State of Infrastructure and Reconciliation Negotiations

After months of protracted backdoor negotiations and lack of public progress, Democratic lawmakers appeared to make a breakthrough on Thursday, October 28, 2021. President Biden announced a framework for a $1.75 trillion reconciliation deal and the House Rules Committee released its 1,684 page proposed legislative text for H.R. 5376, the Build Back Better Act. However, there are still significant hurdles that must be overcome and Democratic lawmakers face the reality that this proposed bill text will almost certainly be modified significantly before it becomes law. Moderate Senators Joe Manchin (D-WV) and Kyrsten Sinema (D-AZ) declined to endorse the White House’s proposed framework, leaving House progressives increasingly frustrated and concerned that their legislative priorities will be scaled back even further. Despite Speaker of the House Nancy Pelosi’s (D-CA) efforts to hold a vote on the bipartisan infrastructure bill that same evening, progressives remained steadfast in their demands that the infrastructure bill be advanced alongside the reconciliation package and blocked the vote. The next weeks will be critical as the White House seeks to nail down support from moderate Senators in order to unlock the rest of its largely social agenda, but continued progress on the design of the legislation signals that Democrats are likely on track to advance the bipartisan infrastructure bill and a modified version of the reconciliation package by the end of the year.

The White House framework includes the following overviews of policy and offset proposals, saying that “The plan is more than fully paid for by asking the wealthiest Americans and most profitable corporations to pay their fair share. It does not raise taxes on small business and anyone making less than $400,000 per year.”

<table>
<thead>
<tr>
<th>Policy</th>
<th>$ billion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child Care and Preschool</td>
<td>400</td>
</tr>
<tr>
<td>Home Care</td>
<td>150</td>
</tr>
<tr>
<td>Child Tax &amp; Earned Income Tax Credits</td>
<td>200</td>
</tr>
<tr>
<td>Clean Energy and Climate Investments</td>
<td>555</td>
</tr>
<tr>
<td>ACA Credits, Including in Uncovered States</td>
<td>130</td>
</tr>
<tr>
<td>Medicare Housing</td>
<td>35</td>
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<tr>
<td>Housing</td>
<td>150</td>
</tr>
<tr>
<td>Higher Ed and Workforce</td>
<td>40</td>
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<tr>
<td>Equity &amp; Other Investments</td>
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</tr>
<tr>
<td><strong>Total</strong></td>
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</tr>
<tr>
<td><strong>Immigration</strong></td>
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</tbody>
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What’s in the White House Framework and Build Back Better Act?

The White House Framework of the Build Back Better Act, released on October 28, 2021 contains a number of health and social spending provisions that will likely impact both patients and providers across the U.S. Below you will find brief notes on what is included in the framework:

- Strengthen the Affordable Care Act and reduce premiums for 9 million Americans. The framework will reduce premiums for more than 9 million Americans who buy insurance through the Affordable Care Act Marketplace by an average of $600 per person per year. For example, a family of four earning $80,000 per year would save nearly $3,000 per year (or $246 per month) on health insurance premiums. Experts predict that more than 3 million people who would otherwise be uninsured will gain health insurance.

- Close the Medicaid coverage gap, leading 4 million uninsured people to gain coverage. The Build Back Better framework will deliver health care coverage through Affordable Care Act premium tax credits to up to 4 million uninsured people in states that have locked them out of Medicaid. A 40-year old in the coverage gap would have to pay $450 per month for benchmark coverage – more than half of their income in many cases. The framework provides individuals $0 premiums, finally making health care affordable and accessible.

- Expand Medicare to cover hearing benefits. Only 30% of seniors over the age of 70 who could benefit from hearing aids have ever used them. The Build Back Better framework will expand Medicare to cover hearing services, so that older Americans can access the affordable care they need.

After the announcement of the proposed framework deal, House Democrats released their own legislative text based on the proposed framework. While this legislation will not be the final package, it serves as a good base to start negotiations with the Senate. Below you will find brief notes on what is included in the legislation:

- SUBTITLE E—AFFORDABLE HEALTHCARE COVERAGE
  - Section 30601. Ensuring Affordability of Coverage for Certain Low-Income Populations. This section provides temporary enhanced Affordable Care Act (ACA) Marketplace cost-sharing reduction assistance to individuals with household incomes below 138 percent of the federal poverty level (FPL) for calendar years 2022 through 2025. Consistent with current law, individuals who
qualify for government sponsored insurance would not qualify for the temporary cost-sharing assistance.

- Section 30602. Establishing a Health Insurance Affordability Fund. This section makes available $10 billion annually to states for calendar years 2023 through 2025, providing the option for states to establish a state reinsurance program or use the funds to provide financial assistance to reduce out-of-pocket costs. The section also requires the Centers for Medicare and Medicaid Services (CMS) to establish and implement a temporary reinsurance program in states that are not expending amounts under the State plan for all individuals described in section 1902(a)(10)(A)(i)(VIII).

- SUBTITLE F—MEDICAID
  - Section 30721. Investments to Ensur e Continued Access to Health Care for Children, Pregnant Individuals, and Other Individuals. This section makes several improvements to expand access and continuity of care to some of our most vulnerable citizens, including low-income children and new moms. It requires that state Medicaid programs provide 12 months of continuous Medicaid and CHIP eligibility to postpartum women; 12 months of continuous eligibility to children enrolled in Medicaid and CHIP; and coverage to justice-involved individuals 30 days prior to their release. It also allows states to smoothly transition out of the coverage requirements put in place during the public health emergency. This section also permanently extends the state option to simplify children’s enrollment in Medicaid and CHIP. Finally, it authorizes a new option for states to provide coordinated care for pregnant and postpartum women through a health home.
  - Section 30742. Ensuring Accurate Payments to Pharmacies Under Medicaid. This section ensures Medicaid accurately reimburses for prescription drugs.

- SUBTITLE I—PUBLIC HEALTH
  - Section 31002. Funding for Health Center Capital Grants. This section provides $1 billion in funding to award grants and enter into cooperative agreements for capital projects to health centers and federally qualified health centers look-alikes. Funds can be used for health center facility alteration, renovation, remodeling, expansion, construction, and other capital improvement costs.

For the House Rules Committee text of the Build Back Better Act click [HERE](#).
For the Build Back Better Act Section by Section click [HERE](#).
For the Build Back Better Framework Fact Sheet click [HERE](#).
For the Build Back Better Framework click [HERE](#).

