

**Statement of the Biotechnology Industry Organization**

**Before the  
Advisory Panel on Hospital Outpatient Payment (HOP)  
March 10-11, 2014**

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## **Statement to the Advisory Panel on Hospital Outpatient Payment March 10-11, 2014**

The Biotechnology Industry Organization (BIO) appreciates this opportunity to testify before the Advisory Panel on Hospital Outpatient Payment (HOP Panel). BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. 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. Our members are devoted to improving health care through the discovery of new therapies, and our testimony today addresses recommended changes to the outpatient prospective payment system (OPPS) to protect access to those therapies and encourage continued investment in innovation.

In recent years, the Centers for Medicare & Medicaid Services (CMS) has made significant changes to the OPPS to make payments under the system “more consistent with those of a prospective payment system and less like those of a per service fee schedule, which pays separately for each coded item.”<sup>1</sup> The OPPS final rule for calendar year (CY) 2014 expanded packaging policies to include additional categories of items and services, including drugs, biologicals, and radiopharmaceuticals used in a diagnostic test or procedure or used as supplies in a surgical procedure; established a single ambulatory payment classification (APC) for all clinic visits; and created comprehensive APCs, which will be implemented in 2015. In the final rule, CMS also expresses interest in considering expanded packaging for other services, such as add-on codes for drug administration services, for future years.

CMS believes that it is “important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible.”<sup>2</sup> BIO wholeheartedly agrees with this statement, and we believe that an open, deliberative approach to any further packaging within the OPPS is needed to ensure that the new policies provide these incentives. Although packaging has the potential to encourage hospitals to provide care more efficiently, it also can create powerful disincentives against using the most clinically appropriate therapy. Payment rates must be sufficient to protect beneficiary access to care.

To ensure that Medicare beneficiaries continue to have access to essential, innovative therapies in the hospital outpatient setting, we ask the HOP Panel to recommend that:

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<sup>1</sup> 78 Fed. Reg. 74826, 74926 (Dec. 10, 2013).

<sup>2</sup> Id. at 74910.

- **CMS not implement further expansions of packaging until it has evaluated the effects on beneficiary access to care of the policies implemented for CY 2014.**
- **CMS allow ample time for stakeholder evaluation of any new packaging policies under the OPPS.**
- **CMS continue to reimburse separately payable drugs without pass-through status at average sales price (ASP) plus six percent.**
- **CMS continue to provide separate reimbursement for drug administration procedures.**
- **CMS develop and implement a data collection and analysis plan in the near future that gives the agency a concrete evidence of the frequency, type, and payment for ambulatory care services furnished in off-campus provider-based hospital departments.**

**I. The HOP Panel should recommend that CMS not implement further expansions of packaging until the effects of packaging on beneficiary access to care have been evaluated.**

As of the time of this meeting, it is too early to evaluate the impact of the new policies implemented in the 2014 final rule. Due to late release of the OPPS final rule for 2014 following the government shutdown, hospitals still are assessing the new rates for 2014 and determining how they affect each institution's choices about the items and services to provide, and what this could mean to patient care and access.

BIO remains concerned that the packaging payment policies finalized in the CY 2014 Hospital Outpatient Prospective Payment System Final Rule will adversely impact patient access to these therapies. Thus, to ensure continued patient access to quality care, thorough and ongoing measurement of how hospitals' utilization of the packaged items and services has been affected by the recent expansion in packaging and new APC for clinic visits is needed. It is crucial that CMS allow time for both the agency and stakeholders to make such evaluations before leaving in place these newly implemented changes or expanding packaging to any additional services in subsequent years. BIO asks the HOP Panel to recommend that CMS evaluate access to care under these new policies before implementing any further expansions of packaging and be prepared to amend now-current policy to ensure robust patient access to quality care.

