

UPPI LEU Walk: Implementation Strategy on the Verge of a Supply Chain Converted to non-HEU Medical Isotopes

**2017 Mo-99 TOPICAL MEETING ON
MOLYBDENUM-99 PRODUCTION TECHNOLOGY DEVELOPMENT**

**SEPTEMBER 10-13, 2017
MONTREAL MARRIOTT CHATEAU CHAMPLAIN
MONTREAL, QC CANADA**

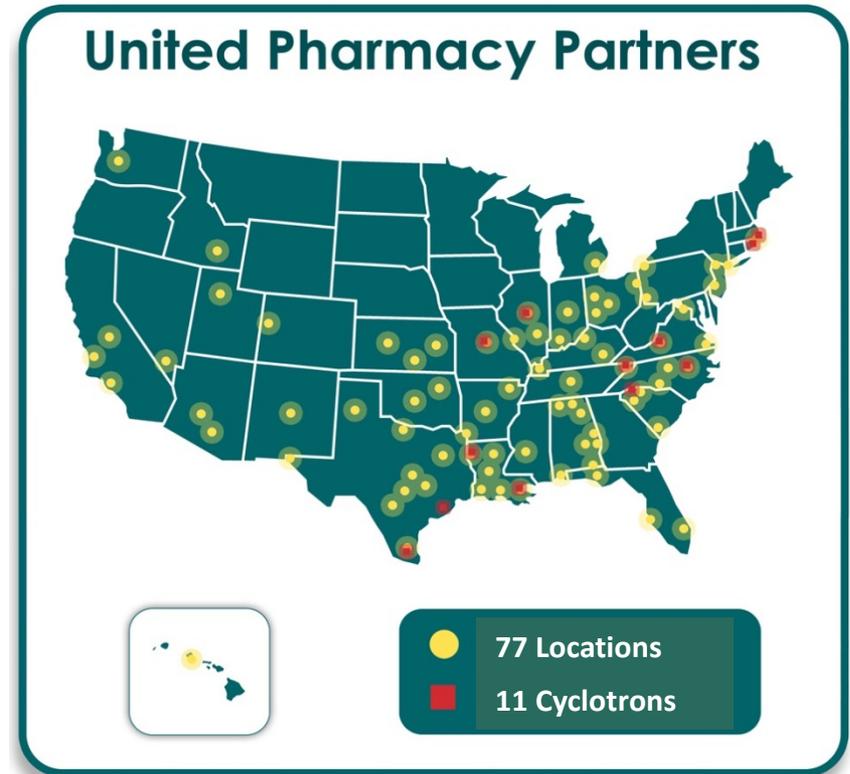


Agenda

- UPPI LEU Walk
- Vizient – UPPI white paper
- ASP and Private Payer C-Suite Initiatives
- Review of FOIA data from the Veterans Administration
- Summary

Overview UPPI LLC.

- UPPI is an alliance of small business and university owned nuclear pharmacies.
- Formed in 1998, with low energy and high energy nuclear pharmacies.
- UPPI represents 8,000 of the 50,000 unit doses dispensed every day in the U.S.



