Biotechnology Industry Organization

September 4, 2012

BY ELECTRONIC DELIVERY

Marilyn Tavenner
Acting Administrator
Centers for Medicare and 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: Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations [CMS-1589-P]

Dear Acting Administrator Tavenner:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding the hospital outpatient prospective payment system (OPPS) and calendar year (CY) 2013 payment rates, published in the Federal Register on July 30, 2012 (the Proposed Rule).[1] BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products.

As the representative of an industry that is devoted to improving health care through the discovery of new therapies, BIO understands that appropriate reimbursement based on an accurate payment methodology is essential to protecting beneficiary access to care and encouraging continued investment in innovation. BIO strongly supports CMS's proposal to reimburse separately payable drugs and biologicals without pass-through status at average sales price (ASP) plus six percent under the outpatient prospective payment system (OPPS) in calendar year 2013. This policy will provide the predictable, appropriate payment rates needed to ensure that beneficiaries can receive critical therapies in the appropriate hospital outpatient setting. We urge CMS to finalize this proposal. In addition, we recommend that CMS apply this reimbursement rate to all drugs and biologicals with Healthcare Common Procedure Coding System (HCPCS) codes, including contrast agents and diagnostic radiopharmaceuticals.

[1] 77 Fed. Reg. 45061 (July 30, 2012).

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In short, we recommend that CMS:

- Implement its proposal to pay ASP plus six percent for separately payable drugs and biologicals administered in the OPPS.
- Make separate payment for all drugs and biologicals with HCPCS codes as it does in the physician office setting or alternatively, not increase the packaging threshold for these therapies. If any drugs remain packaged, CMS should *require* hospitals to bill for them using HCPCS codes and revenue code 636.
- Classify dosemetric doses used in radiopharmaceutical procedures as therapeutic radiopharmaceuticals and reimburse for them separately.
- 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.
- Consider implantable biologicals approved under biologics license applications (BLAs) for pass-through status as drugs or biologicals, or, if CMS does not implement this recommendation, revise its regulation to clarify that a biological will be evaluated as a device for pass-through status only if it is solely surgically implanted according to its Food and Drug Administration (FDA)-approved indication.
- Finalize its proposal to continue to adjust OPPS payments to certain cancer hospitals in CY 2013.
- Finalize its proposal to use the geometric mean of costs, instead of the currently used median, to calculate Ambulatory Payment Classification (APC) relative payment weights.
- Implement quality measures for the treatment of stroke.
- Add medication management measures as a domain to the six domains already proposed or alternatively, include additional medication management outcomes measures within the existing six domains.

These comments are discussed in detail below.

I. <u>Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status</u> – CMS should finalize its proposal to pay ASP plus six percent for separately payable drugs and biologicals administered in the OPPS.

We appreciate CMS's efforts in recent years to achieve a "predictable, accurate, and appropriate" rate-setting methodology for separately payable drugs and biologicals without pass-through status.[2] Over the past several years, based on recommendations from stakeholders and the Advisory Panel on Hospital Outpatient Payment (HOP Panel), CMS has revised its standard rate-setting methodology by reallocating overhead costs from packaged drugs to separately payable drugs and biologicals. These refinements have helped to protect against drastic reductions in payments for separately payable drugs and biologicals, but continued modifications have been needed to prevent significant fluctuations in payment rates. It is likely that further

[2] <u>Id</u>. at 45140.

changes to the methodology would be needed to achieve continued stability and adequate reimbursement for these therapies, particularly if CMS continues to increase the packaging threshold and the number of hospitals participating in the 340B program continues to grow. As CMS recognizes in the proposed rule, "continued use of [its] current drug payment methodologies may not appropriately account for average acquisition and pharmacy overhead cost and therefore could result in future payment rates that are not appropriate."[3]

Instead of continuing to modify an already complicated rate-setting methodology, CMS proposes to use the "statutory default" method of ASP plus six percent.[4] The Social Security Act (SSA) requires Medicare 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.[5] If acquisition cost data are not available, the payment shall be set at the average price for the drug established under section 1842(o), 1847A, or 1847B (e.g., ASP plus six percent or the rates determined under the Competitive Acquisition Program).[6]

BIO supports this proposal because it is consistent with the statute and Congressional intent to reimburse hospitals for these therapies based on either an accurate methodology to determine average acquisition cost for each drug or the rates established under sections 1842(o), 1847A, or 1847B. This approach obviates the need to estimate hospitals' acquisition costs from claims data, a task that has been difficult for CMS to accomplish with stable and accurate results from year to year and from proposed rule to final rule. Although CMS's adjustments for pharmacy overhead costs have helped to produce more appropriate rates than would be reached using the estimates of acquisition alone, the reallocation methodology has produced rates that change from year to year. In contrast, as CMS notes, the statutory default approach "yields increased predictability in payment for drugs and biologicals under the OPPS."[7] BIO appreciates CMS's recognition of the importance of providing predictable reimbursement within the OPPS and urges CMS to finalize this proposal for calendar year 2013.

