# Your Civitas GR Team

**Elinor Hiller**
ALSTON & BIRD

**JP Paluskiewicz**
ALSTON & BIRD

**Lindsay Austin**
troutman pepper strategies

**Sofia Molodanof**
ALSTON & BIRD

**Chris Baxter**
troutman pepper strategies

CIVITAS
Networks for Health

# Public Policy Briefing: Agenda

1. Congressional Activity

2. Administration Activity

3. Political/Election Outlook

4. Questions and Discussion

# Federal Overview

**Congress will continue to take up legislation that will impact health care and health IT –** as the midterm elections nears, House Democrats may look to pass more "messaging" bills, or bills that appeal to voters but have little chance of becoming law or passing in the Senate.

## OVERVIEW

- Fiscal Year (FY) 2023 appropriations
- Health Data Privacy
- Behavioral Health Care
- PREVENT Pandemics Act
- Quality Payment Program (QPP) – Small, Underserved, and Rural Practices (SURS)
- Food and Drug Administration (FDA) user fees
- State All Payer Claims Databases
- Data Modernization Efforts
- Safer Communities Act (gun bill)
- Advanced Research Projects Agency – Health (authorization, funding, HQ)

## OTHER

- Equity and Social Determinants of Health
- COVID-19 Supplemental Funding
- No Surprises Act implementation
- Future Build Back Better Act (BBB) negotiations, potential for public health infrastructure
- Drug pricing, insulin, price transparency, and affordability (some previously in BBB)
- Funding for home and community-based services (previously in BBB)
- Closing the Medicaid coverage gap (previously in BBB)
- Maternal health ("Momnibus")
- Telehealth Expansion beyond Public Health Emergency (PHE) and omnibus extension
- IPPS Rule, Unified Agenda, etc.

CIVITAS
Networks for Health

# Congressional Appropriations

**FY23 Appropriations –** House appropriators have completed subcommittee markups of all twelve funding bills. Floor votes are going to be scheduled. The Senate has not held any markups but is expected to begin in July.

**CIVITAS' FY23 Appropriations Requests** – Civitas made both a programmatic funding request and a report language request in the Labor-HHS bill

**FY23 House Labor-HHS:**

- $124.2 billion for HHS overall , an increase of $15.6 billion above FY22
- $9.6 billion for HRSA, an increase of $683 million
- $10.5 billion for the CDC, an increase of $2 billion
  - $750 million for public health infrastructure and capacity nationwide
  - $250 million to modernize public health data surveillance and analytics
  - $758 million for global health
  - $100 million for social determinants of health
- $9.2 billion for SAMHSA, an increase of $2.6 billion
- $385 million for AHRQ, an increase of $35 million
- $4.3 billion for CMS administrative expenses, an increase of $322 million
- $3.7 billion for PHSSEF(ASPR), an increase of $500 million
  - Includes $262 million for Hospital Preparedness Program cooperative agreements, an increase of $22 million
- $2.75 billion for ARPA-H, an increase of $1.75 billion

*\*FY23 Labor-HHS report expected 6/29, markup full committee 6/30*

**Programmatic Funding:** $445,555,000 (+$165,000,000 over FY2022) to support the development or enhancement of health data utilities. Funding for these cooperative agreements between states and their Health Information Exchanges organizations are a natural and needed extension of the agency's work to support regional collaboration to better respond to disasters and emergencies through health information sharing.

**Report Language:** "Health Data Utility – The Committee recognizes the COVID-19 pandemic has exposed serious gaps in our health care system and the challenges of responding to major public health threats. Real-time clinical data is essential for responding to a pandemic and for improving public health outcomes broadly. The Committee also recognizes the potential for surveillance of public health threats to increase administrative burden on health care providers. The Committee directs $165,000,000 for the Secretary, acting through the Assistant Secretary for Preparedness and Response and in coordination with both the Office of the National Coordinator and the Office of Burden Reduction and Health Informatics at the Centers for Medicare and Medicaid Services, to develop state health data utility grants. For the purposes of this section, the health data utility grant program would help states advance their capacities to collect and share real-time data from and to health care providers while minimizing the administrative burden of such activities through the coordinated services of Health Information Exchange (HIE) organizations."

