# August 31, 2022\*

# Legislative Update: National Cancer Advisory Board (NCAB)

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#### I. Budget and Appropriations

Days after the fiscal year (FY) 2022 omnibus bill, which provided \$6.9 billion for the National Cancer Institute (NCI), was signed into law, the White House released the FY2023 President's Budget on March 28<sup>th</sup>. Due to the delayed finalization of the FY2022 package, administration officials have noted the President's Budget was developed using FY2021 funding levels as a base. Overall, the administration has proposed \$127.3 billion in discretionary budget authority for the Department of Health and Human services (HHS), which is a 1.4% increase relative to the FY2022 enacted level.¹ The proposed budget includes \$49 billion for NIH, \$4.3 billion above the FY2022 enacted funding level, including \$5 billion for ARPA-H. The President's budget also includes \$6.7 billion for NCI, an amount \$199 million less than the FY2022 enacted level. Final FY2022 funding levels, as well as figures from the FY2023 President's Budget proposal and the proposed House and Senate versions of the FY2023 appropriations bills, are provided in Table 1 below.

#### **House Appropriations Progress**

On June 22<sup>nd</sup>, House appropriators released a \$242.1 billion FY2023 Labor, Health and Human Services, Education, and Related Agencies (L-HHS) spending bill. It includes a total of \$47.5 billion for NIH, an increase of \$2.5 billion over FY2022 and a total \$7.4 billion for NCI, which includes \$216 million for the Cancer Moonshot, as authorized in the 21st Century Cures Act (Public Law 114-255). This would represent an overall \$466 million increase for NCI over the FY2022 enacted level. The bill also proposes \$2.75 billion for ARPA-H, an increase of \$1.75 billion, and the bill indicates appropriations will be made available provided "that the President shall appoint in the Department of Health and Human Services a director of advanced research projects for health." On June 23<sup>rd</sup>, the L-HHS subcommittee favorably reported the bill out of the subcommittee by voice vote. A week later, on June 30<sup>th</sup>, the House Committee on Appropriations approved the draft bill during a full committee mark-up with a final vote of 32-24. Republican appropriators opposed the draft bill due to the split between domestic and foreign aid and objected to controversial policy riders related to abortion and immigration enforcement.

#### Senate Appropriations Progress

Senate appropriators released the chamber's versions of all twelve FY2023 appropriations bills on July 28<sup>th</sup> and indicated that they will not hold committee markups. The bills do not have buy-in from Republicans. Senate Committee on Appropriations Ranking Member Richard C. Shelby (R-AL) stated that "these drafts fail to appropriately allocate resources to our national defense, remove important legacy riders that enjoyed broad, bipartisan support just four months ago, and are filled with poison pills." Given that the bills lack bipartisan support, they serve as a starting point in negotiations. The Senate's FY2023 L-HHS spending bill would provide \$216.1 billion to HHS, an increase of \$21 billion over FY2022 levels. It includes \$47.9 billion for NIH and \$7.2 billion for NCI; these funding levels represent an approximately \$290 million increase over FY2022 levels for NCI, including \$216 million for the Cancer Moonshot. The bill provides \$1 billion for ARPA-H, which matches the FY2022 enacted level.

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<sup>&</sup>lt;sup>1</sup> The NIH appropriation is part of the HHS discretionary budget – that is, funding for HHS agencies that is determined through the appropriations process each year. The remainder of HHS's budget is classified as mandatory, meaning that it is required through legislation. For example, the majority of Medicare funds are mandatory; under law, the federal government must provide certain services to eligible Medicare enrollees, regardless of what the cost is each year.

#### **Next Steps**

Acknowledging that negotiations on the reconciliation and semiconductor packages took precedence over appropriations during the summer months, congressional leaders stated in mid-August that they are making plans for a continuing resolution (CR) to begin FY2023. House Majority Leader Steny Hoyer (D-MD-05) noted that the CR will likely extend past the elections: "We're not going to be here in October [due to campaign schedules], so it's got to be December...a date earlier than December is not realistic."