We understand that CMS intends to continue to work on developing a "method that accurately and predictably estimates acquisition and overhead costs for separately payable drugs and biologicals in order to pay for them appropriately."[8] Appropriate payment is essential in order to ensure patient access to drugs and biologicals in the most clinically appropriate setting and to avoid inappropriate, financially driven shifts in the site of care. We strongly support CMS's goal of appropriate payment for drugs and biologicals and their related pharmacy service and overhead costs and look forward to working with the agency to develop a better methodology. Until CMS develops such a methodology, however, CMS should at least reimburse these drugs and biologicals at ASP plus six percent.

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[3] Id. at 45218.
[4] Id. at 45140.
[5] SSA § 1833(t)(14)(A)(iii)(I).
[6] Id. § 1833(t)(14)(A)(iii)(II).
[7] 77 Fed. Reg. at 45218.
[8] Id. at 45140.

II. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

A. CMS should make separate payment for all drugs and biologicals with HCPCS codes or alternatively, not increase the packaging threshold for these therapies. If any drugs and biologicals remain packaged, CMS should *require* hospitals to bill for them using HCPCS codes and revenue code 636.

For 2013, CMS proposes to increase the packaging threshold to $80, after setting it at $75 in 2012, $70 in 2011 and $65 in 2010, and to continue to package payment for all diagnostic radiopharmaceuticals and contrast agents.[9] BIO believes that CMS should make separate payment for all drugs and biologicals with HCPCS codes in the OPPS just as it does for these therapies when they are administered in a physician office. CMS continues to assert that diagnostic radiopharmaceuticals and contrast agents can be treated differently from other SCODs because the statutory packaging threshold has expired and the agency believes that these drugs "function effectively as supplies that enable the provision of an independent service."[10] These assertions ignore the clear language of the statute and Congressional intent. The statute 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.[11]

We note first that the statute does not distinguish between drugs and biologicals that serve as a therapeutic modality and those that are used with other services.[12] CMS has no authority to reclassify a drug or biological as a supply simply to avoid payment as a SCOD. Second, Congress did not intend for CMS to circumvent the statutory payment provisions for SCODs by establishing high packaging thresholds or packaging entire classes of therapies. To do so would render the statute's explicit payment instructions meaningless. When Congress enacted this definition, it established a packaging threshold of $50 per administration for drugs administered in 2005 and 2006[13] because it objected to the $150 packaging threshold that was in effect in 2003. Congress intended for CMS to establish a low packaging threshold for all drugs and biological products, and the absence of a statutory requirement regarding the packaging threshold after 2006 should not be interpreted as support for widespread packaging.

BIO believes that separate payment should be made for every drug or biological, including diagnostic radiopharmaceuticals and contrast agents, with a HCPCS code just as it is made in the physician office. At a minimum, packaging should not be expanded beyond current levels. 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. We appreciate the encouragement CMS gives hospitals in the proposed rule to "change their reporting practices if they are not already reporting HCPCS codes for all drugs and biologicals furnished, whether

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[9] Id. at 45133, 45142-43.
[10] Id. at 45100.
[11] SSA § 1833(t)(14)(B).
[12] Id.
[13] SSA § 1833(t)(16)(B).

specific HCPCS codes are available for those drugs and biologicals,"[14] but we believe that a firm instruction is needed. CMS now is required to measure drug utilization to calculate the pharmaceutical tax under the Affordable Care Act (ACA). Requiring hospitals to bill for drugs and biologicals using HCPCS codes and revenue code 636 not only will help CMS meet this new requirement, but it will provide CMS with better data for future rate-setting.

B. CMS should classify dosemetric doses used in radiopharmaceutical procedures as therapeutic radiopharmaceuticals and reimburse for them separately.

When used in radiopharmaceutical procedures, a dosemetric dose is provided first to determine aspects of the drug's distribution in the body that will allow for the optimization of a second, or therapeutic, dose. These two doses are approved by the FDA as part of a single therapeutic regimen, and cannot be practically uncoupled, and are required by the nature of the therapeutic agent itself (to a much greater degree than many small molecule pharmaceuticals, radiopharmaceuticals' action must be individually tailored to each patient to optimize efficacy). CMS has no authority to isolate the elements of an approved therapy regimen and classify and pay for them separately. Therefore, BIO urges CMS to reclassify dosemetric doses used in radioimmunotherapy and other radiopharmaceutical procedures as therapeutic radiopharmaceuticals. Reclassifying dosemetric doses as part of the radiopharmaceutical procedure, and paying for them as such, accurately reflects their function as part of a single FDA-approved therapeutic regimen.

