Memorandum

To: HCRRC

From: Jayson Slotnik

Date: 8.9.2004

Re: Summary of Inpatient Hospital Final Rule

On August 11, 2004, CMS will publish its final rule entitled, "Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2005 Rates" ("Rule"). The Rule affects hospital discharges occurring on or after October 1, 2004.

In general, the Rule increases payments to acute care and rural hospitals, lowers the outlier threshold and makes several changes to the DRGs. Specifically, the Rule creates a new DRG for certain craniotomy procedures, including those that involve the implantation of a chemotherapeutic agent such as Gliadel®. In addition, the Rule explains that the fall ICD-9-CM Coordination and Maintenance Committee meeting has been moved to October and that requests for new codes must be received at least two months prior to the meeting. The deadline for the next meeting on October 7-8, 2004 was August 7.

In responding to BIO's comments, CMS reasserted that it will use FDA approval dates as the starting point for the 2-3 year period of "newness," refused additional add-on payments for Xigris® and Natrecor® and will not create a new DRG for severe sepsis.

Below is a chart detailing CMS' response to our comments:

Issue	BIO Comment	CMS Response[1]
Add-on Payment Starting Period	BIO urged CMS to withdraw their statements which suggested that the 2-3 year period for add-on payments of new technologies begins on the	CMS refused to reevaluate the starting point for new technologies. CMS states[2] that the intent of the statute[3] and the implementing regulation[4] is

[1] The final rule is available on the CMS website in five separate parts. Unfortunately, each part is separately numbered such that each part begins with the number one. Therefore, each reference will first state which part of the five is referenced.
[2] Part 1, pages 298-301.
[3] SSA 1886(d)(5)(K).
[4] 42 C.F.R. §412.87(b)(2).

Issue	BIO Comment	CMS Response
	date the technology is approved by the FDA. Instead, BIO urged CMS to adhere to current statute and regulation and begin the 2-3 year period on the date on which a new technology receives an ICD-9-CM code.	to pay for new medical services and technologies for the first 2 to 3 years of market availability. CMS uses FDA approval as the indicator for market availability unless proof exists that a product was not marketed and sold until after this date. [5] CMS further states that using the ICD-9-CM code alone is not an appropriate test of newness. Because new technologies are automatically placed into the closest ICD-9-CM code and paid for when they are first available on the market, the newness period should also begin at this time.
Add-on Payments for Natrecor®-Human B-Type Natriuretic Peptide (hBNP) ("Natrecor")	BIO requested that CMS reevaluate the add-on payment application for Natrecor. Further, BIO urged CMS to consider the data collected in fiscal year 2003 regarding the product's use and assess those data to determine whether a DRG reclassification is warranted.	CMS denied[6] the application because the technology is no longer considered new. Natrecor was approved by the FDA on August 8, 2001 and the FY 2003 MedPAR file includes hospital charge information for patients receiving Natrecor. CMS concludes that no new add-on payments are available because the technology is no longer considered new, and the costs for this new technology are currently reflected in the DRG weights.
Full Analysis of Add-on Applications	BIO urged CMS to conduct a full analysis of all add-on payment applications and not just those that meet the agency's restrictive definition of "new."	CMS states[7] that it is not necessary to provide a full analysis of all the add-on payment criteria in cases where the application can be denied based on the newness criterion.

[5] Part 1, page 387.
[6] Part 1, pages 363-368.
[7] Part 1, page 368.