CMS does not require hospitals to report HCPCS codes for packaged drugs<sup>3</sup> (unless CMS adopts a special requirement for coding a particular type of packaged

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<sup>3</sup> See, e.g., 78 Fed. Reg. at 43569 ("We encourage hospitals to report all HCPCS codes that describe packaged services provided, unless the CPT Editorial Panel or CMS provides other specific guidance. The appropriateness of the OPPS payment rates depends on the quality and completeness of the claims data that hospitals submit for the services they furnish to Medicare beneficiaries") (emphasis added).

drug). Further, hospitals have no incentive to list the codes for packaged drugs on their claims (because such coding has no effect on payment), and accordingly they frequently fail to code for packaged drugs, as CMS has often acknowledged. As a result, the reported use of a packaged drug is likely to decline—which in turn would cause the mean packaged APC costs computed from the claims data to decline, driving down the packaged payment and dis-incentivizing hospitals from providing the drug. To short-circuit this type of vicious cycle CMS should require that claims for packaged procedures indicate that a packaged drug is used every time it is provided. To ensure adequate payment, CMS must put mechanisms in place to ensure complete and accurate reporting of all drugs used in a packaged APC.

## **II. The HOP Panel should recommend that CMS allow ample time for stakeholder evaluation of any new packaging policies under the OPPTS.**

As CMS recognized with regard to the new comprehensive APCs, hospitals need time to model complex changes to reimbursement rates and assess the impact on their organization.<sup>4</sup> Indeed, all stakeholders need time to review and replicate CMS's proposed payment rates in order to ensure that the rates are calculated correctly and truly reflect the costs of the items and services included in each APC's rate and to provide meaningful comments on them. The OPPTS rates are calculated using a complex methodology that has become more difficult to replicate as the OPPTS system evolves. Only a few consultants can perform this analysis, and the 60-day comment period following the release of the proposed rule rarely is enough time to run all of the calculations, pose questions about potential technical errors to CMS, and provide comments on the effect of the policies. The even shorter deadline after the proposed rule is released and the written HOP Panel testimony is due also makes it difficult to provide meaningful comments at these meetings. These issues are exacerbated in years such as last, when consultants' analysis of the data initially released with the proposed rule found significant errors. As the attached memorandum explains, some problems have been identified in the final rule's data, as well. CMS received the memo and has been responsive; however, the consultants still are working to determine whether the agency's response resolved all of the issues identified.

To ensure that any new packaging policies produce appropriate reimbursement rates, CMS needs to provide sufficient time for stakeholders to analyze the data and provide meaningful comments. Ideally, packaging expansions that CMS is considering could be presented at the winter HOP Panel meeting, then refined and, if warranted, included in the annual proposed rule. Depending on the complexity of the proposal, CMS then could decide to implement the policy in the final rule or, better yet, wait an additional year to refine it as the agency has done with the comprehensive APCs. Either way, stakeholders would be given early notice that CMS is considering a certain policy, as well as a few different opportunities to

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<sup>4</sup> Id. at 74863.

analyze data and make comments. We ask the HOP Panel to recommend that CMS work with stakeholders and their consultants to make the data available as early as possible to facilitate meaningful analysis throughout this process.

**III. The HOP Panel should recommend that CMS continue to reimburse separately payable drugs without pass-through status at average sales price (ASP) plus six percent.**

BIO continues to support CMS's decision to reimburse all separately payable drugs without pass-through status using the "statutory default" reimbursement method of ASP plus six percent for separately payable drugs and biologicals. BIO supports this straightforward and predictable approach to reimbursement because it is consistent with the statute and Congressional intent and sets Medicare payment for drugs and biologicals at the same rate in the hospital and physician office settings. As a result, it could help to protect access to care in the most clinically appropriate setting for the patient by removing reimbursement incentives to select one setting over another. BIO urges the HOP Panel to recommend that CMS continue to employ this methodology for CY 2015.

As the HOP Panel knows, BIO repeatedly has asked that CMS also make separate payment at ASP plus six percent for non pass-through diagnostic radiopharmaceuticals, contrast agents, and drugs and biological that the agency claims act as supplies in diagnostic or surgical procedures. In addition, we repeatedly have asserted that CMS should make separate payment for all drugs and biologicals with Healthcare Common Procedure Coding System (HCPCS) codes as it does in the physician office setting or alternatively, not increase the packaging threshold for these therapies. Although we do not discuss these issues in depth in our testimony, we continue to make these requests and believe that CMS's current policies are inconsistent with the statute and Congressional intent and harm beneficiary access to appropriate drugs, biologicals, and radiopharmaceuticals.