UPPI LEU Walk Progress: 2013 - Today

UPPI LEU WALK

JULY 2013



Three UPPI LEU Pharmacies

UPPI LEU WALK

June 2017

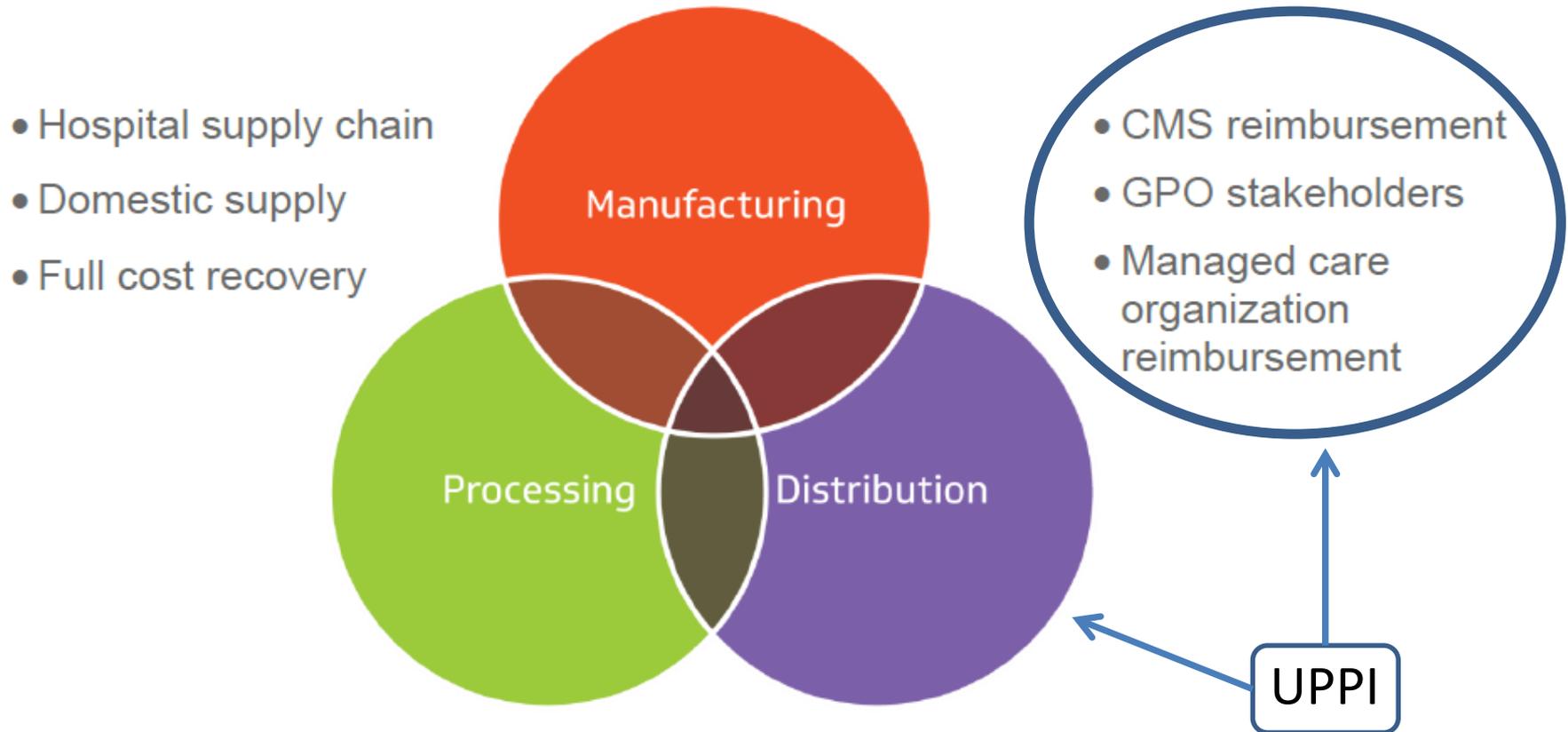


Lighthouse Customers

- UPPI LEU WALK MEMBER
- UPPI MEMBER VA CONVERSION
- UPPI MEMBER FBOP CONVERSION
- UPPI MEMBER DOD CONVERSION
- VIZIENT

Strategic Position

Figure 3. Successfully transitioning to an HEU-free medical isotope supply involves many stakeholders^a



^aReprinted with permission from United Pharmacy Partners, LLC.

Abbreviations: CMS, Centers for Medicare & Medicaid Services; GPO, group purchasing organization; HEU, highly-enriched uranium.

ASP Reimbursement Outreach

Nuclear Pharmacy ASP Model – Sustaining Molecular Imaging

Description	Unit of measure	Average selling price, US \$ (normalized to 100 in 2013)					Trendlines
		2013	2014	2015	2016	2017	
Tc ^{99m} NaTcO ₄ UD	1–25 mCi	100	104	113	122	126	
Tc ^{99m} NaTcO ₄ UD	< 1 mCi	100	100	100	100	113	
Tc ^{99m} Neurolite UD	1-30 mCi	100	123	150	157	173	
Tc ^{99m} PYP UD	1-25 mCi	100	115	123	136	149	
Tc ^{99m} sestamibi UD	1-30 mCi	100	104	110	112	110	
Tc ^{99m} sulfur colloid UD, filtered	0.1-2 mCi	100	109	121	145	146	
Tc ^{99m} sulfur colloid UD	1-8 mCi	100	110	124	149	151	
UltraTag kit	1 vial	100	115	122	139	153	
Xe-133 (xenon) gas	10 mCi	100	126	145	145	145	
Xe-133 (xenon) gas	20 mCi	100	126	144	144	154	

Abbreviat^a Reprinted with permission from United Pharmacy Partners, LLC; based on independent commercial radiopharmacy data.

Radiopharmaceuticals need classification as physician injected drug based on ASP.

Trendline will sharply rise when FCR and ORC for Tc 99m moves through the supply chain.

**C-Suite LEU Tc 99m
Reimbursement Outreach**

Lean Business Case Model: Identify Insurance Opportunity

LEU Tc-99m

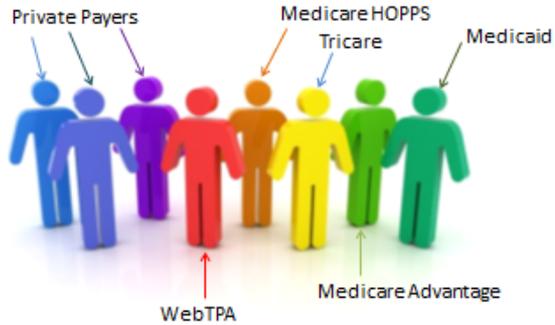
Lean Canvas Business Model				
Problems Product availability Price -Full Cost Recovery Transition timing Reimbursement Clarity	Solutions UPPI LEU Walk LEU Policy Program LMI educational video Key metrics Early Adopter Map Early Majority Map	Unique Value Proposition AMIPA Transition now Private Payer project UPPI First-in/innovator	Unfair Advantage UPPI LEU Walk Innovator Early Adopters Reimbursement expertise Channels Supply Chain Physicians Imaging Directors Radiology Administrators	Customer Segment Hospitals Imaging Centers VA Medical Centers Group Purchasing Organization Integrated Delivery Networks Insurance Payers
Cost Structure GPO contracts Manage price increases			Revenue Streams All insured lives covered by private payers -reimbursement	

C-Suite Initiative :

A **patient –centric non-proliferation policy** to remove Highly Enriched Uranium from medical isotopes production.

