Biotechnology Industry Organization

August 31, 2015

BY ELECTRONIC DELIVERY

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: 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 [CMS-1633-P]

Dear Acting Administrator Slavitt:

The Biotechnology Industry Organization (BIO) is pleased to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule regarding payment policies under the calendar year (CY) 2016 hospital outpatient prospective payment system (OPPS), published in the Federal Register on July 8, 2015 (the "Proposed Rule").[1] BIO represents 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 innovations. CMS proposes to continue reimbursing separately payable drugs and biologicals at the statutory default of average sales price (ASP) plus six percent in CY 2016, and BIO strongly supports this proposal. This methodology helps to ensure that payments are both predictable and equitable, which in turns ensures beneficiary access in the hospital outpatient setting to vital therapies. We urge CMS to finalize this proposal.

On the other hand, we are disappointed that CMS proposes both to continue its 2014 packaging policies and to build upon them by expanding the comprehensive ambulatory payment classifications (C-APCs). CMS has acknowledged that it is "important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible."[2] We urge CMS to remain mindful of this statement as the agency proceeds with the development of its packaging policies. We recognize that packaging can provide incentives for hospitals to provide more efficient care, but a transparent and thoughtful approach to additional packaging policies is necessary to ensure that that these policies do not simultaneously discourage use of the most clinically appropriate therapy. Packaging policies that disincentivize the use of the most appropriate treatment option have the

[1] 80 Fed. Reg. 39200 (July 8, 2015).
[2] 79 Fed. Reg. 40915, 40953 (July 14, 2014).

1201 Maryland Avenue SW
Suite 900
Washington DC 20024
202.962.9200 P
202.488.6306 F
bio.org

potential to result in harm to beneficiaries. Precautions must be taken to ensure that beneficiary access to critical therapies remains safeguarded. As discussed in greater detail below, we respectfully request that the Agency reconsider its packaging proposals.

To ensure that Medicare beneficiaries continue to have access to crucial treatments and therapies in the hospital outpatient setting, we recommend that CMS:

- Finalize its proposal to continue paying ASP plus six percent for separately payable drugs and biologicals administered in the OPPS;
- Pay separately for all Food and Drug Administration (FDA)-approved drugs and biologicals regardless of their function in diagnostic or surgical procedures;
- Restore separate payment for contrast agents and diagnostic radiopharmaceuticals;
- Make separate payment for all drugs and biologicals with HCPCS codes and require, rather than simply encourage, hospitals to bill for any packaged drugs and biologicals using HCPCS codes and revenue code 636;
- Refrain from expanding C-APCs until the outstanding and significant issues with regard to the evidence base for these policies and the impact on patient access can be addressed;
- Collect data over a sufficient period of time before considering changes in payment for adjunctive services furnished prior to the delivery of the primary service;
- Finalize its proposal to continue to adjust OPPS payments for certain cancer hospitals;
- Continue to pay for therapeutic radiopharmaceuticals based on ASP data if submitted by the manufacturer and reimburse these therapies at ASP plus six percent;
- Reimburse blood clotting factors at ASP plus six percent plus an updated furnishing fee;
- Consider implantable biologicals approved under Biologics License Applications (BLAs) for pass-through status as drugs or biologicals;
- Finalize the proposal to base the high/low threshold for packaged skin substitutes on the product's per-day cost;
- Provide the same reimbursement for biosimilar biological products ("biosimilars") in the hospital outpatient setting as the physician office setting to ensure that the choice of care setting is based on clinical appropriateness for an individual only;
- Finalize proposals to incorporate additional measures in the Hospital Outpatient Quality Reporting (OQR) Program, specifically those related to the use of external beam radiotherapy for bone metastases, care coordination, and vaccination of healthcare personnel;
- Include additional immunization performance measures in the OQR Program to help ensure vaccines are routinely offered and administered to patients in the outpatient setting, thereby reducing the number of missed immunization opportunities;
- Include measures in the OQR Program that inform appropriate clinical decision-making for patients with lung cancer;
- Consider initiating a special Quality Improvement Organization (QIO) project(s) to reduce inappropriate variation in the treatment of ischemic stroke; and
- Carefully evaluate proposed changes that restructure APCs, and as a result, impacting payment for drug administration services before finalizing them.

Each of these recommendations is discussed in more detail below.

I. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Status.

A. CMS should finalize its proposal to continue paying ASP plus six percent for separately payable drugs and biologicals administered in the OPPS.

For CY 2016, CMS proposes to continue the CY 2015 policy and pay for separately payable drugs and biologicals at ASP plus 6 percent, referred to as the statutory default.[3] As set forth in the Social Security Act (SSA), Medicare is required to reimburse specified covered outpatient drugs (SCODs) at the "average acquisition cost for the drug for the year," as determined by the Secretary using survey data.[4] Payment must be set at average sales price for the drug as established under 1842(o), 1847A, or 1847B (e.g. ASP plus six percent or the rates determined under the Competitive Acquisition Program) when acquisition costs are not available.[5]

CMS indicated in the CY 2013 OPPS final rule that it 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."[6] We support this objective, and, until an improved methodology is developed, BIO urges CMS to finalize its proposed CY 2016 policy to ensure appropriate payment for separately payable drugs and biologicals in CY 2016.

BIO supports the agency's proposal for CY 2016 because it is consistent with the statute and Congressional intent to reimburse hospitals for these therapies based on an accurate methodology to determine average acquisition cost for each drug or the rates established under section 1842(o), 1847A, and 1847B of the SSA. The statutory default approach 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 2016 to ensure that payments for separately payable drugs and biologicals continue to remain predictable and appropriate.

B. CMS should provide separate payment for FDA-approved drugs and biologicals regardless of their function in diagnostic or surgical procedures. CMS also should restore separate payment for contrast agents and for diagnostic radiopharmaceuticals following the expiration of transitional pass-through payment.

For CY 2016, CMS proposes to continue to package all diagnostic radiopharmaceuticals and contrast agents.[7] BIO continues to oppose the packaging of diagnostic radiopharmaceuticals and contrast agents on the basis that CMS's rationale ignores the plain language of the statute as well as Congressional intent. On the same grounds, we disagree with the packaging of certain drugs and biologicals when used in a diagnostic or surgical procedure.

---

[3] 80 Fed. Reg. 39200, 39281.
[4] Social Security Act (SSA) § 1833(t)14(A)(iii)(I).
[5] Id. § 1833(t)(14)(A)(iii)(II).
[6] 77 Fed. Reg. 68210, 68389 (Nov. 15, 2012).
[7] 80 Fed. Reg. 39200, 39281.

