September 11, 2017

BY ELECTRONIC DELIVERY

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Rule [CMS–1678–P]

Dear Administrator Verma:

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Proposed Rule for calendar year (CY) 2018 (the "Proposed Rule").[1] BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place.

BIO members are eager to improve health care through the discovery and advancement of new therapies and thus are supportive of appropriate reimbursement in our health care system both to ensure that beneficiaries have proper access to care and to encourage investment in innovation. With these goals in mind, we have evaluated each of CMS's proposals to ensure that they support continued access to crucial treatments and therapies in the hospital outpatient setting for Medicare beneficiaries. We briefly describe our feedback on these proposals here, and in more detail in the balance of this letter.

Specifically, although we continue to have concerns regarding the high cost threshold for packaging payment for certain drugs, certain biologicals, and therapeutic radiopharmaceuticals, BIO strongly supports CMS's proposal to continue reimbursing separately payable drugs and biologicals at the statutory default of average sales price plus six percent (ASP+6%) in CY 2018. This methodology helps to ensure that payments are both predictable and equitable, which in turn ensures beneficiary access to vital therapies in the hospital outpatient setting. We urge CMS to finalize this proposal. We similarly encourage CMS to finalize its proposal to make transitional pass-through status payment for

[1] 82 Fed. Reg. 33,558 (Jul. 20, 2017).

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all drugs, biologics, and radiopharmaceuticals as close to three years as possible. Further, as detailed in the balance of this letter, BIO provides comments in support for CMS's proposal to update the date of service policy for certain laboratory diagnostic tests and provides support for updates to the process for issuance of J-codes as a part of CMS's request for additional flexibilities and efficiencies.

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I. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. BIO Opposes CMS's Continued Expansion of its Packaging Policies and Believes That They Have the Potential to Interfere with and Limit Patient Access to Care [p. 33,588]

CMS continues to promote and expand its packaging policies, including the need to package "payment for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with

maximum flexibility."[2] CMS also notes, however, that "a[s] the OPPS continues to move towards a prospectively determined encounter-based payments and away from separate fee schedule-like payments, [it] continues to hear concerns from stakeholders that [its] packaging policies may be hampering patient access or resulting in other undesirable consequences. However, [CMS] ha[s] not observed significant fluctuations in [its] data that show a sharp decline of the volume of packaged services, nor ha[s] [it] heard from Medicare beneficiaries specifically about access issues or other concerns with packaged items and services."[3] As a result, CMS indicated that it is interested in feedback related to packaging payment policies under the OPPS, including common clinical scenarios involving currently packaged Healthcare Common Procedure Coding System (HCPCS) codes that stakeholders believe are not appropriate.

Although efficiency and flexibility are important goals of the Medicare program, packaging policies have the potential to create perverse incentives that could unintentionally limit patient access to certain services and care. Moreover, these potential access issues created by packaging are not necessarily ones that can be identified by a decline in volume of packaged services. Instead, these issues occur when patients do not receive the most clinically appropriate drug, biological, or service that could be provided as one component of a larger package of services because providers and practitioners could be incentivized under packaging policies to make choices that prioritize minimizing costs relative to their expected payment over clinically appropriate care personalized to the patient. CMS may believe that negative and positive cost margins average out when multiple instance of the same services are provided;[4] however, providers also may make more systematic decisions about their preferences as to whether or not to provide a particular drug or biological as part of a packaged service, and offer only limited exceptions to these rules. This can mean in practice that the most clinically effective drug or biological may not always be available to patients. CMS should ensure that it is thoroughly evaluating its packaging policies to determine not only how they impact the volume of packaged services but whether there are individual items or services included in the larger package that are provided less in practice over time as a result of the packaging.

In addition, packaging policies can result in inadequate payment for hospitals. CMS bases its packaged payments on averages of the services that are provided and as CMS itself acknowledges "[t]he payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular patient."[5] Where a hospital does decide to provide a particular drug or biological, even though it may not be fully accounted for in the packaged payment, then the hospital may be significantly undercompensated for the drug or biological, even when that treatment may be the most clinically effective option for the patient.

Finally, packaging policies also are problematic because for every new packaging policy, every change in an existing packaging policy, and every time a new drug, biological,

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[2] *Id.* at 33,588.
[3] *Id*.
[4] *Id*. at 33,584
[5] *Id.*

or service is added to a packaged payment, stakeholders need time to review the changes in reimbursement that result to see how these policies impact their organization and to confirm that they produce appropriate reimbursement rates. To ensure that any new packaging policies produce appropriate reimbursement rates, CMS needs to provide sufficient time for stakeholders to analyze the data and provide meaningful comments.