**Drug Pricing Update**

Noticeably missing from both the White House Framework and the Build Back Better Act text is a key piece of policy that Democrats have been campaigning on since the lead-up to the 2020 election: a drug pricing overhaul. Democrats are said to have left the key provision out of both of proposals in order to appease House and Senate moderates such as Rep. Scott Peters (D-CA) and Senator Kyrsten Sinema (D-AZ).
However, despite drug pricing being dropped, it does not mean that all is lost for inclusion in a final reconciliation bill. Over the weekend, Democratic Senators including Chris Murphy (D-CT), Elizabeth Warren (D-MA), Bernie Sanders (I-VT), Amy Klobuchar (D-MN), and Mark Kelly (D-AZ) met with House Energy and Commerce Chair Frank Pallone (D-NJ) in order to come to a deal that would satisfy both wings of the party. The latest effort includes Medicare negotiation and rebates and a redesign of Medicare Part D. It will likely stop short of H.R. 3, the House Democrats expansive drug pricing bill, but will likely make significant steps along the same parameters.

There is optimism that a deal will be reached to be included in the reconciliation bill and PRG will continue to provide updates on the issue as necessary.

**Appropriations Update**

On October 18, 2021, Senator Patrick Leahy (D-VT), Chair of the Senate Appropriations Committee, released the remaining nine Fiscal Year 2022 Appropriations Bills. These final bills included both the FY2022 Defense spending bill that houses the Peer Review Cancer Research Program, and the FY2022 Health and Human Services spending bill that includes a majority of the Democrats’ health related priorities. Now that these bills have officially been released, negotiations between the House of Representatives and the Senate will commence in order to produce final legislation that will fund the government through FY2022. Appropriators have until a December 3rd deadline before the government runs out of money. Should appropriators not reach a deal by then, another continuing resolution will be needed. Below you will find a cancer and research related report language comparison between FY2022 House and FY2022 Senate Report Language.

**Peer Review Cancer Research Program**

**Senate**

Peer-Reviewed Cancer Research Programs.—The Committee recommends $130,000,000 for the peer-reviewed breast cancer research program, $75,000,000 for the peer-reviewed prostate cancer research program, $40,000,000 for a peer-reviewed melanoma research program, $15,000,000 for the peer-reviewed ovarian cancer research program, $17,500,000 for a peer-reviewed rare cancers research program, and $130,000,000 for the peer-reviewed cancer research program that would research cancers not addressed in the aforementioned programs currently executed by the Department of Defense.

The funds provided in the peer-reviewed cancer research program are directed to be used to conduct research in the following areas: bladder cancer; blood cancers; brain cancer; endometrial cancer, esophageal cancer; kidney cancer; liver cancer; lung cancer; lymphoma, mesothelioma, metastatic cancer, neuroblastoma; pancreatic cancer; pediatric brain tumors; pediatric, adolescent, and young adult cancers; stomach cancer; and Von Hippel-Lindau syndrome.

The funds provided under the peer-reviewed cancer research program shall be used only for the purposes listed above. The Committee directs the Assistant Secretary of Defense (Health Affairs) to provide a report not later than 18 months after the enactment of this act to the congressional
defense committees on the status of the peer-reviewed cancer research program. For each research area, the report should include the funding amount awarded, the progress of the research, and the relevance of the research to servicemembers.

House

The Committee recommends $150,000,000 for the peer-reviewed breast cancer research program, $110,000,000 for the peer-reviewed prostate cancer research program, $45,000,000 for the peer-reviewed ovarian cancer research program, $50,000,000 for the peer reviewed kidney cancer research program, $20,000,000 for the peer reviewed lung cancer research program, $40,000,000 for the peer reviewed melanoma research program, $15,000,000 for the peer-reviewed pancreatic cancer research program, $17,500,000 for the peer-reviewed rare cancer research program, and $115,000,000 for the peer-reviewed cancer research program that would cancers not addressed in the aforementioned programs currently executed by the Department of Defense.

The funds provided in the peer-reviewed cancer research program are directed to be used to conduct research in the following areas: bladder cancer; blood cancers; brain cancer; colorectal cancer; endometrial cancer; esophageal cancer; germ cell cancers; head and neck cancer; liver cancer; lymphoma; mesothelioma; metastatic cancers; neuroblastoma; pediatric brain tumors; pediatric, adolescent, and young adult cancers; sarcoma; stomach cancer; thyroid cancer; and Von Hippel-Lindau cancer. The inclusion of the individual rare cancer research program shall not prohibit the peer-reviewed cancer research program from funding the previously mentioned cancers or cancer subtypes that may be rare by definition.

The funds provided under the peer-reviewed cancer research program shall be used only for the purposes listed above. The Committee directs the Assistant Secretary of Defense for Health Affairs to provide a report not later than 180 days after the enactment of this Act to the congressional defense committees on the status of the peer-reviewed cancer research program. For each research area, the report shall include the funding amount awarded, the progress of the research, and the relevance of the research to servicemembers and their families.

The Committee commends the Department of Defense for ensuring that projects funded through the various peer-reviewed cancer research programs maintain a focus on issues of significance to military populations and the warfighter. This includes promoting collaborative research proposals between Department of Defense researchers and non-military research institutions. These collaborations leverage the knowledge, infrastructure, and access to clinical populations that the partners bring to the research effort. Additionally, promoting these collaborations provides a valuable recruitment and retention incentive for military medical and research personnel. The Committee encourages the Commanding General, United States Army Medical Research and Development Command, to continue to emphasize the importance of these collaborations between military and non-military researchers throughout the peer-review process.

Childhood Cancer STAR Act

Senate
Childhood Cancer STAR Act.—The Committee includes $30,000,000, the same as the fiscal year 2021 enacted level, for continued implementation of the Childhood Cancer Survivorship, Treatment, Access, and Research [STAR] Act to expand existing biorepositories for childhood cancer patients enrolled in NCI-sponsored clinical trials to collect and maintain relevant clinical, biological, and demographic information on all children, adolescents, and young adults with cancer. The Committee has also included sufficient funding to carry out childhood cancer survivorship research and programs as authorized in the STAR Act, such as developing best practices for the treatment of late effects of childhood cancers, improving collaboration among providers so that doctors are better able to care for this population as they age, and creating innovative models of care for childhood cancer survivors. The STAR Act calls on NCI to ensure that all applicable study sections, committees, advisory groups, and panels at NCI include one or more qualified pediatric oncologists, as appropriate. Therefore, the Committee requests an update on the actions NCI has taken to ensure appropriate pediatric cancer expertise is included on all panels.

