September 10, 2012

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Immediate Action Requested Regarding ESRD Nutritional Therapy Crisis

Dear Secretary Sebelius:

I am writing on behalf of the American Nephrology Nurses’ Association (ANNA), our 10,000 members, and the over 430,000 Americans that suffer from kidney failure and end stage renal disease (ESRD), many of whom require kidney dialysis or transplantation to live with such life threatening conditions. It is well documented that patients with end-stage renal disease on chronic hemodialysis have a high incidence of protein-energy malnutrition and that nutritional problems can lead to a host of significant clinical problems.

I would like to express ANNA’s deep concern regarding recent and unanticipated actions which threaten the continued availability of a key nutritional drug therapy for ESRD patients -- known as intradialytic parenteral therapy (IDPN) and intraperitoneal parenteral nutrition (IPN) -- in the Medicare Part D population. IDPN and IPN nutritional therapies are well established clinical therapies used to address protein malnutrition in patients with ESRD. These two drug therapies allow for the delivery of life sustaining protein to ESRD patients suffering from morbid protein malnutrition. These treatments are documented at reducing both mortality and hospitalizations in the ESRD patient population and have been recognized by the Centers for Medicare & Medicaid Services as being a covered drug therapy under Medicare Part D since the launch of this program in January of 2006.

As you may be aware, continued access to this drug therapy is in jeopardy due to an unexpected and unprecedented re-pricing of key macronutrient components of IDPN and IPN therapies, including several key amino acids, dextrose and lipids used by specialty compounding infusion pharmacies. This radical change in pricing, which occurred in mid-July 2012, has resulted in the decrease in Medicare Part D reimbursement by approximately 80% across virtually every Part D plan in the United States. This change occurred without any prior notice to ESRD patients or the specialty compounding pharmacies that provide this therapy to Medicare Part D beneficiaries.

The compounding of any IDPN/IPN drug therapy is costly and complex. IDPN/IPN infusion requires a highly specialized infusion pharmacy, to ensure that risks are not added for these patients, many of whom have compromised immune systems and experience complications related to other co-morbidities. Administering the drug also requires a host of related infusion supplies and clinical services. Since each prescription is custom compounded to meet the needs of an individual patient, and must be maintained under refrigeration, there is not a large back supply of these drugs. As a result, it is likely that there will be significant shortages of these nutritional supplements in the very near future.
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The potential elimination of an entire form of covered Medicare Part D nutritional therapy to ESRD beneficiaries appears to be an unintended consequence of this recent action—yet, without some form of immediate intervention, ANNA is deeply concerned that the entire IDPN and IPN industry will be forced to discontinue providing this critical drug therapy to dialysis patients. The loss of this therapy will have a direct impact on the nutritional options that ESRD patients have today and, importantly, a direct impact on patient health and safety.

While we understand that the Secretary’s general position is to allow private Medicare Part D plans the ability to determine the price to be paid for covered Part D drugs, it is ANNA’s view that the Secretary has the statutory authority—indeed the obligation—to ensure that these covered Part D drug therapies remain available to ESRD beneficiaries. There exist options that should be considered by the Secretary; including issuing guidance to all Part D plans to continue reimbursement at the pre-July 2012 rates at least for the balance of the remaining calendar year or until a permanent solution can be developed by all industry stakeholders to ensure that these critical drug therapies remain available to ESRD beneficiaries.

As this change in reimbursement was drastic, unprecedented, and without any prior notice, IDPN and IPN patients have been put at severe risk of losing access to these critical treatments. ANNA urges CMS to use any and all appropriate administrative measures and plan directives to address the potential loss of this life-saving nutritional drug therapy in what is an extremely fragile patient population in the United States.

I appreciate your consideration of ANNA’s concerns and look forward to your response and action. If you would like to discuss these concerns directly, you may reach me at 214-850-1894 or by email at gpayneful@aol.com.

Sincerely,

Glenda Payne, MS, RN, CNN
President 2012-13
American Nephrology Nurses’ Association

cc: Marilyn Tavenner, Acting Administrator, CMS
Jonathan Blum, Deputy Administrator and Director, Center for Medicare, CMS
Alliance for Renal Nutrition Infusion Therapy Providers