B. Alternative Payment Methodology for Drugs Purchased under the 340B Drug Discount Program [p. 33,632]

In the Proposed Rule, CMS acknowledges the growth of hospital participation in the 340B program as the basis for its decision to reexamine the appropriateness of continuing to pay 340B hospitals under the current OPPS methodology. CMS proposes to adopt an alternative payment methodology for separately-payable drugs and biologicals without pass-through status ("separately payable drugs") that hospitals purchase through the 340B drug discount program. Specifically, CMS proposes to reduce reimbursement for separately payable drugs purchased through the 340B Discount Program from ASP+6% to ASP minus 22.5 percent (ASP-22.5%). According to CMS, reducing the OPPS payment rate for separately payable drugs may curb unnecessary utilization of these drugs, as well as relieve burdens on Medicare beneficiaries, who are responsible for paying a copayment that is 20 percent of the OPPS payment rate.[6]

CMS explains that the proposed payment reduction is designed to make Medicare payment for separately payable drugs more aligned with the resources expended by the covered hospitals to acquire such drugs, while still recognizing the purpose of the 340B program to allow covered entities to serve uninsured, low-income patients.[7] CMS also notes that the confidentiality of 340B ceiling prices limits its ability to precisely calculate the average 340B discounts, but states it believes that the Medicare Payment Advisory Commission (MedPAC) estimate of 22.5 percent represents a reasonable proxy for the average minimum discount. Other sources have estimated a higher amount. In order to address challenges of easily identifying drugs purchased at the 340B ceiling price, CMS proposes to establish a coding modifier for hospitals to report on claims forms to identify separately payable drugs that were not acquired under the 340B program. CMS will assume that a drug is purchased under the 340B program, and is eligible for payment under OPPS at the ASP-22.5% rate, unless the hospital identifies that the drug was not purchased under the 340B program through the use of the proposed modifier.

BIO appreciates CMS's efforts to address the exponential growth of the 340B program and believes the proposed modifier is an important first step in working to increase oversight in, and promote integrity of, the program. We appreciate CMS's attempt to address challenges arising from the 340B program within programs under its purview. BIO believes there are instances where CMS and the Health Resources and Service Administration (HRSA) can further coordinate efforts, particularly in the area of data availability to support covered entity compliance with duplicate discount prohibitions. However, ultimately, HRSA and Congress will need to act in order to achieve the broader goals of improved program integrity and better alignment to the needs of the targeted

[6] *Id.* at 33,633.
[7] *Id.*

patient population served by the 340B program. The proposed modifier will help provide much needed transparency into utilization of drugs acquired under the 340B program by Medicare beneficiaries. The claims data collected without this modifier would help CMS and manufacturers better understand how drugs acquired under the program are used. This data would be especially useful for ensuring covered entity compliance with the 340B program's requirements. For example, certain hospitals use a "replenishment model" to manage their drug inventories under which hospitals identify claims filled using 340B drugs retroactively. Requiring 340B hospitals to identify a drug as not purchased under the 340B program via this modifier would significantly increase accurate identification of 340B product Medicare claims, where a hospital is eligible and participating in the 340B program. However, BIO asks CMS to ensure that the proposed modifier does not unduly burden or disadvantage those entities that are not enrolled in the 340B program.

CMS proposes to include the savings generated by the reduction in payment rate to ASP-22.5% in the budget neutrality adjustments, but seeks comment on alternative methods for reallocation beyond simple inclusion in the conversion factor. CMS requests "whether and how the offsetting increase could be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured." The 340B program is, at its core, intended to provide for low-income and uninsured patients by supporting the safety-net entities that care for the greatest number of these patients. However, in recent years, studies have demonstrated that a minority of the hospitals participating in the 340B program deliver the vast majority of charity care provided by all 340B hospitals. In fact, a 2016 Avalere Health analysis using the most recent available cost report data found that for 37 percent of 340B disproportionate share hospitals (DSH), charity care represented less than one percent of total patient costs. Further, the analysis found that nearly two-thirds of 340B DSH hospitals provided charity care as a percent of total patient costs that was less than the national average of 2.2 percent for short term acute care hospitals.[8]

In addition, MedPAC:

> . . . has found that the amount of Medicare DSH payments a hospital receives is not a good proxy for the amount of uncompensated care (charity care and bad debt) it provides. Our analysis showed that the top 10 percent of hospitals in terms of uncompensated care provided 41 percent of all uncompensated care but received only 10 percent of all DSH payments. By contrast, the bottom 10 percent of hospitals provided less than 2 percent of all uncompensated care but received about 8 percent of DSH payments.[9]