House

Childhood Cancer STAR Act.—The Committee includes no less than $30,000,000, the same as the fiscal year 2021 enacted level, for continued implementation of sections of the Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act to expand existing biorepositories for childhood cancer patients enrolled in NCI-sponsored clinical trials to collect and maintain relevant clinical, biological, and demographic information on children, adolescents, and young adults, with an emphasis on selected cancer subtypes (and their recurrences) for which current treatments are least effective. Funding provided this year will allow NCI to continue to conduct and support childhood cancer survivorship research as authorized in the STAR Act.

Deadliest Cancers

Senate

Deadliest Cancers.—The Recalcitrant Cancer Research Act [RCRA] of 2012 (Public Law 112–239) focuses on cancers with a five-year survival rate below 50 percent, which account for 44 percent of all U.S. cancer deaths. While advances in some cancers have made it possible to reduce the overall rate of cancer deaths over the last two decades, there has been limited progress reducing mortality for these diseases. For fiscal year 2020, Congress directed NCI to develop a scientific framework using the process outlined in the RCRA for gastric, esophageal, and gastroesophageal junction cancers. In this regard, the Committee notes that NCI has taken an important step by receiving approval for a Program in Origins of Gastroesophageal Cancers from the National Cancer Advisory Board and Board of Scientific Advisors. The Committee directs NIH to provide a status update and timeline for the scientific framework within 60 days of enactment of this Act. Alongside the research and advocacy communities, the Committee also expects to be kept informed of NCI’s efforts on pancreatic, lung, glioblastoma, esophageal and stomach cancers. The Committee urges NCI to consider a similar process for primary liver cancer, including cholangiocarcinoma. Given the toll all recalcitrant cancers exact on society and the lack of diagnostic and treatment resources currently available to help patients, the Committee also requests NCI to identify in the fiscal year 2023 CJ its research goals to advance progress for the deadliest cancers: brain, esophagus, liver, lung, ovary, pancreas, stomach and mesothelioma.
Deadliest Cancers. — The Recalcitrant Cancer Research Act (RCRA) of 2012 (P.L. 112–239) focuses on cancers with a five-year survival rate below 50 percent, which account for 44 percent of all U.S. cancer deaths. While advances in some cancers have made it possible to reduce the overall rate of cancer deaths over the last two decades, there has been limited progress reducing mortality for these diseases. For fiscal year 2020, Congress directed NCI to develop a scientific framework using the process outlined in the RCRA for stomach and esophageal cancers. The Committee notes that in addition to the ongoing framework development, NCI has also developed and received approval from its Board of Scientific Advisors to launch a Program in Origins of Gastroesophageal Cancers. Alongside the research and advocacy communities, the Committee appreciates NCI’s efforts to keep the Committee apprised of continued research progress informed by the pancreatic, lung, glioblastoma, esophageal, and stomach cancer frameworks. The Committee encourages NCI to consider a similar process, as appropriate, for primary liver cancer, including cholangiocarcinoma. Given the toll all recalcitrant cancers exact on society and the lack of diagnostic and treatment resources currently available to help patients, the Committee also requests an update in the fiscal year 2023 Congressional Budget Justification on research goals to advance progress for the deadliest cancers (brain, esophagus, liver, lung, ovary, pancreas, stomach and mesothelioma).

Glioblastoma [GBM]. — Glioblastomas are recalcitrant cancers with less than a 5 percent 5 year relative survival rate, and the average survival time from diagnosis has improved by only 6 months over the last 30 years. To date, there have only been five drugs and one medical device approved by the FDA for the treatment of GBM. With prior Congressional investment in NCI programs, Glioblastoma is now one of the most molecularly characterized cancers. This investment has resulted in a new and promising understanding of these tumors, including identified clinical strategies and agents, trial designs, and technologies in the imaging and pathology space. The Committee commends NCI for its establishment and initial implementation of the GBM Therapeutics Network [GTN]. The GTN’s cross cutting teams’ capability of preclinical and early-phase clinical trials necessary to rapidly evaluate potential treatments, including but not limited to 87 drugs, biologics, radiation, and devices, is what is needed to continue to advance toward cures and improved quality of life. Given this initial progress, the Committee urges NCI to continue its implementation of the GTN so that this program is able to rapidly launch clinical trials that speed access to promising qualified treatments to patients consistent with NCI’s Glioblastoma Working Group recommendations in 2019.

House

Glioblastoma (GBM). — The Committee commends NCI for its establishment and initial implementation of the GBM Therapeutics Network (GTN). The GTN’s cross-cutting teams’ capability of preclinical and early-phase clinical trials necessary to rapidly evaluate potential treatments, including but not limited to 87 drugs, biologics, radiation, and devices, is what is needed to continue to advance toward cures and improved quality of life. The Committee urges
NCI to continue to implement the GTN so that this program can rapidly launch clinical trials that speed access to promising qualified treatments to patients consistent with NCI’s Glioblastoma Working Group recommendations in 2019.

**Gabriella Miller Kids First Research Act**

**Senate**

Gabriella Miller Kids First Research Act.—The Committee includes $12,600,000 to continue its support for the Gabriella Miller Kids First Pediatric Research Program.

**House**

Gabriella Miller Kids First Pediatric Research Program.—The Committee recognizes that pediatric cancer is a leading cause of death among children and is still poorly understood. Childhood cancer also has lasting negative health effects on children who do survive due to the high levels of toxicity associated with treatment. The Committee acknowledges that the Gabriella Miller Kids First Pediatric Research Program enables researchers to uncover new insights into the biology of childhood disease. Since its inception, Kids First has initiated the Gabriella Miller Kids First Data Resource Center, which is a comprehensive data resource for research and patient communities meant to advance discoveries. The Committee recognizes the progress that the Program has made towards understanding childhood cancer and disease and provides $12,600,000 to support pediatric research as authorized by the Gabriella Miller Kids First Research Act (P.L. 113–94).

**Cancer Data Sharing**

**Senate**

Cancer Data Sharing.—The Committee applauds the NIH for creating the National COVID Collaborative—a commercial solution leveraged to create a centralized and secure database that researchers in public and private institutions alike can use to study COVID–19 and identify potential treatments as the pandemic continues to evolve. The Committee encourages NIH to continue pursuing similar approaches to other critical areas of research, including cancer, where data sharing continues to be a barrier to progress. The Committee commends NCI’s data sharing efforts through the Cancer Moonshot, the Childhood Cancer Data Initiative, and other programs, and requests an update in the fiscal year 2023 CJ on NCI’s continued progress toward adopting a centralized, secure, national platform to share cancer research data to drive new insights and speed research efforts across the country.

