August 28, 2009

Charlene Frizzera, Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard, C4-01-26
Baltimore, MD 21244

Re: Comments of the Academy of Molecular Imaging/Institute for Molecular Technologies on CMS–1414–P (Proposed Changes to the Hospital Outpatient Prospective Payment System (OPPS) and CY 2010 Payment Rates)

Dear Acting Administrator Frizzera:

The Academy of Molecular Imaging (AMI) and the Institute for Molecular Technologies (IMT) appreciate the opportunity to submit these comments on the CY 2010 Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule, as published in the Federal Register on July 20, 2009.[1] We appreciate the Centers for Medicare & Medicaid Services' (CMS) attention to payment policy for radiopharmaceuticals, and we look forward to working with the agency to make these products more widely available to Medicare beneficiaries.

AMI is composed of academicians, researchers and nuclear medicine providers utilizing molecular imaging technologies, including positron emission tomography (PET) and PET with computed tomography (PET/CT). AMI serves as the focal point for molecular imaging education, training, research and clinical practice through its annual scientific meeting, its educational programs, and its journal, *Molecular Imaging & Biology*.

IMT is a Council of AMI. It is a not-for-profit organization whose mission is to advance the development, approval, appropriate use and reimbursement of molecular imaging technologies. To further its mission, IMT educates medical and science professionals, patients, government, and the public about molecular imaging, and promotes cooperation between AMI and other organizations with similar missions. The IMT membership is composed of representatives of scientific, industrial, manufacturing, product and service companies and service providers.

[1] Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates, 74 Fed. Reg. 35,232 (July 20, 2009).

I. CMS Should Adopt Pass-Through Calculation Mechanisms that Maximize Three-Year Eligibility

AMI/IMT continue to be supportive of changes to the pass-through calculation mechanism that promote the maximization of the full three-year pass-through eligibility period for radiopharmaceuticals. The maximization of the three-year period is particularly crucial for bundled diagnostic radiopharmaceuticals, as it helps ensure that the relevant data on which pass-through payments are made are both current and complete. We therefore support the proposal to expire pass-through status on a quarterly basis. However, we oppose the proposal to adopt "date of first sale after FDA approval" as the date on which the pass-through eligibility period commences for radiopharmaceuticals, as we believe that the former proposal promotes maximization of the three-year period while the latter proposal does precisely the opposite.

As CMS is aware, transitional pass-through payments for a radiopharmaceutical, drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for at least 2 years but not more than 3 years after the product's first payment as a hospital outpatient service under Part B. Currently, the pass-through eligibility period and the period of pass-through payment are identical. The Proposed Rule seeks to redefine this relationship, by 1) commencing the pass-through payment period on the first day of the quarterly system update following the update period during which pass-through status was approved, and 2) expiring the pass-through status on a quarterly basis (whereas currently, pass-through status expires at the end of the eligible calendar year).

AMI/IMT support the proposal to expire pass-through status on a quarterly basis, as doing so would increase the likelihood that the three-year period could be maximized by a given radiopharmaceutical product. We agree with CMS that this proposal advances the aim of maximizing the three-year period for eligible products in circumstances where "a pass-through payment application has been made after the pass-through payment eligibility period has begun."[2] Under the current methodology, it is possible that a radiopharmaceutical would see its pass-through eligibility terminate at the end of the relevant calendar year, even though additional "partial third year" eligibility remained in the subsequent calendar year. The proposal to adopt quarterly expiration would allow many radiopharmaceutical manufacturers to capture a greater portion of the three-year pass-through period than is often possible under the present methodology.

However, AMI/IMT strongly oppose the corollary proposal to commence the pass-through payment eligibility period on the date of first sale after FDA approval. For the reasons articulated in the following section of this comment, AMI/IMT believe that the practical effect of adopting this proposal would be to drastically foreshorten the actual pass-through payment period for radiopharmaceuticals. We therefore encourage CMS to revisit this proposal, as detailed below, and to develop an alternative proxy date that would maximize the three-year eligibility period.

[2] 74 Fed. Reg. 35,316.