The Government Accountability Office (GAO) has identified a similar trend, noting that even as 340B DSH hospitals as a whole provided more charity care than non-340B hospitals, this was not the case for 340B hospitals across the board as "12 percent of 340B DSH hospitals in our analysis were among the hospitals that provided the lowest amounts of

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[8] AIR 340B, "Benefiting Hospitals, Not Patients: An analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program," Spring 2016.
[9] MedPAC, Report to Congress: Overview of the 340B Drug Pricing Program, at 5 (May 2015), *available at* http://medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0.

charity care."[10] These findings suggest that the 340B program currently is not operating consistently with its original intent of helping indigent patients, as described above. These studies also demonstrate that the DSH metric itself does not represent a meaningful indicator of a hospital's role in the safety-net. BIO therefore urges CMS to use the savings it obtains through the proposed payment reduction to address this maldistribution and restore the savings to the hospitals that are the greatest contributors to the safety net and that provide the most charity care.

With this backdrop, BIO understands efforts by CMS to reallocate the savings generated by the reduction in payment in a manner that benefits true safety-net hospitals — and most importantly, the patients they serve – consistent with the intent of the 340B program. BIO recommends that, in considering redistribution methodology, CMS seek to identify the hospitals in the system that provide the most charity care for the outpatients the 340B program is intended to serve. To that end, in the long term, BIO encourages CMS to devise a method to better identify which hospitals are providing a significant proportion of charitable care as a percentage of their overall patient expenditures to low-income and uninsured patients through cost reports to ensure that only appropriate entities actually qualify for the DSH adjustment and thereby the 340B program in the first place.

In the short term, BIO encourages CMS to develop a reallocation policy for the 340B program savings it captures to retroactively redistribute these savings to categories of hospitals that appear to be providing the most care to uninsured and low-income patients. Hospitals receiving these additional 340B program savings could include:

- Rural Referral Centers,
- Sole Community Hospitals, and
- DSH Hospitals shown to have high levels of spending on factors such as charity care and outpatient dual eligible beneficiaries, who are by definition, low-income, as a percentage of their overall patient expenditures.

CMS could consider a reallocation methodology based on performance across multiple factors, as no single data element yet adequately identifies safety-net providers, as discussed previously. Further, BIO notes that CMS should consider evaluation thresholds for receiving reallocated funding that are tied to a hospital's performance in providing charity care and services to dual eligible beneficiaries relative to all other 340B hospitals, rather than achievement of a specified percentage of that entity's own expenditures. We encourage CMS to use a metric for charity care that takes into consideration total charity care for all parts of a hospital where 340B is used – in particular off-campus provider based departments. Over the last decade, acquisitions of physician-based oncology practices by 340B covered entities have increased significantly. In fact, one study found that over half of the acquired sites were located 10 or more miles from the acquiring covered entities and that 85% were located in higher median income locations when compared to the original "parent" covered entity.[11] Therefore, the characteristics of these child sites may be another factor that CMS considers when calculating whether the DSH hospital qualifies for additional savings. We suggest that CMS look to thresholds that accurately assess levels of outpatient

[10] GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, at 12 http://www.gao.gov/assets/680/670676.pdf (June 2015).
[11] Berkeley Research Group. 340B Covered Entity Acquisitions of Physician-based Oncology Practices. April 2014.

charity care. The current DSH metric for instance, is not reflective of charitable care provided in this setting, and therefore is not a comprehensive measure.[12]

BIO proposes that CMS redistribute 340B savings through a reallocation mechanism of interim payments made on a quarterly basis to hospitals that CMS determines are eligible to receive a share of 340B savings based on their ability to meet the criteria outlined above and their ranking as compared to other eligible hospitals. Redistributing these payments on a quarterly basis would give CMS the opportunity to verify a hospital's eligibility to receive a share of 340B savings to be sure that the payments are directed appropriately to entities providing additional charitable care. CMS could then take the opportunity at the end of the year to reconcile these payments against total 340B savings and adjust payment amounts accordingly to ensure that no more payments are distributed than are earned in savings by CMS through the proposed 340B drug payment reduction. CMS has acknowledged that estimating the programmatic impact of the 340B savings in its proposal has been challenging because the Agency does not have access to ceiling price data. At the recent Advisory Panel on Hospital Outpatient Payment (HOP Panel) meeting, several hospitals expressed concern that CMS's estimate of $900 million is too low. By waiting to redistribute savings throughout the year, the Agency will be better able to assess the actual programmatic impact and match it to the amount being redistributed, eliminating the need for readjustments in future years.[13] BIO believes that redistributing 340B program savings to hospitals providing the greatest amount of charity care in this way can help restore the 340B program to its original intent of directly benefiting low-income and uninsured patients.