This includes CMS's proposal to newly, unconditionally package payment for four drugs based on their primary function as a supply in a surgical procedure in CY 2016.[8] We believe these proposals will harm beneficiary access to appropriate drugs, biologicals, and radiopharmaceuticals, and we urge CMS not to adopt them.

These policies affect several drugs and biologicals that meet the statutory definition of a SCOD and thus are subject to specific statutory payment provisions, as well as drugs and biologicals that CMS has treated as SCODs under its longstanding policy of applying a uniform payment methodology to these therapies. The SSA defines a SCOD as a "covered outpatient drug…for which a separate ambulatory payment classification group (APC) has been established" and that is a radiopharmaceutical or a drug or biological for which pass-through payments were made on or before December 31, 2002.[9] The statute does not distinguish between drugs and biologicals that serve a therapeutic modality and those used with other services. CMS does not have the authority to reclassify a drug or biological as a supply simply to avoid payment for these drugs and biologicals as SCODs.

Congress did not intend for CMS to circumvent the statutory payment provisions for SCODs by packaging entire classes of therapies. Congress allows CMS to package drugs and biologicals in certain cases based on the cost of the therapy, but not based on function, as the latter would render the statute's explicit payment instructions meaningless. We continue to urge CMS to make separate payment at ASP plus six percent for all drugs and biologicals, regardless of their function, as CMS does for other SCODs and drugs and biologicals treated as SCODs. In addition, we ask that CMS restore separate payment for contrast agents and for diagnostic radiopharmaceuticals following the expiration of transitional pass-through payment.

If CMS does not make separate payment for these drugs, biologicals, and radiopharmaceuticals, the agency must ensure that payment remains sufficient to protect access to appropriate care. Based on our experience with packaged diagnostic radiopharmaceuticals, we are concerned about the agency's methodology for determining payment for packaged drugs, biologicals and radiopharmaceuticals. CMS's methodology for determining payment for packaged diagnostic radiopharmaceuticals generates rates that do not reasonably and accurately reflect the true resource costs to hospitals offering diagnostic radiopharmaceuticals. Under the agency's methodology, numerous radiopharmaceuticals with widely varying costs are packaged into a single nuclear medicine APC, and the payment for the procedure does not always adequately cover the costs of the appropriate radiopharmaceutical and performance of the procedure. Additionally, packaging drugs and biologicals tends to result in underreporting of their utilization (since reporting does not impact reimbursement), which can decrease the measured costs associated with the procedure and lead to diminishing packaged payment rates over time, exacerbating the financial incentives to stint on appropriate care.

Therefore, we continue to believe that separate payment for all drugs, biologicals, and radiopharmaceuticals following the expiration of transitional pass-through payment is consistent with the statute and Congressional intent and is the best way to ensure beneficiary access to appropriate care. However, if the Agency insists on continuing to package these therapies, we ask CMS to at least create separate APCs for diagnostic and surgical procedures when they are performed with—versus when they are performed without—drugs and biologicals with a cost above CMS's packaging threshold in order to

[8] Id. at 39235.
[9] SSA § 1833(t)(14)(B).

more accurately reimburse for the use of these therapies and track their utilization over time.

II. Proposed Cost Threshold for Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals ("Threshold-Packaged Drugs")—CMS should make separate payment for all drugs and biologicals with HCPCS codes. If any drugs and biologicals remain packaged, CMS should require hospitals to bill for them using HCPCS codes and revenue code 636.

For CY 2016, CMS proposes to 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.[10] CMS has rapidly increased the packaging threshold over the past 5 years, and proposes a $100 threshold for CY 2016, a 54 percent increase over the 2010 threshold of $65.

BIO believes this rapid increase is inconsistent with Congressional intent. When Congress enacted the definition of a SCOD, it also established a packaging threshold of $50 for drugs and biological in 2005 and 2006. Congress codified the $50 threshold for these 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.

BIO asserts that CMS should make separate payment for all drugs and biologicals with HCPCS codes in the OPPS just as the agency does for these therapies when they are administered in a physician office. However, to the extent that drugs and biologicals continue to be packaged, CMS should require hospitals to bill for them using HCPCS codes and revenue code 636. A clear 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 data to facilitate appropriate rate-setting in the future if CMS does not continue reimbursing all separately payable drugs and biologicals at ASP plus six percent after CY 2016. This requirement also would help CMS satisfy the requirement established in the Affordable Care Act (ACA) to measure drug utilization to calculate the pharmaceutical tax.

III. Establishment of Comprehensive APCs (C-APCs)

A. CMS should not expand C-APCs until the outstanding and significant issues related to the evidence base for these policies and the impact on patient access to needed therapies can be addressed.

In the CY 2014 proposed rule, CMS announced its intention to make the OPPS more of a prospective payment system and less of a fee schedule-type payment system.[11] All items and services provided in conjunction with the primary service around which the C-APC is constructed will be packaged, regardless of cost, including all drugs, biologicals, and radiopharmaceuticals, but excluding those drugs with pass-through payment status, drugs that are usually self-administered, and drug administration add-on/ancillary codes. In the CY 2016 Proposed Rule, CMS proposes to further expand its packaging policy, specifically proposing nine additional C-APCs to be paid under the existing C-APC payment policy.[12]

[10] 80 Fed. Reg. 39200, 39275.
[11] 79. Fed. Reg. 40960, 40940.
[12] 80 Fed. Reg. 39200, 39222.

As a broad concern, BIO continues to call into question the comprehensiveness and validity of the data provided in support of this policy as well as the ability of C-APCs to adequately pay for complex services for patients. We also note that no specific clinical quality metrics are associated with this policy, and CMS has not released a process by which it plans to monitor and assess the impact of the policy on quality of care. Moreover, CMS notes in the preamble to the Proposed Rule that "as we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care we have expanded the OPPS packaging policies."[13] Considering this objective, BIO is seriously concerned that CMS's intent to establish larger payment groups requires an ever-greater reliance on assuming that hospital outpatient departments treat an "average" patient, which is contrary to the trend in personalized medicine and may obscure important differences in appropriate, clinical care.

