Memorandum

To: HCRRC

From: Jayson Slotnik

Date: 11.4.2004

Re: Summary of 2005 Physician Fee Schedule Final Rule

On November 15, 2004, CMS will publish its final rule entitled, "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005" ("Rule"). In addition to finalizing the Rule, CMS also announced a $300 million demonstration project to cover the costs of paying oncologists approximately $130 per patient encounter to assess beneficiaries' pain, nausea and fatigue levels during a chemotherapy session. CMS also released its preliminary Average Sales Price (ASP) pricing file based on second quarter data reported by manufacturers.[1] Payment rates for the first quarter of 2005 will be based on third quarter data, however, likely to be released by CMS in early December.

The Rule establishes new payment codes (G-codes) for physicians to use when billing the Medicare program for hydration, therapeutic/ diagnostic injections, and chemotherapy. The infusion of substances such as monoclonal antibody agents or biologic response modifiers are to be included in the chemotherapy administration codes.

The Rule does not finalize CMS' proposal to reimburse drugs and biologicals paid outside the end stage renal disease (ESRD) composite rate at ASP minus three percent. Instead, these therapies will be reimbursed based on acquisition cost updated by the Producer Price Index (PPI) as BIO and other commenters suggested. Drugs and biologicals not studied by the Inspector General (IG) will be paid at ASP plus six percent. The Rule also continues reimbursing influenza, hepatitis B and pneumococcal vaccines at 95 percent of AWP, updated quarterly. Payments for administering the flu vaccine will increase from $8.21 to $19.13 in 2005.

Below is a chart detailing CMS' response to BIO's comments.

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[1] The full data file is available at the following link: http://www.cms.hhs.gov/providers/drugs/asp.asp.

Issue	BIO Comment	CMS Response
Monitoring Patient Access to Drugs, Biologicals, and Physician Services	BIO urged CMS to monitor patient access closely and proactively as CMS implements MMA changes to this Rule. Specifically, BIO urged CMS to: 1. Analyze shifts in site of service as well as numbers of procedures performed and total dollars billed; 2. Begin monitoring before all of the payment changes go into effect; and 3. Provide an easy mechanism for Medicare beneficiaries and their representatives to submit concerns about access issues directly to CMS (i.e. through the CMS website, 1-800-Medicare, or a combination).	CMS states that they do not expect access problems under the new ASP + 6 percent payment system. CMS also stated that they will monitor patient access through their 1-800-MEDICARE line, regional office staff, claims analysis, and other environmental scanning activities. CMS states that they will work with Congress to resolve access issues.
Manufacturers Need Detailed Guidance Immediately So They Can Submit Accurate ASP Data	BIO requested that CMS clarify certain ASP related issues. Specifically, BIO urged CMS to provide direction on the relationship between chargebacks and ASP calculation and how the current estimation methodology applies to those chargebacks, where only some but not all of the price concession data to be incorporated into the ASP calculation are available on a lagged basis.	Unfortunately, CMS does not provide any further guidance on these requests.

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ASP Issues Raised by BIO in Prior Comments and Repeated in these Comments	1. Which drugs and biologicals are subject to the reporting requirements? 2. Which entity has the reporting obligation for a particular product? 3. Which sales are exempted from ASP calculations? 4. Request that usual and customary prompt pay incentives to wholesalers and distributors not be included in the calculation of ASP.	Unfortunately, CMS does not provide any further guidance on these issues.
Calculation of ASP-Based Payment Rates	Seek outside verification for ASP calculations (i.e. involving an outside auditor to perform the function using the same information available to CMS).	CMS does not address this issue in the Rule.
	Promptly compute and release the first quarter 2005 payment rates upon receipt of third quarter 2004 ASP filings; this expedited release should occur each quarter before payment rates are updated.	CMS states that its goal is to provide as much information on drug payment rates as possible as early as possible. The agency released payment rates based on the second quarter filing on its website.
Release of NDCs	Release a list of the NDCs considered in setting the rate for each HCPCS code, similar to the background files currently available on CMS' website.	CMS does not address this issue. However, CMS states that the law does not permit the disclosure of NDC level ASPs in a form

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		that discloses the identity of a specific manufacturer or prices charged by the manufacturer except in accordance with Medicaid pricing.
Payment Methodology for New Drugs	Continue payment based on WAC or 95 percent of AWP until a payment rate for such products can be determined based on manufacturer reported ASP information.	CMS states that where data on prices for sales for a drug are not sufficiently available from the manufacturer to compute an ASP, it will pay based on WAC or 95 percent of AWP for a limited period. This time period will start on the date that sales of the drug begin and end at the beginning of the quarter after they receive information from the manufacturer regarding ASP for the first full quarter of sales.