C. CMS Should Implement its Policy to Make the OPPS Transitional Pass-Through Payment for All Drugs, Biologicals, and Radiopharmaceuticals, Including Those Currently Approved, As Close to Three Years As Possible [p. 33,621]

CMS proposes that 19 drugs and biologicals approved for pass-through status on or before January 1, 2016, would have their pass-through payment status expire on December 31, 2017. CMS notes that pass-through payment status for drugs and biologicals newly approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through period as close to three years as possible.

BIO supported CMS's proposal in the CY 2017 OPPS Proposed Rule to make the transitional pass-through payment period for all drugs, biologicals, and radiopharmaceuticals as close to three years as possible by allowing pass-through status to expire on a quarterly basis. In comments submitted to the CY 2017 OPPS Proposed Rule, BIO also encouraged CMS to retroactively apply this proposed policy to drugs and biologicals that already had been granted pass-through status. BIO again asks the agency to consider retroactively applying this now finalized policy to those products currently under pass-through, and not solely prospectively to those drugs and biologicals approved for pass-

[12] The DSH metric is based on inpatient days and inclusive of bad debt and unreflective of the level of outpatient charity care provided.
[13] For CY 2016, CMS discovered "excess packaged payment" for laboratory services and found it necessary to implement a 2.0 percent reduction to the conversion factor to offset the $1 billion error. *See* CY 2016 Hospital Outpatient Prospective Payment System Final Rule, 80 Fed. Reg. 70,298, 70,357 (Nov. 13, 2015).

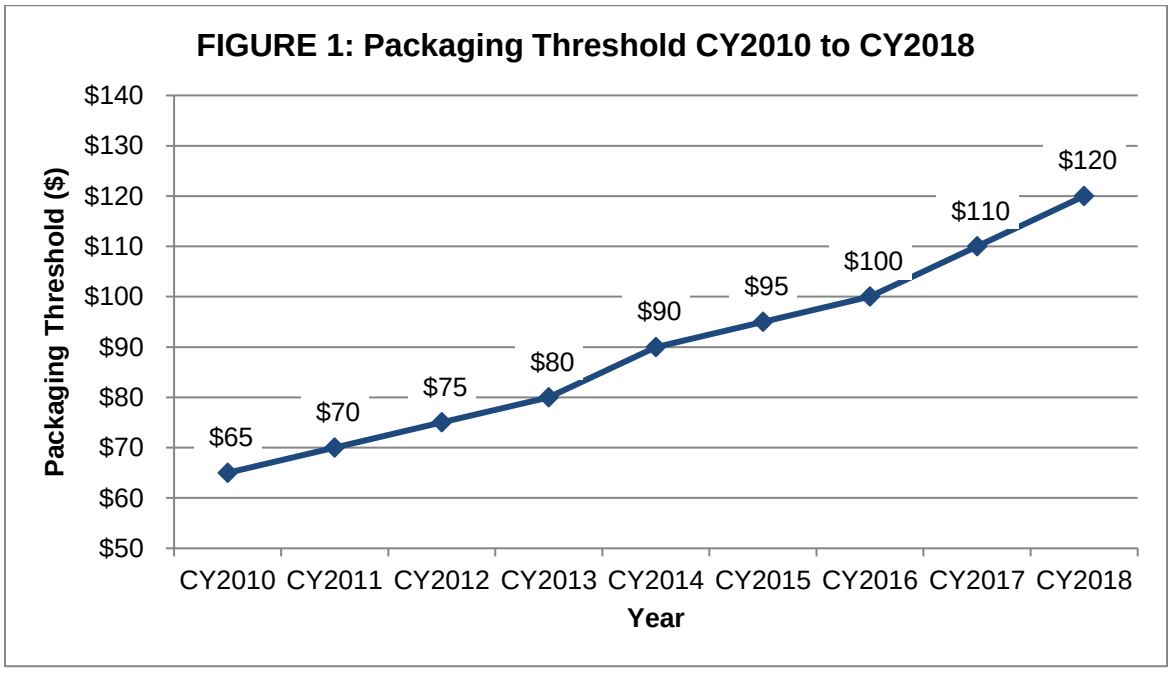
through in CY 2017 and subsequent calendar years. BIO urges CMS to begin the transitional pass-through payment period only when a valid payment is made.