C-suite Non-proliferation Outreach

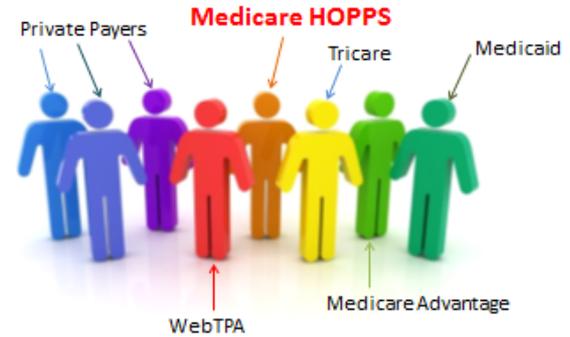
Which Patient is Eligible for CMS HOPPS non-HEU Medical Isotopes Reimbursement?



C-Suite Initiative:
A patient-centric non-proliferation policy to remove Highly Enriched Uranium from medical isotopes production through coverage of all insured lives.

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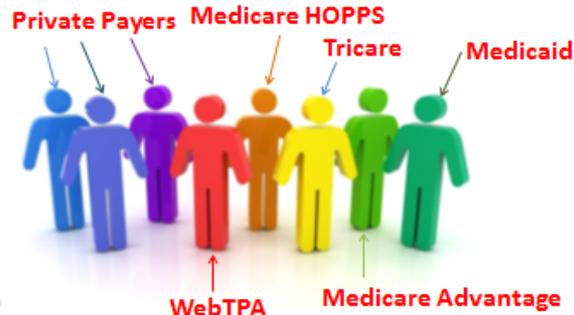
Which Patient is Eligible for CMS HOPPS non-HEU Medical Isotopes Reimbursement?



Medicare HOPPS receives the \$10.00 Q9969 added reimbursement. If one of nine is eligible then how does a busy department separate the one for reimbursement? For \$10.00? Its easier to add another study...

6

Which Patient is Eligible for CMS HOPPS non-HEU Medical Isotopes Reimbursement?



Solution: Establish the Q9969 policy for all covered lives who receive non-HEU Tc99m diagnostic imaging study.

C-Suite Initiative:

A patient-centric non-proliferation policy to remove Highly Enriched Uranium from medical isotopes production through coverage of all insured lives.

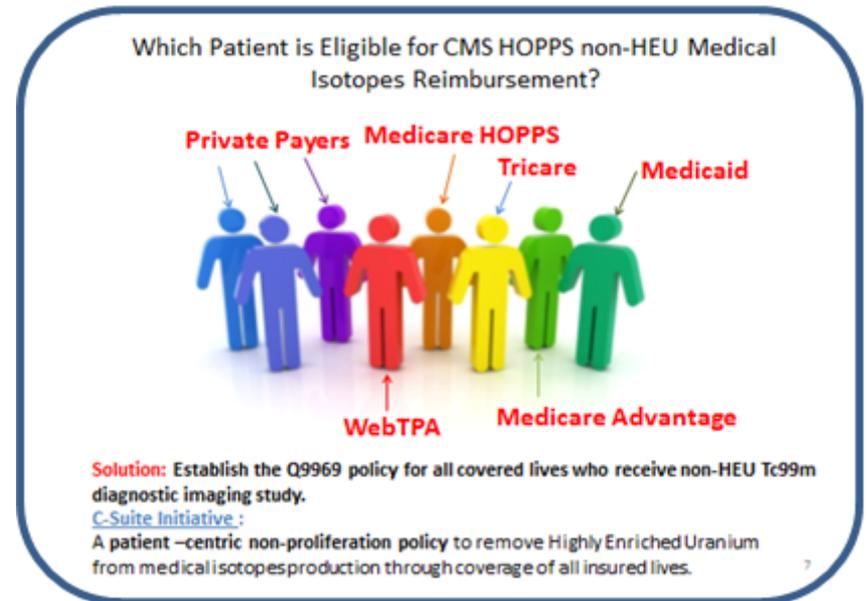
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Why the Need for the Reimbursement Support?

The elimination of Highly Enriched Uranium is a policy of governments. To convert to the non-HEU solution is more expensive with the increased costs due to government policies.

