

VI Advocacy Call

September 27, 2022





Legislative Issues

- FIND Act
- Federal Research Funding
- DOD Funding

Regulatory Efforts

- CMS
- FDA

Coverage from the Insurance/RBM companies

Radiopharmaceutical Supply Issues

- The **Facilitating Innovative Nuclear Diagnostics (FIND) Act** currently has 39 co-sponsors in the House and 4 co-sponsors in the Senate.
- SNMMI continues to host virtual meetings with congressional offices in the House and Senate
- The Coalition is laying the foundation to attach the legislation to a larger “must pass” bill before Congress adjourns
- Simultaneously, also examining new regulatory options to present to CMS

- SNMMI and the Academy of Radiology and Biomedical Imaging Research partnered to urge Congress to pass an FY22 appropriations package that supports the National Institutes of Health (NIH) and biomedical imaging, while stopping the use of harmful continuing resolutions (CRs).
- We recommended a program level of at least \$49.048 billion for the NIH base budget, which would represent an increase of \$4.1 billion over the comparable FY 2022 funding level (an increase of \$3.5 billion or 7.9% in the NIH appropriation plus funding from the 21st Century Cures Act for specific initiatives).
- SNMMI staff attended the recent Rally for Medical Research, which included 190 Capitol Hill meetings.

- Developing strategy to obtain DOD funding from Congress in FY24.
- Will identify several potential requests, which will likely include both short-term and long-term goals.
- Will meet with DOD and targeted Members of Congress to identify champions.
- Develop clear tie to service members and their families.
- Engage Administration's Cancer Moonshot team to discuss the role of NM research and investigate opportunities to be included in the President's budget.



Submitted comments to CMS:

- Medicare Physician Fee Schedule (MPFS)
- Hospital Outpatient Prospective Payment System (HOPPS)
- Continue to address members' coding and reimbursement questions thorough SNMMI Coding Corner and update website on coding & reimbursement materials.

Regulatory Efforts: FDA



- The Quality and Regulatory Compliance Task Force Chairs, Dr Cutler and Dr Dick, met with the FDA to discuss hosting a follow up workshop on inspection management and regulatory considerations for PET drugs. A second meeting with FDA is scheduled for mid October.
- The Task Force is working on submitting comments to the FDA on Draft Guidance to Expand Remote Regulatory Assessments.

- Together with ASNC, SNMMI wrote to AETNA regarding non-coverage policy for hybrid PET/CT. **AETNA reversed their non-coverage after receiving our detailed letter.**
- Met with eviCore jointly with ASNC re: coverage of MBF.
- Met with AIM/Anthem on coverage for PSMA PET for initial staging.
- Sent letters to eviCore, Cigna, and United Healthcare for appropriate coverage of PSMA PET.

- Keeping the membership informed of RP supply shortages
 - Updating RP supply webpage with shortage notices
 - Sending membership-wide emails
 - Responding to member calls
 - Monitoring SNMMI Connect



Society of Nuclear Medicine & Molecular Imaging

Value Initiative Update

September 2022

Congressional Landscape: On the Agenda

Vote on a federal funding Continuing Resolution (CR)

FDA User Fee Amendments Reauthorization

Possible Senate consideration of the *Electoral Count Reform Act of 2022*

Possible Senate vote on the *Right to Contraception Act*

Potential Senate vote on the *Respect for Marriage Act*

Potential vote on omnibus with health and/or tax riders



Government Funding: CR & Omnibus Spending Bill

- FY 2023 continuing resolution (CR) expected this week to prevent a government shut down.
- Congressional leadership has indicated the CR is likely to include:
 - supplemental funding for Ukraine;
 - a “practically clean” five-year reauthorization of the Food and Drug Administration’s (FDA) user fee programs; and
 - energy permitting reform.
- Tees up potential CR or omnibus in mid-December.
 - GOP rump group pushing for CR
 - Ongoing negotiations on policy riders

Omnibus Spending Bill: Potential Health Riders

- As the final must-pass package of the year, the omnibus (or potentially a second CR) could serve as a vehicle for several health-related riders, including, but not limited to:
 - Relief from the physician fee schedule cuts proposed by the Centers for Medicare & Medicaid Services (CMS).
 - Certain FDA-related policies that were originally included in the UFAs, but not included the clean reauthorization to be attached to the September CR.
 - The PREVENT Pandemics Act (S.3799), which aims to improve public health preparedness and response.
 - Bipartisan mental health legislation.

Other Issues: Inflation Reduction Act Implementation

- As the new year approaches, a key focus for CMS will be implementing the Inflation Reduction Act (IRA), which President Biden signed into law on August 16, 2022. The IRA includes significant prescription drug pricing measures, such as a Medicare Drug Price Negotiation Program, inflation rebates for Medicare drugs, and Part D benefit redesign.
- Initial CMS guidance is likely to focus on the Drug Price Negotiation Program, with the Secretary of Health and Human Services (HHS) selecting the first 10 Part D drugs by September 1, 2023, and the inflation rebates, which have already started accruing for Part B drugs and will begin accruing for Part D drugs in January.
- CMS will move quickly over the next several months to increase its capacity to implement and oversee the new IRA programs. CMS Administrator Chiquita Brooks-LaSure has indicated that the agency intends to open at least 100 new positions this fall.
- As CMS works to implement the new IRA programs, Republican focus on oversight of IRA implementation will likely intensify.
 - Energy & Commerce Committee Ranking Member Cathy McMorris Rodgers (R-WA) and Ways & Means Committee Ranking Member Kevin Brady (R-TX) have already begun formally questioning HHS Secretary Xavier Becerra on the implementation of the IRA and have requested regular Congressional briefings on the matter.

SNMMI Priorities: Nuclear Medicine Research Funding



Questions