Table 1: Summary of FY2022 and FY2023 Appropriations

	FY22 Enacted Omnibus Passed 3/15/22	PB FY23 (3/28/22)	House L-HHS Subcomm Mark 6/23/22 and Full Cmt on 6/30	Senate L-HHS Subcommittee Draft Posted 7/28
NIH	\$45 B	\$49 B (+ \$4.3 B)*	\$47.5 B (+2.5B)**	\$48 B (+2 B, as compared to \$46 B after ARPA-H transfer to NIH in FY22)
ARPA -H	\$1.0 B	\$5.0 B (+ \$4 B)	\$2.75 B (+\$1.75 B)	\$1.0 B (Flat)
NCI	\$6.9 B	\$6.7 B (- \$199M)	\$7.4 B (+ 466 M)	\$7.2 B (+ 290 M)

<sup>\*</sup>Includes \$4 B increase for ARPA-H, so non-ARPA-H increase would be \$0.3 B

## **II.** Recent Congressional Events

Sec. Becerra and MD Congressional Delegation Visit to NCI at Frederick (July 22, 2022): HHS Secretary Xavier Becerra, Sen. Ben Cardin (D-MD), Sen. Chris Van Hollen (D-MD), Rep. David Trone (D-MD-06, whose district includes NCI Frederick), and HHS Region 3 Director Dr. Ala Stanford met with NIH and NCI leadership, including from the Frederick facility, to learn about the campus's unique resources. The visitors participated in a scientific roundtable discussion with NCI Acting Director Dr. Doug Lowy; NIH Acting Director Dr. Larry Tabak; NCI Deputy Director Dr. Jim Doroshow; Dr. Jason Yovandich, Chief of the Biological Resources Branch in the Developmental Therapeutics Program (DTP); Dr. Melinda Hollingshead, Chief of the Biological Testing Branch in the DTP; and Dr. Kristin Komschlies, Deputy Director of the Office of Scientific Operations at NCI Frederick. Visitors then toured Dr. Hollingshead's lab to learn about the Patient-Derived Models Repository (PDMR).

National Brain Tumor Society Reception (July 20, 2022): Dr. Doug Lowy provided remarks at a reception to recognize Glioblastoma (GBM) Awareness Day. Other speakers included David Arons, CEO of the National Brain Tumor Society, and several patient advocates. Sen. Lindsey Graham (R-NC) and Reps. Jake Auchincloss (D-MA-04) and Salud Carbajal (D-CA-24) delivered remarks providing support of the bipartisan, bicameral resolution recognizing June 20<sup>th</sup> as National GBM Awareness Day and emphasized the importance of biomedical research. Pre-recorded remarks were provided by Sens. Ed Markey (D-MA) and Kyrsten Sinema (D-AZ), as well as Rep. Brian Mast (R-FL-18).

<sup>\*\*</sup> Does not include ARPA-H (or mandatory request for pandemic preparedness)

#### **III. Special Legislation**

## **Notable Legislative Activities**

## Honoring Our PACT Act

The President signed the Honoring Our PACT Act into law on August 10<sup>th</sup> during a White House ceremony attended by family members of veterans. Among other provisions, the bill creates a presumption that certain illnesses, including some cancers, are a result of toxic exposures experienced during veterans' previous military service and expands VA health care and benefits for veterans exposed to burn pits and other toxic substances.

# *Inflation Reduction Act of 2022*

Following months of negotiations, Democratic Senators reached an agreement on a slimmed-down reconciliation package (H.R. 5376), reflective of several of the Democrats' top legislative priorities. Reconciliation bills are aimed at "reconciling" the federal government's budget by altering mandatory funding and do not require certain parliamentary procedures, eliminating the need for bipartisan support and making them an attractive legislative vehicle for Senate leadership. Chief negotiators on the Inflation Reduction Act were Senate Majority Leader Chuck Schumer (D-NY), who favored progressive legislation that addressed climate change, social infrastructure, and tax provisions, and Sen. Joe Manchin (D-WV), who favored legislation with a narrower scope.

The Senate passed the Inflation Reduction Act of 2022 on August 7<sup>th</sup> with no Republican support and a tie-breaking vote from Vice President Kamala Harris. The House passed the legislation on August 12<sup>th</sup> in a strictly party-line vote, and the President signed the bill into law on August 16<sup>th</sup> during a White House ceremony. The legislation allows Medicare to negotiate on certain prescription drug prices, extends Affordable Care Act subsidies through 2025, provides more than \$300 billion for climate change and clean energy, imposes a 15% minimum tax on large corporations, and institutes a new 1% excise tax on stock buybacks. The bill does not contain any provisions directly related to NIH.