Additionally, BIO is specifically concerned about the proposed adjustment to the CY 2016 rates to offset a mistake made when packaging was expanded in CY 2014. In the Proposed Rule for CY 2016, CMS explains that when it packaged payment for laboratory tests in CY 2014, it "overestimated the adjustment necessary to account for the new policy to package laboratory tests and underestimated the amount of spending that would continue for laboratory tests paid at the [Clinical Laboratory Fee Schedule] rates outside the OPPS by approximately $1 billion."[14] CMS proposes to use its discretionary authority under SSA § 1833(t)(3)(C)(ii) to reduce the CY 2016 conversion factor by 2.0 percent to offset this error.[15] This across-the-board reduction in payment would affect all procedural APCs, including payments for drugs and biologicals that are packaged into those APCs' rates. Our concern is that the combination of expanded packaging, followed by payment reductions to offset "excessive packaging," produces fluctuations, and thus uncertainty, in payment rates. Moreover, these payment rates may not reflect changes in the cost of care for the affected services. BIO urges CMS to not implement this proposed, optional reduction. As part of BIO's recommendation that CMS comprehensively review the impact of its recent packaging policies before further expanding upon it, we urge the Agency to address these concerns with regard to the prospect of similar adjustments being made to correct for errors in setting payment under the expanded packaging policies implemented in 2015 and future years. Overall, BIO urges CMS to refrain from expanding C-APCs until all of these outstanding and significant issues can be addressed.

B. CMS should collect data over a sufficient period of time before considering changes in payment for adjunctive services furnished prior to the delivery of the primary service.

CMS proposes to establish a HCPCS modifier to be reported with every code that is adjunctive to a comprehensive service but is billed on a different claim.[16] CMS notes that the intention of this provision is to identify these adjunctive services that are furnished prior to associated primary services so that payment under the encounter-based C-APC will be more accurate as the Agency expands this policy. CMS envisions discontinuing separate payment for any of these packaged adjunctive services, even when furnished prior to delivery of the primary service.

[13] Id. at 39,233.
[14] Id. at 39,239.
[15] Id. at 39,240.
[16] Id. at 39,228.

While BIO appreciates that CMS is collecting data in advance of considering any changes to the existing C-APC methodology, with which we have expressed broad-based concerns above, we are concerned that the collective definition of "adjunctive services" is not sufficiently detailed to implement this modifier and that, as structured, it will be difficult to operationalize the modifier.[17] In the absence of a standardized, easily-implemented definition of "adjunctive," hospitals may attach the modifier in a non-uniform fashion, compromising the comparability of the utilization data CMS receives from different hospital outpatient departments reporting the modifier. Moreover, as structured, the modifier is likely to be added manually, after a review of multiple codes over a potentially-long timeframe, to determine if a service that fits the definition of "adjunctive" was rendered at a different time than a comprehensive service. This may be overly time-consuming for hospitals and may prove very difficult to the extent that a claim for what would be considered an adjunctive service under this proposed policy is processed at a much earlier (or later) date than the claim for the comprehensive service.

BIO urges CMS to work with stakeholders to address these considerations prior to finalizing the use of the proposed modifier. If the modifier is not implemented in a standardized, reliable fashion, we are concerned that the utilization data it reflects may misrepresent, or lead to the overextension of, the relationship between a service billed on a different claim and the comprehensive service (i.e., the former may not ultimately fit the definition of an adjunctive service). This, in turn, can lead to confusion among hospitals and provide an inaccurate and unintentionally misleading foundation for further policy development.

Finally, once the proposed modifier is refined and implemented, BIO urges CMS to collect information over a significant period of time to serve as a robust evidence base before considering changes in payment for adjunctive services furnished prior to the delivery of the primary service.

IV. Proposed OPPS Payment to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the Act—CMS should finalize its proposal to continue to adjust OPPS payments for certain cancer hospitals in CY 2016.

CMS proposes to continue the policy of providing additional payments to cancer hospitals so that each cancer hospitals' final payment-to-cost ratio (PCR) is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data that are available at the time of the development of this proposed rule.[18] In 2011, CMS conducted a study pursuant to section 3138 of the ACA and determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. In response to these findings, CMS implemented an adjustment for these hospitals beginning in CY 2012. For CY 2016, a target PCR of 0.90 is proposed (as compared to the 2015 target rate of 0.89). BIO asks CMS to finalize this proposal, as cancer hospitals incur substantially higher costs than other hospitals paid under the OPPS. This adjustment helps to ensure that Medicare payments to these hospitals are adequate to cover the costs of care they provide.

V. Proposed Payment Policy for Therapeutic Radiopharmaceuticals—CMS should continue to pay for therapeutic radiopharmaceuticals based on ASP

[17] CMS refers collectively to services that are integral, ancillary, supportive, dependent, and adjunctive as "adjunctive services," noted at 39,228.
[18] Id. at 39244.

data if submitted by the manufacturer and reimburse these therapies at ASP plus six percent.

For CY 2016, CMS proposes to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP plus 6 percent, based on the statutory default.[19] BIO urges CMS to finalize its proposal to reimburse nonpass-through separately payable therapeutic radiopharmaceuticals at ASP plus six percent when ASP information is available. BIO agrees that using ASP data is the most appropriate way to pay for therapeutic radiopharmaceuticals.

VI. Proposed Payment for Blood Clotting Factors–CMS should reimburse blood clotting factors at ASP plus six percent plus an updated furnishing fee.

For CY 2016, CMS is proposing to pay for blood clotting factors at ASP plus 6 percent, consistent with the Agency's proposed payment policy for other nonpass-through separately payable drugs and biologicals, and to continue its policy for payment of the furnishing fee using an updated amount.[20] Though because the furnishing fee is based on the percentage increase in the Consumer Price Index, which had not yet been released by the release of the proposed rules, the actual updated furnishing fee amount will be communicated through applicable program instructions when available. BIO asks CMS to finalize its proposal to pay for blood clotting factors at ASP plus six percent plus an updated furnishing fee—consistent with reimbursement in physician offices and in the hospital inpatient setting—for CY 2016, consistent with our support for ASP plus six percent reimbursement for separately payable drugs, biologicals, and radiopharmaceuticals without pass through status.

VII. Proposed Pass-Through Payments for Implantable Biologicals and Skin Substitutes—CMS should consider implantable biologicals approved under BLAs for pass-through status as drugs or biologicals, or, if CMS does not implement this recommendation, CMS should clarify that it will apply the device pass-through criteria only to biologicals if they are solely surgically implanted according to their FDA-approved indications.

CMS proposes to continue the policy, for CY 2016, that the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only.[21]

BIO continues to oppose this policy. We disagree with this policy because some implantable biologicals meet the SSA's definition of "biological"[22] even though they are approved by the FDA as devices. According to CMS, these implantable biologicals "function as implantable

---

[19] Id. at 39281,

[20] Id. at 39282.

[21] Id. at 39267.

