RADIOPHARMACEUTICAL REIMBURSEMENT UNDER MEDICARE: RECOMMENDATIONS FOR REFORM

**POLICY GOAL:** Ensure Medicare beneficiary access to radiopharmaceuticals that are most appropriate to diagnose and treat the particular disease of each particular patient.

**PRIMARY POLICY OBJECTIVE:** Classify radiopharmaceuticals as drugs, not supplies. Establish appropriate payment policy to accurately reflect radiopharmaceutical acquisition costs.

**Background and Brief Statutory History**

Nuclear medicine specialists use safe, painless, and cost-effective techniques to image the body and treat disease. These imaging techniques are essential to the management of heart disease and cancer today. They provide specific functional information, and the treatment is highly effective targeted therapy.

Nuclear medicine uses small amounts of radioactive materials that are called radiopharmaceuticals. These are unique drugs in the form of (1) either a radionuclide itself or (2) a radionuclide attached to a biologic or to another drug that are targeted to detect or treat disease. A radiopharmaceutical is the primary component of each and every nuclear medicine procedure.

Radiopharmaceuticals are approved by the Food and Drug Administration (FDA) as either drugs or biologics. They meet the statutory definition of drugs under Section 1861(t) of the Social Security Act because they either are included in the various drug compendia or recognized by hospital medical staff as drugs. Radiopharmaceuticals are administered as part of each and every nuclear medicine diagnostic or therapeutic procedure and are integral to such procedures. The section of the Medicare statute authorizing transitional pass-through payments for radiopharmaceuticals expressly states, "A radiopharmaceutical drug or biological product used in diagnostic, monitoring and therapeutic nuclear medicine procedure..." (Section 1833(t)(6)(A)(iii), emphasis supplied). Moreover, from 2004 to 2006, Congress updated the hospital outpatient prospective payment system's (HOPPS) payment methods for drugs and radiopharmaceuticals, requiring transition from average wholesale price to average sales price methodology under the Social Security Act, which specifically defines a "specified covered outpatient drug" as including "a radiopharmaceutical" (Section 1833(t)(14)(B)(i)(I)).

**Current Regulatory Status**

Despite statutory language clearly defining radiopharmaceuticals as drugs, the Centers for Medicare and Medicaid Services (CMS) has reclassified radiopharmaceuticals twice. In November of 2002, CMS published a final rule reclassifying them as either "diagnostic tests" or "radioisotope therapies." The Social Security Act, however, makes no distinction between "diagnostic" and "therapeutic" radiopharmaceuticals. Most recently, under the 2008 HOPPS final rule, CMS took this distinction one step further by reclassifying all diagnostic radiopharmaceuticals as "supplies" instead of "drugs," thereby bundling payment for diagnostic radiopharmaceuticals into the payment for nuclear medicine procedures. CMS continues to reimburse separately only for therapeutic radiopharmaceuticals.¹

¹ The Medicare, Medicaid, and SCHIP Extension Act of 2007 provides for a continuation of payment for therapeutic radiopharmaceuticals based on individual hospital charges adjusted to cost through June 30, 2008. Thereafter, payment for separately payable therapeutic radiopharmaceuticals (i.e. with a mean per-day cost in excess of $60.00) will be made prospectively, based on mean costs from hospital claims data as described in the 2008 HOPPS final rule.
Proposed Recommendations and Rationale

(1) All radiopharmaceuticals should be recognized and treated as drugs, not supplies. They are included, or approved for inclusion in, the United States Pharmacopoeia (the national formulary) or other compendia or are approved by the pharmacy or drug therapeutic committee of the medical staff of the hospital furnishing the radiopharmaceutical.

(2) CMS should continue to reimburse radiopharmaceuticals at charges reduced to cost in 2008 while working with the nuclear medicine industry (nuclear pharmacies and manufacturers) to develop standard payment methodology based on the average radiopharmaceutical invoice price at the distributor or nuclear pharmacy level (patterned after the average sales price model for drugs). It is imperative that an accurate payment methodology for radiopharmaceuticals is developed and that, in the meantime, Medicare patient access to these critical diagnostic drugs is preserved. Drilling down to the distributor or nuclear pharmacy level to capture the average radiopharmaceutical invoice price is critical because as long as payment for radiopharmaceuticals is based on hospital charge data compressed to cost, accurate reimbursement will be compromised by charge compression.  

(3) All radiopharmaceuticals should qualify for the same bundling threshold in 2008 ($60.00) as all other drugs. Bundling or packaging beyond this threshold could force hospitals to use older, less effective radiopharmaceuticals. It deters adoption of new and novel, or low volume but expensive, radiopharmaceuticals and may prevent Medicare beneficiaries from accessing the most appropriate medical care. That is because bundling fails to reflect the reasonable clinical alternatives available to physicians and hospitals when they are determining which radiopharmaceutical drug is most appropriate for each Medicare patient. For example, there is just one CPT code for whole body tumor imaging, and the outpatient payment rate corresponding to that CPT code is never greater than $900. However, the several lower volume radiopharmaceutical products available for tumor imaging range in price from $89 all the way up to $2,500, setting up a significant underpayment for many of these products as currently bundled by CMS. (It should be noted that CMS believes that the costs for whole body imaging radiopharmaceuticals are included in the $900 for the imaging procedure. This is based on the median costs reports generated from all hospitals. But the actual costs for any one hospital reflect the patient population served by that hospital. Treating radiopharmaceuticals as "supplies," and bundling their costs into the procedure, is a serious deterrent to the use of higher cost but more specific radiopharmaceuticals for these cancer patients.)

Moreover, it is probable that the actual cost of radiopharmaceuticals would be lost if bundled into procedures. Bundling would become a double-edged sword resulting in CMS paying more than necessary for some radiopharmaceuticals as they mature from single-source or patented products.

(4) CMS should accept and utilize external data sources to identify and appropriately reimburse radiopharmaceuticals under HOPPS, as the agency does for all other drugs. The most accurate sources of radiopharmaceutical cost data are nuclear pharmacies and manufacturers. Nuclear pharmacies sell more than 90 percent of the unit dose

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2 According to RTI International, “Charge compression refers to the practice of assigning a lower markup to relatively high cost items and a higher markup to lower cost items. Within hospitals, it is a pricing strategy that is said to be common in resale items such as medical supplies or drugs charged to patients. Charge compression is one potential source of bias in the DRG weights when the applicable CCR [cost-to-charge ratio] is an average across both low- and high-markup items. Any aggregation of CCRs across services with different cost-to-charge ratios has the potential to understate or overstate cost estimates for specific DRGs, and therefore bias the weights.” While this definition is in the context of the inpatient system, it applies equally to the outpatient system. (A Study of Charge Compression in Calculating DRG Relative Weights, RTI International, January 2007.)

3 A CPT code, or Current Procedure Terminology code, describes medical procedures performed by physicians or other health care providers. Each code is associated with specific reimbursement amounts for each procedure.
radiopharmaceuticals sold to hospitals. CMS should view the nuclear medicine community – including nuclear pharmacies and manufacturers – as uniquely qualified to supply the most comprehensive radiopharmaceutical data, which can complement other data that the agency may obtain.\textsuperscript{4}

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\textsuperscript{4} Since the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) specifically excluded radiopharmaceuticals from average sales price reporting, a legislative solution may be necessary to require nuclear pharmacies to submit cost data to CMS.