#### CHIPS & Science Act

On August 9<sup>th</sup>, the President signed into law the CHIPS & Science Act (HR 4346), which includes \$52 billion in funding for semiconductor manufacturing grants and semiconductor investment tax credits, as well as several science provisions relating to the National Science Foundation (NSF). It authorizes a total of \$81 billion for NSF over 5 years, including \$20 billion for a new NSF Directorate for Technology, Innovation, and Partnerships to accelerate domestic development of national and economic security technologies. It also seeks to broaden the geographic diversity of NSF grantees by setting a trajectory that would ensure traditionally underrepresented states<sup>2</sup> receive 20% of the funding from NSF by FY 2029.

# Clinical Trials

On June 29<sup>th</sup>, the Energy and Commerce Committee Subcommittee on Health held a legislative hearing to consider 11 public health bills, including <u>H.R.7845</u>, <u>NIH Clinical Trial Diversity Act</u>. Several members of the

<sup>&</sup>lt;sup>2</sup> A jurisdiction is eligible to participate in the Established Program to Stimulate Competitive Research (EPSCoR) if their most recent five-year level of total NSF funding is equal to or less than 0.75% of the total NSF budget. For more information, see <a href="https://beta.nsf.gov/funding/initiatives/epscor/epscor-criteria-eligibility">https://beta.nsf.gov/funding/initiatives/epscor/epscor-criteria-eligibility</a>.

Subcommittee agreed that diversity in clinical trials needs to be improved, and that H.R.7845 would take a step in the right direction by requiring researchers, who receive NIH funding, to submit "clear and measurable goals" in their grant applications to recruit and retain clinical trial participants who reflect the race, ethnicity, age, and sex of the patient or general U.S. population. The Energy and Commerce Committee has yet to release a mark-up schedule to further consider the NIH Clinical Trial Diversity Act.

On July 27<sup>th</sup>, Reps. Jackie Speier (D-CA) and Michael McCaul (R-TX) introduced <u>H.R.8546</u>, <u>Clinical Trial Coverage Act of 2022</u>. The legislation would require that Medicare and private insurers to cover out-of-network routine care for clinical trial participants if no in-network provider is available. The goal of the legislation is to minimize out-of-pocket costs for adult and pediatric patients on clinical trials.

#### Gabriella Miller Kids First Research Act 2.0 and ARPA-H

The Energy and Commerce Committee advanced six bipartisan health care related bills during a <u>mark-up</u> held on May 18<sup>th</sup>, including <u>H.R.623</u>, <u>Gabriella Miller Kids First Research Act 2.0</u>; <u>H.R.5585</u>, <u>Advanced Research Project Agency—Health Act</u>; and <u>H.R.7667</u>, <u>Food and Drug Amendments of 2022</u>. During committee engagements, members of Congress expressed their strong support for the Gabriella Miller Kids First Research Act, P.L. 113 — 94. The law authorized a pediatric research initiative through NIH and is set to expire in FY2024; however, the current version of H.R.623 (version that was voted out of committee) would reauthorize the efforts for 5 years and would authorize an appropriation of \$25 million per year (as compared to the current \$12.6 million per year). The bill does not propose a specific source of funding, a notable difference compared to the original Act, which leveraged unspent funds for presidential nominating conventions.

Members of Congress also expressed their strong support for ARPA-H, while voicing concerns with the current structure. There is a common consensus that the agency should be nimble and dynamic, modeling the spirit of DARPA; however, there are conflicting views regarding where the agency should be housed. Legislation has been introduced in both the House and Senate that provide prescriptive authorizing language for ARPA-H. On June 22<sup>nd</sup>, the House passed the ARPA-H Act, H.R.5585, introduced by Rep. Anna Eshoo (D-CA) by a vote of 336-85. The House bill would establish the agency within HHS and authorize \$500 million annually for FY2023-2027. The bill would require all operations to be moved from NIH to an independent division within HHS no later than 180 days after the bill is enacted into law. A manager's amendment authored by Reps. Eshoo and Brett Guthrie (R-KY), added prior to House passage, would require no more than 15% of funding be used for administrative expenses. The White House released a Statement of Administration Policy (SAP) on the bill, which supports House passage but urges an approach that would allow ARPA-H to leverage NIH's existing infrastructure. The Senate bill, S.3819, ARPA-H Act, introduced by Sens. Patty Murray (D-WA) and Richard Burr (R-NC), would establish ARPA-H within NIH but physically outside of the Washington, D.C. region. Both bills specify that the ARPA-H director is to be appointed by the President. The Senate bill was included as an amendment to the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act, S.3799) during a Senate HELP Committee mark-up in March and was advanced out of committee to be considered by the full Senate. The schedule for further consideration in the Senate is yet to be determined, and differences between the House and Senate approaches would need to be resolved.

