****Medicare Radiopharmaceutical Pricing and Reimbursement****

By way of brief background, under Medicare Part B, radiopharmaceuticals used during myocardial perfusion imaging studies (CPT Codes 78451-78454) are eligible for separate reimbursement under the Medicare program. In accordance with the Medicare Modernization Act of 2003, (the"MMA"), §303(c), effective January 1, 2005, drugs and biologicals not paid on a cost or prospective basis are paid on the Average Sales Price (ASP). However, §303(h) of the MMA, carves out an exception for radiopharmaceuticals. Section 303(h) provides for the continuation of the payment methodology under Medicare Part B, prior to the enactment of the MMA, for radiopharmaceuticals. Therefore, the payment allowance limits for radiopharmaceuticals for dates of service after January 1, 2005, are based on the payment methodology under Part B in effect as of November 2003. Consistent with the MMA, with respect to Medicare Part B, Medicare contractors (or MACs) determine payment limits for radiopharmaceuticals.

Pursuant to the carve-out created by §303(h) of the MMA, Medicare does not set national pricing for reimbursement for radiopharmaceuticals (Myoview, A9502, is not in Medicare's pricing files and, therefore, there is no National payment limit). Thus, Medicare Part B suppliers (e.g., the Practices) must look to local carriers (or MACs) to determine pricing and applicable payment policies/guidelines with respect to radiopharmaceutical billings. Notably, there are no applicable Medicare regulations or other published Medicare guidance/policies which specifically address the manner in which the Practice or another entity is permitted to purchase radiopharmaceuticals. Consistent with the MMA with respect to the Practices' billing and claims submission for A9502, the Practice must follow the applicable Medicare contractor's (or MAC) coverage decision (the "LCD"). ***It is explained that if a Practice submits a claim for reimbursement for A9502 and requests the full allowable reimbursement amount, but the Practice actually paid less per study dose, this could subject the Practice to significant civil monetary penalties and other administrative sanctions.***

Practices are required by the Medicare carriers to submit claims for A9502 to carrier, which represent the amount that reflects the purchase price of the isotope, carriers provide that the Practice should submit claims reflecting the cost to the Practice, **and such cost could and should include associated administrative fees due third party organizations.** Although, it is likely that the Practices desire to profit from the billings of radiopharmaceuticals, Medicare carriers' policy generally reflect that the ***Practices should NOT be directly marking up the cost of the radiopharmaceuticals to the carriers***. This, however, does not mean that Practices cannot submit for charges billed by a third party (ie, a testing arrangement), including any and all administrative fees associated with the isotope costs.

It is important to understand that recently the focus of many CMS audits (and studies regarding the cost to the Medicare program) has been on high-end imaging studies, including nuclear diagnostic studies. Because of this regulatory environment, it is believed that there may be an increase in requests for detailing the costs of radiopharmaceuticals for tests performed on specific patients.