II. CMS Should Not Adopt "Date of First Sale in the U.S. After FDA Approval" as the Alternative Proxy Date for the Commencement of the Pass-Through Eligibility Period

As CMS is aware, the transitional pass-through eligibility period is required by statute to commence on the first date on which payment is made under Part B for the drug or biological as an outpatient hospital service. These transitional pass-through provisions are codified 42 C.F.R. § 419.64. Of particular relevance here, Section 419.64(c)(2) currently provides that the pass-through payment eligibility period for "new" drugs and biologicals commences on "the date that CMS makes its first pass-through payment for the drug or biological."[3]

The Proposed Rule suggests, however, that Section 419.64(c)(2) "does not most accurately reflect the statutory requirements," and thus proposes to change the starting date for the eligibility period "from the first date on which pass-through payment is made to the date on which payment is first made for a drug or biological as an outpatient hospital service under Part B."[4] Moreover, the Proposed Rule reasons that "due to the 2-year delay in the availability of claims data, [CMS] would not be able to identify an exact date of first payment for a drug or biological as an outpatient hospital service under Part B in order to determine the start date of the pass-through payment eligibility period until years after an application for pass-through payment for a 'new' drug or biological has been submitted." As a result, the Proposed Rule suggests that it would be "desirable to identify an appropriate and timely proxy for the date of first payment for the drug or biological as an outpatient hospital service under Part B." The Proposed Rule proposes that "the date of first sale for a drug or biological in the U.S. following FDA approval" serve as this proxy date.

AMI/IMT understand the desire of CMS to conform the regulations more closely to the statute, and applaud the effort to identify an appropriate proxy date (particularly given the limitations posed by the lack of timely availability of claims data). However, AMI/IMT respectfully encourage CMS to reconsider the specific proposal to use the date of FDA approval as the proxy date. While Medicare beneficiaries may indeed be "among the first to use these drugs and nonimplantable biologicals,"[5] few (if any) radiopharmaceuticals are available for Medicare purposes immediately upon FDA approval. Instead, radiopharmaceutical manufacturers usually require several months — and sometimes up to one year — following FDA approval to obtain national or local Medicare coverage decisions for their products.

In light of such circumstances, AMI/IMT do not believe that the express statutory requirement that the transitional pass-through period "commence after the product's first payment as a hospital outpatient service under Part B" would be well-served by the adoption of a proxy date that commences the running of the eligibility period well before any "first payment as a hospital outpatient service under Part B" could possibly be made in practice.[6] Under the

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[3] 42 C.F.R. § 419.64 (2008).

[4] 74 Fed. Reg. 35,314-315.

[5] 74 Fed. Reg. 35,315.

[6] AMI/IMT fully acknowledge that the first sale after FDA approval date is already used to identify "single source drugs" and "biological products" for ASP purposes, and to determine whether a drug or biological is "new" for

Proposed Rule, a substantial portion of the Medicare pass-through eligibility period could expire before CMS even makes a decision about a new drug's pass-through status. We therefore encourage CMS to reject the date of first sale after FDA approval as an appropriate proxy, and to engage further with stakeholders in order to assess how best to identify an appropriate proxy date for this specific purpose.

Should CMS nevertheless remain intent upon implementing a new proxy date for CY 2010, AMI/IMT believe that — at least in the context of radiopharmaceuticals — there is a more accurate and readily-available proxy for the first date of payment under Part B as an outpatient hospital service: *The date of approval of the first national or local Medicare coverage decision following FDA approval*. The adoption of this alternative proxy date for radiopharmaceuticals has two significant advantages. First, the date of a national or local coverage decision is unambiguous, clear, and publicly available, and thus offers the same advantages in this regard as does adoption of the date of first sale following FDA approval. Second—and more important—the date of approval of the first national or local Medicare coverage decision is much more closely connected to the "first payment as a hospital outpatient service under Part B" than is the date of first sale after FDA approval, since no payments for radiopharmaceuticals under Part B can commence in the absence of Medicare coverage. AMI/IMT believe that "date of approval of the first national or local Medicare coverage decision following FDA approval" is an acceptable and available indicator of initial payment for radiopharmaceuticals under the Medicare program, and is of greater relevance as a proxy for the specific purpose of determining the commencement of the pass-through payment eligibility period than is the date of first sale after FDA approval.

