

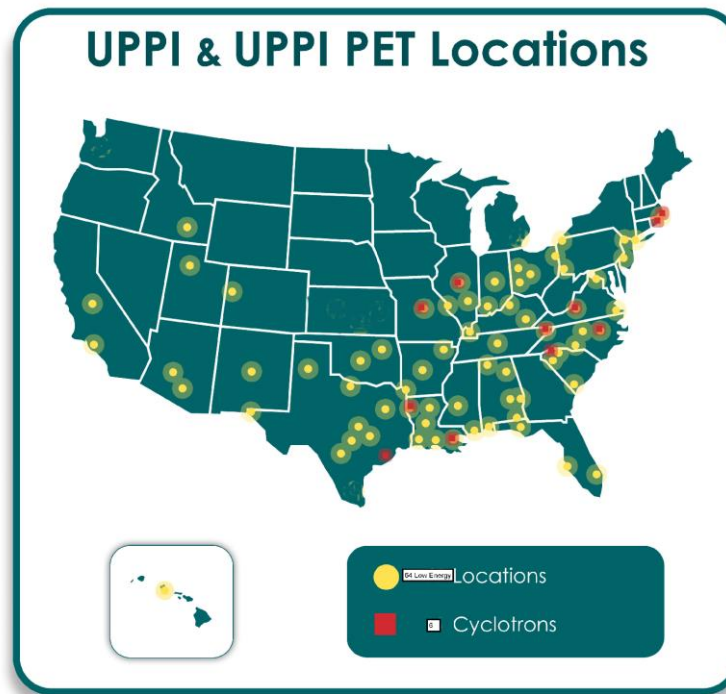
U.S. Mo-99 Supply Status – Industry Perspectives

**NNSA Mo-99 Stakeholder Meeting
Agenda**

August 29, 2023



About UPPI



- UPPI is an alliance of small business and hospital/university-owned nuclear pharmacies.
- Formed in 1998, with 60 low energy (Tc-99m) and 5 high energy (PET) nuclear pharmacies.
- UPPI represents 8,000 Tc-99m unit doses dispensed nationally each day.

UPPI LEU Walk



LEU Walk provided distribution in a limited, and growing, non-HEU Mo-99 generator placement in the early stages of availability.

UPPI Efforts

- Distribution of non-HEU Mo-99 which led to growth of users “UPPI LEU Walk”.
- Advocacy for the CMS added-on reimbursement for non-HEU Tc-99m that continues through 2024.
- IAEA TECHDOC Mo-99 and UPPI Model published soon.

CMS HCPCS Code Q9969

Will be included in 2024 HCPCS Codes

2023 HCPCS Code Q9969|

Tc-99m from non-highly enriched uranium source, full cost recovery add-on, per study dose

Short Description

Non-HEU Tc-99m add-on/dose

Procedure Note

0179 = CY 2013 OPPTS/ASC FINAL RULE.

HCPCS Coverage Code

D = Special coverage instructions apply

HCPCS Action Code

N = No maintenance for this code

HCPCS Action Effective Date

January 01, 2013

HCPCS Code Added Date

January 01, 2013

HCPCS Pricing Indicator Code

53 = Statute

HCPCS Multiple Pricing Indicator Code

A = Not applicable as HCPCS priced under one methodology

<https://www.hcpcsdata.com/Codes/Q/Q9969#:~:text=2023%20HCPCS%20Code%20Q9969%20%3A%20Tc,add%2Don%2C%20per%20study%20dose>

CMS Medicare Enrollees

The Centers for Medicare & Medicaid Services (CMS) released the latest enrollment figures for Medicare on January 5th. As of March 2023, 65,748,297 people are enrolled in Medicare, an increase of almost 100,000 since the last report in September. Of those:

- 33,948,778 are enrolled in Original Medicare.
- 31,799,519 are enrolled in Medicare Advantage or other health plans. This includes enrollment in Medicare Advantage plans with and without prescription drug coverage.
- 51,591,776 are enrolled in Medicare Part D. This includes enrollment in stand-alone prescription drug plans as well as Medicare Advantage plans that offer prescription drug coverage. (Enrollment in private, for-profit Part D or MA-PD plans remains the only option for drug coverage in the Medicare program).

You can see the enrollment figures for CMS programs at <https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment>, including the number of Part D enrollees who receive the low-income subsidy.

