



THE KIDNEY CARE COUNCIL

Providers of Quality Care for the Nation's Dialysis Patients

June 6, 2013

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Tavenner:

Congratulations on your recent confirmation as Administrator of the Centers for Medicare & Medicaid Services (“CMS”). The Kidney Care Council (“KCC”), the nation’s largest association of dialysis facilities that collectively provide life sustaining dialysis treatment to more than 85 percent of individuals with kidney failure in the United States, appreciates your prior work on behalf of patients with kidney failure, and looks forward to continuing the productive relationship we have enjoyed to date extending into the future.

As your agency is in the process of designing the policy to rebase the Medicare End Stage Renal Disease Prospective Payment System (“ESRD PPS”), as called for by the American Taxpayer Relief Act of 2012 (“ATRA”; Pub. L. No. 112-240), we wanted to impress upon you our serious concerns regarding the impact this provision could have on patient access to care if it is not implemented correctly. KCC member companies worked closely with CMS in designing and implementing the current ESRD PPS and even agreed to have facility payments reduced by two percent under the new payment system in anticipation of reductions in pharmaceutical use and other efficiencies, a reduction that translates to approximately 8-10 percent less pharmaceutical utilization.

That cut, taken together with other reimbursement reductions, the sequester, and dialysis treatment input price increases, has created significant strain for many facilities and puts additional downward pressure on facilities’ already thin Medicare margins, which the Medicare Payment Advisory Committee has consistently found to be in the low single digits, among the lowest of any health care sector. Still, we remain committed to working with the Agency to further improve the ESRD PPS and ensure ongoing access to the highest quality dialysis care for beneficiaries with kidney failure.

Unlike many other providers, dialysis facilities are disproportionately dependent on Medicare. In fact, more than 80 percent of our patients have Medicare as primary coverage. As a result, unlike providers in many other sectors, dialysis providers are unable to cost shift to other payers. Not surprisingly, given our thin Medicare margins, any change adversely affecting the ESRD PPS will have significant ramifications on facilities and could, in turn, dramatically

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impact patient access to care. In order to prevent this from happening, we respectfully urge you to carefully consider facilities' costs associated with caring for some of Medicare's sickest beneficiaries. We believe that in complying with ATRA, the Agency also maintains the affirmative obligation to establish the ESRD PPS rate on a cost or other equitable basis, to ensure that facilities' ability to continue providing quality dialysis care is not compromised. In short, we believe the ATRA reduction cannot and should not be viewed in a vacuum.

As stewards of the Medicare program, members of the KCC support rebasing the ESRD PPS in a comprehensive manner, taking into consideration our facilities' true and current economics. While the language found in Section 632 of ATRA requires the ESRD PPS to be updated to reflect decreased pharmaceutical utilization, the language also affords the Agency the opportunity to accurately capture facility costs where the bundle does not provide for adequate reimbursements.

For example, late last month, KCC member companies received an important notice regarding the pricing of a major, clinically essential pharmaceutical that we believe CMS must take into consideration as it assesses dialysis provider costs and their input prices in the context of the ATRA implementation. In a public announcement dated May 23, 2013, distributed broadly to the provider community, wholesalers, and distributors, Amgen, the nation's only manufacturer of Epogen, advised purchasers that, effective May 24, 2013, the selling price for this critical pharmaceutical would increase by approximately *5 percent*. (See Attached.) As you know, Epogen is an essential clinical component of quality dialysis care.