**CIVITAS**
Networks for Health

# H.R. 8152 - American Data Privacy and Protection Act (ADPPA)

## Summary of Legislation

At its core, the ADPPA would establish a fundamental "privacy by design" paradigm for data privacy, which shifts the burden of privacy from the individual to entities that collect data. The ADPPA would:

- Establish a "data minimization" standard: covered entities could not collect, process, or transfer covered data beyond what is reasonably necessary, proportionate, and limited to providing specifically requested products and services or communicating with individuals in a manner they reasonably anticipate.
- Address discriminatory data collection and use, including by requiring large data holders to conduct algorithm bias assessments.
- Grant individuals the right to access, correct, and delete their data.
- Require third-party brokers to register with the FTC.
- Preempt some (not all) state data privacy laws.
- Establish a private right of action for individuals to sue entities that violate the law.
- Strengthen protections for children, broadly prohibiting targeted advertising to children under 17.

## ADPPA and HIPAA

With respect to the healthcare industry, ADPPA would not preempt HIPAA where HIPAA applies.

- However, its definition of "sensitive covered data" would include "any information that describes or reveals the past, present, or future physical
- health, mental health, disability, diagnosis, or healthcare treatment of an individual."
- As such, health data that are not subject to HIPAA (e.g., user-generated health app data, etc.) would be subject to the ADPPA. The law would apply to a broad scope of entities, including nonprofit organizations.
- Public health agencies are not considered a "covered entity" under the legislation

**CIVITAS**
Networks for Health

# H.R. 8152 - American Data Privacy and Protection Act: Current Status and Challenges

## Status of Legislation

- The ADPPA has strong bipartisan support. The bill is a "three corners bill"– it has the support of three of the four leaders on the Committees of jurisdiction (Reps. Pallone (D-NJ), McMorris Rodgers (R-WA), and Sen. Wicker (R-MI).

- Sen. Cantwell (D-WA), the "fourth corner," wants the bill to have stronger standards and private right of action. On Wednesday June 22, she told reporters that "there is no way they are bringing that bill up in the Senate" in its current form.

- On June 14, 2022, the House E&C Subcommittee on Consumer Protection and Commerce held a hearing entitled, "Protecting America's Consumers: Bipartisan Legislation to Strengthen Data Privacy and Security".

- On June 23, 2022, the House E&C Subcommittee on Consumer Protection and Commerce held a markup where H.R. 8152, as amended, was ordered favorably reported to the full Committee.

## Challenges

- House lawmakers, seeking to advance the legislation, must contend with several issues

- The two most divisive:
  - Whether individuals should be able to sue technology companies directly; and
  - Whether federal law should supersede state privacy laws.

## Industry Concerns

- As health care industry stakeholders review the proposed language, questions have begun surfacing focusing on:
  - Relation to HIPAA and contours of preemption
    - De-identification definition incongruous
    - "sensitive data" definition incongruous
    - "Deemed ADPPA compliance" based on HIPAA compliance
  - Clinical Research
  - Algorithm Assessments

# Behavioral and Mental Health

Behavioral and mental health continues to be a key bipartisan issue for members in both the House and Senate. Activity will continue through 2022 and into 2023.

- **Safer Communities Act** – Last week, Congress passed gun safety legislation, and President Biden signed it into law Saturday. The bill included several healthcare related provisions, including:

  - $50 million for HHS grants to expand Medicaid or CHIP assistance through school-based entities, including school health centers

  - $40 million for additional planning grants and demonstration programs under the certified community behavioral health clinics program

  - $31 million for the Pediatric Mental Health Care Access program

  - $5 million for FY23 and FY24 for early screening, diagnostic, and treatment benefits for children younger than 21

  - HHS would have to provide technical assistance and guidance to states to improve access to telehealth for services covered under Medicaid and CHIP

  - $800 million in funding over 4 years for the SAMHSA, of which $250 million would be allocated to community mental health services block grants

- Earlier in the year, the Senate Finance Committee launched effort to develop bipartisan legislation to address barriers to mental health care, with the goal of introducing a package this summer. Focus areas and co-chairs for each workstream include:

  - **Strengthening the workforce:** Senators Debbie Stabenow (D-MI) and Steve Daines (R-MT)

  - **Increasing integration, coordination and access to care:** Senators Catherine Cortez Masto (D-NV) and John Cornyn (R-TX)

  - **Ensuring parity between behavioral and physical health care:** Senators Michael Bennet (D-CO) and Richard Burr (R-NC)

  - **Furthering the use of telehealth:** Senators Ben Cardin (D-MD) and John Thune (R-SD)