Potential remains to utilize the Q9969 additional reimbursement for Medicare OPPS

<https://medicareadvocacy.org/medicare-enrollment-numbers/#:~:text=33%2C948%2C778%20are%20enrolled%20in%20Original,enrolled%20in%20Medicare%20Part%20D.>

Today's Issue: Supply Chain Disruption

PHARMALOT

More hospital pharmacists are rationing drugs due to increasing shortages

By [Ed Silverman](#) Aug. 11, 2023



LEON KEITH/AP

Nearly every hospital pharmacy across the U.S. is experiencing shortages of prescription drugs. And the problem has become so bad — especially for chemotherapies — that one-third of hospital pharmacists reported their institutions are rationing, delaying, or canceling treatments or procedures, according to a new survey. Specifically, 99% of hospitals pharmacists reported shortages, which is causing 85% to ration treatments and 84% to rely on different dosages. At the same time, more pharmacists are changing their purchasing practices, with nine out of 10 pivoting toward different vial sizes or concentrations, while 59% percent are buying more from compounding pharmacies.

https://www.statnews.com/pharmalot/2023/08/11/hospitals-pharmacist-shortages-fda-intas-cancer/?utm_campaign=pharmalittle&utm_medium=email&_hsme=270176120&_hsenc=2ANots-TrBi8MfMlHQmo5X84N-YdwN3Kv_2m2uJF9GGCcw-qrQRH0lrrxmvt7Kv5fF9eXih1474P65_9Uf093VwXvMewB&utm_content=270176120&utm_source=hs_email

Impact: Supply Chain Disruption

[POLITICS](#)

White House drug shortages task force MIA with lawmakers while Congress works on fixes

By [John Wilkerson](#) Aug. 11, 2023

WASHINGTON — A White House task force created to work on drug shortage reforms has yet to contact the lawmakers who are writing legislation to stem shortages — and it's not clear when the task force will recommend policies.

The White House formed a task force [at the beginning of 2023](#) to deal with the issue of [persistent drug shortages](#). Fifty-seven percent of hospital pharmacists said they are facing critical shortages of chemotherapy drugs in a [new survey](#) from the American Society of Health-System Pharmacists. Hospital pharmacists also reported significant shortages of steroids, hormonal drugs, and oral liquids such as amoxicillin and lidocaine.

Yet industry and patient representatives who [have met with task force members](#) said there has been no indication of when they will make recommendations that could spur federal agencies to act and steer the debate in Congress.

At least some lawmakers working on drug shortage policies don't even know who is running the White House task force. Sen. Bernie Sanders (I-Vt.), the chair of the Senate health committee that passed pandemic-preparedness legislation that [includes a few minor measures](#) on drug shortages, said he hadn't spoken to anyone on the White House task force and didn't know who is in charge of it. A spokesperson for Sen. Bill Cassidy (La.), the ranking Republican on the health committee, said there has been no communication from the task force.

https://www.statnews.com/2023/08/11/drug-shortages-white-house/?utm_campaign=pharmalittle&utm_medium=email&_hsmi=270176120&hsenc=p2ANetz-PpJIFP1PFNINekTpeQrXferInj1_4l9Ro2yigortlYV58HtNcPdWLYoPukJmNtwvYMD98mUWYK3H83eXQyRKSw5mgQ&utm_content=270176120&utm_source=hs_email

Supply Chain Shortages: Tc-99m Labeled Products

2021 - 2022

- Tc-99m methylene diphosphonate
- Tc-99m pyrophosphates
- Tc-99m mebrofenin
- Tc-99m human serum albumin
- Tc-99m sulfur colloid
- Tc-99m Cardiolite/sestamibi
- Tc-99m mertiatide
- Bone imaging
- Bone/blood pool imaging
- Biliary imaging
- Blood pool imaging
- Liver, sentinel node imaging
- Heart imaging
- Renal imaging

Cold kit shortages lead to loss of patient studies
and Mo-99/Tc-99m waste.

