OPINION

Most Vulnerable Patients Need Lawmakers to Act

BY **TODD HRABAK**

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As a seasoned allergist and immunologist practicing in the Phoenix area for many years, I am deeply concerned about the changes resulting from a technical issue in the 21st Century Cures Act, and the unintended consequences it will have on my patients.

Currently, I manage approximately 100 patients who are receiving supplemental Immunoglobulin Replacement Therapy for underlying primary immunodeficiencies. These patients are among the most vulnerable in our healthcare system. Over the past several years, there has been an overall trend and transition in managing patients, taking them from hospital-based IgG therapies, commonly known as Intravenous Immunoglobulin, to the home setting to receive similar therapies, also known as Subcutaneous Immunoglobulin Therapy. This cost-effective transition improves patient tolerance, side effect profile, quality of life and care flexibility.

In addition to positive health outcomes, in-home treatment has budgetary benefits: Patient infusions in a home-based setting, rather than in the hospital setting, are likely to be less expensive. Further, the transition from hospital-based to home-based infusion therapies has only been made possible due to the significant impact and role of specialty home infusion pharmacies. These pharmacies provide care and clinical services ranging from health insurance benefit verification to nursing training to supply, medication and technical troubleshooting for patients requiring IgG therapy. Without the invaluable support and efforts of these specialty home infusion pharmacies, many of these patients would not

be able to initiate or continue their home-based therapies, thereby impacting their quality of life.

In recognition of the importance of services provided by home infusion providers, Congress acted to ensure reimbursement for such services in the 21st Century Cures Act. Unfortunately, that provision of the law does not begin until 2021, and another provision cut reimbursement starting in January, creating a four-year care gap and dramatically impacting access to home infusion for patients with Medicare. Thankfully, in July the House passed H.R. 3178, legislation that would remedy this problem by providing a transition reimbursement to bridge the gap starting in 2019, and a Senate companion bill (S. 1738) has been introduced. We are still advocating for the Senate to pass H.R. 3178 so that the president may sign the measure into law.

Secondary to the underlying costs associated with IgG replacement therapies, some patients have been forced to transition to a hospital setting when they were being adequately controlled, managed and satisfied with home-based therapies. As one might imagine, patients who were happy with their home-based infusions were frustrated and upset having to change to a different infusion setting, and concerned about the potential of product and manufacturer change to their protocols. Many of these patients also voiced their concerns regarding potential prolonged exposure to other ill patients during the IVIG infusions, as well as the increased, real possibility of acquiring infections from the hospital exposure. Other patients have significant logistical difficulties obtaining transportation to and from the hospital infusion center, which, in some instances, may be located far from their homes.

Although some specialty home infusion pharmacies have attempted to accommodate existing patients and their current home-based therapy requirements, many specialty pharmacies are no longer supplying home-based therapies, due to the substantial reimbursement cut. These patients have been transitioned to the hospital setting, where it actually costs more to treat them. The patients have been

frustrated and upset with these decisions, and expressed their concern for lack of control over them and their medical decision-making. Many patients have informed me they are considering discontinuing IVIG as a result of the changes from home-based to hospital-based IV therapies and the changes to their medications.

Not only has the primary immunodeficiency patient experienced significant frustration as a result of the four-year care gap, our office and staff has also experienced significant logistical issues. Oftentimes, we are bogged down with trying to find specialty pharmacy providers willing to take on new patients requiring subcutaneous, home-based, IgG therapies amid this new regulatory landscape. This increased work load has placed a tremendous strain on our office and staff, and further decreased our efficiencies in managing patient workload.

While the 21st Century Cures Act had many positive attributes, it unfortunately has also had far-reaching, unanticipated effects on home infusion patients, caregivers and medical providers. Specifically, the care gap created by a technical issue in the legislation has caused significant changes relating to these patients, infusions, medications, cost of care, transportation logistics and access to care. It has been my experience that the vast majority of my patients on home-based therapies are significantly happier and satisfied with the greater quality of life it affords them when compared with patients receiving hospital-based or IVIG infusions. The inability to continue, or initiate, home-based infusions has had significant psychological, social and financial stress on many Medicare patients.

Ideally, Congress must pass legislation to ensure specialty home infusion pharmacy reimbursement between now and 2021. It remains in the best interest of the patient, physician, provider and, of course, our nation's healthcare system.

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