

September 11, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1676-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018 [Docket No. CMS-1676-P]

Dear Administrator Verma:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide comments in response to the solicitation of public comments on biosimilars included in the proposed rule “*Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018 [Docket No. CMS-1676-P]*” as published in the *Federal Register* on July 21, 2017. The introduction of biosimilars in the United States marketplace has the potential to save the United States healthcare industry billions of dollars in annual expenditures, and encourages a competitive marketplace that could result in substantial savings to patients and public and private payers. AMCP supports the implementation of a robust biosimilars pathway to ensure that Americans continue to receive access to safe, effective, and affordable biologics and biosimilars. AMCP offers comments on the following areas of biosimilars coding and reimbursement under Medicare that it believes can be improved to better meet the needs of beneficiaries:

- I. Coding & Reimbursement Under Medicare Part B
- II. Documentation of Medicare Part B Drug Claims Using National Drug Codes (NDC)
- III. Coding & Reimbursement Under Medicare Part D

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

I. CMS Should Critically Evaluate Coding & Reimbursement Options Under Medicare Part B to Ensure Patient Access and Affordability of Biologics and Biosimilars

AMCP encourages CMS to critically evaluate all possible options for the coding and reimbursement of biosimilars under Medicare Part B by considering existing economic analyses conducted by private sector entities and performing its own economic analysis and modeling of options that include both single codes for each biologic and biosimilar and also bundled codes, including options that may require statutory changes to implement. AMCP also encourages CMS to carefully consider the consequences to patient access under the various options, implications on provider prescribing habits as a result of varied incentives amongst the options, and ramifications to commercial contracts that use the Health Care Common Procedure Coding System (HCPCS). AMCP further encourages CMS to consider how the allowance for formularies and utilization management tools under Medicare Part B may decrease costs, improve quality, and increase value as demonstrated in Medicare Part D, Medicaid, and the commercial market. To this end, CMS may consider pilot programs to test new payment and coding models for biologics and biosimilars through the Center for Medicare & Medicaid Innovation (CMMI). Finally, AMCP encourages CMS to continuously evaluate the impact of any coding and reimbursement strategy adopted under Medicare Part B to determine success and areas for improvement as the biosimilars marketplace grows in the coming years.

II. CMS Should Require Documentation of Medicare Part B Drug Claims Using NDCs

AMCP recognizes that performing diligent pharmacovigilance for biologic products by collecting data through active post-marketing surveillance is vital to ensuring safe use by patients and to provide clinicians and payers with information to use in making product selection determinations. Use of HCPCS codes by Medicare Part B for billing and payment of medications is insufficient for tracking specific products and therefore, AMCP advocates for the use of NDCs on all medication claims. The ability to track the medication administered to the specific NDC number is critical to truly implement pharmacovigilance activities as documentation of NDCs will allow for specific data analysis and measure assessment.

In the final rule “*Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016*,”¹ CMS noted that it will be developing an approach for using manufacturer-specific modifiers, such as NDC numbers, on Part B claims to assist with pharmacovigilance. AMCP is disappointed with the two-letter modifier approach that CMS has developed², because it will likely cause great confusion with the naming convention for biosimilars adopted by the FDA which requires the use of a four-letter suffix.³ AMCP supports the use of NDCs on claims as a means to track product selection and

¹ Available at <https://www.gpo.gov/fdsys/pkg/FR-2015-11-16/pdf/2015-28005.pdf>. Accessed September 11, 2017.

² Part B Biosimilar Biological Product Payment and Required Modifiers. Available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Part-B-Biosimilar-Biological-Product-Payment.html>. Accessed September 11, 2017.

³ Nonproprietary Naming of Biological Products Guidance for Industry January 2017. Available at <https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf>. Accessed September 11, 2017.

believes that any additional modifiers or unnecessary data points could lead to errors in transmission of information on claims and the prescribing process leading to the potential for patient harm.

Therefore, AMCP strongly urges CMS to move forward with development of this process to require NDCs on all Part B claims to allow for meaningful assessment of a products safety. This approach would not be overly burdensome considering that NDCs are required on all Medicaid claims and are often required on claims submitted by physicians in the commercial market. Furthermore, every medication product has a specific NDC and therefore, its use on claims does not represent a new piece of data that could create confusion in product identification that may lead to prescribing or dispensing errors.

III. CMS Should Consider Categorizing Biosimilars as Applicable Drugs under Medicare Part D

As CMS reconsiders coding and reimbursement of biosimilars under Medicare Part B, it should also reconsider the categorization of biosimilars under Medicare Part D. AMCP remains concerned that biosimilars continue to be classified as non-applicable drugs under section 1860D-14A of the Social Security Act, which means they are not subject to the 50% manufacturer discount as required of manufacturers under the Affordable Care Act for applicable drugs during the coverage gap discount, known as the “donut hole.” While AMCP recognizes that this is a statutory issue, it is a barrier to the use of biosimilars by Medicare Part D beneficiaries because it may result in the use of a reference product that is subject to cost sharing reductions and not a biosimilar. Therefore, AMCP encourages CMS to determine policy solutions to provide incentives in all phases of Medicare Part D payment policy to encourage the use of biosimilars and other more affordable alternative medications.

IV. Conclusion

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP’s comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,



Susan A. Cantrell, RPh, CAE
Chief Executive Officer