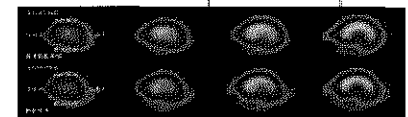


CORAR – OMB Meeting

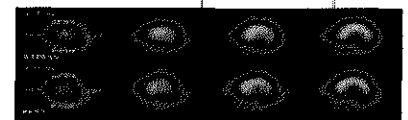
2013 OPPS Proposals and Payment Policy Impacting Radiopharmaceuticals

October 3, 2012



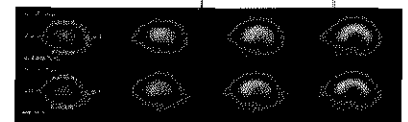
Overview

- Introduction and background on Council on Radionuclides and Radiopharmaceuticals (CORAR)
- Proposed payment adjustment; non-Highly Enriched Uranium (HEU) sources
- Payment policy for diagnostic (Dx) radiopharmaceuticals (RPs) under OPPS
- CORAR Recommendations for non-HEU Proposal
- Closing Comments



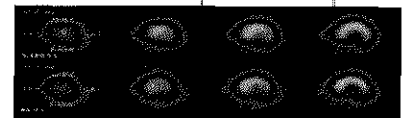
Background on CORAR

- CORAR is comprised of companies that:
 - Develop manufacture, and distribute radiopharmaceuticals, sealed sources, radionuclides, and contrast agents primarily used in clinical care, medicine and life science research.
- CORAR/GAO/Congress/CMS:
 - Worked with leaders on Capitol Hill to refine sections of the Social Security Act with respect to radiopharmaceutical payment.
 - Have a long-standing history of working together to resolve OPPS payment challenges that are unique to RPs.



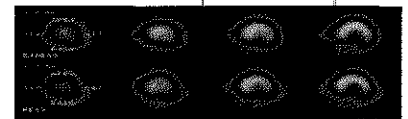
Proposed Payment Adjustment (non-HEU Sources)

- CORAR:
 - Strongly supports the Administration's objective to eliminate the use of HEU in medical isotope production.
 - Recognizes that the 2013 OPPS non-HEU proposal is an important first step.
 - Believes the OPPS proposal, as drafted, will not on its own adequately achieve the objectives.
 - Anticipates significant operational and logistical challenges for industry and providers.
 - Offers recommendations to facilitate the accomplishment of the Administration's objectives for non-HEU sourced products.



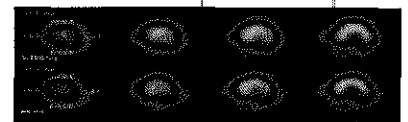
Improvements on Non-HEU Proposal

- Additional years of add-on payments will increase likelihood of non-HEU product pull-through.
- Extend add-on payments to all Medicare and government payment systems to achieve wider application.
- Simplify hurdles for manufacturers to produce non-HEU molybdenum/technetium generators (Mo-99/Tc-99m) in 2013.
- Recognize operational challenges for radiopharmacies to segregate and dispense HEU vs. non-HEU products.



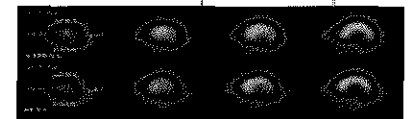
Improvements on Non-HEU Proposal

- Simplification of process to track and report non-HEU sourced Tc-99m doses would make implementation less burdensome.
- Greater clarity on reimbursement changes for nuclear medicine (NM) procedures will reduce confusion.
- Increased non-HEU “cost” transparency in claims data would improve acceptance.



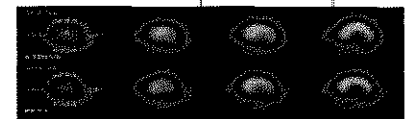
Other NM Stakeholder Observations

- In 2013, total Mo-99 demand can only be partly covered by available non-HEU Mo-99.
- Questions/confusion on hospital certification of non-HEU product received from radiopharmacies.
- Lack of transparency on CMS methodology used to calculate \$10.00 add-on payment.
- Concerns using proposed best available market data (versus CMS claims data) to calculate marginal cost on non-HEU sourced products.
- Uncertainty whether the \$10.00 add-on payment is sufficient to cover anticipated cost increases through the supply chain.