III. Proposed Payment Policy for Therapeutic Radiopharmaceuticals – CMS should continue to pay for therapeutic radiopharmaceuticals based on ASP data if submitted by the manufacturer and reimburse these therapies at ASP plus six percent.

For 2013, CMS proposes to continue to reimburse all nonpass-through, separately payable therapeutic radiopharmaceuticals at the same rate as nonpass-through drugs and biologicals (ASP plus six percent) based on ASP information, if available, for a "patient ready" dose and updated on a quarterly basis for products for which manufacturers report ASP data.[15] If ASP data are not available, CMS proposes to use CY 2011 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals.[16] BIO agrees that using ASP data provides an opportunity to improve payment accuracy for therapeutic radiopharmaceuticals, and we support CMS's proposal to reimburse these therapies, along with all other separately payable drugs, biologicals, and radiopharmaceuticals at ASP plus six percent.

[14] 77 Fed. Reg. at 45141.
[15] Id.
[16] Id.

IV. Proposed Payment for Blood Clotting Factors – CMS should reimburse blood clotting factors at ASP plus six percent.

CMS proposes to pay for blood clotting factors at ASP plus six percent, consistent with the proposed rates for other separately paid drugs and biologicals without pass-through status, and to continue to pay an additional furnishing fee using an updated amount.[17] Consistent with our recommendation for other drugs and biologicals, we support this proposal and urge CMS to finalize it.

V. Pass-Through Payments for Implantable Biologicals – Biologicals approved under BLAs should be eligible for pass-through drug status.

CMS proposes to continue to treat implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) as devices for payment purposes under the OPPS.[18] Under this policy, CMS evaluates new implantable biologicals under the device pass-through evaluation process and packages payment for all nonpass-through implantable biologicals. BIO continues to be opposed to this policy. Some implantable biologicals meet the SSA's definition of "biological"[19] even though they are approved by the FDA as devices. As CMS explained in the final rule for 2010, it believes these products "function as implantable devices," thus should be subject to the same reimbursement policies as devices.[20] CMS also noted 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."[21] 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 nonbiological, only under the device pass-through process."[22] 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.

BIO believes that biologicals approved by the FDA under a BLA should be eligible for pass-through payment as drugs, regardless of whether they are implanted. When Congress implemented the current payment system for SCODs that previously had pass-through status, it intended for biologicals approved under BLAs to be reimbursed under the specific statutory

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[17] Id.
[18] Id. at 45100-01.
[19] 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.").
[20] 74 Fed. Reg. 60316, 60496 (Nov. 20, 2009).
[21] Id. at 60474.
[22] Id.

provisions for drugs.[23] Therefore, it is only logical that Congress would have intended for these BLA-approved therapies to be reimbursed as pass-through drugs as well. Our recommended change is thus consistent with both Congressional intent to reimburse biologicals approved under BLAs under the methodologies for drugs and biologicals and CMS's goal of treating products approved as devices similarly. Therefore, we urge CMS to revise its regulatory language at 42 CFR § 419.64(a)(4) to include the following bold, italicized language:

> (iii) A biological ***approved under a biologics license application or a drug***.
> (iv) A biological ***not approved under a biologics license application*** that is surgically implanted or inserted into the body, for which pass-through payment as a biological is made on or before December 31, 2009.

Our revisions would allow biological therapies approved under BLAs to continue to be considered for drug pass-through status and be paid separately at ASP plus six percent as Congress intended.

If CMS does not implement our recommendation and continues to evaluate implantable biologicals for pass-through status as devices, we urge CMS to 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."[24] This interpretation of the regulation is inconsistent with CMS's prior description of its policy, its application of the policy to date, and its 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)."[25] 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.[26] Under these instructions, hospitals can bill separately for these biologicals when they are not used as implantable devices. In addition, 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.[27] To make the regulation text consistent with CMS's policy and practices, we recommend that CMS revise the regulation to refer to "a biological that is not always surgically implanted or inserted into the body."

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[23] Conference Report, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, H. Rep. No. 108-391, at 679.
[24] 76 Fed. Reg. 74122, 74280 (Nov. 30, 2011).
[25] 74 Fed. Reg. at 60532; 75 Fed. Reg. 71800, 71975 (Nov. 24, 2010) (emphasis added).
[26] 75 Fed. Reg. at 71928; 76 Fed. Reg. at 74310 (emphasis added).
[27] 74 Fed. Reg. 60472, 60496; 75 Fed. Reg. 71800, 71928 (Nov. 24, 2010); 76 Fed. Reg. at 74310.