Supply Chain Shortages: Tc-99m Labeled Products

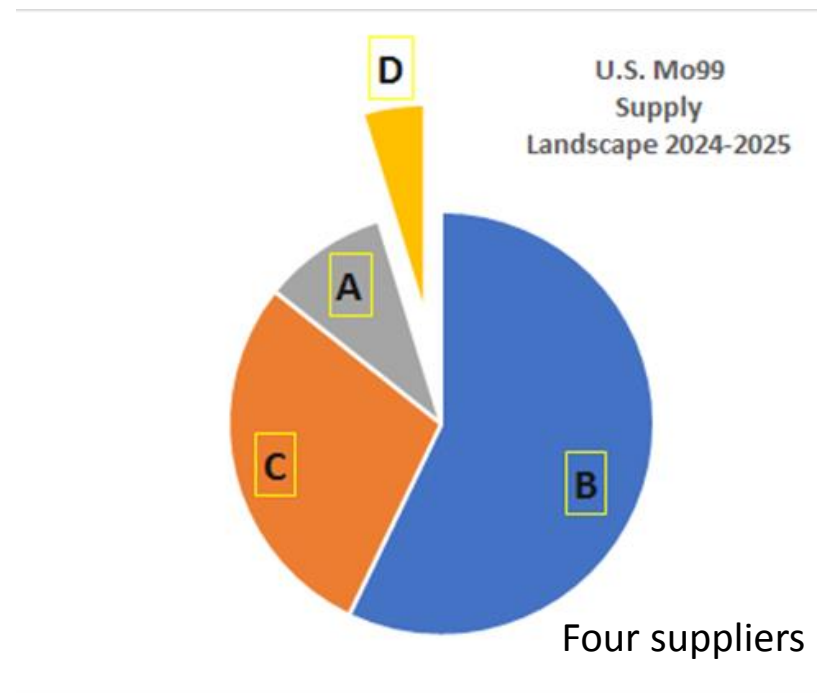
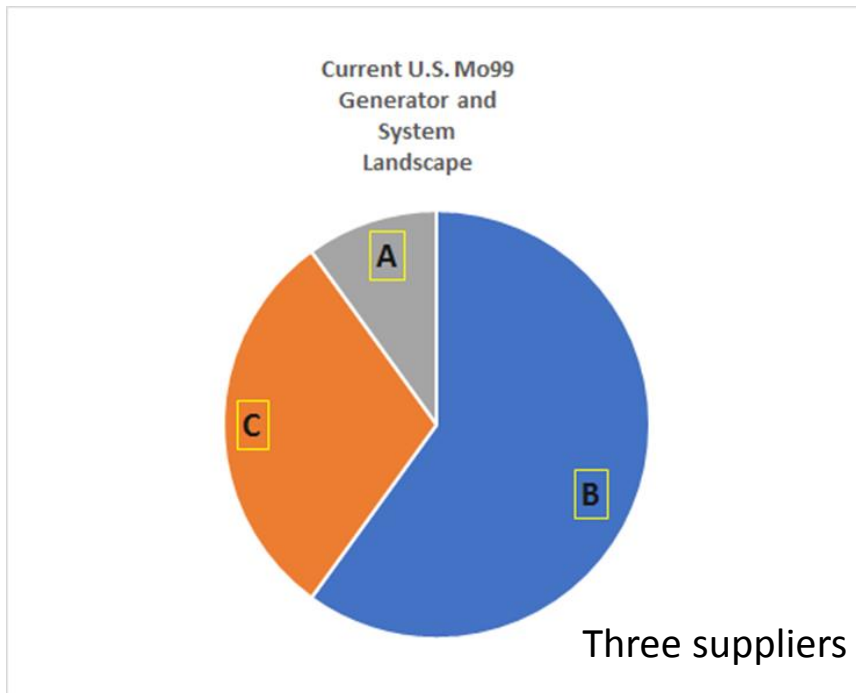
2023

- Tc-99m methylene diphosphonate
- Tc-99m pyrophosphates
- Tc-99m mebrofenin
- Tc-99m sulfur colloid
- Tc-99m Cardiolite/sestamibi
- Tc-99m mertiatide
- Supply issue
- Supply issue
- Resolved
- Resolved
- Resolved
- New generic supplier

Cold kit shortages reduced –supply of Tc99m cold kits improved.

Views of the Future Market for Mo-99

- Mo99 production, processing, generator fills should increase with new Mo99 manufacturer late 2024 and years beyond.
- A new Mo99 supplier will introduce additional Curies which will disrupt the current alignment of providers which will drive supply and economic implications.



Views of the Future Market for Mo-99

- Tc99m demand at 2% per annum growth over the next several years.
- **Priority investment needed to bring forward Tc99m imaging in oncology for prostate, breast, colon and lung cancers.**
- Theranostics is an imaging and radiotherapeutic pairing:
 - Ga68 DOTATE (Imaging) and Lu177 DOTATE (Radiotherapy)
 - Ga68 PSMA (imaging) and Lu177 PSMA (Radiotherapy)
- **Theranostics is an opportunity with Tc99m:**
 - **Tc99m imaging and Re188 radiotherapy is that theranostic pair.**

Views of the Future Market for Mo-99

- Theranostics and PET applications are leaders for investment and growth.
- Recent FDA approvals of PET imaging radiopharmaceuticals have incrementally added 200,000+ patients annually:
 - Ga68 NETSPOT neuroendocrine tumors
 - F-18 PSMA (2 cyclotron products) prostate cancer
 - Ga68 PSMA (2 generator products) prostate cancer
- New Alzheimer's drug approvals moving CMS to change reimbursement on beta amyloid imaging could add thousands of new patients for PET imaging.
- By 2025, PET imaging sites and imaging spaces could be saturated.

Views of the Future Market for Mo-99

- Should PET imaging reach saturation, Tc99m is a solution.
- Number of SPECT/CT cameras greater than PET cameras –provides greater number of imaging opportunities.
- Approval of radiotherapeutics drives imaging –including pre-treatment and post-treatment imaging.
- The promising products for oncology imaging with Tc99m:
 - Small molecule inhibitors -prostate
 - Peptides -gastrin-releasing peptide receptor (GRPR) -breast
 - Fibroblast-activating protein inhibitors -cancer-associated fibroblasts
- Pairing with a chemically homogenous nuclide for therapy: Re188
 - Primary tumors and metastasis
 - Rheumatoid arthritis

Summary

- Supply chain issues include radiopharmaceuticals which continues to be resolved.
- New entrant to Mo99 production expected in the next 24 months.
- With a flat Tc99m annual growth rate investment in new Tc99m products and theranostic pairings should be a priority drive demand for Tc99m and to match growth projected in Mo99 production.

End

Thank You

