National Renal Administrators Association

August 10, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Acting Administrator Slavitt,

On behalf of our members, who are dialysis organizations treating Medicare beneficiaries across the country, we are writing to express our concerns with provisions relating to biosimilar reimbursement in the Centers for Medicare and Medicaid Services' (CMS) 2016 Medicare Physician Fee Schedule proposed rule.

The National Renal Administrators Association (NRAA) is a voluntary organization representing dialysis providers throughout the United States. Our membership is primarily small dialysis organizations, both for-profit and non-profit providers serving patients in urban, rural and suburban areas in both free-standing and hospital-based facilities.

NRAA is optimistic about the introduction of biosimilars into the U.S. market. We believe biosimilars have the potential to produce new drug options for our patients while producing some savings into the healthcare system. However, we are concerned with the agency's proposal to assign all biosimilars of a single reference product one Healthcare Common Procedure Coding System (HCPCS) code and to reimburse biosimilars with the same HCPCS code based on the sum of their average sales price. NRAA is concerned the proposal from CMS could place an administrative burden on providers, which would ultimately lead to less treatment options for dialysis patients.

As healthcare providers, we rely upon stable payment policies to ensure our patients have continued access to the medication they need. An accurate payment system is essential to dialysis facilities' ability to serve dialysis patients. This is especially true for the small and independent dialysis facilities that NRAA represents, where even the smallest fluctuation in payment rates does make a big impact. If multiple biosimilars to the same reference product share the same HCPCS codes, payers may be unable to properly adjudicate claims at the correct payment level. Payers may also require submission of medical records and invoices in order to determine payment levels, which would delay payment. Further, the provider could be forced to appeal the payer's decision which would delay payment even further. Ultimately, this burdensome process will cause providers to choose treatments that they know will be covered at the appropriate cost and that will limit their revenue exposure. As a result, new therapies will not be as accessible for dialysis patients.

When administering medication to patients, as providers we should be confident we will receive appropriate payment for the products we administer. Stable and accurate payment policies lead to the increased use of innovative therapies that benefit our patients.

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As biosimilars are unique, a "one-size-fits-all" approach to reimbursement is not appropriate. Assigning biosimilars a unique and permanent J-Code will allow for proper reimbursement, competition and investment, ultimately leading to sufficient access to biosimilars for patients in a range of therapeutic areas.

The NRAA respectfully requests CMS to assign biosimilars a unique and permanent J-Code that will allow for proper reimbursement, competition and investment, all toward the benefit of our patients, who in turn will receive timely access to innovative medicine. Requiring a biosimilar to use the miscellaneous J-code will increase the administrative burden for providers and impact Medicare beneficiaries by potentially reducing the use of biosimilar products by clinicians concerned with non-payment.

NRAA appreciates the opportunity to comment on these matters and appreciates your consideration of these issues. If you have any questions, please do not hesitate to contact Debbie Cote at (434) 924-5590 or dcote@nraa.org or Cary Gibson at (202) 530-4875 or cary.gibson@prime-policy.com.

Sincerely,

Deborah A Cote MSN, RN, CNN, NE-BC

Debbie Cote
President

Cc:
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