[22] SSA § 1861(t)(1) ("The term 'drugs' and the term 'biologicals', except for purposes of subsection (m)(5) and paragraph (2), include only such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.").

devices," and therefore should be subject to the same reimbursement policies as devices.[23] CMS also notes that biological and non-biological implantable devices share payment methodologies during their non-pass-through periods, have "overlapping and sometimes identical clinical uses," and "similar regulation by the FDA as devices."[24] CMS believes that "the most consistent pass-through payment policy for these different types of items that are surgically inserted or implanted and that may sometimes substitute for one another is to evaluate all such devices, both biological and non-biological, only under the device pass-through process."[25] To implement this policy, CMS revised the pass-through regulations at 42 CFR § 419.64 to exclude implantable biologicals from consideration for drug and biological pass-through payment beginning on January 1, 2010.[26]

CMS should allow biologicals approved by the FDA under a BLA to be eligible for pass-through payment as drugs or biologicals, regardless of whether they are implanted. When implementing the current payment system for SCODs that previously had pass-through status, Congress intended for biologicals approved under BLAs to be reimbursed under the specific statutory provisions for drugs.[27] Therefore, Congressional intent was that these BLA-approved therapies be reimbursed as pass-through drugs as well. BIO's position is therefore consistent with both Congressional intent to reimburse biologicals approved under BLAs under the methodologies for drugs and biologicals and with CMS's goal of treating products approved as devices similarly.

If CMS continues to evaluate implantable biologicals for pass-through status as devices, CMS should clarify that it will apply the device pass-through criteria only to biologicals if they are solely surgically implanted according to their FDA-approved indications. In the final rule for 2012, CMS explained that it "mean[s] to exclude from consideration for drug and biological pass-through status any biological that has an indication such that it may function as a surgically implanted or inserted biological, even if there are also other indications in which the biological is not surgically implanted or inserted."[28] This interpretation of the regulation contradicts CMS's prior description of its policy, its application of the policy to date, and the agency's billing instructions to hospitals for biological products that do not always function as devices.

In the final rules for 2010 and 2011, CMS describes the current approach as applying to "implantable biologicals that are *always* surgically inserted or implanted (through a surgical incision or a natural orifice)."[29] CMS also refers to its instructions to hospitals to not bill separately for biologicals that *sometimes* can be used as implantable devices when used as such.[30] Per CMS instructions, hospitals can bill separately for these biologicals when they are not used as implantable devices. Furthermore, the products that CMS has treated as implantable biologicals for determination of separate payment upon expiration of pass-through status have been products that are solely surgically implanted according to their FDA-approved indications.[31] We recommend that CMS revise the regulation to refer to "a biological that is not always surgically implanted or inserted into the body" to ensure that the regulatory text aligns with CMS policy and practices.

---

[23] 74 Fed. Reg. 60316, 60496 (Nov. 20, 2009).
[24] Id. at 60473.
[25] Id. at 60473.
[26] Id. at 60474.
[27] Conference Report, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, H. Rep. No. 108-391, at 679.
[28] 76 Fed. Reg. at 74280.
[29] 74 Fed. Reg. at 60532; 75 Fed. Reg. 71800, 71975 (Nov. 24, 2010) (emphasis added).
[30] 75 Fed. Reg. at 71928; 76 Fed. Reg. at 74310 (emphasis added).
[31] 74 Fed. Reg. at 60472, 60496; 75 Fed. Reg. at 71928; 76 Fed. Reg. at 74310.

In particular, BIO continues to oppose CMS's policy, effective January 1, 2015, that skin substitutes are evaluated for pass-through status and payment using the device pass-through evaluation process. Treating skin substitutes and similar products that aid wound healing as devices is inconsistent with the longstanding treatment of these therapies for purposes of pass-through payment, and may impede further development of technology in this field. Moreover, treating biologicals approved under Section 351 of the PHSA as devices is inconsistent with the statutory provision for pass-through payments, congressional intent, and the treatment of any other similar biological product. Instead, BIO believes that biologicals should be eligible for pass-through payments as drugs or biologicals when they are approved under a BLA rather than as a device.

Therefore, based on these numerous concerns, BIO urges CMS to allow biologicals approved by the FDA under a BLA to be eligible for pass-through payment as drugs or biologicals, regardless of whether they are implanted. If CMS continues to evaluate implantable biologicals for pass-through status as devices, CMS should clarify that it will apply the device pass-through criteria only to biologicals if they are solely surgically implanted according to their FDA-approved indications.

VIII. Proposed High/Low Cost Threshold for Packaged Skin Substitutes—CMS should finalize the proposal to base the high/low threshold on the product's per-day cost, to the extent that CMS continues to package skin substitutes.

For CY 2016, CMS proposes to maintain the high/low cost APC structure for skin substitute procedures but proposes to revise the current methodology used to establish the high/low cost threshold.[32] Specifically, CMS proposes to determine the high/low cost threshold based on either a product's mean unit cost (MUC) exceeding the MUC threshold or the product's per day cost (PDC) exceeding the PDC threshold. Skin substitutes that exceed either of these thresholds would be assigned to the high cost group, with all other skin substitutes assigned to the low cost group. CMS proposes a PDC threshold of $1,050 and a MUC threshold of $25 per cm^2. CMS also proposes to remove all implantable biologicals from the skin substitute cost group list, although implantable biologicals are treated as packaged surgical supplies under the OPPS.

BIO continues to oppose packaging skin substitutes based on their function. Not only does this policy provide a prevailing economic, rather than clinical, incentive to drive utilization of these important products, but we strongly believe that this is impermissible under the plain language of the statute. Where products meet the definition of a SCOD, the SSA requires that payment be made either at the average acquisition cost for the drug or biological or under the statutory default. In the 2013 final OPPS rule, CMS adopted the statutory default for SCODs and has proposed continuing this policy in CY 2016. BIO continues to be concerned that packaging skin substitutes provides an economic, rather than clinical, incentive to use the least expensive therapy—not necessarily the most clinically appropriate one. BIO urges CMS to pay separately for all drugs and biologicals approved by the FDA under section 351 of the PHSA at the statutory default of ASP plus six percent.

