August 6, 2008

Kerry N. Weems, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244-1850
Mail Stop C4-26-05

Re: CMS – 1404- P
Comments on the 2009 Proposed Payment Rules and Regulations under the Hospital Outpatient Prospective Payment System

Dear Administrator Weems:

Thank you for providing Molecular Insight Pharmaceuticals (MIP) with this opportunity to comment on the 2009 Medicare Hospital Outpatient Prospective Payment System (HOPPS) proposed rules published in the July 18, 2008 Federal Register (Vol. 73 Fed. Reg. No.139).

MIP is a biopharmaceutical company located in Cambridge, MA. We specialize in the emerging field of molecular medicine, applying innovations in the identification and targeting of disease at the molecular level to improve patient healthcare by addressing significant unmet medical needs. We are focused on discovering, developing and commercializing innovative and targeted radiotherapeutics and molecular imaging pharmaceuticals with initial applications in the areas of oncology and cardiology.

Radiopharmaceutical Pass-Through Status

We applaud the Centers for Medicare and Medicaid Services (CMS) for clarifying that both new diagnostic and therapeutic radiopharmaceuticals are eligible for a transitional pass through payment. However, MIP is concerned that the pass through eligibility criteria for a new diagnostic radiopharmaceutical is not clear. The pass through application and process information document that is available on the CMS website addresses the statutory provisions that allow for transitional pass-through status; but does not provide specific information on what qualifies a *new* radiopharmaceutical for pass-through status. We note that the new drug section of the most recent Drug, Biological, and Radiopharmaceutical Pass Though application (last modified in April, 2007) reads:

Transitional pass-through payments are also provided for certain "new" drugs, devices and biological agents that were not being paid for as a hospital outpatient department service as of December 31, 1996, and whose cost is "not insignificant" in relation to the OPPS payment for the procedures or services associated with the new drug, device, or biological[1].

Although CMS has clarified in this proposed rule that diagnostic radiopharmaceuticals are eligible for pass through status, it has also reaffirmed its intent to continue to treat diagnostic radiopharmaceuticals as "supplies". Therefore, we are unclear as to if the definition of "new drug" would apply to diagnostic radiopharmaceuticals as opposed to that of a supply or device. ***For these reasons, we recommend that CMS update the drug, biologic and radiopharmaceutical pass through application by clarifying that new radiopharmaceuticals (both therapeutic and diagnostic) are indeed eligible for "drug" pass through provided that the product is new, FDA approved, and that the cost is not insignificant in relation to payment for the procedure or service associated with the new radiopharmaceutical.***

Payment Offset for New Diagnostic Radiopharmaceuticals

Within the 2009 OPPS proposed rule, CMS indicates that diagnostic radiopharmaceuticals that are eligible for payment for pass-through would receive separate payment less a payment offset. CMS states that the payment offset is necessary to avoid duplicate payment for the diagnostic radiopharmaceutical portion of a nuclear medicine procedure where the packaged radiopharmaceutical cost is included in the procedural APC payment for the nuclear medicine procedure.

MIP appreciates CMS's desire to avoid duplicate payments. Conversely, payment offsetting is a new concept for the nuclear medicine community. This new concept coupled with the fact that most radiopharmaceuticals were "grandfathered" into pass through status as a result of the Balanced Budget Refinement Act of 1999 (BBRA) would suggest that education for the hospital facilities, manufacturing industry, and Medicare Administrative Contractors (MAC) is necessary. Otherwise, we fear that the hospital facilities may believe that they did not receive sufficient reimbursement for the new radiopharmaceuticals. This may result in inappropriate charges to the Medicare beneficiary when an Advanced Beneficiary Notice (ABN) wavier has been signed or if hospitals do not believe that the reimbursement is sufficient to sustain operating cost, it is likely that they will discontinue providing services or

[1] *Process and Information Required to Determine Drugs, Biologicals, and Radiopharmaceutical Agents, Eligible for Transitional Pass-Through Provisions Under the Hospital Outpatient Prospective Payment System (OPPS):* *http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/drugapplication.pdf*

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procedures associated with the new radiopharmaceutical, thus prohibiting beneficiary access to care.

Finally, based on past experience we have learned that the Medicare Fiscal Intermediaries (FI) or MACs often ignore Medicare payment policy changes when they are finalized in the annual rules and published in the Federal Register. Instead, the FIs and MACs only acknowledge these changes when CMS publishes a claims processing transmittal that provides instruction to the FI or MAC to implement the new payment policy. We are concerned that the FI or MAC may bundle the entire cost of the new diagnostic agent into the cost of the bundled procedure if CMS does not publish specific guidance to the FI or MAC on the payment off set for radiopharmaceuticals.

For all of these reason, we recommend that CMS publish a claims processing transmittal that provides instruction to the FI or MAC on how to apply off set payments for new diagnostic radiopharmaceuticals and includes information that clarifies the percentage of the total nuclear medicine payment bundle that is attributed to a radiopharmaceutical.

Average Sales Price for Therapeutic Radiopharmaceuticals

We are very pleased that CMS is proposing to expand the Average Sales Price (ASP) reporting payment policy to include therapeutic radiopharmaceuticals and we encourage CMS to implement a similar model for new diagnostic radiopharmaceuticals beyond the pass through payment period. Though, we are concerned that reporting ASP in the same fashion as traditional drug manufacturers provides significant challenges for our organization.