## FDA User Fees Reauthorization

Congress is focusing on reauthorizing FDA user fee legislation - the programs were last reauthorized in 2017 and will expire at the end of September 2022 unless Congress enacts a reauthorization. This legislation allows FDA to collect user fees from developers of medical products. The reauthorizations of user fees are typically considered as "must-pass," considering the substantive funding collected to support the premarket review budget at FDA.

The House bill, H.R.7667, includes several provisions to extend user fees, and others related to diversity in clinical trials, alternatives to animal testing, and FDA's accelerated approval pathway. The Senate HELP Committee released a draft reauthorization bill on May 17<sup>th</sup> and advanced the package for the full Senate to consider, after a June 14<sup>th</sup> mark-up. There are several differences between the House and Senate bills. For instance, only the House bill includes provisions aimed to improve diversity of patients enrolled in clinical trials and to accelerate approval reform. It also incorporates provisions from the "Give Kids a Chance Act," which aims to provide the FDA with additional authorities to require preclinical and clinical studies of combinations of therapies for pediatric cancers under certain circumstances. The House passed H.R.7667 on June 8<sup>th</sup> with a vote of 392-28. The Senate bill, S.4348, includes provisions not accounted for in the House bill, such as provisions related to *in vitro* diagnostics, including laboratory developed tests; increased regulation over cosmetic products; greater authority for HHS to regulate laboratory-developed tests; and the establishment of an intraagency coordinating council to ensure the consistent and appropriate use of accelerated approval across HHS. The current Senate bill does not include the "Give Kids a Chance Act" legislation nor the provisions in the House bill addressing diversity in clinical trials enrollment. These differences will need to be resolved by Congress before the President receives a final bill to consider.

#### SBIR/STTR Reauthorization

Authorization for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, set-aside federal programs for domestic small businesses to engage in research and development, is set to expire at the end of FY2022. These programs are considered a must-pass for Congress. Both chambers are considering a number of avenues to extend the programs, including through the National Defense Authorization Act (NDAA), an amendment to a continuing resolution, or a standalone bill.

# **Recent Legislation of Interest**

The following bills were selected for inclusion in this update due to anticipated interest among NCAB members. Legislation listed below reflects proposals introduced since NCAB's last meeting in June 2022.

#### Selected Bills - 117th Congress

#### Clinical Trial Coverage Act of 2022 (H.R. 8546)

- Rep. Jackie Speier (D-CA-14) introduced this legislation on 7/27/2022.
- The bill would require out-of-network coverage for qualified individuals participating in approved clinical trials.

# Screening for Communities to Receive Early and Equitable Needed Services (SCREENS) for Cancer Act (H.R.8185)

- Sens. Tammy Baldwin (D-WI) and Susan Collins (R-ME) & Reps. Joe Morelle (D-NY-25) and Brian Fitzpatrick (R-PA-1) introduced the legislation on 6/22/2022.
- The bills would reauthorize the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), which is a CDC program that provides breast and cervical cancer screening and diagnostic services for women who are low-income, uninsured, and underinsured who do not qualify for Medicaid.

## NIH Clinical Trial Diversity Act (H.R.7845)

- Rep. Robin Kelly (D-IL-2) introduced the legislation on 5/19/2022.
- The bill would require NIH to work with clinical trial sponsors to develop clear and measurable recruitment
  and retention goals based on disease/condition prevalence as well as a rationale for specified goals and a
  recruitment plan; ensure the availability of less burdensome follow-ups during clinical trials (e.g. fewer
  follow ups, phone participation, weekend hours) to increase participation of underrepresented populations;

the bill would also direct NIH and FDA to launch a public awareness campaign across federal agencies related to research participation opportunities.