**House**

Cancer Data Sharing.—The Committee applauds NIH for creating the National COVID Collaborative (N3C), a commercial solution leveraged to create a centralized and secure database that researchers in academic institutions can use to study COVID–19 and identify potential treatments. The Committee encourages NIH to continue pursuing similar approaches to other critical areas of research, including cancer, where data sharing continues to be a barrier to progress. The Committee commends NCI’s data sharing efforts through the Cancer Moonshot,
the Childhood Cancer Data Initiative, and other programs, and requests an update in the fiscal year 2023 Congressional Budget Justification on NCI’s continued progress toward adopting a centralized, secure, national platform to share cancer research data to drive new insights and speed research efforts across the country.

**Cancer Immunotherapy**

**Senate**

Cancer Immunotherapy.—The Committee recognizes that NCI supported research exploring cancer immunology, cancer immunotherapy and cancer vaccines that started years before the emergence of COVID–19 contributed to the rapid development of COVID–19 treatments and vaccines. Applying lessons learned from COVID–19 therapeutic development to cancer immunotherapy clinical trials has the potential to greatly improve treatment options and outcomes for cancer patients. Therefore, the Committee encourages NCI to accelerate the translation of discoveries in cancer immunotherapy by means of the same innovations used to develop COVID–19 treatments and vaccines. This should include expediting consideration and support for potential high-impact cancer immunotherapy clinical trials, and for correlative science based on planned and ongoing clinical trials.

**House**

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**Childhood Cancer Data Initiative**

**Senate**

Childhood Cancer Data Initiative.—The Committee includes the full budget request for this fiscal year of $50,000,000 for the Childhood Cancer Data Initiative, the same level as in fiscal year 2021, which will facilitate a connected data infrastructure and integrate multiple data sources to make data work better for patients, clinicians, and researchers.

**House**

Childhood Cancer Data Initiative (CCDI).—The Committee includes $50,000,000 for the second year of the CCDI, as proposed in the fiscal year 2022 budget request. The development of new therapies is important to finding a cure for childhood cancers, many of which have not seen new therapies in decades. The Committee commends NCI for its support of the establishment of the
National Childhood Cancer Registry as a part of the Childhood Cancer Data Initiative. Data sets for childhood cancers are often small and spread out across institutions or aggregated into Statewide or Federal registries where the particulars of incidence rate by cancer are lost. Traditional disease registries such as the Federally-supported Surveillance Epidemiology and End Results Program (SEER) and the CDC’s National Program for Cancer Registries (NPCR) aggregated into the U.S. Cancer Statistics (USCS) do not yet include all of the data relevant to cutting-edge pediatric cancer research, such as the molecular characteristics of each child’s cancer. The committee urges NCI to use available resources to ensure all relevant data needed to assist childhood cancer researchers in developing innovative treatments for childhood cancer are made available through the National Childhood Cancer Registry and other integrated CCDI programs. The Committee requests an update on the progress made to increase available childhood cancer data in the fiscal year 2023 Congressional Budget Justification.

**Cancer Moonshot**

**Senate**

No direct language for Cancer Moonshot.

**House**

Cancer Moonshot.—The Committee directs NIH to transfer $194,000,000 from the NIH Innovation Account to NCI to support the Cancer Moonshot initiative. These funds were authorized in the 21st Century Cures Act (P.L. 114–255).

**Cancer Vaccines**

**Senate**

No direct language for cancer vaccines.

**House**

Cancer Vaccines.—The Committee recognizes that the success of the COVID–19 vaccines—which became available less than a year from the outset of the pandemic and now deliver up to 95 percent protection rates—is due to the fact that these vaccines were built on messenger RNA technology, or mRNA, an approach that had been initiated for cancer research. While most traditional vaccines use inactivated viruses to stimulate an immune response, a complicated process that can take several years, mRNA vaccines use the body’s own genetic material, and can be developed much more quickly. The Committee understands that with further research, mRNA cancer vaccines could potentially be among the most cost-effective methods of preventing recurrences and the high costs of cancer care. The Committee commends the work of NCI, which is currently supporting multiple research projects focusing on the use of mRNA vaccines, and encourages its continued commitment to moving the field forward for mRNA vaccines as an approach for cancer immunotherapy treatment and prevention. To better understand NCI’s progress to date and the potential of new breakthroughs with mRNA, the Committee requests an update in the fiscal year 2023 Congressional Budget Justification on NCI’s work on mRNA vaccines, noting existing barriers or challenges, if any.
Telehealth-based Services for Vulnerable Patients

Senate

Telehealth-based Services for Vulnerable Patients.—The Committee recognizes that COVID–19 has significantly exacerbated the physical, emotional, and mental toll on cancer patients and families, and providing clinical and psychosocial services to address these challenges is an essential component of comprehensive cancer care. Cancer centers across the United States pivoted to providing support and services via telehealth, yet the extent to which all patients and families had equitable access to these services is unknown. The Committee urges NCI to continue to support research on the delivery and evaluation of telehealth-based clinical and psychosocial services, particularly among vulnerable patients and disadvantaged communities.

House

Telehealth-Based Services for Vulnerable Patients.—The COVID–19 pandemic significantly exacerbated the physical, emotional, and mental toll on cancer patients and families. Providing clinical and psychosocial services to address these challenges is an essential component of comprehensive cancer care across a patient’s lifespan. Cancer centers across the U.S. quickly pivoted to providing patient support and related health services by telehealth, although the extent to which all patients and families had equitable access to these services and the impact for those who have attended them is unknown. For example, both rural and urban underserved areas disproportionately lack reliable home-based Internet service, creating barriers for patients to access telehealth-based clinical and psychosocial support services. To overcome this, many cancer centers provided technical assistance to patients during the pandemic to support their use of telehealth. The Committee urges NCI to increase its support of research on the delivery and evaluation of telehealth-based clinical and psychosocial services, particularly among vulnerable patients and disadvantaged communities. This enhanced research would lead to evidence-based best practices, so that all patients can benefit from the most effective cancer care at all stages of the disease.

PRG will continue to monitor the situation and provide updates as necessary.

Surprise Billing Update

On October 1, 2021, the Biden administration issued a new rule that resolves one of the trickiest issues for the administration’s surprise billing ban: how dispute resolution between out-of-network providers and insurers will work. The rule details how there must be a 30-day open negotiation period to determine the rate. If that does not result in a determined rate, the two groups can go to arbitration, where arbitrators will determine a price based on what the insurer pays other providers for the same service in the area. The rule also requires both providers and hospitals to give an estimate of cost of services to patients that are uninsured.