Sustainability of the supply is a result of the costs –not driven by profit –and **reimbursement is a key factor to sustainability.**

Private payers play essential role in the transition to non-HEU (LEU) medical isotopes

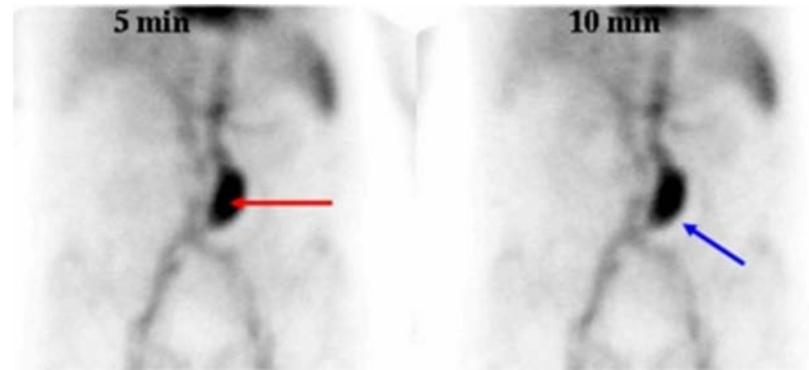


Private Payer Outreach

- Why not provide the Qcode coverage for a boy with a sarcoma needing a bone scan?
- Why not provide the Qcode coverage middle-aged patient with a GI bleed?



<https://radiopaedia.org/cases/osteosarcoma-of-the-distal-femur>

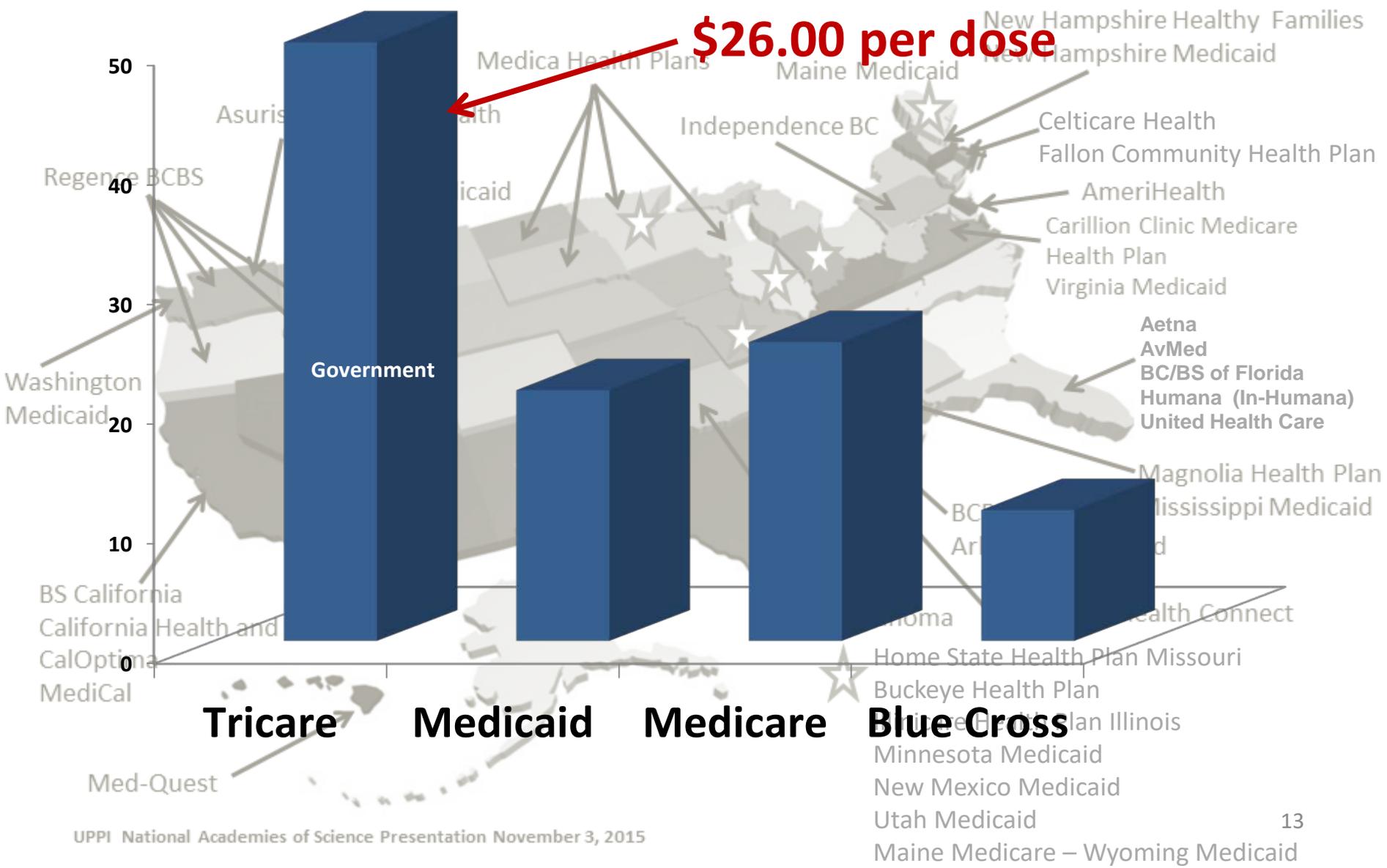


G Currie, J Wheat. *Incidental Findings On RBC Gastrointestinal Haemorrhage Blood Pool Scintigraphy.*