## Prostate Cancer Community Assistance, Research and Education Act of 2022 (H.R.7750)

- Reps. Greg Murphy (R-NC-3) and Bobby Rush (D-IL-1) introduced this bill on 5/12/2022.
- The legislation would establish a Prostate Cancer Coordinating Committee to monitor, coordinate and evaluate activities for prostate cancer research programs carried out by Federal agencies.

## Health Equity and Accountability Act (H.R.7585)

- Rep. Robin Kelly (D-IL-02) reintroduced this legislation on 4/26/2022.
- This bill would address social determinants of health, improve access for underserved communities, address maternal health and mental health crises, gun violence and more.

## Preventive Care Awareness Act of 2022 (H.R.7617/S.3098)

- Rep. Lisa Blunt Rochester (D-DE-At large) introduced this legislation on 4/28/2022. Sen. Amy Klobuchar (D-MN) introduced a similar proposal on 10/28/21.
- The bill aims to encourage Americans to get screened for cancer and other preventable diseases by creating a national public health education campaign, grant program, and task force for recommended preventive health care services during the COVID-19 pandemic and future pandemics.

## Childhood Cancer STAR Reauthorization Act (S.4120/H.R.7630)

- Sens. Jack Reed (D-RI), Shelley Moore Capito (R-WV), Chris Van Hollen (D-MD), and Lisa Murkowski (R-AK) & Reps. Michael McCaul (R-TX-10), Jackie Speier (D-CA-14), G.K. Butterfield (D-NC-1), and Mike Kelly (R-PA-16) introduced these bills on 4/28/2022.
- The bills are a five-year reauthorization of the Childhood Cancer STAR Act and aims to maximize discovery, and accelerate development and availability, of promising childhood cancer treatments. Provisions directed toward NCI would continue to focus on childhood cancer biobanking efforts and childhood cancer survivorship research.

#### **Additional Pending Legislation**

Many legislative proposals continue to be introduced in the 117<sup>th</sup> Congress with an emphasis on biomedical and/or cancer research and cancer care. Pending legislation listed below were selected for inclusion due to anticipated interest among NCAB members.

## Cancer and Biomedical Research

- <u>Give Kids a Chance Act (H.R.5416/S.4215, Introduced 3/8/22 & 5/12/22)</u>: This legislation would authorize the FDA to require preclinical and clinical studies of combinations of therapies for pediatric cancers under certain circumstances.
- ARPA-H Act (S.3819, Introduced 3/10/22): The bill would establish ARPA-H within NIH and the ARPA-H
  Director would be presidentially appointed for a 4-year term (up to one reappointment). The bill includes
  provisions indicating that ARPA-H may not be located on any part of the NIH campuses, nor in the
  Washington, D.C. area. The bill would also authorize "such sums as may be necessary for each of fiscal years
  2023 through 2027."
- <u>Diverse and Equitable Participation in Clinical Trials (DEPICT) Act (H.R.6584, Introduced 2/3/22)</u>: The bill
  would require the FDA to issue regulations aimed at improving reporting standards for clinical trials,
  including requiring a diversity action plan for how the sponsor will meet enrollment targets. Provisions
  would also require NIH to conduct additional community engagement and outreach, and would direct the
  Health Resources and Services Administration, in consultation with NIH, to support community health center
  grants to improve access to clinical trials in underrepresented communities.</u>