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Payment for Separately Billed ESRD Drugs	Pay for the 10 top, separately billed dialysis drugs [at the 122 smaller facilities included in the OIG report] at acquisition cost for independent facilities, updated by the same 3.39 percent annual price growth factor that CMS used in its computation of the drug add-on adjustment to the composite rate. For drugs and biologicals that were not included in the OIG report, pay at ASP plus 6 percent.	The final rule established 2005 payment rates for separately billable ESRD drugs at weighted average of the actual acquisition costs of both large and small dialysis providers, as determined by the OIG and updated by the Producer Price Index (PPI). CMS agrees and states that drugs not contained in the OIG study should be paid at ASP plus 6 percent. However, CMS will not establish separate payment rates for large and small providers. CMS believes that it is more appropriate to base the 2005 payment amounts for these drugs on a weighted average of the acquisition costs of the four largest providers and the other facilities rather than base the 2005 payment amounts solely on the acquisition costs of the other facilities.

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Reporting and Billing for Physicians' Services Associated with Administration of Covered Outpatient Drugs	Adopt the CPT Editorial Panel's proposals to improve the recognition of the administration of complex drug and biological therapies in the coding system no later than January 1, 2005.	CMS adopted the CPT Editorial Panel recommendations and divided the new codes into three categories: infusion codes for hydration, codes for therapeutic/diagnostic injections, and chemotherapy. Due to time limitations, providers must use G-codes until permanent codes are assigned for 2006.
Payment for Items and Services Associated with Furnishing Blood Clotting Factor	Examine more recent data than the 2000-01 data in the GAO study and propose a new rate (not the previously proposed $0.05 per unit to hemophilia treatment centers and homecare companies for the items and services associated with furnishing blood clotting factor) that will appropriately reimburse providers and ensure patient access to life-saving clotting factor.	CMS established the furnishing fee for 2005 at $0.14 per unit of clotting factor. The MMS specifies that after 2005, the furnishing fee for clotting factor must be updated by the percentage increase in the CPI for medical care.
Supplying Fees and Billing and Shipping Reforms	BIO is not convinced that the $10 per prescription is adequate to cover the costs of providing immunosuppressive and oral anticancer drugs. Therefore, BIO urged CMS to work with pharmacies to analyze the costs of providing oral anticancer, immunosuppressive, and anti-emetic drugs in order to protect	CMS is increasing the per prescription supplying fee to $24. Additionally, CMS is establishing a higher supplying fee of $50 for the supplying of the initial oral immunosuppressive prescription in the first month after a beneficiary has a transplant. The

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	beneficiary access to them. Common sense reforms to billing requirements and shipping time frames should be implemented.	agency also finalized its reforms to billing requirements and shipping time frames.
Cardiovascular Screening Blood Tests	Forgo the NCD process and instead adopt the USPSTF's recommendations on screening tests for conditions associated with cardiovascular disease as soon as they are adopted.	CMS disagrees and states that they will continue to use the NCD process. CMS stresses that the NCD process is most appropriate because it allows for public comment.
Extension of Coverage of IVIG for the Treatment of Primary Immune Deficiency Diseases in the Home	Explore methods of covering under Part D the items and supplies needed for administration of IVIG in the home.	CMS states that the statute specifically precludes coverage for the items and services related to the home infusion of IVIG.
Coverage for Routine Costs of Category A Clinical Trials	Issue self-certifying criteria relating to clinical trials so that more beneficiaries can participate in such trials.	CMS does not address this issue in the Rule.

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Publishing ASP-Based Payment Rates for All Drugs and Biologicals	Publish ASPs for all drugs and biologicals administered in physician offices, even those for which some carriers are applying LCA policies. • Publish an ASP-based rate for J9217 (Leuprolide acetate suspension) as well as for J9202 (Goserelin acetate implant). • Clearly state in the final rule that CMS does not mandate a national LCA policy for any drug, including Leuprolide acetate suspension.	CMS states that use of the LCA policy when pricing drugs is outside the scope of the Rule, and no changes to the LCA policy were proposed. The agency does report different ASP-based rates for J9217 and J9202 in its preliminary ASP pricing file, however.