This rule was met with scrutiny from providers as they feel that the rule arbitrarily favors insurers, while insurers stated that they were encouraged by the rule. Additionally, the Coalition
Against Surprise Medical Billing – a group that includes more than 30 employer, union and health plan groups - sent a letter to top Biden officials urging them to formalize the arbitration process.

**Up to Date List of Drug Related Legislation for the 117th Congress**

- **S.3080** – This bill, introduced by Senator Tina Smith (D-MN) on October 27, 2021, amends 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 health care provider.

- **H.R.5632** – This bill, introduced by Rep. Kurt Schrader (D-OR) on October 19, 2021, establishes a statutory definition for long-term care pharmacy under the Medicare prescription drug benefit.

- **H.R.5576** – This bill, introduced by Rep. Susan Wild (D-PA) on October 12, 2021, allows states to apply the requirements of the Medicaid Drug Rebate Program to covered outpatient drugs under the Children's Health Insurance Program (CHIP).

- **H.R.5463** – This bill, introduced by Rep. Matthew Rosendale (R-MT) on September 30, 2021, increases reporting requirements and transparency requirements in the 340B Drug Pricing Program, and for other purposes.

- **H.R.5237** – This bill, introduced by Rep. Scott Peters (D-CA) on September 10, 2021, amends titles XI, XVIII, and XIX of the Social Security Act to lower prescription drug prices in the Medicare and Medicaid programs, to improve transparency related to pharmaceutical prices and transactions, to lower patients' out-of-pocket costs, and to ensure accountability to taxpayers, and for other purposes.

- **S. 2595** - Drug Shortages Prevention and Quality Improvement Act
  This bill, introduced by Senator Ben Cardin (D-MD) on August 4, 2021, address prescription drug shortages and improve the quality of prescription drugs, and for other purposes.

- **H.R. 4991** - Affordable Pricing for Taxpayer-Funded Prescription Drugs Act of 2021
  This bill, introduced by Rep. Peter DeFazio (D-OR) on August 10, 2021, requires persons who undertake federally funded research and development of a biomedical product or service to enter into reasonable pricing agreements with the Secretary of Health and Human Services, and for other purposes.

- **H.R. 5099** - Lowering Medicare Premiums and Prescription Drug Costs Act
  This bill, introduced by Rep. Bradley Schneider (D-IL) on August 24, 2021, amends title XVIII of the Social Security Act to move Medicare cost-sharing benefits from Medicaid to Medicare, and for other purposes.

- **H.R. 3662**
This bill, introduced by Rep. Morgan Griffith (R-VA) on June 1, 2021, amends the Federal Food, Drug, and Cosmetic Act to ensure patients have access to certain urgent-use compounded medications, and for other purposes.

- **H.R. 3761**
  This bill, introduced by Rep. Mike Gallagher (R-WI) on June 8, 2021, amends the Federal Food, Drug, and Cosmetic Act to establish a time-limited provisional approval pathway, subject to specific obligations, for certain drugs and biological products, and for other purposes.

- **H.R. 3927 and S. 2082**
  This bill, introduced by Rep. Buddy Carter (R-GA) and Sen. Tim Scott (R-SC) on June 16, 2021, mitigates drug shortages and provide incentives for maintaining, expanding, and relocating the manufacturing of active pharmaceutical ingredients, excipients, medical diagnostic devices, pharmaceuticals, and personal protective equipment in the United States, and for other purposes.

- **S. 2257**
  This bill, introduced by Sen. Jacky Rosen (D-NV) on June 24, 2021, provides Federal support for nonprofit generic and essential medicine and device manufacturers to increase the availability of drugs and devices in order to reduce drug or device shortages and drug and device costs.

- **S. 2304**
  This bill, introduced by Sen. Dick Durbin (D-IL) on June 24, 2021, amends title XI of the Social Security Act to require that direct-to-consumer advertisements for prescription drugs and biological products include an appropriate disclosure of pricing information.

- **H.R. 4121**
  This bill, introduced by Rep. Jody Arrington (R-TX) on June 24, 2021, codifies a final rule issued by the Secretary of Health and Human Services relating to fraud and abuse and the removal of safe harbor protection for certain drug rebates, and for other purposes.

- **H.R. 4158**
  This bill, introduced by Rep. Bobby Rush (D-IL) on June 24, 2021, amends titles XVIII and XIX of the Social Security Act to eliminate cost sharing with respect to coverage of insulin as a covered part D drug under the Medicare program or as a covered outpatient drug under the Medicaid program.

- **H.R. 4287**
  This bill, introduced by Rep. Greg Murphy (R-NC) on June 30, 2021, directs the Comptroller General of the United States to conduct a study on how direct-to-consumer pharmaceutical advertising negatively impacts drug costs to consumers, and for other purposes.

- **S. 1644**
  This bill, introduced by Sen. Mike Braun (R-IN) on May 13, 2021, amends the Federal Food, Drug, and Cosmetic Act to establish a time-limited provisional approval pathway,
subject to specific obligations, for certain drugs and biological products, and for other purposes.

- **S. 1645**
  This bill, introduced by Sen. Mike Braun (R-IN) on May 13, 2021, provides for an accelerated approval pathway for certain drugs that are authorized to be lawfully marketed in other countries.

- **H.R. 3203**
  This bill, introduced by Rep. Doris Matsui (D-CA) on May 13, 2021, enables certain hospitals that were participating in or applied for the drug discount program under section 340B of the Public Health Service Act prior to the COVID-19 public health emergency to temporarily maintain eligibility for such program, and for other purposes.

- **S. 1773**
  This bill, introduced by Sen. Bob Casey (D-PA) on May 20, 2021, amends title XI of the Social Security Act to establish internet website-based dashboards to allow the public to review information on spending for, and utilization of, prescription drugs and biologicals covered under the Medicare and Medicaid programs.

- **H.R. 3437**
  This bill, introduced by Rep. Bobby Rush (D-IL) on May 20, 2021, requires the Secretary of Health and Human Services to guarantee BioBonds in order to provide funding for loans to eligible biomedical companies and universities to carry out clinical trials approved by the Food and Drug Administration, and for other purposes.

- **H.R. 2344**
  This bill, introduced by Rep. Tim Ryan (D-OH) on April 1, 2021, requires the use of prescription drug monitoring programs.

