ALSTON&BIRD

WWW.ALSTON.COM

Health Care ADVISORY ■

JULY 10, 2015

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.[1] 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.[2] 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.

"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.[3] 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

---

[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.[4] 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

---

[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,"[5] 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.

---

[5] Mulcahy, Andrew W., Zachary Predmore, and Soeren Mattke, "The Cost Savings Potential of Biosimilar Drugs in the United States," RAND Perspectives, Nov. 3, 2014.

If you would like to receive future ***Health Care Advisories*** electronically, please forward your contact information to **healthcare.advisory@alston.com**. Be sure to put "**subscribe**" in the subject line.

If you have any questions, or would like additional information, please contact any of the following:

Robert A. Bauman
202.239.3366
bob.bauman@alston.com

Saul Ben-Meyer
212.210.9545
saul.ben-meyer@alston.com

Donna P. Bergeson
404.881.7278
donna.bergeson@alston.com

Kristine McAlister Brown
404.881.7584
kristy.brown@alston.com

Michael L. Brown
404.881.7589
mike.brown@alston.com

Cathy L. Burgess
202.239.3648
cathy.burgess@alston.com

Angela T. Burnette
404.881.7665
angie.burnette@alston.com

Jennifer L. Butler
202.239.3326
jennifer.butler@alston.com

Mark Timothy Calloway
704.444.1089
mark.calloway@alston.com

Craig Carpenito
212.210.9582
craig.carpenito@alston.com

Stacy C. Clark
404.881.7897
stacy.clark@alston.com

Patrick C. DiCarlo
404.881.4512
pat.dicarlo@alston.com

Hon. Robert J. Dole
202.654.4848
bob.dole@alston.com

Dan Elling
202.239.3530
dan.elling@alston.com

Sarah Ernst
404.881.4940
sarah.ernst@alston.com

Larry Gage
202.239.3614
larry.gage@alston.com

Ashley Gillihan
404.881.7390
ashley.gillihan@alston.com

David R. Godofsky, F.S.A.
202.239.3392
david.godofsky@alston.com

Katherine E. Hertel
213.576.2600
kate.hertel@alston.com

John R. Hickman
404.881.7885
john.hickman@alston.com

H. Douglas Hinson
404.881.7590
doug.hinson@alston.com

Sean C. Hyatt
404.881.4410
sean.hyatt@alston.com

Daniel G. Jarcho
202.239.3254
daniel.jarcho@alston.com

Bill Jordan
404.881.7850
bill.jordan@alston.com

Ted Kang
202.239.3728
edward.kang@alston.com

Peter M. Kazon
202.239.3334
peter.kazon@alston.com

Johann Lee
202.239.3574
johann.lee@alston.com

Blake Calvin MacKay
404.881.4982
blake.mackay@alston.com

Emily W. Mao
202.239.3374
emily.mao@alston.com

Dawnmarie R. Matlock
404.881.4253
dawnmarie.matlock@alston.com

Kimyatta E. McClary
404.881.7982
kimyatta.mcclary@alston.com

Wade Miller
404.881.4971
wade.miller@alston.com

Steven C. Mindy
202.239.3816
steven.mindy@alston.com

William (Mitch) R. Mitchelson, Jr.
404.881.7661
mitch.mitchelson@alston.com

Michael H. Park
202.239.3630
michael.park@alston.com

Craig R. Pett
404.881.7469
craig.pett@alston.com

Hon. Earl Pomeroy
202.239.3835
earl.pomeroy@alston.com

Steven L. Pottle
404.881.7554
steve.pottle@alston.com

T.C. Spencer Pryor
404.881.7978
spence.pryor@alston.com

J. Mark Ray
404.881.7739
mark.ray@alston.com

Mark H. Rayder
202.239.3562
mark.rayder@alston.com

Jonathan G. Rose
202.239.3693
jonathan.rose@alston.com

Colin Roskey
202.239.3436
colin.roskey@alston.com

Sam Rutherford
404.881.4454
sam.rutherford@alston.com

Karen M. Sanzaro
202.239.3719
karen.sanzaro@alston.com

Marc J. Scheineson
202.239.3465
marc.scheineson@alston.com

Thomas G. Schendt
202.239.3330
thomas.schendt@alston.com

Thomas A. Scully
202.239.3459
thomas.scully@alston.com

Donald E. Segal
202.239.3449
donald.segal@alston.com

John B. Shannon
404.881.7466
john.shannon@alston.com

Dominique Shelton
213.576.1170
dominique.shelton@alston.com

Regina M. Sherick
202.239.3383
gina.sherick@alston.com

Robert G. Siggins
202.239.3836
bob.siggins@alston.com

Carolyn Smith
202.239.3566
carolyn.smith@alston.com

Paula M. Stannard
202.239.3626
paula.stannard@alston.com

Michael L. Stevens
404.881.7970
mike.stevens@alston.com

Brian Stimson
404.881.4972
brian.stimson@alston.com

Robert D. Stone
404.881.7270
rob.stone@alston.com

Daniel G. Taylor
404.881.7567
dan.taylor@alston.com

Julie K. Tibbets
202.239.3444
julie.tibbets@alston.com

Timothy P. Trysla
202.239.3420
tim.trysla@alston.com

Kenneth G. Weigel
202.239.3431
ken.weigel@alston.com

Kerry T. Wenzel
404.881.4983
kerry.wenzel@alston.com

Danielle F. White
202.239.3073
danielle.white@alston.com

Michelle A. Williams
404.881.7594
michelle.williams@alston.com

Marilyn K. Yager
202.239.3341
marilyn.yager@alston.com

ALSTON&BIRD

WWW.ALSTON.COM