CMS proposes to continue pass-through payment status in CY 2018 for 38 drugs and biologicals at the statutorily required payment amount of ASP+6%. Some of these drugs and biologicals would have been policy packaged if not for their pass-through status. BIO supports these proposals, including the continued payment for pass-through drugs and biologicals at ASP+6%.

CMS also proposes to continue to apply its longstanding policy-packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. BIO supports the continued application of this offset policy.

D. BIO Is Concerned About the Rapidly Increasing Packaging Threshold for Certain Drugs, Biologicals, and Therapeutic Radiopharmaceuticals [p. 33,625]

For CY 2018, CMS proposes to package drugs, biological and therapeutic radiopharmaceuticals with a per-day cost less than or equal to $120 and to identify items with a per-day cost greater than $120 as separately payable. BIO remains concerned that CMS is continuing its policy of rapidly increasing the packaging threshold, which has increased more than 84 percent since CY 2010. Figure 1, below, illustrates the rapid increase of the OPPS drug packaging threshold from $65 in 2010 to $120 proposed for CY 2018.



BIO believes that this rapid and sustained increase of the packaging threshold is inconsistent with Congressional intent. When Congress enacted the definition of a "specified

covered outpatient drug" (SCOD), it also established a packaging threshold of $50 for drugs and biologicals in 2005 and 2006. Congress codified the $50 threshold for these two years because it objected to the $150 packaging threshold that was in effect in 2003 and wanted to lower the threshold. The absence of a statutory requirement regarding a packaging threshold after 2006 should not be interpreted as support for widespread packaging or the support of a rapidly increasing packaging threshold. We ask CMS to reconsider its packaging threshold. Instead, as described in greater depth below, CMS should pay separately for all drugs with Healthcare Common Procedure Coding System (HCPCS) codes as it does when these therapies are administered in physician offices.

E. BIO Continues To Believe the Proposed Per-Day-Cost Threshold Methodology is the Preferable Methodology for Calculating the High Cost/Low Cost Threshold for Packaged Skin Substitutes [p. 33,626]

CMS currently packages skin substitutes as supplies in surgical procedures—a policy that BIO generally opposes. Not only does this policy provide a prevailing economic, rather than clinical, incentive to drive utilization of these important products to the lowest-cost therapy, but we believe that this is impermissible under the plain language of the statute. Where products, including skin substitutes, meet the definition of a SCOD, the Social Security Act (SSA) requires that payment be made either at the average acquisition cost for the drug or biological, or under the statutory default of ASP+6%. As noted in section I.E, below, CMS is proposing to continue its now longstanding policy of adopting the statutory default for SCODs in CY 2018. BIO therefore urges CMS to pay separately for all drugs and biologicals under this statutory default.

However, if CMS continues to package skin substitutes as it has proposed, we believe that the per-day-cost threshold (PDC) methodology is the preferable methodology for calculating the high/low cost threshold. Since the implementation of CMS's policy to package skin substitutes in CY 2014, the payment for procedures involving skin substitutes can differ based on whether the skin substitute product being used was of relatively low or high cost.[14] For CY 2015, CMS implemented a policy to set the high-cost threshold using weighted mean unit cost (MUC) from claims data.[15] Then in CY 2016, CMS revised this methodology to also consider, in the alternative, whether a skin substitute exceeded a set PDC threshold. Although we continue to believe that the hybrid methodology adopted in CY 2016 represents an improvement over the prior sole reliance on the MUC threshold, the sole use of the PDC methodology may be preferable. This is because, as articulated in prior BIO comments, the MUC methodology allows larger products with lower costs per cm^2, but higher total costs, to be assigned to the low-cost bundle—a concern largely mitigated by the PDC methodology.

BIO also continues to support the use of ASP data to calculate the MUC and PDC thresholds, as these data provide a more accurate reflection of true market cost than

[14] *See* CY 2014 Hospital Outpatient Prospective Payment System Final Rule, 78 Fed. Reg. 74,826, 74,933 (Dec. 10, 2013).
[15] *See* CY 2015 Hospital Outpatient Prospective Payment System Final Rule, 79 Fed. Reg. 66,770, 66,882-85 (Nov. 10, 2014).

hospital claims data that estimate costs from product-specific charges reduced by departmental ratios of cost-to-charges overall.