III. AMI/IMT Support the Proposal for ASP-based Payments for Therapeutic Radiopharmaceuticals

AMI/IMT support CMS's proposal to allow for the payment of therapeutic radiopharmaceuticals based on the Average Sales Price (ASP) methodology, as this is "an established methodology that has already been successfully implemented under the OPPS for other separately payable drugs and biologicals."[7] Under the Proposed Rule, manufacturers would have the option either to submit ASP data to the CMS or rely on the "most recent hospital mean unit cost data"[8] available to Medicare. The Proposed Rule expressly recognizes that payment at ASP would be optional and not compulsory, since "not all therapeutic radiopharmaceutical manufacturers may be willing or able to submit ASP information for a variety of reasons."[9]

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purposes of determining eligibility for OPPS pass-through payment application process. 74 Fed. Reg. 35,315. However, in the ASP context, the first sale after FDA approval date is employed simply as a variable in a recurring annual calculation, while in the pass-through application process context, the first sale after FDA approval date is used as a "gatekeeper" to determine the applicability of the statute to a particular product. Neither situation is analogous to the context of the disbursement of pass-through transitional payments, where statutory eligibility is already established and no calculation needs to be made.

[7] 74 Fed. Reg. 35,335.

[8] *Id.*

[9] *Id*.

AMI/IMT believe that adoption of ASP is sensible for several reasons. First, for most outpatient drugs and biologicals, CMS sets payment rates based on the ASP methodology. CMS has recognized that ASP reflects actual market pricing of drugs because it is based on manufacturers' sales and associated price concessions. In the hospital outpatient department context, CMS has relied on ASP as the best available payment methodology for separately payable drugs and biologicals and associated pharmacy overhead. Second, CMS has concluded that ASP-based payment is the most accurate rate-setting methodology for other drugs and biologics. As CMS observes in the Proposed Rule: "We continue to believe that the use of ASP information for OPPS payment would provide an opportunity to improve payment accuracy for these products by applying an established methodology that has already been successfully implemented under the OPPS for other separately payable drugs and biologicals."[10] Payment for the therapeutic radiopharmaceuticals based on ASP is therefore consistent with the Social Security Act. Finally, because manufacturers report ASP quarterly, this methodology allows CMS to update rates on a quarterly basis to reflect changing drug costs.

In addition, AMI/IMT support the proposal to set the payment for pass-through therapeutic radiopharmaceuticals ASP+6 percent, consistent with the payment for other separately payable drugs and biologicals. If ASP data are not available for a radiopharmaceutical, CMS proposes to base the pass-through payment on the product's wholesale acquisition cost (WAC). If WAC information is also not available, CMS proposes to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent average wholesale price (AWP).

AMI/IMT applaud CMS for proposing to expand its payment policy for therapeutic radiopharmaceuticals to allow for ASP, and recommends that CMS implement a similar model for new diagnostic radiopharmaceuticals entering the market beyond the pass through payment period. However, we remain concerned that some manufacturers who would otherwise be willing to report ASP will be discouraged from doing so because of the challenges in collecting and reporting ASP data as required for traditional drug manufacturers. Having accurate cost data to set payment rates for therapeutic radiopharmaceuticals is of significant benefit to CMS and its beneficiaries. We would therefore encourage CMS to continue working with manufacturers of radiopharmaceuticals products to refine and improve their ability to participate fully in this process.

IV. CMS Should Allow Manufacturer Reporting of ASP, AWP, or WAC to Determine Payment for Diagnostic Radiopharmaceuticals During the Pass-Through Period

CMS proposes to both continue pass-through status in 2010 for new diagnostic radiopharmaceuticals, and to utilize the ASP methodology to pay for new diagnostic radiopharmaceuticals that are granted pass-through status.[11] Specifically, CMS proposes that the payment be at ASP+6 percent if ASP information is available, or at WAC+6 percent if ASP data is not available. If WAC information is not available, CMS proposes to set payment at 95 percent

[10] *Id.*

[11] 74 Fed. Reg. 35,310.

of the most recent AWP. AMI/IMT agree with CMS that, consistent with the Act, payment during the transitional pass-through period could be based on ASP+6 percent, WAC, or AWP. AMI/IMT recommends that in its Final Rule, CMS establish reimbursement based on ASP, WAC or AWP, but would also suggest that CMS consider paying a higher percentage above ASP to cover the additional pharmacy handling and overhead costs associated with radiopharmaceuticals, as recommended by MedPAC.[12]

V. CMS Should Create New Nuclear Medicine APCs As Necessary

Section 1833(t)(2) of the Act provides that the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median for an item or service in the group is more than 2 times greater than the lowest median cost for an item or service within the same group (referred to as the "2 times rule").