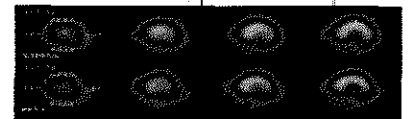
Medicare OPPS Payment Challenges for RPs

- CMS proposed payment adjustment for non-HEU sources seeks to address significant new cost for industry.
- However, it does not address current, underlying problem in Medicare Dx RP reimbursement – packaged payment.
- Acknowledging/mitigating packaging problem necessary for industry to be in position for transition to non-HEU.



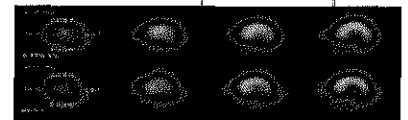
Separate Payment is Necessary

- Separate payment for Dx RPs under OPPS does not solve all the implementation challenges discussed earlier.
- However, Dx RPs are currently inadequately reimbursed under OPPS. Significant cost increases associated with non-HEU transition will exacerbate this problem.
- Separate reimbursement (for Dx RPs that meet the threshold for payment) will help ensure that transition costs to non-HEU sources can be recouped by industry consistent with the full-cost recovery methodology.



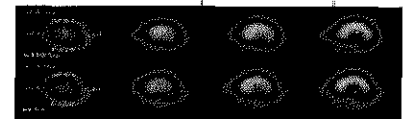
Recommendations on non-HEU Proposal

- **Separate OPPS payment (starting in 2013)** for all Dx RPs with establishment of **parallel HCPCS codes** for non-HEU RPs to base future non-HEU payments.
 - Include \$10.00 add-on
- **Benefits of separate payment include:**
 - Allow CMS to more effectively gather cost data – improved cost transparency.
 - Provide accurate reporting of charges for non-HEU RPs to ensure full cost recovery.
 - Maintain predictable and appropriate charges for NM procedures.
 - Minimize operational and logistic disruptions to hospitals, Mo-99/Tc-99m generator manufacturers, and radiopharmacies.
 - Ensure consistent payment policy of Dx RPs under both OPPS and the physician office setting.



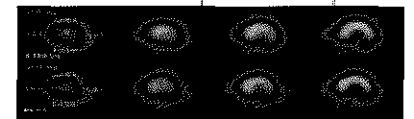
RPs are Drugs and Should be Paid as Drugs in All Instances

- RPs are approved by the FDA as drugs.
- §1833(t)(6) of the Social Security Act provides recognition of new drugs including RPs for pass-through.
- Failure to pay for Dx RPs that meet the threshold for separate payment results in:
 - Lack of Transparency in cost of diagnostic RP's .
 - Nuclear medicine procedures and RPs being underpaid.



Packaging Methodology Applied to Dx RPs

- CORAR Concerns:
 - CMS's packaging policy does not accurately capture average hospital acquisition costs in hospital outpatient setting of diagnostic RPs including HEU RPs.
 - Numerous RPs with widely varying costs are packaged into a single nuclear medicine APC
 - Especially undercompensates high-cost, low-volume RPs.
- Results in disparity/disconnect between costs and Medicare payment in hospital outpatient setting.



Hospital Cost Versus Medicare Payment Disparity

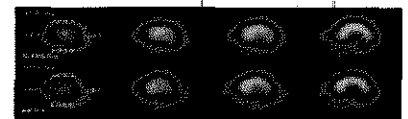
APC	Group Title	Proposed 2013 APC Rate (procedure + RP)	RP Cost Only (2011 Mean Cost/Day) *		
			A9582 ¹	A9572 ²	A9569 ³
406	Level I Tumor/Infection Imaging	\$301	\$1,273	\$1,154	\$500
408	Level III Tumor/Infection Imaging	\$976	\$1,273	\$1,154	N/A
414	Level II Tumor/Infection Imaging	\$507	\$1,273	\$1,154	\$500

1. HCPCS code A9582: Iodine I-123 iobenguane

2. HCPCS Code A9572: Indium in-111 pentetreotide

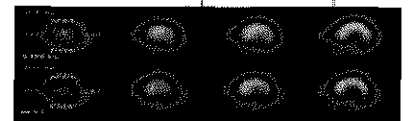
3. HCPCS Code A9569- Technetium Tc-99m Examatazime labeled autologous white blood cells

•Source of information <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1589-P.html>



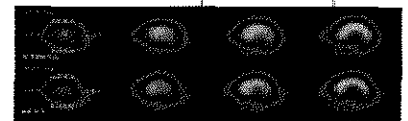
CORAR Recommendations

- Separate payment for RPs in the OPPIs and ASC settings: CMS should set threshold to trigger separate payment for Dx RP drugs, when:
 - Per-day cost of RP exceeds threshold for all other specified outpatient drugs