F. BIO Supports Payment for SCODs and Other Separately Payable and Packaged Drugs and Biologicals at ASP+6% [p. 33,629]

For CY 2018, CMS proposes to continue the CY 2013 policy of paying for separately payable drugs and biologicals at ASP+6%, referred to as the "statutory default." The SSA directs CMS to pay for SCODS at either the "average acquisition cost of the drug for [the] year," as determined by the Agency using survey data,[16] or—if such survey data are not available—based on "the average price for the drug in the year" established under section 1842(o), section 1847A, or section 1847B, as applicable.[17]

CMS indicated in the CY 2013 OPPS final rule that the Agency intends in the future to develop a methodology that more "accurately and predictably estimates acquisition and overhead costs for separately payable drugs and biologicals in order to pay for them appropriately."[18] We support this objective, and, until an improved methodology is developed, BIO urges CMS to finalize its proposed policy to ensure appropriate payment for separately payable drugs and biologicals in CY 2018.

BIO supports the agency's proposal for CY 2018 because it is consistent with the statute and congressional intent to reimburse hospitals based on the statutory default. This approach also generates far more predictable payments for drugs and biologicals under the OPPS than the approach previously employed by CMS of adjusting pharmacy overhead costs. In addition, using the statutory default approach ensures that Medicare payment rates for drugs and biologicals are equivalent in both the hospital and physician-office setting, eliminating reimbursement incentives that can drive inappropriate shifts in the site of care and helping to ensure that patients are able to obtain care in the most clinically appropriate setting. CMS should finalize this proposal for CY 2018 to ensure that payments for separately payable drugs and biologicals continue to remain predictable and appropriate.

Furthermore, BIO once again recommends that CMS make separate payment for all drugs and biologicals with HCPCS codes in the OPPS, in the same manner as the Agency does for these therapies when they are administered in a physician's office. For example, we believe that factors such as the method of administration or type of procedure in which it is used should not determine whether a drug or biological is considered a supply and result in subsequent packaging, as is the case for certain drugs and biologicals when used in a diagnostic or surgical procedure. We believe such polices are harmful to beneficiary access to appropriate treatment.

To the extent that CMS continues to package drugs and biologicals under the OPPS, CMS should require hospitals to report HCPCS codes and revenue code 636 for all billed drugs and biological. A clear program requirement from CMS that hospitals must bill for drugs and biologicals using HCPCS codes and revenue code 636 is critical to ensuring that CMS has reliable and robust data to facilitate appropriate rate-setting in the future if CMS

[16] SSA § 1833(t)(14)(A)(iii)(I).
[17] SSA § 1833(t)(14)(A)(iii)(II).
[18] CY 2013 Hospital Outpatient Prospective Payment System Final Rule, 77 Fed. Reg. 68,210, 68,389 (Nov. 15, 2012).

does not continue reimbursing all separately payable drugs and biologicals at the statutory default (ASP+6%) after CY 2018.

G. CMS Should Finalize its Proposed Payment Policy for Therapeutic Radiopharmaceuticals [p. 33,630]

For CY 2018, CMS proposes to pay all non-pass-through, separately payable therapeutic radiopharmaceuticals at ASP+6%, based on the statutory default, when ASP information is available. BIO strongly supports this proposal and urges CMS to finalize it.

H. CMS Should Finalize its Proposed Payment for Blood Clotting Factors [p. 33,631]

BIO supports CMS's proposal to pay for blood-clotting factors at ASP+6%, consistent with the Agency's proposed payment policy for other non-pass-through, separately payable drugs and biological. We also support CMS's proposal to continue its policy for payment of the furnishing fee using an updated amount, consistent with reimbursement in physician offices and in the hospital inpatient setting. We therefore ask CMS to finalize this proposal.

II. Payment for Certain Items and Services Furnished by Certain Off-Campus Departments of a Provider [p. 33,645]

Comments regarding proposals related to payment for certain items and services furnished by certain off-campus departments of a provider are included in the comment letter submitted by BIO on the CY 2017 Medicare Physician Fee Schedule Proposed Rule (CMS-1676-P).

III. BIO Urges CMS to Reevaluate its Comprehensive APC (C-APCs) Policy [p. 33,753]

Since it was first proposed for CY 2014, BIO has had serious concerns about CMS's C-APC policy. Under this policy, all items and services provided in conjunction with the primary service around which the C-APC is constructed are packaged—regardless of cost—including many drugs, biologicals, and radiopharmaceuticals. As articulated in our comments submitted in response to the CY 2017 proposed rule, BIO continues to have significant concerns about CMS's C-APC policy.[19] Among other things, we believe that this policy is based on the presumption that all hospital outpatient departments are treating the "average" patient. This presumption is not only inaccurate, as many hospitals treat disproportionately complex patients, incurring significantly higher costs, but also is contrary to the trend in personalized medicine. Therefore, this policy may likely obscure important differences in appropriate clinical care across patients and therefore inappropriately account for the costs incurred by different hospitals. Although we are encouraged by the apparent pause in the expansion of C-APCs by CMS's proposal to not create any new C-APCs for 2018, we strongly urge CMS to reevaluate its existing C-APC policy.