  - **Improving access to behavioral health care for children and young people:** Senators Tom Carper (D-DE) and Bill Cassidy (R-LA)

- On 6/22, the House passed a large package (H.R. 7666) reauthorizing several mental health and substance use disorder block grant programs, including $857 million annually for Community Mental Health Services Block Grants and $1.91 billion annually for Substance Abuse Prevention and Treatment Block Grants

CIVITAS
Networks for Health

# Health Legislation and Opportunities

## FDA User Fees

- Lowering the cost of prescription drugs has been a longtime priority in Congress

- FDA user fees <u>must</u> be reauthorized by the end of the fiscal year (required every 5 years), creating a must-past legislative vehicle

- House passed their version on 6/8, Senate HELP passed the bill 6/14

- Senate version includes new regulatory structure for in vitro clinical tests

- Could pass by the end of the fiscal year

## PREVENT Pandemics Act

- Senate HELP Committee passed the PREVENT Pandemics Act on March 15, 2022

- Civitas's supported language changes were included in the Manager's Amendment:

  - Sec. 201 – expanded definition of eligible entities in addressing SDOH, including public-private and community partnerships

  - Sec. 213 – included HIEs and HINs around activities related to information sharing

- We continue to work with HELP, they have an interest in HIEs

## QPP-SURS

- Expired 2/4, Senators Bennet (D-CO), Cassidy (R-LA), Reps. Welch (D-VT), and Burgess (R-TX) introduced legislation extending the program through 2027

- Civitas signed on to a support letter and advocated

## Build Back Better

- Original bill failed to gain support from key Democrats

- Sens. Schumer and Manchin hold occasional discussions

- SALT deduction has emerged as new roadblock

CIVITAS
Networks for Health

# Key Political Dates Ahead



- Phase in of additional 1% Medicare sequester

- Congressional recess: House 8/1-9/12 & Senate 8/8-9/5

- Midterm elections

| July 1 | July 15 | August | September 30 | November 8 | November 28 |

- Expiration of the Public Health Emergency (PHE) declaration

- Government funding expires
- Budget reconciliation instructions expire

- Possible "lame duck" session begins

**CIVITAS**
Networks for Health

# Administration Activity

## WH Maternal Health Blueprint

- The Biden-Harris admin recently released a blueprint to cut the rates of maternal mortality and morbidity, reduce the disparities in maternal health outcomes, and improve the overall experience of pregnancy, birth, and postpartum

- Key pillars of the blueprint include;
  - Improved maternal health data
  - Expanding postpartum Medicaid coverage
  - Investments in rural maternal care
  - Other expanded social services

## CMS Policy Pillars

- To advance health equity by advance addressing health disparities

- Building on the ACA and expanding access to Medicare, Medicaid, CHIP, and the marketplaces

- Addressing issues throughout the process of regulation

- Promoting value-based, person-centered care

- Protecting the Medicare program's sustainability through future generations.

- Fostering a positive, inclusive workplace, and promote excellence

## State All Payer Claims Database

- HHS must still make available the grants included in the NSA

- Grants will be made to states to either establish a State All Payer Claims Database; or improve existing State All Payer Claims Databases

- To be eligible, a state must submit an application to the HHS Secretary, including information with specifics on how the State will ensure uniform data collection and the privacy and security of such data

- $2,500,000 grants will be awarded for a 3-year period, of which $1,000,000 will be made available to the state for each of the first 2 years and $500,000 will be available to the State the third year



**CIVITAS**
Networks for Health

# Spring 2022 Unified Agenda

**On June 21, the Biden administration released its Spring 2022 Unified Agenda of Regulatory and Deregulatory Actions –** These semi-annual regulatory agendas outline federal agency goals for the months ahead and include several health and health IT related agenda items.