- <u>KO (Knock Out) Cancer Act (H.R. 6342, Introduced 12/23/21)</u>: The bill calls for additional funds to NIH, from FY23 FY27, in an amount equal to 25 percent of what was allocated to the NIH for cancer research in FY21 to support cancer research.
- <u>Cures 2.0 Act (H.R. 6000, Introduced 11/16/21)</u>: The legislation would establish ARPA-H within NIH, make certain telehealth expansions permanent, give recommendations for decentralizing clinical trials, provide support for research interrupted by COVID-19, aim to increase diversity in clinical trials and expand access to breakthrough therapies, and expand access to genetics-based testing, among other provisions.
- Advanced Research Project Agency—Health Act (H.R.5585, Introduced 10/15/21): This legislation would establish ARPA-H, to coordinate with the NIH on "high-need cures", defined as a "drug, biological product, or device (A) that should be prioritized to detect, diagnose, mitigate, prevent, or treat any disease or medical condition; and (B) for which incentives in commercial market are unlikely to result in the adequate or timely development of such drug, biological project, or device".
- <u>DIVERSE Trials Act (H.R.5030, Introduced 8/13/21):</u> The legislation aims to improve diversity in clinical trials and data collection for COVID-19 and future public health threats to address social determinants of health.
- <u>Jonny Wade Pediatric Cancer Research Act (H.R.3032, Introduced 5/7/21):</u> The bill would increase funding for the 10-year Pediatric Research Initiative Fund by eliminating taxpayer financing of presidential election campaigns.
- <u>Fairness to Kids with Cancer Act (H.R. 2210; Introduced 3/26/21):</u> This bill requires the share of federal funds for cancer research that supports pediatric cancer research to equal the percentage of the U.S. population that is under the age of 18.
- American Cures Act (S.962, Introduced 3/24/21): The bill would provide annual budget increases of five percent plus inflation at America's top four biomedical research agencies: the National Institutes of Health, the Centers for Disease Control and Prevention, the Department of Defense Health Program, and the Veterans Medical and Prosthetics Research Program.
- Women and Lung Cancer Research and Preventive Services Act of 2021 (S.699 & H.R.1800, Introduced 3/11/21): The proposed legislation would require the Department of Health and Human Services to conduct an interagency review of the status of women and lung cancer.
- Gabriella Miller Kids First Research Act 2.0 (H.R. 623 & S.1521, Introduced 1/28/21 & 4/29/21): The bill
  would require certain civil penalties collected from pharmaceutical, cosmetic, supplement, and medical
  device companies to be transferred to a fund at NIH for the Gabriella Miller Kids First Pediatric Research
  Program.
- Research Investment to Spark the Economy (RISE) Act (S.289 & H.R.869, Introduced 2/5/21): This legislation
  would authorize nearly \$25 billion in emergency relief funds for federal science agencies, including \$10
  billion for the NIH.
- <u>Triple-Negative Breast Cancer Research and Education Act of 2021 (H.R.113, Introduced 1/4/21):</u> This legislation would provide for research and education with respect to triple-negative breast cancer.

#### **Telehealth**

- <u>Telehealth Extension and Evaluation Act (H.R.7573, Introduced 4/26/2022):</u> The bill would extend certain telehealth services covered by Medicare and would also evaluate the impact of telehealth services on Medicare beneficiaries.
- <u>Protecting Access to Post COVID-19 Telehealth Act (H.R.366, Introduced 1/19/21):</u> The bill would allow for the expanded use of telehealth after the Coronavirus public health emergency by eliminating restrictions on telehealth services in Medicare.
- The Temporary Reciprocity to Ensure Access to Treatment (TREAT) Act (S.168 & H.R.708, Introduced 2/2/21): The bill would provide temporary licensing reciprocity for all practitioners and health professionals for all types of services (in-person and telehealth) during the COVID-19 response and for future national

- emergencies.
- Telehealth Modernization Act (S.368 & H.R. 1332, Introduced 2/23/21 & 2/26/21): The bill would revise the
  originating site requirements (geographic and site of service) after the public health emergency to mean any
  site at which the beneficiary is located, including the home of the beneficiary. It would also provide the HHS
  Secretary the authority to expand the types of practitioners who are eligible to furnish telehealth, among
  other provisions.
- <u>Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2021 (H.R. 2903 & S.1512, Introduced 4/28/21 & 4/29/21):</u> The bill would permanently remove geographic restrictions on telehealth services and provide the HHS Secretary with the permanent authority to waive telehealth restrictions, a provision currently in place due to the pandemic but on a temporary basis.

