Health Care ADVISORY

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Update on Biosimilar Reimbursement Pathways: CMS Guidance and Outstanding Issues

Earlier this year, the U.S. Food and Drug Administration (FDA) approved the first biosimilar in the United States. The Centers for Medicare & Medicaid Services (CMS) recently issued three guidances regarding reimbursement for biosimilars under Medicare Parts B and D, as well as under Medicaid. These guidances address questions that have arisen regarding reimbursement policies that CMS will implement for biosimilars. When these guidances were released, a number of issues were left outstanding, including the applicability of pass-through payment eligibility to biosimilars and Healthcare Common Procedure Coding System (HCPCS) coding policies.

On July 8, 2015, CMS published in the Federal Register a proposed rule that would revise the Medicare hospital outpatient prospective payment system (OPPS) for CY 2016. In the OPPS proposed rule, CMS proposes to pay for biosimilars as required under Section 1847A of the Social Security Act and addresses one of the key outstanding questions around biosimilars reimbursement by proposing to extend pass-through payment eligibility to biosimilars and defining how such payment would be set.

The same day, CMS put on display at the Public Inspection Desk a proposed rule to revise the Medicare physician fee schedule (MPFS) for CY 2016. In the MPFS proposed rule, CMS proposes to amend existing regulations at 42 C.F.R. §414.904(j) to clarify that the payment amount for a biosimilar biological product will be based on the average sales prices (ASP) of all National Drug Codes (NDCs) assigned to the various biosimilar biological products included within the same billing and payment code.

Despite this additional guidance – which remains proposed only – additional questions remain that will need to be addressed by CMS and the FDA in future guidances or regulations.

Medicare Part B

Medicare Part B generally covers drugs and biologicals that are not usually self-administered, including those that are administered in a physician's office or hospital outpatient department. On March 31, 2015, CMS issued a

1 Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Prospective Payment System, Proposed Rule (80 Fed. Reg. 39199), available here.

2 Medicare Programs: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-16875.pdf. The proposed rule is scheduled to be published in the Federal Register on July 15, after which it will be available here.

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“Medicare Learning Network (MLN) Matters” (SE1509) that addresses frequently raised questions regarding biosimilar reimbursement under Medicare Part B. CMS clarifies, among other things, that the agency will incorporate biosimilars that are approved under the abbreviated biological approval pathway into the ASP payment methodology. Initially, Medicare will pay 106 percent of the product’s wholesale acquisition cost (WAC). Once ASP information is available for the biosimilar product, Medicare will pay an amount equal to ASP for the product plus 6 percent of the reference product, as required by the Affordable Care Act (ACA).

Reimbursement for the biosimilar will be effective retroactively to the FDA approval date. CMS will create a separate code to distinguish the biosimilar from the reference product and is “considering policy options for coding of additional biosimilars.”

The “MLN Matters” notes that CMS will release further guidance on coding and incorporation of biosimilars into the ASP payment methodology in the future.

Additional Proposed Part B Payment Policies for Biosimilars

In the CY 2016 OPPS proposed rule, CMS notes that the ACA amended Section 1847A of the Social Security Act to add the definition of “biosimilar biological product” and set forth a payment methodology for biosimilar biological products. CMS explains that the agency has the statutory authority under Section 1833(t)(14)(A)(iii)(II) of the Social Security Act to establish payments for biosimilars in accordance with Section 1847A of the Social Security Act. According to CMS, this section also provides discretionary authority for these payments to be calculated and adjusted by the Secretary of Health and Human Services as necessary. In light of this, CMS believes “that it is reasonable to adopt a policy to pay for biosimilar biological products as provided under section 1847A(b)(8) of the [Social Security] Act.” CMS therefore proposes to extend the application of the methodology for determining the amount of payment applicable to separately covered outpatient drugs (SCODs) to biosimilars. Practically speaking, CMS is proposing to pay for biosimilars based on the payment allowance of the product as determined under Section 1847A (ASP + 6 percent of ASP of the reference biological product). CMS also proposes that nonpass-through biosimilar biological products be subject to the proposed threshold-packaged policy, under which CMS would package items with a per-day cost less than or equal to $100 and identify items with a per-day cost greater than $100 as separately payable.