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[19] BIO, Comments in response to CY 2017 Medicare Outpatient Prospective Payment System (OPPS) Proposed Rule (Sept. 5, 2016) *available at* https://www.regulations.gov/contentStreamer?documentId=CMS-2016-0115-1698&attachmentNumber=1&contentType=pdf.

IV. CMS Should Finalize its Suggested Revisions to the Laboratory Date of Service Policy for Both Molecular Pathology and Advanced Diagnostic Laboratory Tests. [p. 33,652]

CMS is considering modifications to the Medicare laboratory date of service (DOS) requirements that are used to determine when a hospital may bill Medicare for a clinical diagnostic laboratory test (CDLT) and when the laboratory performing the test may bill Medicare directly. Currently, when the DOS falls during an inpatient or outpatient stay, payment for the laboratory test (if ordered within 14 days of discharge) usually is bundled with the hospital service and is not separately payable. This commonly is referred to as the "14-day-rule." Unfortunately, this policy is complicated and confusing, to the detriment of both patients relying on the tests as well as to the laboratories conducting them.

In the Proposed Rule, CMS requests specific comments on a potential modification to the current laboratory DOS policy that would allow laboratories to bill Medicare directly for molecular pathology and ADLTs that meet certain criteria outlined in section 1834A(d)(5)(A) of the SSA when the specimen is collected during a hospital outpatient procedure and the test is ordered after the patient is discharged from the hospital outpatient department. BIO applauds CMS for revisiting the current DOS policy and urges the Agency to finalize its suggested revisions.

Tests on tissue samples acquired from patients during hospital stays are critically important for determining future treatment planning and responsible patient care. Access to future treatments, however, may be inappropriate delayed under CMS's current policy because of the perverse incentives created by the 14-day-rule. CMS's suggested revisions to the 14-day-rule will help ensure that these services and subsequent decisions relating to patient care move forward quickly and without unnecessary delay and support the programmatic objectives of providing high value, personalized patient care. CMS should finalize them for both molecular pathology and ADLTs.

V. CMS Should Not Conditionally Package Level I and Level II Drug Administration Codes or Package Level III and IV Drug Administration Codes in the Future [p. 33,585]

For CY 2018, CMS proposes to conditionally package Level I and Level II drug administration codes. This proposal is the latest installment of CMS's implementation of its aggressive packaging policy for certain items and services under the OPPS. Under this policy, CMS packages ancillary services into payment with a primary service where it believes that the proposed packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code. According to CMS, its packaging policies incentivize hospitals to provide care in the most efficient manner by reducing what CMS perceives to be incentives to routinely use a more expensive item when a cost-efficient item also would meet the patient's needs, encouraging negotiations with manufacturers and suppliers to reduce costs, and promoting predictability and accuracy of payment for services over time.[20]

[20] 82 Fed. Reg. at 33,584.

In the CY 2015 final rule, CMS conditionally packaged payment for ancillary services assigned to APCs with a geometric mean cost of less than or equal to $100, but the Agency specifically excluded low-cost drug administration services in that packaging. CMS stated at that time that it was considering examining various alternative payment policies for drug administration services.[21] Without any substantive discussion of the interim examination of these potential alternative payment policies, CMS now has identified drug administration codes as "an example of an inconsistent application of [its] packaging policy" and determined that it is "no longer necessary to exclude low cost drug administration services from packaging under the ancillary services packaging policy adopted in CY 2015."[22] CMS also claims that "conditional packaging of drug administration services would promote equitable payment between the physician office and the hospital outpatient hospital department."[23] CMS thus proposes to conditionally package Level I and Level II drug administration codes, excluding drug administration codes for Medicare Part B vaccine administration services. Additionally, in the Proposed Rule, CMS notes they are not proposing to package Level III and Level IV drug administration codes but are interested in comments on whether these services may be appropriate for packaging.

BIO strongly opposes the current proposal and future packaging of drugs administration codes. This policy would lead to severely inadequate reimbursement under the OPPS for drug administration services, as well as for the drugs and biologicals packaged with these services. Under CMS's packaging methodology, the cost of packaged items and services is included in the average cost data used to establish payment for a given service. Presumably, therefore, if drug administration services are packaged into the payment for other services, the drug administration costs would proportionally be included as part of packaged service. In practice, the outcome of this policy would be that the proposed packaged payment only would partially account for the cost of administering the drug and would therefore leave the hospital undercompensated for providing the drug administration service.