Key upcoming regulations include:

- **CMS:** Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2023 Rates (Final action expected October 2022)

- **CMS:** Interoperability and Prior Authorization for MA Organizations, Medicaid and CHIP Managed Care and State Agencies, FFE QHP Issuers, MIPS Eligible Clinicians, Eligible Hospitals and Cash (NPRM expected September 2022)

- **CMS:** Requirements Related to Surprise Billing; Part II (Final action expected June 2022)

- **OCR:** HIPAA Privacy: Changes to Support, and Remove Barriers to, Coordinated Care and Individual Engagement (Final action expected March 2023)

- **OCR**: Considerations for Implementing the Health Information Technology for Economic and Clinical Health (HITECH) Act, as Amended (RFI comment period ended June 6, 2022)

- **OIG:** Amendments to Civil Monetary Penalty Law Regarding Grants, Contracts, and Information Blocking ("Info blocking enforcement") (Final action expected September 2022)

- **ONC:** ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing (NPRM expected October 2022 with comment period ending December 2022)

**CIVITAS**
Networks for Health

# IPPS Rule Comments

CIVITAS submitted a comment letter to CMS on the IPPS rule addressing several key components of the rule

Topics the Civitas letter addressed included:

- Social determinants of health diagnosis codes

- Advancing the TEFCA

- The query of PDMP

- Improving maternal health

- The use of FHIR in Hospital Quality Programs

- Condition of Participation (CoP) Requirements for Hospitals and CAHs To Report Data Elements To Address Any Future Pandemics and Epidemics.

**CIVITAS**
Networks for Health

# Data Modernization Initiative

CDC's Data Modernization Initiative (DMI) is a multi-year, billion-plus dollar effort to modernize core data and surveillance infrastructure across the federal and state public health landscape.

- On June 16, The CDC Foundation and CIVITAS held a listening session on the DMI
  - ONC's Micky Tripathi (National Coordinator), Suzi Connor (CDC CIO), and CDC's Dan Jernigan (Deputy Director for Public Health Science and Surveillance) participated (among many others)
  - Presentation focused on how states and HIEs are working together on public health activities for better "systemness"
- Key pillars of the DMI initiative include:
  1. Building the right foundation
  2. Accelerating data into action
  3. Developing a state-of-the-are workforce
  4. Supporting and extending partnerships
  5. Managing change and governance

## 4 SUPPORTING AND EXTENDING PARTNERSHIPS

In 2021, we worked closely with state, local, tribal, and territorial partners, as well as with healthcare and private industry, to ensure transparency, address policy challenges, and solve problems together.

**POLICIES >** We worked across the federal government and with partners on policies that support the exchange and use of data between CDC, jurisdictions, partners, and data providers.

**ACCESS >** We increased access to our data modernization plans and progress to increase participation and alignment.

**DATA USE AGREEMENTS >** We increased the use of standardized data use agreements, allowing jurisdictions and partners to seamlessly access more than 1,300 datasets that enable research and inform decision making nationwide.

**COLLABORATION >** We worked with research and academic partners on innovative projects that streamline information flow, reduce burden on data providers, and accelerate data from the local to the federal level.

