”

Patient testimonial: Christian Donoghue

Christian Donoghue has chronic inflammatory demyelinating polyneuropathy and chronic immune deficiency. So far, he has been able to continue receiving treatments in his physician’s office, but the infusions have become less frequent.

“When the reimbursement rate was decreased, I became very concerned because I wasn’t able to access treatment with

“This goes right to my core, and it burns. There needs to be more fiscal responsibility and accountability in our system, and we need to put people’s health first.”

the frequency I need to stay as physically fit as I should with a chronic illness. My normal treat-

ment is every four weeks, but I just went over six weeks. Initially, I experienced a lot more prickling and numbness. Then I began a slow decline in muscle strength. I just got my treatment today or it would have gotten worse.

“Without the IVIG, I become more lethargic and run down than normal. If it goes too long, the weakness affects my ability to ambulate and I can actually

go into partial paralysis.

“We have great medical care available in the United States, the best you can get. But the channel to it is cumbersome with a bottom-line business approach. A lot of the costs are exorbitant and inflated. And, if you’re forced to go to the

hospital for treatment, the costs are much higher than in my physician’s office, so the system spends more money than is necessary. This is a terrible dysfunction in our healthcare system. It’s a waste of money – and the patient’s health pays the cost. “This goes right to my core, and it burns. There needs to be more

fiscal responsibility and accountability in our system, and we need to put people’s health first.”

Clinician testimonial: Rob Hirsh

Rob Hirsh, a registered pharmacist and president of SBH Medical, a specialty pharmacy, is associated with a hospital-based outpatient clinic and numerous physician office-based infusion centers that provide IVIG to hundreds of neurological patients yearly. Approximately 20 to 25% of the population being treated represents Medicare recipients. As of April 1, 2005 the Medicare reimbursement rates have been significantly reduced to such an extreme, that actual product costs far exceed reimbursement. These patients are now being referred to hospitals, but the hospitals are ill prepared to treat them – for lack of appropriate IVIG products and staff.

“We’ve been involved in large outpatient neurology clinics for many years. We know how hard it is to get product and how much it costs, so we’re dealing with this problem as best we can but the situation isn’t good.

“In January, when the first

“As a clinician for 30 years, this situation is very disturbing. We have created a very cost-effective and safe platform for delivering high-tech infusion therapies to patients. Now we are shifting the care back into the hospital where traditionally, costs are higher and not as convenient for the patient.”

Medicare cuts came, we were led to believe that CMS was going to review the reimbursement rates and we’d see an improvement in the second quarter. The second quarter came, and we saw yet another significant cut in reimbursement. Now we have been put in a situation that leaves us no alternative but to discontinue providing services to the Medicare population of neurological and immune deficiency patients being

treated with immune globulin.

“As a clinician for 30 years, this situation is very disturbing. We have created a very cost-effective and safe platform for delivering high-tech infusion therapies to patients. Now we are shifting the care back into the hospital where traditionally, costs are higher and not as convenient for the patient.

“And, the private insurers follow Medicare guidelines. We’re expecting them to drop their rates soon, also. So, basically we’re being driven out of the business of caring for patients. And where will these patients go?”

Patient testimonial: Brook

Brook, an immunodeficient patient in Palm Beach County, Florida, recently had her first hospital infusion. She was treated so poorly, she is afraid to use her real name publicly, but she wants people to know what happened to her.

“For more than 15 years, I’ve normally received my IVIG infusions in my doctor’s office, but I just had to have my first infusion in a hospital. It did not go well.

“I had put a numbing cream on my hand that I always use at the infusion site. The nurse told me she didn’t ever want to see it on me again, and she wanted to know why it was on my hand. I explained that that was where I always get my infusions. She said she’d give me my IV any

“By the time I was finished I was having reactions – shaking, confusion and a headache that lasted all night and the next day.”

place she wanted, not necessarily on my hand, but I’ve had it there for 15 years.