Section 1847A (b)(3)(A) of the Act for multiple source drugs and section 1847A(b)(4)(A)for single source drugs, requires that the ASP for all drug products included within the same billing and payment code (or Healthcare Common Procedural Coding System code-- HCPCS code) is the volume-weighted average of the manufacturers' average sales prices reported to us across all the National Drug Codes (NDC) assigned to the HCPCS code.[2] Most radiopharmaceuticals are compounded drugs and like many manufacturers of radiopharmaceutical products, MIP will manufacturer and sell a kit that is used to create a compounded product. This kit will be given its own NDC number by the FDA. MIP's kit will be sold (generally) to a nuclear pharmacy where it will be mixed with a compounding agent (which has its own NDC number) and a new product is created. This new product is then sold by nuclear pharmacy by the vial (generally) to the provider or hospital facility. The provider then uses a unique HCPCS code to report the use of the compounded product in a nuclear medicine procedure or service.

[2] Page, 66300 Federal Register / Vol. 69, No. 219 / Monday, November 15, 2004 / Rules and Regulations: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005

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In order to comply with the current ASP statue, the manufacturer of the kit would have to collect data from all of the nuclear pharmacies that it works with as well as the manufacturers of the compounding agent in order to arrive at an a compliant average selling price. While some manufacturers may sell both the kit, the compounding agent, and own nuclear pharmacy facilities, others like MIP do not. As a result, MIP would only be able to control and certify data related to the sale of its kits used to compound and create the radiopharmaceutical. And of course, we realize that providing information on the kit alone would not assist CMS in arriving at an accurate ASP for the compounded product. We ask that CMS consider the financial and administrative implications that present for a small manufacturer in trying to collect and certify data complied from secondary and tertiary sources that may not use the same accounting techniques as MIP.

Respectively, we believe that providing accurate cost data to set payment rates for both diagnostic and therapeutic radiopharmaceuticals will ensure Medicare beneficiary access to nuclear medicine services and procedures. Although our lead products have not yet entered the United States (US) market place, we remain committed to working with CMS and other stakeholders such as the Society for Nuclear Medicine (SNM) and the Council on Radiopharmaceuticals and Radionuclides (CORAR) to find solutions to these concerns in advance of the commercial launch dates for our products.

The Medicare Improvements for Patients and Providers Act of 2008[3] was enacted on July 15, 2008 and extended (Section 142) the current payment for therapeutic radiopharmaceuticals until 2010, we hope that CMS views this extension period as an opportunity to work with manufacturers to arrive at a solution that addresses the challenges of traditional ASP reporting for radiopharmaceuticals while maintaining the integrity of the ASP reporting system.

Composite APCs

MIP is disappointed by CMS' decision to continue to distinguish between therapeutic and diagnostic radiopharmaceuticals. It is important to note that some radiopharmaceutical products serve as "theranostics," meaning they can be used in both a therapeutic and diagnostic capacity. The continued distinction between therapeutic and diagnostic radiopharmaceuticals for payment purposes causes confusion for coders and billers who work in an industry that is already very complex in its clinical nature. We encourage CMS to adopt a consistent payment policy for all separately payable radiopharmaceuticals.

Nonetheless, if CMS chooses to continue this distinction between therapeutics and diagnostics for the purposes of payment, then ***we ask that CMS consider composite Ambulatory Payment Classifications (APC) for diagnostic nuclear medicine/molecular imaging procedures that are not driven by the***

[3] Medicare Improvements for Patients and Providers Act of 2008, Section 142: http://thomas.loc.gov/cgi-bin/query/z?c110:H.R.6331:

procedure codes and use external data such as a radiopharmaceutical ASP to arrive at cost for the radiopharmaceuticals within these composites. Similar to the proposed composites for imaging services, the current bundling methodology that CMS employs for diagnostic nuclear medicine procedures are driven by the procedure. This does not work for all nuclear medicine procedures. CMS must understand that some current and many future diagnostic radiopharmaceuticals are not like contrast agents, they are molecular imaging agents. This means that the type of radiopharmaceutical used in the diagnostic nuclear medicine procedures is determined by the patient's suspected diagnosis or current illness rather than the type of equipment that the provider chooses to use. These products are not "me to agents", they are not versions of products that are already on the market. As such these products are low in volume and higher in cost and will continue to fail under the HOPPS system of averages.

In a time when CMS is promoting value based purchase decisions, we encourage CMS to allow equitable reimbursement for those providers who chose to use diagnostic and prognostic tools that will increase their ability to predict the likely outcomes of drug therapy, expand the use of biomarkers (biological molecules that indicate a particular disease state), improve health outcomes, and has the potential to make healthcare more cost-effective.

Molecular Insight Pharmaceuticals recognizes the challenges that CMS faces in revising payment methodologies and we appreciate the time that Dr. Carol Bazell and her staff took to meet with us on July 28, 2008 to introduce our product pipeline to CMS and discuss the 2009 proposed radiopharmaceutical payment policies under HOPPS.

We welcome the opportunity to meet with CMS once more and expand upon our recommendations concerning ASP and Composite APCs for radiopharmaceuticals in greater detail after the close of the comment period. Again, we thank CMS for the opportunity to comment on this important ruling. Please direct questions or comments me via telephone at 857 753 3567 or email tthompson@molecularinsight.com

Respectfully,

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Director, Health Policy and Reimbursement

cc: John McCray, COO (Molecular Insight Pharmaceuticals)
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Ken McKusick, MD, Chair NM APC Task Force (SNM)