The Internet Journal of Nuclear Medicine. 2006 Volume 3 Number 2. 12

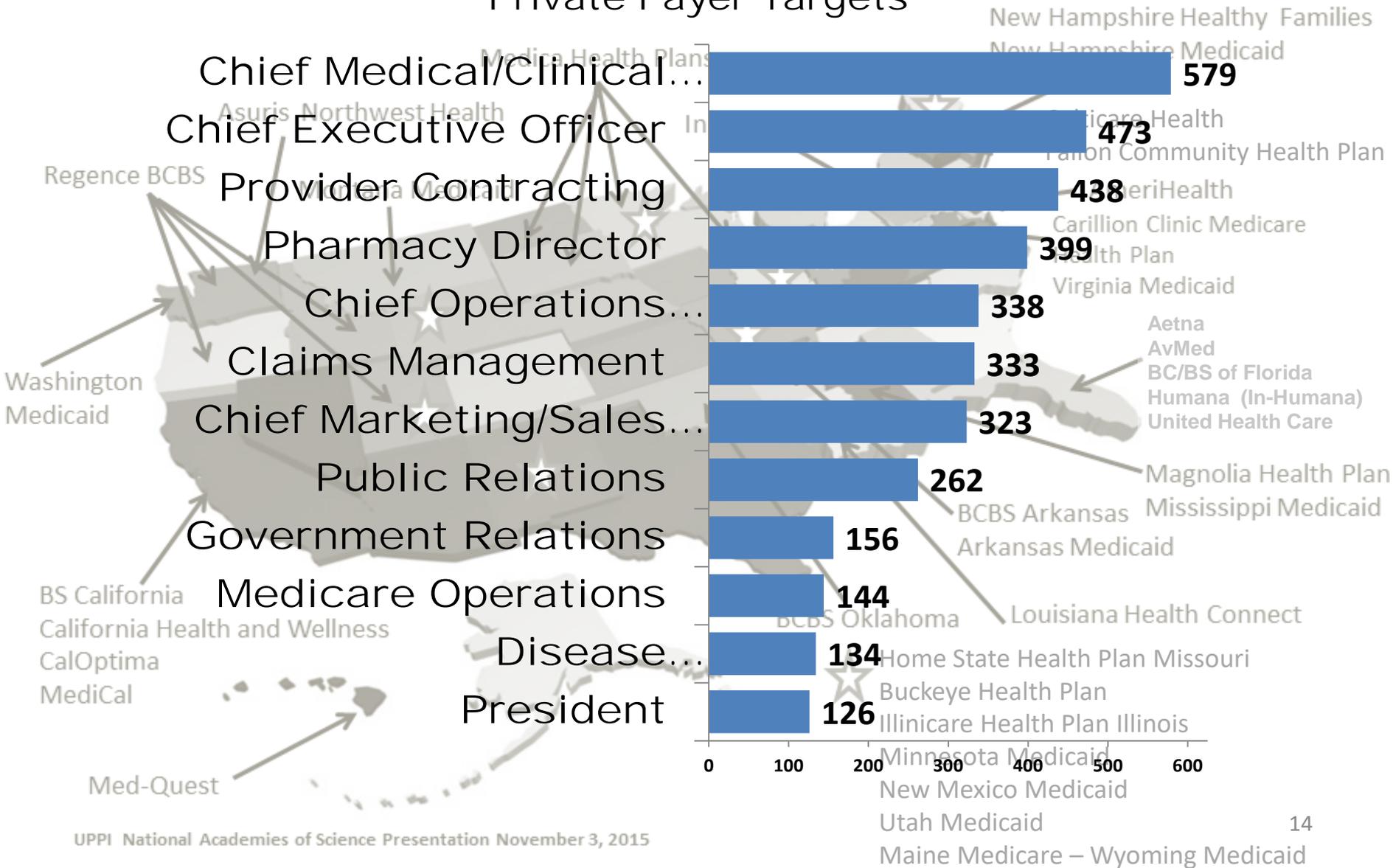
Q9969 non-HEU 99mTc -Private Payer/Medicaid

Private Payers State Coverage



Q9969 non-HEU 99mTc -Private Payer/Medicaid

Private Payer Targets



C-Suite LEU Tc 99m Reimbursement Outreach



UNITED PHARMACY
PARTNERS

Facilitating the Availability of Safe Nuclear Medicine: Reducing the Dependence on Highly Enriched Uranium

“Highly enriched uranium (HEU)—one of the key ingredients for nuclear weapons—is one of the most dangerous materials on the planet.”

-[The Nuclear Threat Initiative](#)

Problem: The use of HEU is still too prevalent in U.S. medical procedures even though LEU is broadly available and could serve as an easy substitute to HEU.