However, if skin substitutes continue to be packaged, as is proposed for CY 2016, we are supportive of the revised methodology to calculate the high/low cost threshold, which we feel more appropriately compares skin substitutes with similar functions. Moreover, we support CMS's use of the PDC threshold specifically. As BIO expressed in our comments to

[32] 80 Fed. Reg. 39200, 39276.

the Agency in response to the CY 2015 Proposed Rule, the methodology currently in place for 2015 allows larger products with lower per cm^2 costs, but higher total costs, to be assigned to the low-cost bundle. This is, in part, because certain types of products included in CMS's definition of skin substitutes—namely wound dressings, on the market through FDA's 510(k) regulatory process, and human tissue products (e.g., cadaver skin or placental tissue)—have more flexibility in determining the available sizes of a marketed product. For example, manufacturers of 510(k) and human tissue products can make smaller product sizes commercially available by merely demonstrating that they are substantially similar to their larger, already commercialized, "sister" products without having to demonstrate clinical safety or efficacy.[33] Conversely, therapies approved through a BLA must reapply for an updated label through the FDA to change or add a marketed dose—which is the correlate to "size" in the case of many skin substitutes.[34] This requires a demonstration of safety and efficacy data that can be costly and time-consuming. Products approved through premarket approval (PMA) also may have to submit a supplemental application with additional data prior to making this type of change.[35] In turn, this can cause the very bundle instability that CMS had stated it is trying to avoid, and can and can incentivize the use of particular products based on financial, rather than clinical, considerations.

Thus, while the hybrid policy of allowing products to be placed in the high-cost group mitigates these concerns, the sole use of the PDC methodology may be preferable. BIO also supports the use of ASP data to calculate the threshold. These data provide a more accurate reflection of true market cost than hospital claims data, which estimate costs from product-specific charges reduced by departmental ratios of cost-to-charges overall. BIO urges CMS to finalize this proposal for CY 2016.

IX. <u>Proposed OPPS Payment for Biosimilar Biological Products</u>—CMS should structure payment for biosimilar biological products ("biosimilars") in the hospital outpatient setting to mirror payment in the physician office setting to ensure there is no financial incentive to utilize one setting over the other.

For CY 2016, CMS makes several proposals related to payment for biosimilars in the hospital outpatient setting.[36] First, CMS proposes to pay for biosimilars based on the payment allowance of the product as determined under section 1847A of the SSA (the statutory reference for payment of biosimilars under the Physician Fee Schedule (PFS)). Consistent with the established OPPS drug and biological payment policy, CMS also proposes that HCPCS coding and modifiers for biosimilars will be based on policy established under the CY 2016 Medicare PFS.

---

[33] 21 CFR 807.81(a)(3); *Also see* FDA. 2014. *Is a new 510(k) required for a modification to the device?* Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134575.htm.

[34] Changes to a dose would require labeling changes [*See* Food and Drug Administration (FDA). 2010 (March). Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format. Silver Spring, MD: FDA, available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075066.pdf.]. Labelling changes are governed by 21 C.F.R. 601.12(a). *Also see* FDA. 1997. Changes to an Approved Application: Biological Products. Silver Spring, MD: FDA, available at: http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM170166.pdf.

[35] 21 CFR 814.39(a).

[36] 80 Fed. Reg. 39200, 39285.

BIO has consistently advocated for payment policies that enable patients, in conjunction with their provider, to make treatment decisions based on what is most appropriate for their individual clinical circumstances, including patient and disease characteristics. This extends to the setting in which a patient receives care: decisions with regard to where a patient receives care should be based solely on clinical appropriateness and patient preferences, and not influenced by financial incentives created, for example, by differential payment rates for a therapy when provided in different settings (i.e., hospital outpatient department versus physician office). Therefore, BIO supports CMS's proposal to align Medicare payment for biosimilars between physician office and hospital outpatient settings.

Second, CMS also proposes to extend pass-through payment eligibility to biosimilars and to establish pass-through payment based on the difference between the payment allowance of the product determined under section 1847A and the otherwise applicable hospital outpatient department fee schedule amount. CMS also proposes that nonpass-through biosimilars would be subject to the annual threshold-packaged policy. BIO also has consistently supported the pass-through payment mechanism for drugs and biologicals to help ensure that patients have timely access to new-to-market therapies. Pass-through status provides a more predictable reimbursement for these therapies during the first two to three years in which providers begin to integrate them into treatment plans where appropriate for an individual patient. Appropriate utilization of these therapies, in turn, can produce significant benefits over the standard of care, including improved short- and longer-term health outcomes, diminished side-effects, and/or fewer hospitalizations, physician office visits, and the need for surgical interventions. BIO supports CMS's proposal to extend pass-through status to biosimilars beginning in CY 2016, and asks the Agency to finalize this proposal.

On the issue of coding and reimbursement for biosimilars under the PFS, BIO has serious concerns with the methodology CMS proposes to employ. These concerns will be addressed in detail in our comments in response to the CY 2016 PFS as CMS's payment methodology and HCPCS coding proposals are developed through that rulemaking process. However, a summary of BIO's comments in response to the CY 2015 PFS is included below.

First, we disagree with CMS's assessment in the CY 2016 PFS Proposed Rule that the Agency's proposal to blend payment rates for biosimilars of the same reference product is authorized by the text of section 1847A(b)(8) of the SSA, which establishes the reimbursement methodology for biosimilars. In fact, the language of section 1847A(b)(8), which applies the ASP payment methodology to "[a] biosimilar biologic *product* for all National Drug Codes assigned to such *product…*" (emphasis added) requires the use of unblended reimbursement for each biosimilar product.

Second, we further believe that CMS's proposed approach would result in negative impacts for patients by potentially pushing patients to one biosimilar over another based on price rather than clinical appropriateness. This is due to the fact that a blended ASP for all biosimilars of a reference product would necessarily exceed the ASP of the less expensive biosimilar, but generally would fall below the ASP of the more expensive product, and could potentially result in a total biosimilar payment that fell below the ASP of the more expensive biosimilar product. This result, in turn, would provide a real financial incentive for providers to prescribe one over the other.

Third, as part of this broader payment proposal for biosimilars, CMS also suggests that biosimilars that share a reference product will be grouped into the same HCPCS code. BIO continues to disagree strongly with this approach. We firmly believe that the absence of a

distinct HCPCS code for each and every biosimilar, including those that share a reference product, would confuse providers and dispensers and could potentially harm patients. HCPCS codes, not National Drug Codes (NDCs), are most often used to report utilization of biological products (since they are often administered in the physician office setting). The absence of distinct HCPCS codes will lead to confusion with regard to which product was prescribed by the provider. Moreover, the implication of multiple biosimilars sharing the same HCPCS code—namely, that these therapies are somehow equivalent and/or interchangeable—would be confusing for prescribers, dispensers, and Medicare contractors as no such relationship would have been established during the regulatory approval process. In fact, the Food and Drug Administration (FDA) has identified the need to distinguish between biosimilars that utilize the same reference product, stating that "[t]here is a need to clearly identify biological products for the purpose of pharmacovigilance, and, for the purposes of safe use, to clearly differentiate among biological products that have not been determined to be interchangeable."[37]

Based on these concerns, in our comments in response to the CY 2016 PFS Proposed Rule, BIO urges the Agency to reimburse each biosimilar based on its own ASP, consistent with the reimbursement methodology required for all single-source products and required for biosimilars under section 1847(A)(b)(8). Moreover, in line with our prior comments to the Agency, BIO urges CMS to establish a unique HCPCS code for each and every biosimilar product.