VI. Proposed OPPS Payments to Certain Cancer Hospitals – CMS should finalize its proposal to continue to adjust payments for certain cancer hospitals in CY 2013.

CMS proposes to continue its policy of providing hospital-specific payment adjustments for certain cancer hospitals "so that each cancer hospital's final PCR [payment-to-cost ratio] is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals using the most recent submitted or settled cost report data that are available at the time of this proposed rule."[28] CMS first implemented such an adjustment, as required by section 3138 of ACA for CY 2012. Using the most current data available, CMS proposes to use a target PCR of 0.91 to determine the CY 2013 cancer hospital payment adjustment that would be paid at cost report settlement.[29] BIO believes CMS should finalize this proposal to adjust payment for certain cancer hospitals paid under OPPS. As CMS confirmed through its analysis, cancer hospitals incur substantially higher costs, including the costs of drugs and biologicals, than other hospitals paid under OPPS. This adjustment helps to ensure that Medicare payment to these hospitals is adequate to cover the costs of providing care.

VII. Proposed Change in Calculating APC Relative Weights – CMS should finalize its proposal to use the geometric mean for calculating APCs.

BIO supports CMS's proposal to use the geometric mean costs, instead of the median costs, to calculate relative payment weights for hospital outpatient services in CY2013. Because statistical medians do not reflect subtle changes in cost distribution as well as geometric means, relative payment weights based on median costs are less sensitive to packaging decisions or changes in the cost model. The geometric mean can capture changes in costs earlier and better captures the range of costs over which services are provided (e.g., cases with high-cost packaged services or cases in which hospitals are able to efficiently provide services at very low costs). BIO agrees that using the geometric mean of costs to calculate CY 2013 APC relative payment weights will be a more accurate reflection of the costs of providing outpatient services, and urges CMS to finalize this proposal.

VIII. Quality Reporting Initiatives

A. BIO urges CMS to implement quality measures for the treatment of stroke.

Stroke is a condition where serious disparities exist in care, disability-related costs are staggering, and treatment is inconsistent. As such, BIO urges CMS to adopt the National Quality Forum (NQF)-endorsed stroke chart-abstracted measure set (excluding those related to discharge) within the OPPS, similar to their incorporation within the Inpatient Quality Reporting (IQR) Program for the FY 2015 payment determination.[30] Such an inclusion would address a category of hospitals that may treat, but not admit, stroke patients under a "drip and ship" model. A "drip and ship" model plays a critical role in the continuum of quality stroke care, as many

[28] 77 Fed. Reg. at 45110.
[29] Id.
[30] 77 Fed. Reg. 53258, 53530 (Aug. 31, 2012).

parts of the United States are without access to acute stroke services. Under this arrangement, thrombolytic therapy for stroke is initiated at the hospital where the patient presents, and the patient is then transferred to a stroke center or hospital with specialized expertise that is better equipped to care for the stroke patient's needs. Including this stroke measures set will provide these smaller or rural hospitals an opportunity to demonstrate their competencies in initiating stroke treatment as well.

B. CMS should include medication management measures as a domain to the six measurement domains already proposed or alternatively, include additional medication management outcomes measures within the existing six domains.

CMS has proposed a Hospital Outpatient Quality Reporting (OQR) Program to support patient decision-making and quality improvement through increased transparency around hospital outpatient department's quality of care. To do this, six measurement domains are outlined, and reflect the six priorities of the National Quality Strategy—clinical care; person- and caregiver-centered experience and outcomes; safety, efficiency and cost reduction; care coordination; and community/population health.[31] In addition to these six, BIO encourages CMS to include medication management measures as a primary measurement domain or alternatively, include additional medication management outcomes measures within the existing six domains. BIO believes it is appropriate to add this domain because it fulfills the criteria used to include the original six: well-validated medication management measures are available; including these measures is not overly burdensome as many outpatient departments have experience tracking them; and these measures have the potential to improve outpatient care through informing patient decision-making. Including medication management as a measurement domain will significantly contribute to the effort to improve the transparency around the quality of care beneficiaries receive in hospital outpatient departments.

[31] 77 Fed. Reg. at 45176.

IX. Conclusion

BIO thanks CMS for this opportunity to comment on the OPPS Proposed Rule for CY 2013. We look forward to continuing to work with the agency to ensure that hospitals are reimbursed appropriately for the costs of acquiring, preparing, and administering drug and biological therapies. We urge CMS to finalize its proposal to reimburse separately payable drugs and biologicals at ASP plus six percent and look forward to continuing to work with the agency to ensure that hospitals are reimbursed appropriately for the costs of acquiring, preparing, and administering drug and biological therapies in the future.

Please contact me at (202) 962-9220 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

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