In addition, CMS incorrectly describes the payment policies that apply in the physician office to justify expanded packaging in the hospital outpatient setting. CMS asserts that hospitals may receive separate payment for clinic visits, but "physicians are not eligible to receive payments for an office visit when a drug administration service is also provided."[24] This is not correct. Under the provisions in the Claims Processing Manual, "when a medically necessary, significant and *separately identifiable E/M service (which meets a higher complexity level than CPT code 99211)* is performed in addition to one of those drug administration services, the appropriate E/M CPT code should be reported with modifier -25."[25] In other words, a physician may be paid for an office visit in addition to a drug administration service. The physician also would receive separate payment for each drug administered, in contrast to the packaging policies that apply in the hospital outpatient setting. Thus, by all accounts, packaging drug administration services with other services

[21] 79 Fed. Reg. at 66,819.
[22] 82 Fed. Reg. at 33,585.
[23] *Id.*
[24] *Id.*
[25] Medicare Claims Processing Manual (MCPM), ch. 12, § 30.6.7(D) (last revised Apr. 14, 2017) (emphasis added).

would not "promote equitable payment between the physician office and hospital outpatient department" as CMS suggests.[26]

Should CMS finalize the above packaging proposal, despite BIO's objection, BIO supports CMS's determination to not conditionally package drug administration services described by add-on codes. As CMS notes, drug administration add-on codes typically describe each additional hour of infusion or each additional intravenous push, among others, in addition to the initial drug administration service. Packaging drug administration add-on codes would disadvantage providers of longer drug administration services. Such drug administration services are dictated by the characteristics of the specific drug or biological being administered to the patient, and therefore are not subject to the pressures for efficient delivery of care CMS cites as the justification for its packaging policy.

VI. CMS Should Finalize its Proposed Payment Adjustment to Certain Cancer Hospitals [p. 33,595]

CMS proposes to provide additional payments to the 11 specified cancer hospitals described in Section 1886(d)(1)(B)(v) of the SSA so that each cancer hospital's final payment-to-cost ratio (PCR) is equal to the weight average PCR for the other OPPS hospitals. BIO asks CMS to finalize its proposal and continue to provide additional payments to IPPS-exempt cancer hospitals. This policy continues to be important, as cancer hospitals incur substantially higher costs than other hospitals paid under the OPPS. This adjustment therefore helps to ensure that Medicare payments to these hospitals adequately cover the costs of the care they provide.

VII. CMS Should Advance Vaccination Uptake Through the Use of Robust Immunization Measures in the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Reporting Program [p. 33,671; 33,685]

Under the measure sets detailed for the Hospital Outpatient Quality Reporting (OQR) and Ambulatory Surgical Center Quality Reporting (ASCQR) Program, BIO appreciates CMS's continued inclusion of the *Influenza Vaccination Coverage among Healthcare Personnel* (NQF #0431) measure. Healthcare providers are the first line of defense in preventing illness and this measure helps ensure both patients and providers are protected. In addition to this important measure, we ask CMS to consider inclusion of additional measures, such as pneumococcal immunization measures, into the OQR and ASCQR programs, eventually recognizing all Advisory Committee for Immunization Practices (ACIP) recommended vaccines for adults. The inclusion of these and other future measures that assess patient immunization status help to ensure positive patient health outcomes and access to appropriate preventative care.

[26] *Id.*

VIII. Request for Information on CMS Flexibilities and Efficiencies [p. 33,703]

In addition to the comments provided above, BIO asks CMS to further refine the following areas through future policy proposals and updates as part of the Request for Information (RFI):

IX. CMS Should Issue J-Codes More Frequently than Annually

As a part of the RFI, the Agency requests information on ideas for regulatory procedural changes in order to improve the quality of care for Medicare beneficiaries. BIO believes that the current annual issuance of J-codes could be improved by issuing J-codes quarterly, as is current policy for granting pass-through status and issuing temporary codes. This change is needed to respond to lag-times – which can be as long as 21 months between when a therapy is available on the market and when it receives a permanent J-code – created by the existing process of issuing codes only once a year. For example, a new drug or biologic approved by the FDA on April 1, 2014 will not receive a J-code until January 1, 2016. Such delays result in logistical complexities and confusion at the point of care that can delay patient access to innovative new drugs and biologicals.

X. Conclusion

BIO appreciates the opportunity to comment on the Proposed Rule. We look forward to continuing to work with CMS in the future to address the issues raised in this letter. Please contact me at (202) 962-9200 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Mallory O'Connor
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