CMS states that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under Section 1842(o) of the Social Security Act and the otherwise applicable hospital outpatient department fee schedule amount. Accordingly, “[b]ecause section 1842(o)(1)(C) of the Act cross references section 1847A of the Act,” CMS believes that it is reasonable to infer that biosimilars are eligible for transitional pass-through payment. CMS therefore proposes “to extend pass-through payment eligibility to biosimilar biological products and to establish pass-through payment based on the difference between the amount paid under section 1842(o) of the Act (that is, the payment allowance of the product determined under section 1847A(b)(8) of the Act) and the otherwise applicable hospital outpatient department [(HOPD)] fee schedule amount.” This would equate to the difference between ASP + 6 percent of ASP of the reference biological product and the otherwise applicable HOPD fee schedule amount.

CMS specifically solicits comments on these proposed payment policies for biosimilars, including whether biosimilar biological products should be eligible for transitional pass-through payment, and the appropriate methodologies for determining payment for biosimilar biological products eligible for transitional pass-through payment. CMS will accept comments through August 31, 2015.
In the CY 2016 MPFS proposed rule, CMS further proposes to update existing regulations regarding payment for biosimilars. As proposed, CMS would amend the effective date and add the following highlighted language to the existing regulations at 42 C.F.R. § 414.904:

(j) Biosimilar biological products. Effective January 1, 2016, the payment amount for a biosimilar biological drug product (as defined in §414.902) for all NDCs assigned to such product is the sum of the average sales price of all NDCs assigned to the biosimilar biological products included within the same billing and payment code as determined under section 1847A(b)(6) of the Act and 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference drug product (as defined in §414.902).

CMS notes that the intent of this proposed change is to clarify that “the payment amount for a biosimilar biological product is based on the ASP of all NDCs assigned to the biosimilar biological products included within the same billing and payment code.” CMS also reiterates that payment for biosimilars will ultimately be made based on ASP data. However, as with all newly approved drugs and biologicals, ASP data may not be available before those drugs are eligible for payment (i.e., when the drug is approved by the FDA). Until ASP data is available, CMS proposes to use WAC-based pricing (106 percent of WAC), once such data is available. CMS also proposes that payment for biosimilars under Part B may be made before an HCPCS code has been released, “provided that the claim is reasonable and necessary, and meets applicable coverage and claims submission criteria.” CMS will accept comments on these proposals through September 8, 2015.

Medicare Part D

Medicare Part D generally covers self-administered drugs from every therapeutic category of prescription drugs, with formularies varying to a certain extent by plan. On March 30, 2015, CMS issued to Part D sponsors a memorandum on coverage of biosimilars under Part D that clarifies the application of formulary review policies, low-income subsidy (LIS) and catastrophic cost sharing rules, and Coverage Gap Discount Program requirements for biosimilars. The memo also notes that follow-on biological products approved by the FDA under Section 351(k) of the Public Health Service Act will be listed in a new Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations.

Regarding formulary review, CMS clarifies that reference and biosimilar products generally will not be considered different drugs for purposes of satisfying the two distinct drugs requirement for each of the categories and classes submitted by a Part D sponsor. CMS also provides that biosimilars may be added to Part D plan formularies at any time as a formulary enhancement. The addition of a biosimilar (or the removal of the reference biological product) will be considered a non-maintenance change, to be evaluated on a case-by-case basis. For purposes of the Part D transition supply and notice requirements, CMS states that biosimilars and the reference biological product should be treated as different products.