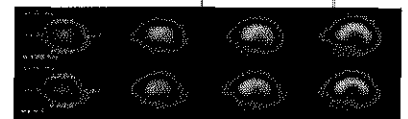
CORAR Recommendations

- Reconsider interpretation/application of 2-times rule: CMS has statutory authority/mandate to consider cost of diagnostic RPs in determining whether APCs meet the 2x rule
 - Statute directs CMS to look at “items” and services within APC group to ensure they are comparable with respect to use of resources
 - CMS currently looks only at cost of procedure, not RP, in determining integrity of APC



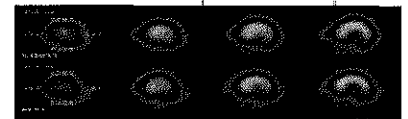
CORAR Recommendations

- Use ASP data, when available, to pay separately for RPs and/or account for packaged RP costs in nuclear medicine APCs
 - CMS has indicated on numerous occasions that ASP is most accurate, transparent payment methodology
 - CMS revised reporting requirements to accommodate “patient-ready” dose ASP reporting for RPs
 - Using ASP data, when available, is consistent with CMS’s overall actions and goals



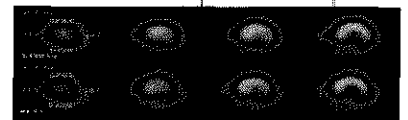
Recommendations non-HEU Proposal

- **Reduce** the 100% non-HEU content requirement for 2013.
 - 100% non-HEU content standard does not realistically recognize the state of the domestic supply of non-HEU Mo-99 in 2013
 - Total World/US Mo-99 demand can only partly be covered in 2013 by currently available non-HEU sourced material.
 - Industry will need to make significant investments (in time and capital) to quickly adjust:
 - Current Mo-99 sourcing
 - Manufacturing processes
 - Compounding and dispensing processes



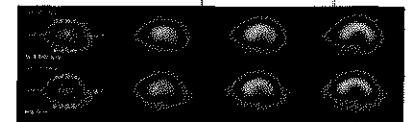
Recommendations non-HEU Source Proposal -- 2013 and Beyond

- Provide add-on payment for at least **five years** – consistent projections on conversion period.
- **No reduced Medicare payment for nuclear medicine procedures scans** (do not “take back” \$10.00 dose payment through reduced procedure payment in 2013).
- Provide **public comment period** on annual updates to add-on payment amount.
- **Extend add-on payment** to other Medicare settings, Medicaid, Department of Defense/Veterans Affairs, Indian Health Services, and all other government nuclear medicine settings where non-HEU Tc-99m will be used.
- CMS should **work with private payers** to encourage broad adoption.



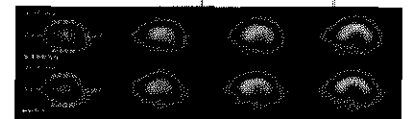
Additional OPPS Recommendations

- CORAR opposes the repeated increases in the packaging threshold for outpatient drugs.
- CORAR recommends that the outpatient drug packaging threshold amount be equal to hospital update for the year (reflective of all statutory adjustments).
- CORAR supports CMS's proposal to increase the payment rate for separately payable drugs and therapeutic RPs from ASP+4 to ASP+6.
 - CORAR strongly suggests that CMS examine ways to compensate hospitals for the unique, higher overhead and handling costs associated with RPs.



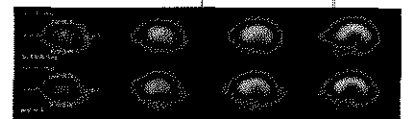
Additional OPPS Recommendations

- CORAR recommends that CMS continue to apply RP edits for nuclear medicine procedures using RPs as long as diagnostic RPs are packaged.
- CORAR supports CMS's policy to treat RPs as drugs that are eligible for pass-through status.



Closing Comments

- CORAR requests separate payment for RPs more accurately reflects hospital acquisition costs of RP drugs.
 - Better enables non-HEU proposal for success.
- CORAR is committed to eliminating the use of HEU in medical isotope production.
 - CORAR has provided comments and recommendations we believe will help achieve policy goals and objectives in 2013 (and beyond).



Closing Comments

- CORAR seeks to continue to work with CMS OPPS staff to implement fair reimbursement policies for RPs to preserve patient access.

Thank You

