Memorandum

To: HCRRC

From: Jayson Slotnik

Date: 11.4.2004

Re: Summary of Outpatient Prospective Payment System Final Rule

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On November 15, 2004, CMS will publish its final rule entitled, "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates" ("Rule"). The Rule provides for a 3.3 percent inflation update in payment rates for outpatient services, which together with other policies, will increase projected Medicare payments to hospitals for outpatient services to $24.6 billion compared to projected payments of $23.1 billion in 2004.

CMS is required to pay for pass-through products at 106 percent of the Average Sales Price (ASP) in 2005. For products that have yet to be approved for pass-through status, but where a HCPCS code applies, CMS also will pay 106 percent of ASP. CMS continued to apply an equitable adjustment to the payment rate for darbepoetin alfa.

Among the other provisions, CMS will:

- Continue its current drug packaging policy that provides for separate payment for drugs, biologicals, and radiopharmaceuticals that cost more than $50 a day, rather than packaging them into an APC.
- Reimburse orphan drugs at the higher rate of 88 percent of average wholesale price (AWP) or 106 percent of ASP, without applying a 95 percent of AWP cap;
- Pay at the 83 percent floor or the median cost for a drug or biological up to a ceiling of 95 percent of the May 1, 2003 AWP for single source specified covered outpatient drugs (SCODs);
- Reimburse multiple-source SCODs at no more than 68 percent of the May 1, 2003 AWP and noninnovator SCODs at no more than 46 percent of the May 1, 2003 AWP; and
- Reimburse SCODs without AWPs based on median costs findings until such time that an AWP becomes available.

Issue	BIO Comment	CMS Response
Pass-Through –Transitional Pass Through Payment for Additional Costs of Drugs and Biologicals: Concern About Payment at 106% of ASP	Clarify that the ASP-based payment rates for therapies with transitional pass-through status will be based on the latest ASP data available and will be updated quarterly as in the physician office setting.	CMS verified that new drugs and biologicals with a HCPCS code and transitional pass-through status will be based on the latest ASP data available and will be updated quarterly as in the physician office setting.
	Pay radiopharmaceuticals using the methodology applicable to SCODs or using external data.	CMS explained that in the absence of ASP and hospital claims data, payment for pass-through radiopharmaceuticals will be based on the methodology applicable for sole source SCODs.
Other Pass-Through Reforms	Implement the proposal to set pass-through payments at zero and to apply unused funds from the pass-through pool to increase the conversion factor.	Beginning in 2005, the pass-through payments for drugs will be zero. CMS adjusted the conversion factor by the difference in estimated pass-through payments of 1.20%.

Issue	BIO Comment	CMS Response
	Implement the proposal to treat all new drugs with HCPCS codes as pass-through therapies, regardless of whether a pass-through application actually is submitted.	CMS finalized this proposal.
Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals	Maintain the $50 threshold for drugs and biologicals unless CMS can show with a thorough study that patient care will not be affected by increasing it.	CMS will maintain this threshold amount for CYs 2005 and 2006 and will take commenters' recommendations into consideration for 2007 and afterward.
	Implement the proposal to exclude injectible and oral forms of anti-emetic treatments from the $50 packaging threshold, and to consider whether the packaging threshold harms patient access to other drug and biological therapies.	CMS finalized its proposal and will be paying separately for all six injectible and oral forms of anti-emetics.

Issue	BIO Comment	CMS Response
Extending the Future Rate-Setting Methodology for SCODs to All Separately Paid Drugs	Expand the future rate-setting methodology for SCODs to include all separately-paid drugs.	The agency expressed appreciation for these comments but explained that they fall outside the scope of this rule because they affect payment in 2006 and afterward.
Inclusion of Three Expiring Pass-Through Products.	BIO urged CMS to include the three expiring pass-through products that CMS proposes to treat as SCODs (and any therapies that will roll off pass-through status in 2006) in the second round of surveys to be issued next summer, if they cannot be surveyed now.	The agency finalized its proposal to treat the three expiring pass-thoughs as SCODs, but did not address working with GAO to include these three products in the acquisition cost survey.

Issue	BIO Comment	CMS Response
Payment for Specified Covered Outpatient Drugs – Zevalin and Bexxar	Evaluate payment rates for Bexxar and Zevalin to ensure that these unique radio-pharmaceutical therapies and their related preparation and administration costs and associated procedures are appropriately reimbursed.	CMS disagreed and is treating these products as sole source SCODs to be paid no less than 83% of AWP in 2005. The agency notes that to the extent that if hospitals incur additional compounding costs for the radiolabeled monoclonal antibodies, these costs could be reported as a separate line item charge that could result in an outlier payment.
Equitable Adjustments	Never apply functional equivalence or a similar standard again.	CMS continues to apply functional equivalence under its equitable payment authority.[1]
Proposed Payment for New Drugs, Biologicals, and Radiopharmaceuticals Before HCPCS Codes are Assigned	Monitor implementation of the agency's proposed method of providing immediate reimbursement for drugs for which HCPCS codes have not been assigned and modify it if necessary to ensure patients have access to cutting-edge drugs.	CMS states that it intends to monitor claims submission, timely processing, and payments for new drugs closely and make changes to the system if necessary.
Vaccines	Continue to reimburse vaccines under the reasonable cost methodology.	CMS agreed, and vaccines will continue to be reimbursed at reasonable cost.

[1] SSA 1833(t)(2)(E).

Issue	BIO Comment	CMS Response
Proposed Changes in Payment for Single Indication Orphan Drugs	Implement the proposal to reimburse designated orphan drugs at the higher of 88% of AWP or 106% of ASP, using the latest information available and updated quarterly, and remove the 95% of AWP cap.	The agency agreed and implemented its proposal without the 95% of AWP cap, using the latest information available to be updated quarterly.
	Freeze the current payment rate for J0256, Alpha 1-Proteinase Inhibitor for 2005.	CMS will base the payment rate for J0256 on the volume-weighted average of all three brands currently available on the market, updated quarterly.
	Expand the number of therapies that qualify as orphan by the agency to other deserving orphan therapies.	Although CMS does not expand its criteria to identify qualifying orphan drugs, the agency states that it will consider a utilization threshold in future changes to the OPPS orphan drug list. The agency also extended orphan treatment to Campath (J9010) and Vidaza (C9218).

Issue	BIO Comment	CMS Response
Proposal to Change Payment Policy for Radiopharmaceuticals	Finalize the proposal to treat radiopharmaceuticals as drugs and biologicals and work with GAO and MedPAC now to ensure that the acquisition cost and pharmacy services and overhead data collected will enable CMS to set appropriate payment rates for radiopharmaceuticals in 2006 and beyond.	CMS finalized its proposal to treat radiopharmaceuticals as drugs and biologicals but did not address these other issues.
Proposed Coding and Payment for Drug Administration	Adopt G-codes for drug administration services to reflect the new CPT codes that will be effective in 2006 and begin collecting the data necessary to set more appropriate rates for these important services in the future.	CMS will implement the existing CPT codes for drug administration rather than the G-codes that will be used in the physician office setting.