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Add-on Payments for Xigris®—Drotrecogin Alfa (Activated) ("Xigris")	BIO asked CMS to continue add-on payments for Xigris for an additional year. If CMS refuses, BIO asked that the payments be maintained at least until CMS has analyzed the available data and has classified cases in which Xigris is administered into an appropriate DRG.	CMS denied both requests stating[8] that because the technology was approved by the FDA on November 21, 2001, it no longer meets the newness criterion. Furthermore, CMS believes that they have adequate data reflecting Xigris' use over the past 3 years.
New DRG for Severe Sepsis	BIO urged CMS to reconsider its decision not to create a unique DRG for severe sepsis, especially if the proposed add-on payments for Xigris are terminated.	CMS will not create a unique DRG for severe sepsis. CMS states[9] that the defining criteria for severe sepsis, using the currently available ICD-9-CM codes, are not specific, accurate, or unique enough to warrant a new DRG classification and that the subset of sepsis patients that have severe sepsis is not sufficient to justify a unique DRG for severe sepsis.
Recommendation of the Conference Report to Consider Increasing the Payment Factor	BIO urged CMS to abide by the recommendation of Congress in the Conference Report to the MMA that CMS "consider increasing the percent of payment associated with the add-on payments up to the marginal rate used for the inpatient outlier" – i.e., 80 percent.	CMS has determined[10] that they will not make the change this year; rather, they "will analyze the impacts of the other MMA changes…before [they] consider making changes in the payment percentage."
Guidance on New Section 1886(d)(5)(K)(ix)	BIO asked CMS for guidance on how they plan to implement new section 1886(d)(5)(K)(ix) which requires the Secretary to identify one or more DRGs associated with new	CMS states[11] that at the time an application is submitted, the DRGs associated with the new technology are identified. CMS only determines that a new technology add-on

[8] Part 1, pages 313-320.
[9] Part 1, pages 216-217.
[10] Part 1, page 310.
[11] Part 1, page 297.

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	technology before establishing add-on payments.[12] BIO believes that payment for new technologies should not be deemed to be adequate unless payment under the proposed DRG assignment is equal to or greater than the combination of the maximum add-on payment amount and the DRG payment that would have been made in the absence of assignment of the new technology to a DRG in lieu of an add-on payment.	payment is appropriate when the reimbursement under these DRGs is not sufficient. The criterion for this determination is the cost threshold.
New Add-on Payments for a Different DRG	BIO urged CMS to affirm in the final rule its original policy of allowing new technologies to be eligible for add-on payments each time their use is expanded to a different DRG.	CMS notes[13] that in their final rule[14] they stated that if an existing technology was assigned to different DRGs than those in which the technology was initially used, the new use may be considered for new technology add-on payments if it also meets the substantial clinical improvement and inadequacy of payment criteria.
Gliadel® Chemotherapy Wafers ("Gliadel")	BIO recommended that CMS, in the short term, assign Gliadel cases to DRG 528[15] to ensure immediate adequate reimbursement. BIO also recommended that CMS, for the long term, create a new DRG for intracerebral therapies.	CMS denied[16] re-assigning Gliadel wafer cases to DRG 528; they assert that this would produce a clinically incoherent DRG because DRG 528 contains cases where a craniotomy is performed as part of a vascular procedure with a primary diagnosis of hemorrhage. Also, CMS

[12] The Secretary must make this identification based on similar clinical or anatomical characteristics and the cost of new technology and assign the new technology to these DRGs instead of making add-on payments.
[13] Part 1, page 334.
[14] September 7, 2001 (66 FR 46915).
[15] The DRG is entitled "Intracranial Vascular Procedure with a Principal Diagnosis of Hemorrhage."
[16] Part 1, pages 179-188 and 329.

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		denied creating a separate DRG for Gliadel because of the insufficient volume of cases. However, CMS created DRG 543[17] to include cases involving treatment using chemotherapeutic agents and devices implanted in the brain, such as the Gliadel wafer.
Updating ICD-9-CM Codes More Often	BIO asked CMS to expand its proposal to update ICD-9-CM codes twice each year to all new technologies, not just those seeking add-on payments.	CMS acknowledged[18] that section 503 of the MMA covers all ICD-9-CM codes, which includes both diagnoses and procedures codes. The agency reasoned that because of the administrative burden on providers and because many coding changes apply to longstanding medical issues,[19] those seeking April implementation of an ICD-9-CM diagnosis or procedure code must make a strong and convincing case as to why April implementation is necessary for purposes of the new technology process.[20]

[17] The DRG is entitled "Craniotomy with Implantation of Chemotherapeutic Agent or Acute Complex Central Nervous System Principle Diagnosis."
[18] Part 1, page 177.
[19] Part 1, page 169.
[20] Part 1, page 178.