#### **Cancer Care and Healthcare Access**

- Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021 (S.1873 & H.R.1946, Introduced on 5/27/2021 & 3/16/2022): The bills propose providing for Medicare coverage and payment for multi-cancer early detection screening tests that are approved by the Food and Drug Administration and that are used to screen for cancer across many cancer types.
- Reducing Hereditary Cancer Act (S.3656/H.R.4110, Introduced 2/16/22): This bill would expand Medicare to cover screening for hereditary cancer for individuals with a family history of hereditary cancer, as well as provide Medicare coverage for risk-reducing surgeries and increased preventative screening frequency.
- <u>Cancer Patient Equity Act of 2021 (H.R.5377, Introduced 9/29/21)</u>: The bill would mandate coverage for molecular diagnostics and genetic counseling at the time of diagnosis for patients on Medicare, Medicaid & CHIP.
- Expanding Access to Palliative Care Act (S.2565, Introduced 7/29/2021): The legislation would amend the Social Security Act to provide for the testing of a community-based palliative care model.
- <u>Cancer Care Planning and Communications Act (H.R.4414, Introduced 7/13/21):</u> The legislation would amend the Social Security Act to provide for coverage of cancer care planning and coordination under the Medicare program.
- Cancer Drug Parity Act of 2021 (H.R.4385, Introduced 7/9/21): This legislation would amend the Employee Retirement Income Security Act of 1974 to require a group health plan (or health insurance coverage offered in connection with such a plan) to provide for cost sharing for oral anticancer drugs on terms no less favorable than the cost sharing provided for anticancer medications administered by a healthcare provider.
- Reducing Hereditary Cancer Act (H.R.4110, Introduced 6/23/2021): The bill would amend the Social Security Act to provide hereditary cancer genetic testing for individuals with a history of a hereditary cancer gene mutation in a blood relative or a personal or ancestral history suspicious for hereditary cancer.
- Katherine's Law for Lung Cancer Early Detection and Survival Act (H.R.3749 and S.1966, Introduced 6/8/21): This bill would expand the availability of coverage for lung cancer screenings without the imposition of cost sharing for high-risk individuals by removing limitations on screening for people over the age of 80 and for individuals who quit smoking more than 15 years ago.
- <u>Timely Access to Cancer Treatment (TACT) Act of 2021 (H.R.3258, Introduced 5/14/21):</u> The bill aims to
  improve patient access to anti-cancer oral medications and prevent any undo delay in the initiation of the
  patient's cancer treatment.
- Metastatic Breast Cancer Access to Care Act (S.1312 & H.R.3183, Introduced 4/22/21 & 5/13/21): The
  legislation would amend the Social Security Act to eliminate the waiting periods for disability insurance
  benefits and Medicare coverage for individuals with metastatic breast cancer.
- <u>Colorectal Cancer Payment Fairness Act (H.R.2594, Introduced 4/15/21):</u> This legislation would amend the Social Security Act to eliminate coinsurance requirements for certain colorectal cancer screening tests furnished under the Medicare program.

- Access to Breast Cancer Diagnosis Act of 2021 (S.1067 & H.R.5769, Introduced 4/12/21 & 10/28/21): This bill
  prohibits private health insurance plans from imposing higher cost-sharing requirements on breast cancer
  diagnostic examinations than initial breast cancer screening examinations. Diagnostic examinations are
  generally required after an initial screening detects an abnormality and typically require additional
  mammogram images (e.g., x-rays).
- <u>Jeanette Acosta Invest in Women's Health Act (S. 1063 & H.R. 2216, Introduced 3/25/21 & 3/26/21):</u> This bill establishes, or authorizes to be established, a series of programs relating to cancer screenings for women.
- Donald Payne Sr. Colorectal Cancer Detection Act of 2021 (H.R.1655 & S.2149, Introduced 3/8/21 & 6/21/21): The bill would require Medicare to cover FDA-approved blood-based screening tests for colorectal cancer.
- Promoting Resources to Expand Vaccination, Education, and New Treatments (PREVENT) for HPV Cancers
   <u>Act of 2021 (H.R. 1550, Introduced 3/3/21)</u>: The bill aims to increase human papillomavirus (HPV)
   vaccination rates and otherwise prevent and treat cervical cancer and other cancers associated with HPV.
- <u>Prostate-Specific Antigen Screening for High-risk Insured Men (PSA Screening for HIM) Act (H.R.1176, Introduced 2/18/21):</u> The bill would waive deductibles, copayments, and coinsurances for prostate cancer screenings for men who have a family history of prostate cancer or who are African American.
- Comprehensive Breast Reconstruction Act of 2021 (H.R.469, Introduced 1/25/21): The bill would provide for Medicare, Medicaid, and private health insurance coverage of certain tattooing services in connection with post-mastectomy breast reconstruction, and aligns the scope of Medicare and Medicaid coverage of such breast reconstruction with that of private health insurance.
- <u>Lung Cancer Screening Registry and Quality Improvement Act of 2021 (H.R. 107, Introduced 1/4/21):</u> The bill aims to provide funds for FY22-FY26 for grants to help entities establish free lung cancer screening registries and requires registries to be interoperable in order to receive federal funds.