Given that the ATRA adjustment is focused, in part, on utilization changes in pharmaceutical use, we strongly believe that change and the related ESRD PPS rebasing should be considered in the full and complete context of the steady and repeated Epogen price increases to which KCC member companies and Medicare beneficiaries have been subject since the ESRD PPS was implemented (approximately 15 percent overall since the beginning of 2011) *and* the newly announced increase of almost 5 percent. This substantial mid-year price increase for the single most clinically important pharmaceutical we provide is emblematic of the ongoing increase in the cost of providing dialysis care.¹

As a result, we respectfully request that, in the context of your current review and analysis in preparation for the CY 2014 Proposed ESRD PPS Rule and the ATRA adjustment within it, you consider not only all of the downward economic pressures dialysis providers face

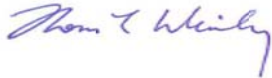
¹ Compounding matters, this price increase took effect after the ESRD payment amount had already been set for the year.

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in the current environment², but also the highly pressurized, distorted marketplace for Epogen that exists and the price consequences our member companies and patients pay as a result of it.³

If the ATRA provision is implemented correctly, the ESRD PPS has the potential to be a dramatic improvement over the prior payment system and a model for other bundled payment systems. Our member companies look forward to working with you as you continue to develop and implement this provision.

Respectfully Submitted,



Thomas L. Weinberg
Chairman
Kidney Care Council

Attachment

Cc. Chairman Max Baucus
Ranking Member Orrin Hatch

Chairman Fred Upton
Ranking Member Henry Waxman
Chairman Joe Pitts
Ranking Member Frank Pallone

Chairman Dave Camp
Ranking Member Sander Levin
Chairman Kevin Brady
Ranking Member Jim McDermott

² The Epogen increase comes as KCC member companies continue to struggle with still other downward economic pressures that threaten providers' viability, such as sequestration, the disallowance of significant costs associated with network and medical director fees, and unreimbursed bad debts.

³ As you know Epogen's manufacturer enjoys monopoly market power in the United States, leaving dialysis providers with little, if any, negotiating power.



Amgen USA Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799
805.447.1000
www.amgen.com

Price Change for EPOGEN[®] (epoetin alfa)

May 23, 2013

Dear Valued Trading Partner:

Effective **May 24, 2013, at 12:01 AM PDT (3:01 AM EDT)**, Amgen will implement a change to the Wholesaler Acquisition Cost ("WAC") for **EPOGEN[®]**. **All orders received on or after 12:01 AM PDT (3:01 AM EDT), May 24, 2013, will be invoiced at the new WAC.** The new WAC for this product is attached.

Please note that the contracted price for **EPOGEN[®]** may change on different dates for contracted customers as designated by Amgen.

If you have any questions please contact Amgen Trade Operations at 1-800-282-6436.

Sincerely,

Mark Bubany
Director, Corporate Accounts

Pricing Description Document
EPOGEN[®] (epoetin alfa)
Effective May 24, 2013 at 12:01 AM PDT (3:01 AM EDT)

EPOGEN[®] (epoetin alfa):

NDC	Description	New WAC* Per Pack	New WAC* Per Case
55513-126-10	2,000 Unit, 1 mL (2,000 Units/mL) single-use vial 10 vials/pack, 10 packs/case	\$275.60	\$2,756.00
55513-267-10	3,000 Unit, 1 mL (3,000 Units/mL) single-use vial 10 vials/pack, 10 packs/case	\$413.40	\$4,134.00
55513-148-10	4,000 Unit, 1 mL (4,000 Units/mL) single-use vial 10 vials/pack, 10 packs/case	\$551.20	\$5,512.00
55513-144-10	10,000 Unit, 1 mL (10,000 Units/mL) single-use vial 10 vials/pack, 10 packs/case	\$1,378.00	\$13,780.00
55513-283-10	20,000 Unit, 2 mL (10,000 Units/mL) multi-use vial 10 vials/pack, 4 packs/case	\$2,756.00	\$11,024.00
55513-478-10	20,000 Unit, 1 mL (20,000 Units/mL) multi-use vial 10 vials/pack, 4 packs/case	\$2,756.00	\$11,024.00

* WAC is Amgen's list price to wholesalers without taking into account wholesaler prompt payment terms, introductory launch terms, or other discounts, rebates, or chargebacks.