- **H.R. 2484**
  This bill, introduced by Rep. Katie Porter (D-CA) on April 13, 2021, amends title XXVII of the Public Health Service Act and title XVIII of the Social Security Act to require pharmacies to disclose any differential between the cost of a prescription drug based on whether certain individuals use prescription drug coverage to acquire such drug, and for other purposes.

- **S. 1124**
  This bill, introduced by Sen. Marsha Blackburn on April 14, 2021, preserves non-interference under the Medicare part D Prescription Drug Benefit program.

- **H.R. 2608**
  This bill, introduced by Rep. Peter Welch (D-VT) on April 15, 2021, amends title XVIII of the Social Security Act to ensure equal access of Medicare beneficiaries to community pharmacies in underserved areas as network pharmacies under Medicare prescription drug coverage, and for other purposes.
This bill, introduced by Rep. Josh Gottheimer (D-NJ) on April 16, 2021, amends the Internal Revenue Code of 1986 to restore the amount of the orphan drug tax credit, and for other purposes.

- **H.R. 2706**
  This bill, introduced by Rep. Katie Porter (D-CA) on April 20, 2021, amends title XVIII of the Social Security Act to require drug manufacturers to pay a Medicare part B rebate for certain drugs if the price of such drugs increases faster than inflation.

- **H.R. 2829 and S. 1323**
  This bill, introduced by Rep. Peter Welch (D-VT) and Sen. Jeff Merkley (D-OR) on April 22, 2021, requires the Secretary of Health and Human Services to establish reference prices for prescription drugs for purposes of Federal health programs, and for other purposes.

- **S. 1366**
  This bill, introduced by Sen. Elizabeth Warren (D-MA) on April 26, 2021, secures the supply of drugs in the United States, and for other purposes.

- **H.R. 2846**
  This bill, introduced by Rep. David McKinley (R-WV) on April 27, 2021, amends title XVIII of the Social Security Act to require PDP sponsors of a prescription drug plan under part D of the Medicare program that use a formulary to include certain generic drugs and biosimilar biological products on such formulary, and for other purposes.

- **H.R. 2853**
  This bill, introduced by Rep. Kurt Schrader (D-OR) on April 27, 2021, amends the Federal Food, Drug, and Cosmetic Act, with respect to eligibility for approval of a subsequent generic drug, to remove the barrier to that approval posed by the 180-day exclusivity period afforded to a first generic applicant that has not yet received final approval, and for other purposes.

- **S. 1425**
  This bill, introduced by Sen. Amy Klobuchar (D-MN) on April 28, 2021, enables the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition, and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns, and for other purposes.

- **S. 1428**
  This bill, introduced by Sen. Amy Klobuchar (D-MN) on April 28, 2021, prohibits brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable companies to delay the entry of biosimilar biological products and interchangeable biological products.

- **H.R. 2868**
This bill, introduced by Rep. G.K. Butterfield (D-NC) on April 28, 2021, amends title XIX of the Social Security Act to prohibit additional rebates under the Medicaid program for certain noninnovator multiple source drugs.

- **H.R. 2870**
  This bill, introduced by Rep. Buddy Carter (R-GA) on April 28, 2021, amends the Public Health Service Act to provide for stockpiles to ensure that all Americans have access to generic drugs at risk of shortage, and for other purposes.

- **H.R. 2883**
  This bill, introduced by Rep. Hakeem Jeffries (D-NY) on April 28, 2021, enables the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition and facilitate the efficient review of petitions filed in good faith to raise legitimate public health concerns, and for other purposes.

- **H.R. 2891**
  This bill, introduced by Rep. Jerry Nadler (D-NY) on April 28, 2021, prohibits prescription drug companies from compensating other prescription drug companies to delay the entry of a generic, biosimilar biological product, or interchangeable biological product into the market.

- **S. 1462**
  This bill, introduced by Sen. Bill Cassidy on April 29, 2021, amends the Federal Food, Drug, and Cosmetic Act to simplify the generic drug application process.

- **S. 1463**

- **S. 1508**
  This bill, introduced by Sen. Roger Marshall (R-KS) on April 29, 2021, provides for the use of emergency use authorization data and real world evidence gathered during an emergency to support premarket applications for drugs, biological products, and devices, and for other purposes.

- **S. 1523**
  This bill, introduced by Sen. Mike Braun (R-IN) on April 29, 2021, amends title XI of the Social Security Act and title XXVII of the Public Health Service Act to establish requirements with respect to prescription drug benefits.

- **H.R. 2148**
  This bill, introduced by Rep. Ro Khanna (D-CA) on March 23, 2021, aims to significantly lower prescription drug prices for patients in the United States by ending government-granted monopolies for manufacturers who charge drug prices that are higher than the median prices at which the drugs are available in other countries.
• **S. 909**
  This bill, introduced by Sen. Bernie Sanders (I-VT) on March 23, 2021, aims to significantly lower prescription drug prices for patients in the United States by ending government-granted monopolies for manufacturers who charge drug prices that are higher than the median prices at which the drugs are available in other countries.

• **S. 898**
  This bill, introduced by Sen. Tammy Baldwin (D-WI) on March 23, 2021, requires reporting regarding certain drug price increases, and for other purposes.

• **S. 833**
  This bill, introduced by Sen. Amy Klobuchar (D-MN) on March 18, 2021, amends XVII of the Social Security Act to allow the Secretary of Health and Human Services to negotiate fair prescription drug prices under part D of the Medicare program.

• **H.R. 597**
  This bill, introduced by Re. Jan Schakowsky (D-IL) on January 28, 2021, requires any COVID-19 drug developed in whole or in part with Federal support to be affordable and accessible by prohibiting monopolies and price gouging, and for other purposes.

• **S. 141**
  This bill, introduced by Sen. Jeanne Shaheen (D-NH) on January 28, 2021, amends the Internal Revenue Code of 1986 to deny the deduction for advertising and promotional expenses for prescription drugs.

• **H.R. 153**
  This bill, introduced by Rep. Bobby Rush (D-IL) on January 4, 2021, prohibits brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products, and for other purposes.

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**In The News**

**Bloomberg** (10/29/2021): *Democrats’ Drug-Pricing Fault Lines Emerge* - Democrats remain at odds over how to design legislation to allow the government to negotiate for lower drug prices, a divide that may keep a solution out of their sweeping domestic policy package. The White House omitted measures meant to lower drug prices from its framework for a $1.75 trillion domestic spending package released yesterday. There isn’t enough agreement among Democrats on drug price negotiation to include it in the framework, a Biden administration official told reporters yesterday.
Politico Pro (10/29/2021): **DEMS’ DRUG PRICE DREAM EVAPORATES** — The social spending bill is on course to be Democrats’ latest defeat at the hands of the pharmaceutical lobby – but perhaps its most painful one, POLITICO’s Alice Miranda Ollstein, Megan R. Wilson and Hailey Fuchs report.