X. Proposed New Hospital Outpatient Quality Reporting (OQR) Program Quality Measures for the CY 2018 and CY 2019 Payment Determinations and Subsequent Years

A. CMS should finalize proposals to incorporate additional measures related to the use of external beam radiotherapy for bone metastases and care coordination into the Hospital OQR Program.

For CY 2016, CMS proposes to adopt two new measures for the Hospital OQR Program: (1) "OP-33: External Beam Radiotherapy for Bone Metastases (NQF #1822); and (2) "OP-34: Emergency Department Transfer Communication (EDTC) (NQF #0291)."[38] BIO supports the finalization of both of these measures. We appreciate that CMS chose measures to address the identified gap in quality assessment that have been assessed and recommended by the Measure Applications Partnership (MAP), a multi-stakeholder group convened by the National Quality Forum (NQF), and are endorsed by the NQF. Specifically, with regard to the second proposed measure on timely communications, BIO notes the utility of the specificity of the subcomponents of the measure: there are seven subcomponents, and twenty additional elements that compromise these seven. However, hospitals will only be required to report "yes" or "no" as to whether these clinical indicators were recorded and communicated to the receiving facility prior to departure or within 60 minutes of transfer. We are sensitive to the need to ensure quality reporting metrics are not overly burdensome to hospitals, however, we encourage CMS to consider how to measure whether the use of this metric is having a significant impact on improving effective and timely communication of a patient's clinical status at the time of transfer from a hospital.

[37] 80 Fed. Reg. 52,224 (August 28, 2015).
[38] Id. at 39328.

B. CMS should finalize the proposed inclusion of the "Influenza Vaccination Coverage among Healthcare Personnel" measure (NQF 0431) for CY 2018 and CY 2019 payment determinations.

In the Proposed Rule, CMS proposes to maintain NQF 0431, entitled the "Influenza Vaccination Coverage among Healthcare Personnel" measure, in the Hospital OQR Program measures set for the CY 2018 and 2019 payment determinations and subsequent years.[39] This measure was previously adopted for both the 2017 and 2018 payment determination years, and BIO strongly supports its continued inclusion. The U.S. Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) has recognized the importance of vaccinations in this population, recommending that all healthcare personnel be vaccinated annually against influenza.[40] This is because there is robust evidence that vaccination in this population "can reduce influenza-related morbidity and mortality among both HCP and their patients."[41] While vaccination rates among healthcare personnel are estimated to be relatively high—89.6 percent in 2014 for personnel working in hospitals—BIO believes the inclusion of this measure in the Hospital OQR Program is important to maintaining, and improving upon, these vaccination rates.[42] Thus, we urge the Agency to finalize the continued inclusion of this measure for the CY 2018 and CY 2019 payment determination years.

C. BIO encourages CMS to include additional immunization performance measures in the OQR Program to help ensure vaccines are routinely offered and administered to patients in the outpatient setting.

Immunization measures help ensure that healthcare providers routinely discuss and offer recommended vaccines to their patients, resulting in higher vaccine uptake, better health outcomes, and cost savings for the healthcare system. According to data published by CMS, the inclusion of an immunization quality measure evaluating provider behavior results in an increase in vaccination rates.[43] BIO encourages CMS to include additional immunization measures in the OQR Program so immunization opportunities are not missed in the outpatient setting.

With the goal of increasing alignment across reporting programs and healthcare settings, BIO recommends inclusion of both an influenza immunization measure, such as NQF #0041, and a pneumococcal immunization measure, such as NQF #0043. Both measures are currently part of CMS's Physician Quality Reporting System (PQRS). Influenza and pneumococcal disease are high-burden, high-cost conditions, and vaccination is the primary

---

[39] Id. at 39329 and 39334.
[40] Shefer, A., *et. al.* 2011 (November 25). Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *Morbidity and Mortality Weekly Report* 60(RR07):1-45, available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6007a1.htm.
[41] For example, *see* Carman W. F., *et. al.* 2000. Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomized controlled trial. *Lancet* 355:93–7. 3; *also see* Hayward A.C., *et. al.* 2006. Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. *BMJ* 333:1241; *also see* Lemaitre M., *et. al.* 2009. Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster randomized trial. *Journal of the American Geriatrics Society* 57:1580–6.
[42] Black, C. L., *et. al.* 2014 (September 19). Influenza Vaccination Coverage Among Health Care Personnel — United States, 2013–14 Influenza Season. *Morbidity and Mortality Weekly Report* 63(37):805-811, available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a1.htm.
[43] Centers for Medicare & Medicaid Services. National Impact Assessment of Medicare Quality Measures. March 2012. pp. 40-42. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/NationalImpactAssessmentofQualityMeasuresFINAL.PDF. Accessed August 15, 2013.

method for preventing them. Yet, immunization coverage rates remain suboptimal. For instance, in 2013, pneumococcal vaccination coverage among adults age 65 and older was only 59.7 percent, and among high-risk adults age 19-64 with conditions such as COPD, diabetes, and CVD, it was only 20 percent.[44] These rates could increase significantly should quality measures be implemented in various healthcare settings. This was clearly shown following the introduction of performance measures for influenza and pneumococcal vaccination in the Veterans Health Administration (VHA) in 1995. Among eligible adults, influenza vaccination rates increased from 27 percent to 70 percent, and pneumococcal vaccination rates rose from 28 percent to 85 percent, with limited variability in performance between networks; pneumonia hospitalization rates decreased by 50 percent, and it is estimated that the VHA saved $117 for each vaccine administered.[45] BIO also recommends that CMS consider developing and including adult immunization measures to address gaps recently identified by the NQF in the 2014 report, "Priority Setting for Healthcare Performance Measurement: Addressing Performance Measure Gaps for Adult Immunizations."[46] The committee identified four age-specific priorities for measurement:

- HPV vaccination catch-up for females ages 19-26 years and for males ages 19-21 years
- Tdap/pertussis-containing vaccine for ages 19+ years
- Zoster vaccination for ages 60-64 years
- Zoster vaccination for ages 65+ years

The committee also identified a number of composite measure priorities, such as measures to help manage chronic diseases like diabetes and end stage renal disease which are prevalent in the Medicare population.