**IV. The HOP Panel should recommend that CMS continue to provide separate reimbursement for drug administration procedures.**

BIO believes that protecting access to appropriate drug and biological therapies requires sufficient reimbursement for the related drug administration services. We are pleased that CMS did not finalize its proposal to package payment for add-on codes for drug administration. CMS concluded that further study of this payment methodology is warranted in light of "the frequency of drug administration services in the hospital outpatient department and their use in such a wide variety of different drug treatment protocols for various diseases in all types of hospitals."<sup>5</sup> CMS also explained that it may continue to explore other payment options, including "packaging and variations on packaging," however.<sup>6</sup>

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<sup>5</sup> Id. at 74945.

<sup>6</sup> Id.

We agree that the variety of combinations of drugs and drug administration services that would be affected by such a policy make thorough analysis essential to ensure that the resulting payment rates are sufficient. As we explained above, analysis of changes of this nature is a complex and time consuming task, and CMS must allow access to the data with ample time to review and comment before any such policy is finalized, and sufficient time for hospitals to assess the impact of the final policy before it is implemented. We ask the HOP Panel to recommend that CMS continue to provide separate reimbursement for drug administration procedures in CY 2015.

**V. The HOP Panel should recommend that CMS develop and implement a data collection and analysis plan in the near future that gives the agency concrete evidence of the frequency, type, and payment for ambulatory care services furnished in off-campus provider-based hospital departments.**

In the 2014 OPPS final rule, CMS acknowledged that “the increased trend toward hospital acquisition of physician practices, integration of those practices as a department of the hospital, and the resultant increase in the delivery of physicians’ services in a hospital setting.”<sup>7</sup> The agency signaled its concern that this shift in setting for items and services commonly furnished to Medicare beneficiaries was increasing costs to the program but not improving the quality of care. In the proposed rule, CMS sought comments from the public on several approaches to collecting information that would allow it to analyze the frequency, type, and payment for services furnished in off-campus provider-based hospital departments. It raised the possibility of collecting data by creating a new “place-of-service” code for off-campus provider departments, creating a HCPCS modifier that would be reported with every code for services furnished in an off-campus provider-based department, or requiring hospitals to break out costs and charges for provider-based departments on Medicare hospital cost reports. Although CMS received numerous comments on this issue, in the final rule, CMS said only that it appreciated the public feedback and would take comments into consideration as it considers approaches for collecting data on services furnished in off-campus provider-based departments.

In the final rule, CMS noted that when a Medicare beneficiary receives outpatient services in a hospital, the total payment amount generally is higher than when a physician furnishes those same services in a freestanding clinic or in a physician’s office. This is attributable to several factors. When a service is furnished in a physician’s office or clinic, Medicare makes one payment to the physician under the Medicare Physician Fee Schedule. When the same service is provided in a hospital or in a provider-based department of a hospital, Medicare pays the physician for furnishing the service and also pays the hospital a facility fee. The physician furnishing the service in the hospital department is reimbursed

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<sup>7</sup> Id. at 75061.

less than a physician providing the same service in a physician's office setting, yet the total payment for the service in the hospital department setting is higher.

This site-dependent reimbursement system has several adverse consequences. Most troubling is the additional beneficiary costs for the same treatment. Under Part B, Medicare beneficiaries must pay some form of cost-sharing for most of the treatments that have been migrating from physicians' offices to off-campus provider-based departments, such as chemotherapy, echocardiogram, and routine evaluation and management (E&M) visits. When those services are furnished to a Medicare beneficiary in a physician's office, generally the beneficiary pays coinsurance equal to 20 percent of the Physician Fee Schedule allowable amount. In contrast, when the same services are furnished to the same beneficiary in a provider-based department, the beneficiary pays a coinsurance amount both for the physician payment and for the hospital outpatient payment. As the total payment for the services in the hospital department setting is higher, the beneficiary coinsurance amount also is higher. A study conducted by Avalere Health showed that chemotherapy treatments are less expensive in a physician's office than hospitals.<sup>8</sup> Another study, by Milliman, showed that per-patient per-month costs for chemotherapy were almost \$600 higher in the hospital setting, with an annualized per-patient cost difference between a hospital department and a physician's office of about \$6,500.<sup>9</sup> This translates to an additional \$1,300 out of pocket for Medicare beneficiaries, many of whom are on fixed incomes, for merely being treated by a physician whose affiliation has changed but the physical location has not. This exceeds the average monthly Social Security benefit in 2013 dollars.<sup>10</sup> Clearly, the place-of-service cost differential is not without consequence for Medicare beneficiaries. These differences in price can place some treatments out of the reach of Medicare beneficiaries or limit the scope and duration of treatment.