Modern Healthcare (10/29/2021): **Pharma campaign cash delivered to key lawmakers with surgical precision** - In the first half of this year Republicans and Democrats in Congress were virtually neck and neck in pulling in drug industry money, according to a KHN analysis of campaign contributions.

Axios (10/29/2021): **Democrats’ risky health care play** - Some Democrats say it’s possible that pieces of their social policy agenda end up being enacted or extended for only a year or two, including major Affordable Care Act and Medicaid provisions, Axios’ Caitlin Owens reports.

Politico Pro (10/28/2021): **INSIDE THE DEM STANDOFF ON HEALTH CARE** — As Democrats close in on the deadline for finalizing their social spending package, nearly all the proposal’s major health policies remain unresolved — leaving party leaders struggling to manage the competing ideological forces surrounding each.

Bloomberg (10/28/2021): **Health Agenda Consensus Eluding Democrats** - Democrats remain at odds over three key elements of their health-care agenda: expanding Medicaid, adding new Medicare benefits, and empowering the government to negotiate with drugmakers. Party members are weighing those proposals as they seek to narrow their sweeping domestic policy bill, searching for a path that appeases both moderates and progressives. Leaders had planned action on the bill by Oct. 31, but look increasingly unlikely to meet that deadline.

Politico Pro (10/27/2021): **HEALTH ADVOCATES PRESS FOR SURPRISE BILLING GUARDRAILS** — More than 30 employer, union and health plan groups sent a letter to top Biden officials Tuesday urging the administration to formalize an arbitration process that would protect consumers with large hospital bills.

Politico Pro (10/27/2021): **DEMS STILL DIVIDED OVER MEDICARE, MEDICAID EXPANSIONS** — Top Democrats negotiating the party’s social spending package are still hung up on a series of key issues — including how to handle proposals expanding the nation’s Medicare and Medicaid programs, POLITICO’s Nicholas Wu, Sarah Ferris and Heather Caygle report.

Axios (10/26/2021): **Crunch time on Capitol Hill** - As Democrats try to reach a deal on a massive social policy bill, the legislation's health care measures are emerging as key sticking points, Axios' Caitlin Owens writes.

Bloomberg (10/26/2021): **Democrats Mull Dropping Medicare, Medicaid** - Two significant elements of Democrats' ambitious health agenda, expanding Medicare and Medicaid, face an uphill battle after a key party moderate signaled his opposition Monday. Sen. Joe Manchin (D-W.Va.) said yesterday he doesn’t want to expand Medicare benefits without first protecting the rest of the program from insolvency later this decade. He also rebuffed legislation to extend coverage to millions of Americans in states that have refused to expand their Medicaid programs.
Politico Pro (10/26/2021): TELEHEALTH ADVOCATES PUSH FOR INTERNET ACCESS — More than 40 groups led by the Connect Americans Now coalition sent letters to Congressional leaders this week pressing for better broadband access to improve telehealth services, which have become critical during the pandemic.

Politico Pro (10/26/2021): THE STATE OF RECONCILIATION — West Virginia Democrat Joe Manchin — who met with President Joe Biden this weekend to settle some agenda priorities — doesn’t seem to be settled on the path forward.

Politico Pro (10/25/2021): DOES MEDICARE EXPANSION GO? — Lawmakers, staffers, advocates and lobbyists said that a plan to expand Medicare with dental, vision and hearing benefits for tens of millions of seniors — as well as a pitch to guarantee paid family and medical leave to all U.S. workers — are now in danger of getting cut from the $1 trillion-plus reconciliation package entirely.

Bloomberg (10/25/2021): Democrats Set to Scale Back Ambitions - Democrats working on President Joe Biden’s big social-spending bill discussed over the weekend a proposal to limit the main tool for lowering drug prices to medicines that already face competition, people familiar with the talks said, Alex Ruoff reports.

STAT News (10/22/2021): The four senators who could make or break Democrats’ drug pricing ambitions - WASHINGTON — The fate of the Democratic party’s ambitious goal of allowing Medicare to negotiate drug prices rests with a handful of key moderate senators.

Politico (10/22/2021): HEALTH CARE LOBBYING: SO HOT RIGHT NOW — Lobbying spending by the health care industry’s largest players surged in the third quarter, compared to the same period last year, as Covid-19 and Democrats’ bid to pass major health policies as part of their spending package dominated the agenda.

Politico (10/22/2021): HEALTH CARE HOLDS UP DEMS’ SPENDING DEAL — Proposals to expand Medicare benefits and crack down on pharmaceutical costs are among the final items dividing Democrats as they race to assemble a $2 trillion spending package, POLITICO’s Sarah Ferris, Marianne LeVine and Nicholas Wu report.

Bloomberg (10/22/2021): Wyden Sees a ‘Practical’ Drug Pricing Bill - The Senate Democrat leading the charge on reining in drug prices says he is crafting a plan to empower the federal government to negotiate with pharmaceutical companies that offers “flexibility.”

Bloomberg (10/21/2021): Democrats Continue Negotiations on Agenda - Congressional Democrats are at odds over both the tax and spending sides of a bill to enact the bulk of President Joe Biden’s economic agenda, even as party leaders aim to have an outline of a deal by the end of the week, Laura Davison and Erik Wasson report.

Bloomberg (10/21/2021): Biden Plan to Tackle Medicare Drug Pricing, Sanders, Wyden Say - President Joe Biden’s social plan will include a provision to renegotiate Medicare drug prices, Democratic Senator Bernie Sanders and Senate Finance Committee Chairman Ron Wyden say.

Politico (10/20/2021): ADVOCACY GROUPS PUSH TO KEEP DRUG PRICING PROVISIONS — A slew of health care, labor, religious and other advocacy groups wrote to Speaker Nancy Pelosi and
Senate Majority Leader Chuck Schumer today demanding they not yield to calls from centrist Democrats to weaken the drug pricing provisions of the social spending bill and expressing “growing concern” with the state of the negotiations.

Politico (10/20/2021): **CBO: DEM SPENDING BILL WOULD EXPAND COVERAGE, COST $550B** — Major health provisions included in the Democrats’ initial proposal for their social spending bill would expand coverage to 4.1 million people across Medicaid and the individual insurance market over the next decade, according to a new Congressional Budget Office analysis.

