ISSUE BRIEF

PROPOSED MEDICARE PART B REIMBURSEMENT RATE FOR BIOSIMILARS
August 2015

INTRODUCTION

The Centers for Medicare and Medicaid Services (CMS) is the largest single payor of healthcare in the United States. Nearly 90 million Americans rely on healthcare benefits provided through programs that are administered through Medicare, Medicaid, and the State Children’s Health Insurance Program (SCHIP)\(^1\). Their programmatic reach is broad, and their reimbursement policies form the contextual framework within which the commercial sector defines its payment parameters.

On July 8, 2015, CMS proposed the addition of a new rule to its 2016 Medicare Physician Fee Schedule that seeks to assign one Healthcare Common Procedure Coding System (HCPCS) code to all biosimilars to a particular reference product.\(^2\) This new rule also defines reimbursement for all biosimilars associated with a particular HCPCS code as the volume weighted average of the average sales price (ASP) of the biosimilars within a shared code. This proposed reimbursement policy, which treats biosimilars as multiple source drugs, will have the effect of limiting patient and provider access based upon economic considerations, and without consideration of heterogeneity of treatment effect.

The National Minority Quality Forum (The Forum) is encouraged by the promise of biologics and biosimilars to address diseases for which there are currently no effective therapies. The CMS proposed rule for reimbursement of biosimilars betrays that promise.

The Forum supports efforts to maximize the potential of innovation and precision medicine to address the unmet health services needs of populations who continue to be under-represented in the clinical trials and research that inform the clinical guidelines that define standards of care. This proposed reimbursement policy will compromise that future by constraining growth and innovation in this new and promising sector of health services research and development.

The Forum opposes all reimbursement policies with a price-control orientation, rather than assigning the highest value to the quality of the care that is available for and provided to all Americans. The Forum believes that public and private sector reimbursement policies should be designed to enable providers and patients to access all appropriate therapeutic options without being constrained by burdensome and potentially discriminatory formulary management and

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reimbursement policies. The CMS proposed rule for reimbursement biosimilars does not meet that standard.

**BACKGROUND**

Biologics are a category of therapeutics (medical products) that are derived from, or made by, the biological processes of a living organism, such as human cells, animals, microorganisms, or yeast. Many biologics are made from a variety of natural sources (human, animal or microorganism). Like drugs, some biologics are intended to treat diseases and medical conditions. Other biologics are used to prevent or diagnose diseases. Examples of biological products include vaccines; blood and blood products for transfusion and/or manufacturing into other products; allergenic extracts, which are used for both diagnosis and treatment (for example, allergy shots); human cells and tissues used for transplantation (for example, tendons, ligaments and bone); gene therapies; cellular therapies; and tests to screen potential blood donors for infectious agents such as HIV.

Unlike standard chemical drugs, which are relatively small molecules, biologics are larger and more complex molecules that are not produced through synthetic manufacturing pathways, but instead via organic means. Accordingly, unlike generics of small molecule drugs, due to this complex production mechanism it is challenging to create biological products that are highly similar to a biologic therapeutic molecule (a reference product) that has already received FDA approval, or to other biosimilars to that reference product.

The National Minority Quality Forum is concerned that the proposed biosimilars reimbursement rule could create financial incentives that will drive provider prescribing, rather than quality-based incentives that encourage clinicians to provide the best care by evaluating the relative efficacy of all available biosimilar options. As noted above, individual biosimilars are “biosimilar” to a reference product, but are not “biosimilar” to each other. Therefore, substitutability cannot be assumed. The proposed reimbursement policy therefore, by treating “biosimilars” as “generics”, puts patients at unacceptable risk.

**Conflicting Interpretations**

There is controversy surrounding this proposed rule, fueled by convoluted language in Section 1847A of the Social Security Act regarding the manner in which reimbursement should be calculated. In the proposed rule, CMS states that they are planning to use a single ASP payment limit for biosimilar products that are assigned to a specific HCPCS code. In short, this means that

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3 U.S. Food and Drug Administration, FDA approves first bio-similar product Zarxio, FDA.GOVL (March 6, 2015), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.htm

4 http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194516.htm

5 The Food and Drug Administration defines a generic drug as “identical—or bioequivalent—to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.” http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/ucm216146.pdf
products that rely on a common reference product's biologics license application will be grouped into the same payment calculation. CMS asserts that this approach is similar to the ASP calculation for multiple source drugs, and is authorized by section 1847A(b)(8)(A) of the Act. It is unclear why CMS elected to treat biosimilars as multiple source products, rather than in the manner clearly specified for biosimilars as outlined in 1847A(b)(8).

CONCLUSION

This proposed reimbursement policy is ill-conceived and short-sighted. The failure of CMS to propose a reimbursement rule for biosimilars that assigns a separate and distinct HCPCS code and reimbursement rate to each biosimilar puts the sustainability of nascent biosimilar research in jeopardy by creating a hostile marketplace. The collective damage to the physical and economic health of American consumers, their communities, and their employers cannot be dismissed.

The Biologics Price Competition and Innovation Act (BPCIA), a component of the Patient Protection and Affordable Care Act, created a long-awaited abbreviated licensure pathway for biological products that are demonstrated to be “biosimilar” to or “interchangeable” with an FDA-licensed biological product. Any conflicting regulatory interpretations, and potentially constraining market incentives, must be resolved before a reimbursement policy is promulgated that results in increased morbidity and mortality, constraints on innovation, and increases in the costs of care that CMS asserts it is endeavoring to avoid.

The National Minority Quality Forum strongly encourages the Centers for Medicare and Medicaid Services to rescind the proposed rule pending an assessment of the short- and long-term impact of implementation on patient access and costs.

For additional information, please contact:

Gretchen Clark Wartman
Vice President for Policy and Program
National Minority Quality Forum
202-223-7563