Further, in the 2015 report of the NQF Health and Well-Being Standing Committee, the organization proposed and approved standard specifications for pneumococcal vaccination to enable measure stewards for the existing measures (CMS and NCQA) to assess, and presumably modify, their measures based on the revised standardized specifications. [47] We encourage CMS to work with relevant stakeholders, including NQF, to implement the recommended Pneumococcal Vaccination Standard Specifications, which align to the current ACIP recommendation for PCV13 and PPSV23 vaccination in adults age 65 and older as well as at risk adults 19-64 years old, for the PQRS and across CMS programs.[48,49]

In summary, we encourage CMS to incorporate into the OQR Program existing measures that align with other quality reporting programs and to consider the development and inclusion of new measures that are reflective of NQF's recommendations, as the addition of

---

[44] Centers for Disease Control and Prevention. Noninfluenza Vaccination Coverage among Adults – United States, 2011. *MMWR Morb Mortal Wkly Rep*. 2013;63(04):66-72.
[45] A. Jha, S. Wright, J. Perlin, *Performance measures, vaccinations, and pneumonia rates among high-risk patients in Veterans Administration Health Care*, 97 Am. J. Public Health 2167-2172 (2007).
[46] National Quality Forum, *Final Report: Priority Setting for Healthcare Performance Measurement: Addressing Performance Measure Gaps for Adult Immunizations* (2014). Available at: http://www.qualityforum.org/Publications/2014/08/Priority_Setting_for_Healthcare_Performance_Measurement__Addressing_Performance_Measure_Gaps_for_Adult_Immunizations.aspx
[47] National Quality Forum, Health and Well-Being, *Phase 2 Draft Report for Comment, pp. 11-13 and 35-37, May 29, 2015*
[48] Centers for Disease Control and Prevention. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥ 65 years: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep*. 2014;63(37):822-825.
[49] Centers for Disease Control and Prevention. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromising Conditions: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep*. 2012;61(40):816-819.

immunization measures would help reduce vaccine-preventable diseases and therefore improve the health of both Medicare beneficiaries and the broader U.S. population.

D. BIO encourages CMS to include measures in the OQR Program that inform appropriate clinical decision-making for patients with lung cancer.

Robust quality metrics can not only retrospectively assess the quality of care a patient received, but—if developed, implemented, and refined in a timely manner—can inform patient/provider decision-making at the point of care by reflecting the most recent advances in the standard of care for a specific disease and patient population or subpopulation. BIO identifies two lung cancer-related examples of quality measures that can fulfill this dual role. This is by no means an exhaustive list but is meant to be illustrative to the Agency with regard to the importance of choosing and updating quality measures in a timely manner that keeps pace with emerging clinical evidence.

As an initial example, lung cancer is the third most common cancer and the leading cause of cancer death in the U.S.[50] Given the burden of the disease on the U.S. population and the health care system, we support CMS's National Coverage Decision (NCD) for the Screening for Lung Cancer with Low Dose Computed Tomography (LDCT).[51] While the NCD is a significant step in improving early detection rates, we believe there is more to be done to increase the adoption of proper LDCT screening. We ask that CMS encourage the development of quality measures that ensure LDCT screening to all patients who meet the eligibility criteria. We believe this will increase the proper screening rates, thereby reducing mortality rates and the burden of disease for this population and for Medicare.[52,53]

As a second example, we encourage CMS to support the development of a measure to track timely testing for known driver mutations with available targeted therapies for patients with advanced non-small cell lung cancer (NSCLC). [54,55] Such a measure would be consistent with current oncology and pathology practice guidelines (specifically for EGFR and ALK testing in adenocarcinomas/mixed lung cancers with an adenocarcinoma component regardless of histologic grade).[56] The current College of American Pathologists (CAP)/ International Association for the Study of Lung Cancer (IASLC)/ Association for Molecular Pathology (AMP) clinical practice guidelines specify that patients should be tested at the time of diagnosis and that results should be available within 10 working days of laboratory receipt of the specimen (with additional specificity on the timeliness of tissue delivery for testing following histopathological diagnosis).[57] Timely testing and rapid turnaround would also allow treatment decisions that are consistent with current National Comprehensive Cancer

---

[50] American Cancer Society. Cancer Facts & Figures 2013. Atlanta: American Cancer Society; 2013. Accessed at http://www.cancer.org/research/cancerfactsfigures/cancerfactsfigures/cancer-facts-figures-2013This link goes offsite. Click to read the external link disclaimer on August 5, 2015.

[51] Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT), 2015. Accessed at https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274 on August 5, 2015

[52] Aberle DR, Adams AM, Berg CD, Black WC, Clapp JD, Fagerstrom RM, et al.; National Lung Screening Trial Research Team. Reduced lung-cancer mortality with low-dose computed tomographic screening. *New Engl J Med*. 2011;365(5):395-409

[53] Pinsky PF, Church TR, Izmirlian G, Kramer BS. The National Lung Screening Trial: results stratified by demographics, smoking history, and lung cancer histology. *Cancer*. 2013.

[54] Molecular testing guideline for selection of lung cancer patients for EGFR and ALK tyrosine kinase inhibitors: guideline from the College of American Pathologists, International Association for the Study of Lung Cancer, and Association for Molecular Pathology**;** Arch Pathol Lab Med. 2013 Jun; 137(6): 828–860.

[55] See CAP/IASLC/AMP guideline for complete information on staging and recurrence.

[56] Molecular testing guideline, CAP/IASLC/AMP, 2013, Recommendation 1.2.

[57] Molecular testing guideline, CAP/IASLC/AMP, 2013. Expert Consensus Opinion 3.3.

Network (NCCN) guidelines for NSCLC.[58] According to NCCN guidelines and the American Society of Clinical Oncologists (ASCO), while patients may benefit from first-line chemotherapy followed by targeted therapies in second line, patients with EGFR and ALK mutations show superior outcomes with first-line administration of targeted therapies. [59,60] BIO recommends CMS to encourage the development of a measure of timely diagnosis and testing to allow the most appropriate clinical decisions in NSCLC.

E. BIO asks CMS to initiate a special Quality Improvement Organization (QIO) project(s) to reduce inappropriate variation in the treatment of ischemic stroke.