Every year in the US, more than 15 million medical tests are performed using enriched uranium byproducts – more than 41,000 procedures per day. These tests are used to diagnose and assess cancer treatment effectiveness, detect heart disease and other disease processes.

Over 78% of these procedures use Highly Enriched Uranium (HEU), which has been called “one of the most dangerous materials on the planet” by the Nuclear Threat Initiative because it is relatively easy for terrorists or others use that material to make a simple nuclear bomb.

LEU, which does not present the same risk, is an approved substitute that could be used instead of HEU.

There has been a long-term effort to substitute the use of LEU for HEU in U.S. medical

Veterans Affairs non-HEU Tc 99m

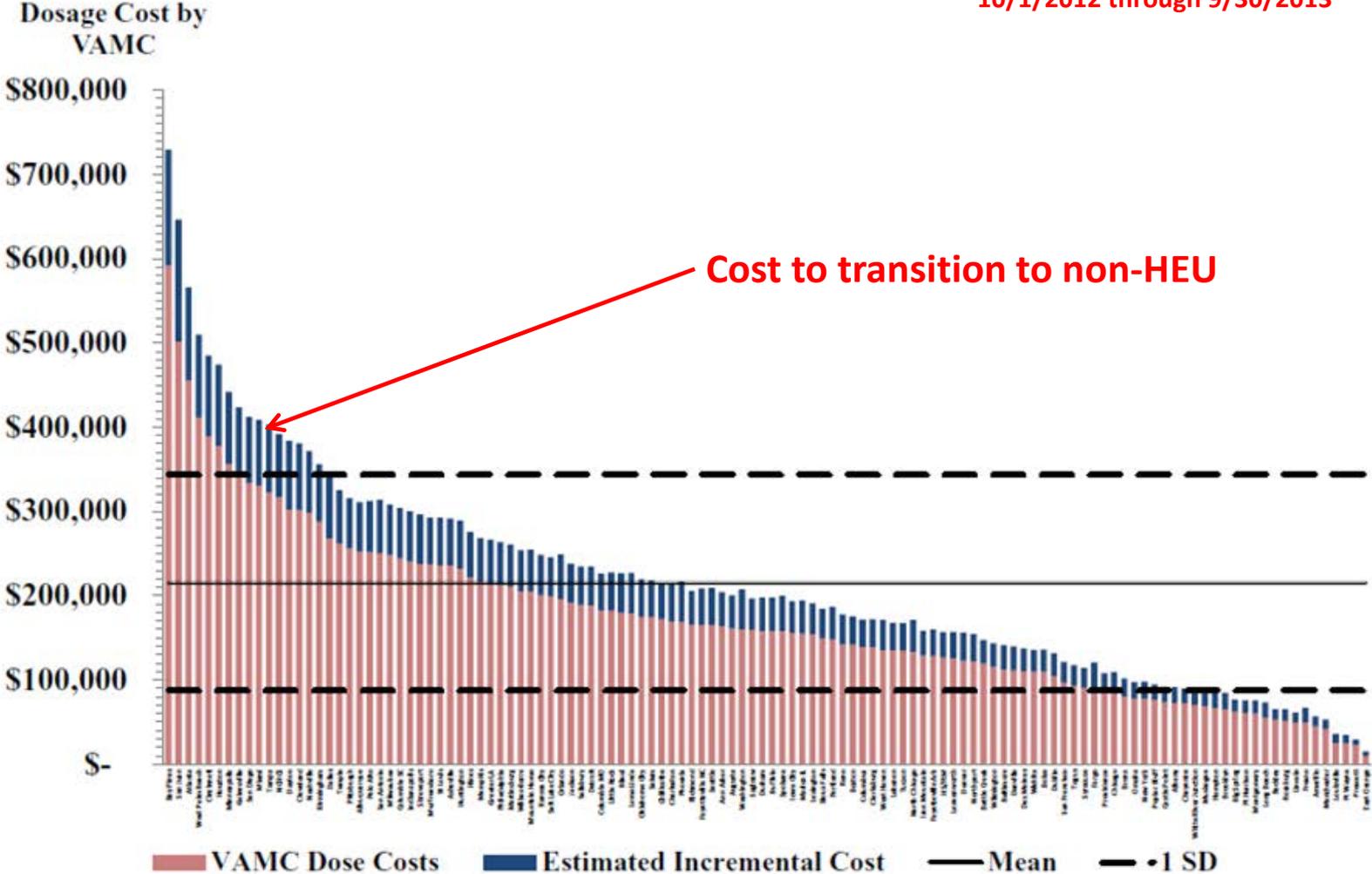
UPPI Freedom of Information Request

- How many VA facilities receive LEU Tc ⁹⁹m doses?
- What is the verification process/procedure that ensures doses are indeed LEU when awarded on a solicitation?
- Regarding the contracting process, if non-HEU (LEU) is required by the agency and is written into the solicitation by the Contracting Officer, under what conditions is it not procured? What inquiries are made in option years to determine if LEU is available?
- Provide copies of all communications related to the notifications, and any training, materials, communications or other material related to that notification.