For the purposes of LIS and catastrophic cost sharing rules, CMS clarifies that biosimilars do not meet the CMS definition of either a generic drug or a multiple source drug. Biosimilars are therefore subject to the higher maximum copayments for LIS eligible individuals applicable to all other Part D drugs. In 2015, the maximum copayments for LIS individuals were set at either $3.60 or $6.60, depending upon an individual’s subsidy level. At the same time, CMS

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3 Except as provided in 42 C.F.R. 423.120(b)(2)(ii), which provides that a Part D plan must include at least one Part D drug within a particular category or class of Part D drugs to the extent the Part D plan demonstrates, and CMS approves, that only two drugs are available in that category or class of Part D drugs and that one drug is clinically superior to the other drug in that category or class of Part D drugs.
clarifies that the lower minimum copayments applicable to non-LIS eligible individuals in catastrophic coverage under the standard Part D benefit would not apply to biosimilars. Nevertheless, CMS “generally expects” that individuals who are not eligible for LIS will pay the 5 percent coinsurance for biosimilars in the catastrophic portion of the standard Part D benefit.

CMS also clarifies that biosimilars are non-applicable drugs for purposes of establishing coverage gap cost sharing under the basic Part D benefit. Biosimilars are therefore not discounted in the coverage gap or otherwise subject to Discount Program requirements.

**Medicaid**

Reimbursement for drugs and biologicals under Medicaid—and the rebates established under this program—have far-reaching impacts for manufacturers, as they may not charge any 340B entity a price greater than that derived under the Medicaid rebate formula. On March 30, 2015, CMS issued guidance on biosimilars and the Medicaid Drug Rebate (MDR) Program. Through this guidance, CMS clarifies that biosimilars fall within the definition of “single source drugs” for purposes of the MDR program. As a result, biosimilars will be subject to a 23.1 percent rebate (based on average manufacturer price (AMP)) and potentially subject to a penalty for any increases in AMP over inflation.

CMS specifically suggests that cost savings may be achieved by states by applying traditional drug utilization and cost management tools to biosimilars, as well as through supplemental rebate agreements between states and manufacturers. CMS also notes that prescribers may not be able to “simply write the proprietary name of a reference biological product and expect the pharmacist to substitute it with the biosimilar biological product,” as may be the case today with certain brand name and generic chemical compounds. Finally, to ensure “safe and efficacious use” of biosimilars, CMS encourages states to use drug utilization review programs and pharmacy and therapeutics (P&T) committees to inform physicians and pharmacists about appropriate prescribing and dispensing of biologics, including biosimilars.

**Key Outstanding Reimbursement Issues**

Beyond the issue areas on which CMS has already noted additional guidance is forthcoming, there are several key issues around biosimilar reimbursement which have not yet been addressed by CMS, all of which may be ripe for additional action from Congress.

- **Interchangeability.** CMS's memo to Part D sponsors specifically notes that additional guidance for “interchangeable” biological products may be issued at a later date. Neither CMS nor the FDA has provided final guidance or regulations on interchangeability.

- **Medicare Part A.** The administration and procurement costs of drugs and biologicals for use in certain provider settings, such as a hospital inpatient department, may subject the drug or biologic to payment under Medicare Part A. In general, Part A pays for such drugs or biological products as part of an overall prospective payment, akin to a “bundled payment.” CMS has not yet addressed how these payment systems will be updated to account for biosimilars, and additional guidance may be forthcoming. Research suggests that “it may be challenging to

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4 CMS issued separate guidances to drug manufacturers and state technical contacts, which are substantively identical.
adjust [prospective] payment rates to reflect lower biologic prices,” potentially impacting provider incentives to use certain biological products.

- **Bundled Payments and Demonstration Projects.** As CMS continues to implement an array of payment reform demonstration projects (largely through the Center for Medicare and Medicaid Innovation (CMMI)), guidance on how payments for biosimilars will be made under these programs will be necessary.

These and other issues will impact the acceptance of biosimilars by providers and patients alike, dictating the clinical success of biosimilars as well as their ability to drive down overall health care spending. We continue to closely monitor how CMS is regulating and how Congress is legislating on these new products.

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