BIO appreciates CMS's commitment to advancing policies designed to ensure that all Medicare beneficiaries have access to care that reduces morbidity and the risk of disability. In considering mechanisms to fulfill this commitment, we ask the Agency to consider the burden of ischemic stroke among the Medicare population and the potential to improve care in the hospital outpatient setting related to disease.[61]

Ischemic stroke affects hundreds of thousands each year and leaves many with new disability and at increased risk for complications, recurrent stroke, and clinical deterioration. Less than a decade ago, stroke was the third leading cause of death in the United States, but today it is the fifth.[62] Mortality rates from stroke are dropping; however, the number of people having strokes in the U.S. is rising each year due to the aging of our population.[63] Functional outcomes for this population vary widely based-on regional and local differences, and many of these patients are discharged to long-term care. It has been shown from a variety of research studies and data sources that increased hospital focus on stroke protocols and other quality measures can significantly improve long-term patient outcomes and reduce long-term costs for stroke patients.[64] It is through this lens that we recommend CMS to investigate increased attention toward stroke care and encourage hospitals to continue to improve on well-defined processes, for example, through a special project by the QIO.

Specifically, we would like to highlight an important quality of care issue where QIOs could support stroke care: specifically, in improving door-to-needle times. There are a wealth of studies showing the ability and benefits of implementing protocols aimed at reducing door-

---

[58] National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for Non-Small Cell Lung Cancer; Version 7.2015.
[59] Keedy VL, Temin S, Somerfield MR, et al. American Society of Clinical Oncology provisional clinical opinion: epidermal growth factor receptor (EGFR) mutation testing for patients with advanced non-small-cell lung cancer considering first-line EGFR tyrosine kinase inhibitor therapy. J Clin Oncol. 2011;29(15):2121–2127.
[60] NCCN Clinical Practice Guidelines, Version 7.2015.
[61] CMS estimates that 4 percent of Medicare beneficiaries have suffered a stroke and as much as 31 percent suffer from ischemic heart disease, *see* CMS Chartbook: 2012 Edition. *Chronic Conditions Among Medicare Beneficiaries*, p.6, Figure 1.1a, available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf.
[62] Kochanek, K.D., S. L. Murphy, J. Xu, and E. Arias. 2014 (December). *Mortality in the United States*. CDC: National Center for Health Statistics Data Brief, Number 178, available at: http://www.cdc.gov/nchs/data/databriefs/db178.htm.
[63] Fang, M. C., *et. al.* 2014. Trends in Stroke Rates, Risk, and Outcomes in the United States, 1988 to 2008. *American Journal of Medicine* 127(7)608-615.
[64] For example, *see* Caso, V. and P. Michel. 2015. Thrombolysis in acute stroke. *Lancet* 385(9976):1395-1396; *also see* Emberson, J. *e.t, al*. 2014. Effect of treatment delay, age, and stroke severity on the effects of intravenous thrombolysis with alteplase for acute ischaemic stroke: a meta-analysis of individual patient data from randomised trials. *Lancet* 384(9958): 1929–1935.

to-needle times.[65] Focusing on driving greater accountability in these protocols will have a direct positive effect on patients and on reducing disability in the health care system. In fact, how long a patient takes to receive thrombolysis is one of the best predictors of his or her outcomes.[66]

This is critically important as a recent study by the University of Michigan highlighted the large variation of tissue plasminogen activator (tPA) rates in different counties in the United States.[67] Moreover, a study in the Journal of the American Heart Association found that just 29 percent of 141 hospitals correctly judged their promptness in administering crucial thrombolytic treatment to stroke patients.[68] Nearly 57 percent of patients admitted to top-performing facilities received thrombolysis within the recommended first hour, while staff estimated the figure was 60 percent. Lower-performing facilities tended to estimate at least 20 percent of patients were treated promptly, yet none were. If the latter hospitals are small, they will not show up in hospital compare due to a low volume of cases. Given the discrepancy of tPA usage across different regions and by hospital size, a QIO special project addressing the geographic variation can be invaluable in targeting better care.

Thus, given the potential to improve the quality of care for patients suffering from ischemic stroke, BIO encourages CMS to explore mechanisms to improve adherence to best practices in this population. This should include, but is not limited to, incorporating an assessment of practitioners' adherence to such best practice protocols in a QIO special project. In addition it would be helpful for CMS to publish the data on door-to-needle time that the Agency is collecting through the Hospital OQR program quality measures.

XI. Proposed OPPS Ambulatory Payment Classification (APC) Updates [Data Analysis of Addendum B]—CMS should carefully evaluate proposed changes that restructure APCs impacting payment for drug administration services before finalizing them.

For CY 2016, CMS proposes APC updates, including restructuring many APCs that may affect payment for drug administration services. We note that the proposed payment rates for many common drug administration procedures introduce broad variations from the 2015 payment rates. For example, the proposed restructuring of codes currently part of APC 0438 and APC 0437 into renumbered APC 5693 results in a loss in payment per procedure of, on average, 12.1 percent. This is in contrast to other procedures, which would experience payment increases. For example, the restructuring of current APC 0436 and several codes from APC 0437 into a renumbered APC 5691 will result in a payment increase per procedure of 1.8 percent, on average. After preliminary data analysis, BIO is concerned by the high degree of variability with regard to the impact of these proposed changes on the proposed payment rates for drug administration. We ask CMS to evaluate these proposed changes carefully before finalizing them to ensure that they appropriately reflect the costs of providing these important services.

---

[65] For example, *see* Shah, S. *et. al*. 2015. Screening with MRI for Accurate and Rapid Stroke Treatment: SMART. *Neurology* 16(84):2438-2444; *also see* Newby, K. 2014 (December 8). Stanford team designs process for reducing stroke disability, costs. *Stanford Medicine News Center*, available at: https://med.stanford.edu/news/all-news/2014/12/stanford-team-designs-process-for-reducing-stroke-disability.html.

[66] Lin, C. B. 2015. Perception Versus Actual Performance in Timely Tissue Plasminogen Activation Administration in the Management of Acute Ischemic Stroke. *Journal of the American Heart Association* 4:e001298, available at: http://jaha.ahajournals.org/content/4/7/e001298.full.pdf+html.

[67] Skolarus, L. et. al. 2015. Marked Regional Variation in Acute Stroke Treatment Among Medicare Beneficiaries. *Stroke* 46(7):1890-1896.

[68] Lin *et. al.* 2015. *Journal of the American Health Association*.

XII. Conclusion

BIO appreciates this opportunity to comment on the CY 2016 OPPS Proposed Rule. We again urge CMS to finalize its proposal to continue reimbursing separately payable drugs and biologicals at ASP plus six percent and also urge CMS to continue making separate payments for drugs, biologicals (including biosimilars), and radiopharmaceuticals, and drug administration services in the circumstances that we have described above.

We look forward to continuing to work with the agency to ensure that OPPS reimbursement policies remain equitable for hospitals and thereby safeguard patient access to necessary therapies. Please contact me at (202) 962-9200 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Laurel L. Todd
Managing Director
Reimbursement and Health Policy