UPPI FOIA Request

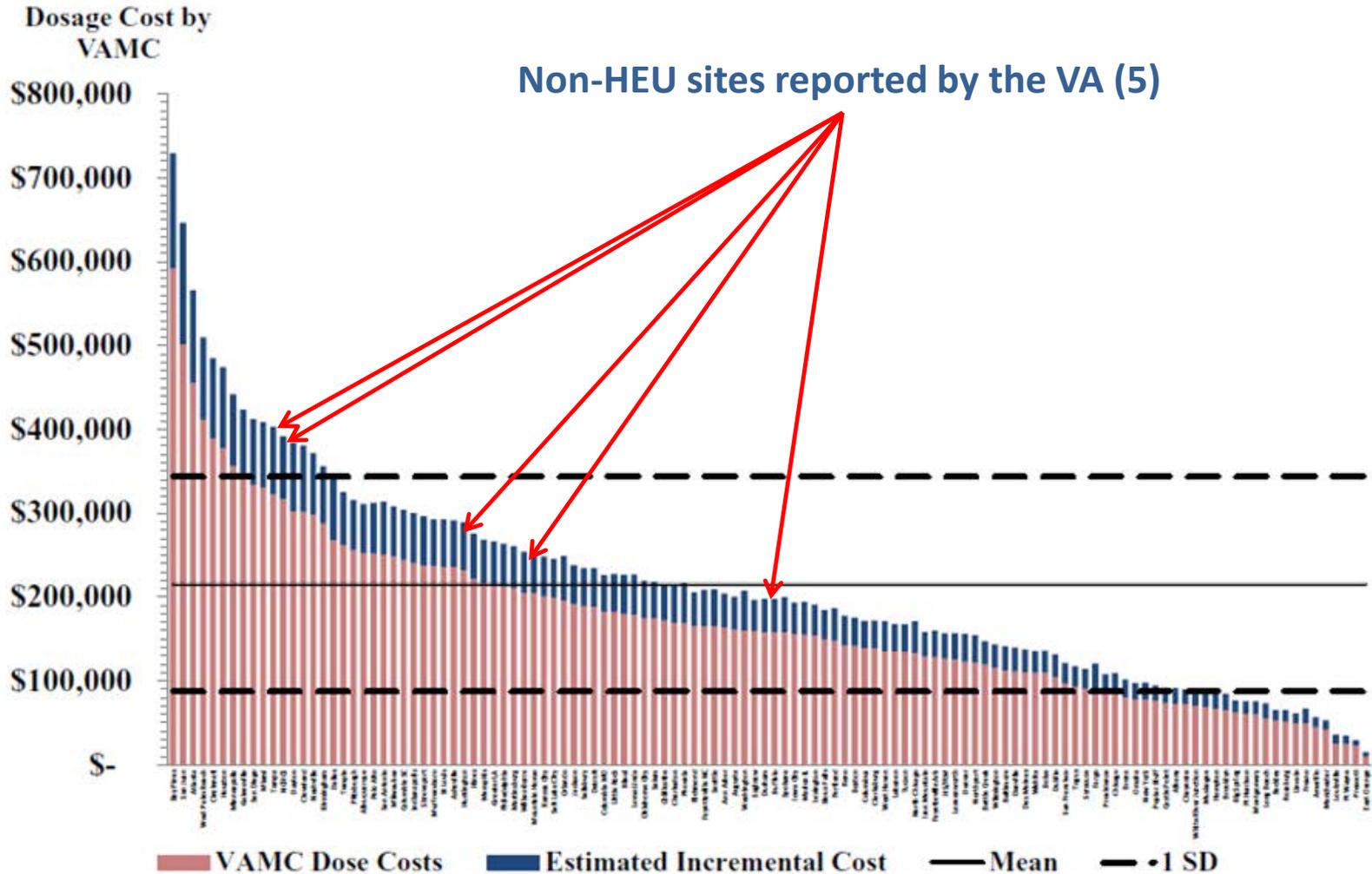
VHA Non-HEU Tc-99m Estimated Dose Cost (FY 2012)