A staff presentation to members of the Medicare Payment Advisory Commission (MedPAC) in March 2013 showed that if the unchecked migration of physician's services to provider-based outpatient departments continues, Medicare spending on E&M visits would be \$1.2 billion higher per year by 2021, and beneficiary cost-sharing would be \$310 million higher. Medicare spending on echocardiograms and nuclear cardiology studies would be \$1.1 billion higher per year by that time, and beneficiary cost-sharing would be \$285 million a year higher.<sup>11</sup>

Site-of-service shifts have other unintended consequences, including distortions in the marketplace via the expansion of the 340B program. The 340B

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<sup>8</sup> Avalere Health, *Total Cost of Cancer Care by Site of Service: Physician Office vs. Outpatient Hospital* (March 2012).

<sup>9</sup> Milliman Inc., *Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy* (October 2011).

<sup>10</sup> [http://www.ssa.gov/policy/docs/quickfacts/stat\\_snapshot/](http://www.ssa.gov/policy/docs/quickfacts/stat_snapshot/).

<sup>11</sup> Dan Zabinski and Ariel Winter, *Addressing Medicare Payment Differences Across Settings: Ambulatory Care Services*, presentation to MedPAC (March 7, 2013).

drug-pricing program helps more than 16,500 covered entities, including more than one-third of all hospitals, purchase drugs for their patients, who oftentimes are low-income or medically vulnerable. Since its inception, the 340B program has experienced tremendous expansion, particularly among hospitals. For example, from 2005 to 2011, the number of hospitals participating in the program nearly tripled.<sup>12</sup> Moreover, as hospitals have acquired formerly-independent physician practices, the number of 340B hospital sites has nearly quadrupled in that same time frame (separate locations of a given hospital that participate in the 340B program).<sup>13</sup> CMS should assist HHS and the Health Resources and Services Administration (HRSA) in evaluating the impact of these shifts on the 340B program. Although the 340B program is not administered by CMS, CMS is uniquely positioned to collect claims data that can shed light on certain program integrity issues and better characterize the relationship between site-of-care shift and 340B growth, and vice versa.

BIO believes that CMS should consider requiring more granularity in its place-of-service coding on Medicare claims to capture additional information about the clinical contexts in which 340B patients are being treated. Specifically, CMS should require the use of HCPCS claims modifiers to identify services provided at a hospital-owned clinic or hospital-owned physician office that is not part of a hospital campus. The CMS-1450 has unlimited fields for the collection of HCPCS modifiers. Modifiers serve both payment specific purposes (one side or both sides) and other purposes.<sup>14</sup> These data could help determine whether covered entities are purchasing outpatient drugs at 340B prices for patients who are not intended recipients of the 340B drug pricing program's discount benefits but who become eligible only through hospital acquisition of physician groups.

For all these reasons, we ask the HOP Panel to recommend that CMS develop and implement a data collection and analysis plan in the near future that gives the agency concrete evidence of the frequency, type, and payment for ambulatory care services furnished in off-campus provider-based hospital departments and of the increasing shift of the place-of-service from the lower-cost physician's office to more costly provider-based outpatient departments. This plan should include more granularity in its place-of-service coding on Medicare claims to capture additional information relevant to ensure the integrity of the 340B program.

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Thank you for the opportunity to present this statement on behalf of BIO. I would be pleased to answer any questions.

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<sup>12</sup> GAO, *Manufacturer Discount in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, September 2011, available at: <http://www.gao.gov/new.items/d11836.pdf> (last accessed Jan. 26, 2014).

<sup>13</sup> *Id.*

<sup>14</sup> For example, state Medicaid agencies are beginning to require the use of the -UD modifier to identify claims for drugs and biologicals purchased under the 340B program, to assist in the agencies' compliance roles in avoiding duplicate discounts and Medicaid drug rebates.