“She asked me how long my infusions last, and I told her it was usually around eight hours. She said that it has to be done on her shift and that the hospital’s protocol was four hours. I explained that it takes longer for me, because I have allergic reactions if the infusion is too fast. She just said that four hours was their protocol, and

she proceeded to set me up for four hours. By the time I was finished I was having reactions – shaking, confusion and a headache that lasted all night and the next day.

“She took the IV off, and I asked her to use Coban to hold the gauze down to cover the infusion location, because my skin is so sensitive. She said they didn’t have it, so I gave her some of mine. When I asked another nurse about the shaking, she said, ‘What do you want me to do about it?’

“My next infusion should be next week, and I’m not too happy about going back there.”

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Fact Sheet: Diseases Treated with Immune Globulin (IVIG) Therapy

About Primary Immune Deficiency Diseases

Primary immune deficiency diseases (PIDD) are disorders in which part of the body's immune system is missing or does not function properly. In contrast to secondary immune deficiency disease in which the immune system is compromised by factors outside the immune system, such as viruses or chemotherapy, the primary immune deficiency diseases are caused by intrinsic or genetic defects in the immune system. In some cases, the body fails to produce any or enough antibodies to fight infection. In other cases, the cellular defenses against infection fail to work properly. There are more than 120 different primary immune deficiency diseases currently recognized by the World Health Organization.

Untreated primary immune deficiencies may be characterized by frequent life-threatening infections and debilitating illnesses. However, because of advances in medical understanding and treatment of PIDD, individuals who in the past would not have survived childhood are now able to live nearly normal lives. Many individuals affected by PIDD require lifelong therapies, including intravenous immune globulin infusions, antibiotic therapies or bone marrow transplantation.

Statistics

- An estimated 50,000 people in the United States suffer from a primary immune deficiency disease.
- Approximately 7,000 PIDD patients are Medicare beneficiaries.

Symptoms of Primary Immune Deficiency Diseases

- Frequent and recurrent ear infections, especially after early childhood
- Frequent and recurrent sinus infections
- Frequent and/or recurrent pneumonia and/or bronchitis
- Infections and/or complications of the gastrointestinal tract
- Failure of an infant to gain weight
- Recurrent, deep skin or organ abscesses
- Associated autoimmune or inflammatory disease
- Persistent thrush in mouth or elsewhere on skin, after age one
- Deep-seated infections that do not clear with a regular course of antibiotic therapy

The Immune Deficiency Foundation website: www.primaryimmune.org.

About Peripheral Neuropathy

Peripheral Neuropathy is a neurological disorder that causes debilitating pain, weakness in the arms and legs, and difficulty walking. Neuropathy results from damage

to the peripheral nerves. It can cause weakness, pain, loss of coordination and sensory loss in the arms and legs. The disorder varies in severity, but in some cases it can be debilitating or even crippling or fatal. However, if diagnosed early, it can often be controlled. Most people have never heard of it, so patients feel alone and without a place to turn to for help. Too often neuropathy is discovered after it has already caused irreparable harm.

The peripheral nervous system is one of the two main divisions of the body's nervous system. (The other is the central nervous system, which includes the brain and spinal cord.) "Peripheral" means away from the center: This system contains the nerves that connect the central nervous system to the muscles, skin and internal organs.

In about one-third of patients, the cause of neuropathy is unknown. Known causes include: diabetes, auto-immunity, genetic defects, cancer, kidney disease, nutritional imbalance, toxins, nerve compression and infections such as hepatitis C, Lyme and leprosy, among others.

Statistics

- An estimated 15-20 million Americans suffer from Peripheral Neuropathy.
- Peripheral Neuropathy is more common among adults, but can occur at any age.

Symptoms of Peripheral Neuropathy

- Burning sensation or freezing pain
- Sharp, jabbing or electric-like pain
- Extreme sensitivity to touch
- Numbness, tingling and pain
- Loss of balance and coordination
- Muscle weakness
- Difficulty walking or moving the arms
- Unusual sweating
- Abnormal blood pressure or pulse
- A sensation of wearing an invisible glove

The Neuropathy Association website: www.neuropathy.org.