Bloomberg (10/20/2021): **Democrats Move to Break Stalemate by Scaling Back Plan** - Congressional Democrats made significant headway in breaking their stalemate on Biden’s economic agenda yesterday by jettisoning or trimming portions of the multitrillion-dollar tax and spending package. The progress came after Biden met with representatives of both wings of the party at the White House yesterday and as Senate Majority Leader Chuck Schumer (D-N.Y.) put pressure on Democrats to sew up a deal this week.

Bloomberg (10/20/2021): **Democrat Warns Biden He Opposes Top FDA Choice** - A top Senate Democrat is pushing back on Biden’s likely choice to lead the Food and Drug Administration, potentially complicating Robert Califf’s road to confirmation before he’s even officially nominated. Sen. Richard Blumenthal (D-Conn.) said his staff reached out to the White House with his concerns about Califf, who ran the FDA under President Barack Obama, over his ties to pharmaceutical companies.

Politico (10/15/2021): **Biden Eyeing FDA Veteran Robert Califf to Lead the Agency** — President Joe Biden is likely to nominate former Food and Drug Administration Commissioner Robert Califf to return to the top role at the sweeping regulatory agency, people with knowledge of the situation told POLITICO.

Bloomberg (10/15/2021): **Democrats Prep Shift on Drug Pricing Push** - Democratic leaders say they’re eyeing a less aggressive drug pricing proposal in their broad tax and social spending package, which may offer some relief to drugmakers concerned about the original plan.

Bloomberg (10/15/2021): **Bills to Avoid ‘Telehealth Cliff’ Delayed by Higher Priorities** - Lawmakers are struggling to push widely supported legislation that would end the “telehealth cliff” through a logjam created by their intense focus on more divisive priorities—such as the Democratic spending package, bipartisan infrastructure bill, addressing the debt ceiling and funding the government. “There’s not much oxygen in the room, even for an issue of agreement,” said Kyle Zebley, vice president of public policy for the American Telemedicine Association. Read more from Allie Reed.

Bloomberg (10/13/2021): **Progressives Press for Medicare Benefits** - New vision, dental, and hearing benefits under Medicare must be included in Democrats’ social spending package if it’s going to win support from progressives, lawmakers said yesterday.

Bloomberg (10/13/2021): **Democrats Divided Over How Best to Slice Biden’s Economic Agenda** - Democrats are coalescing around a tax and spending plan totaling about $2 trillion, but the party’s progressives and moderates remain divided over which pieces of Biden’s agenda to pay for -- and how long to pay for them.
**Bloomberg** (10/13/2021): Poll Shows Drug Pricing Negotiation Support - A new poll from the Kaiser Family Foundation shows Americans of all party affiliations want government to negotiate for better drug prices—an effort being debated in Congress—even after hearing common arguments about it, Alex Ruoff reports. Eighty three percent of the public in the survey said they favored allowing government to negotiate to lower drug prices, including 76% of Republicans. After hearing key arguments being made for and against that plan, “little” change was seen overall, with Republican support overall dipping to 71%, Alex Ruoff reports.

**Politico** (10/12/2021): SINEMA NOT SOLD ON A DRUG PLAN, STILL — Senate Democrats still haven’t agreed on a key component of President Joe Biden’s sweeping social spending package — drug pricing reform.

**Bloomberg** (10/12/2021): Biomedical Agency’s Future is Complicated - President Joe Biden’s proposed new biomedical research agency may fall short of funding or approval from Congress this year after Senate Democrats signaled they’ve booted the initiative from their pending social spending and tax package.

**Modern Healthcare** (10/11/2021): Cancer care must crack the diversity code - We can credit clinical trials for great improvements made in cancer care in recent years. But there’s a large hole in these gains—the lack of diversity.

**Politico** (10/1/2021): BUTTERFIELD, BILIRAKIS BILL AIMS TO BOOST CANCER TEST COVERAGE — Two lawmakers are making a bipartisan push to require Medicare, Medicaid and the Children’s Health Insurance Program to provide coverage of molecular cancer diagnostics when individuals are diagnosed with cancer. The new bill, H.R. 5377, introduced by Reps. G.K. Butterfield (D-N.C.) and Gus Bilirakis (R-Fla.), also would require HHS to run a national education campaign to raise awareness of the role of genetic testing and counseling.

**Politico** (10/1/2021): FDA ISSUES DRAFT GUIDANCE ON USING REAL-WORLD DATA FOR DRUG REGULATION — The Food and Drug Administration on Wednesday released draft guidance for industry on using real-world evidence, including electronic health records and other medical records, to evaluate novel therapies, Katherine reports. These kinds of real-world data show insight that clinical trials can’t, like how well drugs work in patients with additional conditions or how they fare after being on the drugs for long periods of time.

**Modern Healthcare** (10/1/2021): As Democrats bicker over massive spending plan, here’s what’s at stake for Medicaid - With Democrats controlling both chambers of Congress and the White House, health experts say this could be the only time such a fix to the “Medicaid gap” will be possible for many years.

**Modern Healthcare** (10/1/2021): HHS kills Trump-era 340B rule targeting community health clinics - The rule would have required community health clinics to pass on insulin and Epi-Pen savings directly to patients.

**Modern Healthcare** (10/1/2021): HHS lays out surprise billing resolution process in new rule - The Biden administration gave new details on the independent dispute resolution process that out-of-network providers and plans can use to settle surprise billing disputes.
Politico (10/1/2021): **AMERICANS WANT DRUG PRICE NEGOTIATION** — ... Even if many lawmakers don’t. Americans support letting the government negotiate drug prices above all the other major priorities in the infrastructure and social spending packages now before Congress, according to a new POLITICO-Harvard poll.

Politico (10/1/2021): ‘**SURPRISE BILL BAN ON DECK**’ — The Biden administration is finalizing a key element of its ban on surprise medical bills, laying out new procedures for how insurers and providers should settle pay disputes for out-of-network care.

Politico (10/1/2021): **DEMPS’ DOMESTIC AMBITIONS SLAM INTO REALITY** — Top Democrats dreamed of making generational progress this year on health coverage, drug pricing, family leave and all manner of other big priorities — and doing it in a single masterful stroke.

Axios (10/1/2021): Proteins give clearer picture of cancer growth - Unique networks of hundreds of proteins may drive the growth of breast, head and neck cancers, according to three new studies, Axios’ Eileen Drage O’Reilly reports.

Axios (10/1/2021): **More details on surprise billing ban** - Insurers are happy with the Biden administration’s planned implementation of Congress’ ban on surprise medical bills. Hospitals are not.