AMI/IMT encourage CMS to apply the 2 times rule to APCs that include radiopharmaceuticals, recognizing the full range of potential costs associated with the radiopharmaceuticals bundled in the APC. We feel strongly that CMS should not package multiple, different radiopharmaceuticals with widely varying costs into the same APCs. CMS currently bundles very distinct radiopharmaceuticals with dramatically different price/cost points into the same Nuclear Medicine APC, in apparent violation of the statutory standard.

For example, CMS places 78645 CSF shunt evaluation in APC 0403 with brain imaging (rather than APC 0402 with other CSF studies); 78608 Brain PET with body PET and PET/CT studies in APC 0308; and 78000-1 thyroid uptake in a separate APC 0389 from other non-imaging studies in 0392. CMS has also reconfigured several APC categories, apparently based on cost claims data alone: CPT 78003 *Thyroid uptake; stimulation, suppression or discharge (not including initial uptake studies)* from APC 0392, $166.93 to APC 0389, $110.99; CPT 78601 *Brain imaging, less than 4 static views; with vascular flow* from APC 403, $203.47 to APC 402, $604.72; CPT *78610 Brain imaging, vascular flow only* from APC 402, $604.72 to APC 403, $203.47; CPT 78803 *Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); tomographic (SPECT)* APC 408, $1040.88 to APC 414, $523.75; and CPT 78807 *Radiopharmaceutical localization of inflammatory process; tomographic (SPECT*) from APC 414, $523.75 to APC 406, $298.63.

AMI/IMT understand that CMS is basing some of these decisions on hospital claims data; however, we caution that reliance on hospital-derived cost data without consideration of clinical and *other external* information (such as ASP data for radiopharmaceuticals) may be contrary to the intent that APCs are to be both clinically and resource homogeneous. Based on the application of the 2 times rule, AMI/IMT request that CMS create new APCs as necessary to achieve appropriate resource and clinical homogeneity within nuclear medicine APCs.

[12] 73 Fed. Reg. 41,488 (July 18, 2008).

VI. CMS Should Continue to Require the Radiopharmaceutical Edits to Nuclear Medicine Claims

For CY 2010, CMS is proposing to use 2008 OPPS claims that were subject to the "procedure-to-radiolabeled product" edits.[13] For this reason, CMS believes that there is no longer a need to do further editing for the presence of a radiopharmaceutical product. AMI/IMT supported CMS's implementation of radiopharmaceutical edits for nuclear medicine procedures, and continues to do so. CMS has acknowledged previously that when hospitals submit claims with radiopharmaceuticals billed, the claims are more likely to include charges for these drugs, thus providing CMS with more robust data on actual hospital costs. Accordingly, AMI/IMT request that CMS continue — at least for one or two more years — to conduct further editing, and use only claims with a radiopharmaceutical code and nuclear medicine procedure billed in setting prospective payment rates. This added measure will help ensure that the process and edits are working appropriately, and that all the costs are appropriately captured.

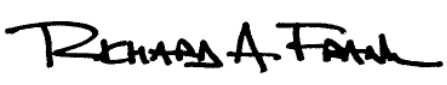
VII. CMS Should Provide Stability for PET Myocardial Imaging Reimbursement

AMI/IMT are increasingly concerned about the significant and dramatic fluctuations in reimbursement rates for PET myocardial imaging over the past several years. While we are pleased to see that the proposed payment rate for CY 2010 has increased by approximately $273, that increase comes on the heels of a CY 2009 reduction in excess of $1,500 when compared to CY 2008 rates. The adverse practical consequence of such instability in year-on-year reimbursement rates is that it becomes exceptionally challenging for hospitals to predict their annual budgets or otherwise adjust to such rapid oscillation in Medicare payment policy. AMI/IMT therefore request that CMS carefully review the claims data (subject to the current radiopharmaceuticals edits) and consider measures that would restrict the year-on-year variability in payment rates, thereby improving predictability for hospitals and their administrators. One such option would be for CMS to impose outer limits on the allowable annual percentage changes in payment rates, by restricting such variation to (for instance) a 20 percent increase or decrease relative to the previous calendar year.

Conclusion

Thank you for your time and attention to these comments. We look forward to providing CMS with any additional information that may be of value in developing the Final Rule.

Sincerely,



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[13] 74 Fed. Reg. 35,276.