10/1/2012 through 9/30/2013



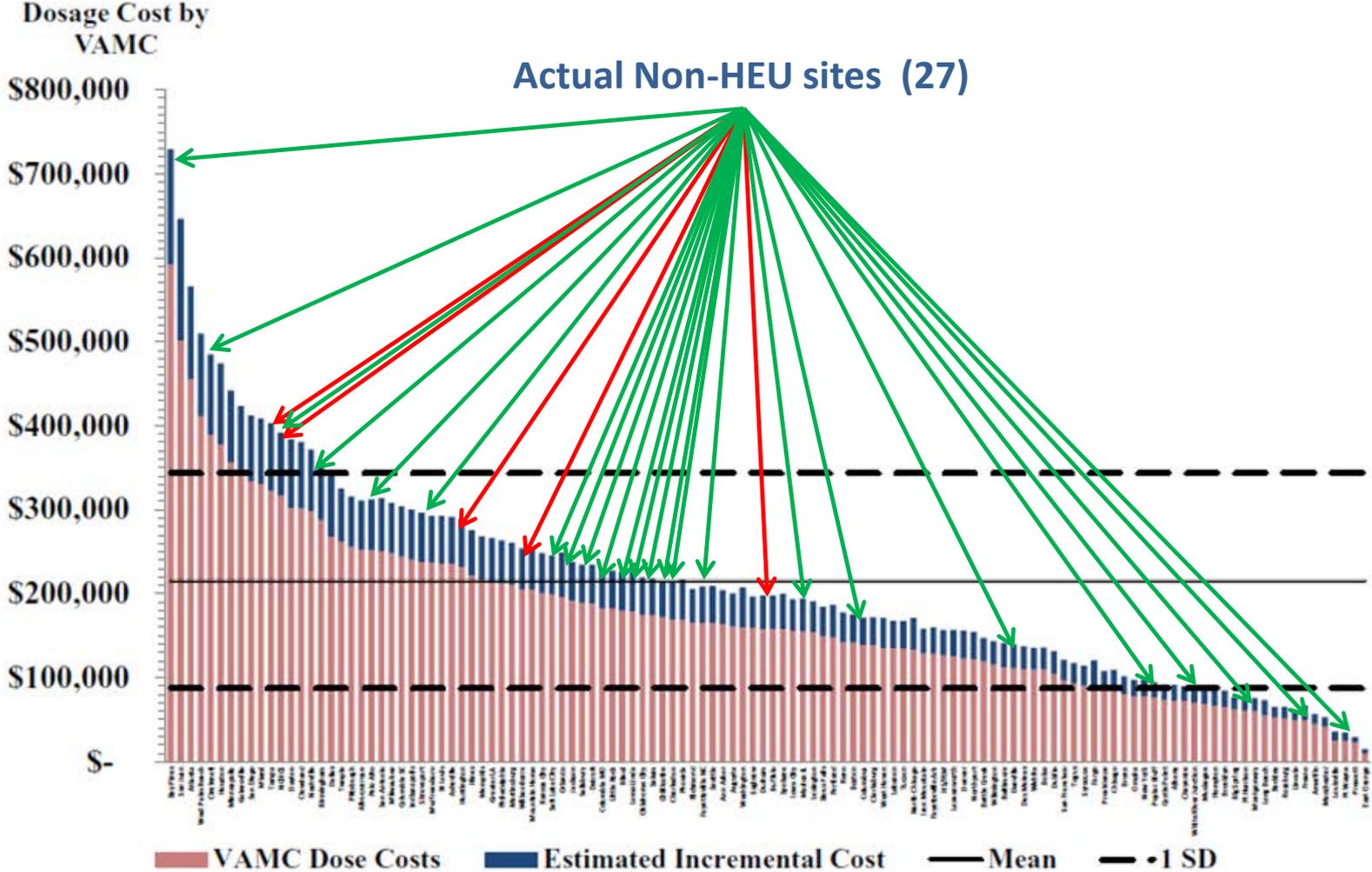
UPPI FOIA Request

VHA Non-HEU Tc-99m Estimated Dose Cost (FY 2012)



UPPI FOIA Request

VHA Non-HEU Tc-99m Estimated Dose Cost (FY 2012)



UPPI FOIA Request



These facilities awarded LEU Tc 99m doses in 2015. Neither ordered a single LEU dose and used HEU product instead.

UPPI FOIA Request

VA Solicitation in July 2017

Statement of Work: Background

The Department of Veterans Affairs (VA) has been directed to preferentially procure medical radioisotopes from non-High Enriched Uranium (HEU) sources.

Contract Line Item Number specified HEU:

Exametazime (Ceretek) Brain Tc-99m HEU

Exametazime (Ceretek) WBC Tc-99m HEU

Mebrofenin (Generic) Tc-99m HEU

Medronate (MDP) Tc-99m HEU

Mertiatide (MAG-3) Tc-99m HEU

Oxidronate (HDP) Tc-99m HEU

Pentetate (DTPA) Tc-99m HEU

Pentetate (DTPA) Tc-99m HEU, Bulk

Conclusion of the FOIA Information

- Of 117 RAM licensed facilities <**25%** converted to non-HEU
- Estimated non-HEU dose cost analysis in 2013
- **Two memoranda** regarding preferential procurement
- ***De minimus*** response to questions
- Clinical group received preferential procurement notices
- **Contracts group did not receive notices** –contract officers are the **warrant holders** for the bid solicitations and specifications.

Summary

Sustaining the Transition to non-HEU Medical Isotopes

- Initiatives:
 - Change reimbursement to an ASP model to sustain nuclear medicine.
 - C-Suite outreach to private payers to drive adequate non-HEU reimbursement through 2020.
 - Work-with the Veterans Administration to understand its non-HEU transition.



KEEP
CALM WITH LEU
AND
CARRY
ON