CIVITAS
Networks for Health

# Political Outlook 2022 - House

**All 435 members of the House of Representatives are up for reelection. Republicans need a net gain of 5 seats to win the majority.**
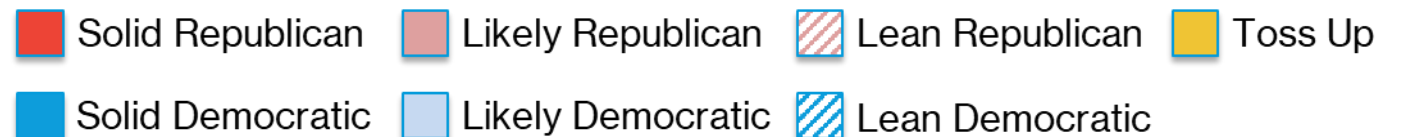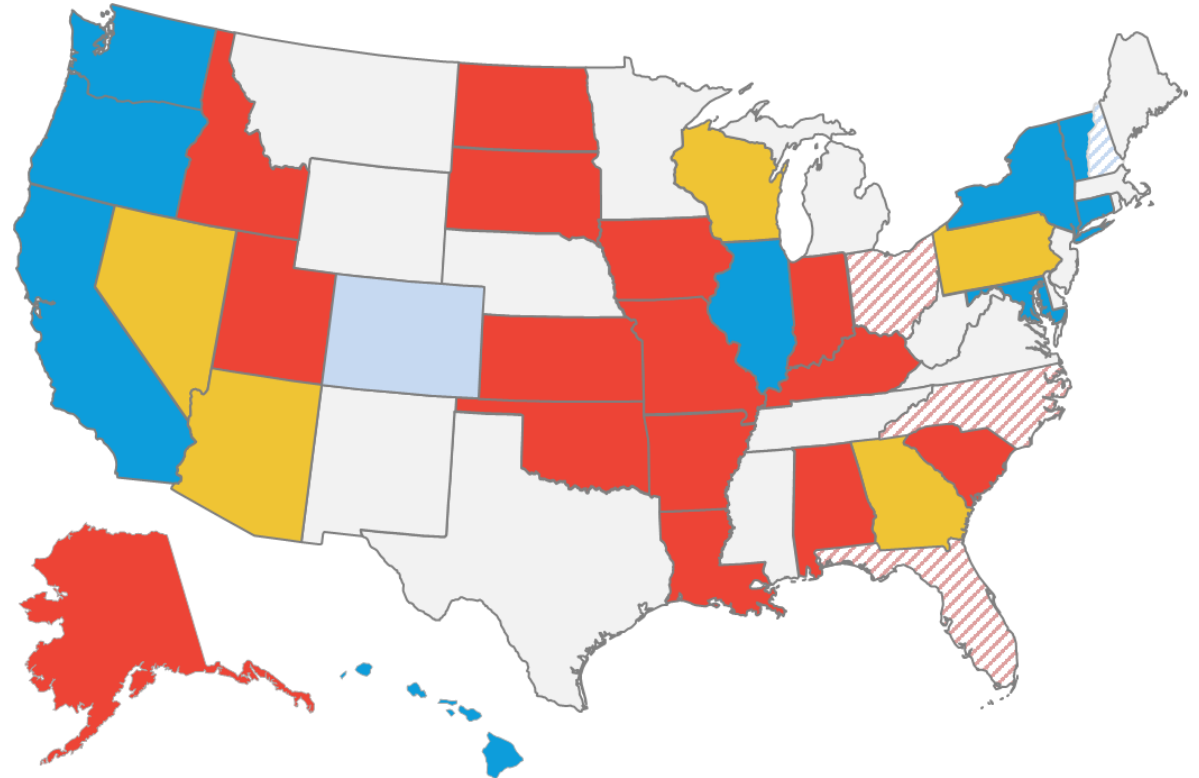
- Historically, the president's party loses seats in midterm elections

- Redistricting has had a significant impact on shaping the House come 2023, including 6 pairs of incumbent vs. incumbent primaries

- Democrats are defending several more competitive seats than Republicans

- Republicans flipping the House and/or the Senate could (potentially) impact health and health IT policy in the 118th Congress:
  - Reduced federal spending for programs in FY24
  - Legislation on ACA premiums and cost-sharing
  - Reforming Medicare/Medicaid
  - Focus on expanding rural access to healthcare and other services
  - More oversight of HHS/subagency spending
  - Protecting patient privacy

- Election implications of Roe v. Wade?

| LIKELY DEMOCRATIC 13 Dem • 0 Rep 0 Ind | LEAN DEMOCRATIC 11 Dem • 2 Rep 0 Ind | DEMOCRATIC TOSS UP 23 Dem • 0 Rep 0 Ind | REPUBLICAN TOSS UP 0 Dem • 9 Rep 0 Ind | LEAN REPUBLICAN 7 Dem • 3 Rep 0 Ind | LIKELY REPUBLICAN 3 Dem • 8 Rep 0 Ind |
|---|---|---|---|---|---|
| CA-09 Harder | AZ-04 Stanton | IL-17 Open | CA-22 Valadao | AZ-01 Schweikert | AZ-02 O'Halleran |
| CO-07 Open | CA-13 Open | KS-03 Davids | CA-27 Garcia | AZ-06 Open | CA-03 Open |
| CT-02 Courtney | CA-47 Porter | ME-02 Golden | CA-45 Steel | CA-40 Kim | CA-41 Calvert |
| GA-02 Bishop | CA-49 Levin | MI-07 Slotkin | CO-08 New Seat | IA-03 Axne | FL-07 Open |
| IL-11 Foster | CT-05 Hayes | MI-08 Kildee | MI-03 Meijer | MI-10 Open | FL-13 Open |
| IL-14 Underwood | IL-06 Merged Seat | MN-02 Craig | NC-13 Open | NJ-07 Malinowski | FL-15 New Seat |
| NC-06 Manning | IL-13 Open | NH-01 Pappas | NM-02 Herrell | NY-01 Open | IA-01 Miller-Meeks |
| NJ-03 Kim | IN-01 Mrvan | NH-02 Kuster | NY-22 Open | PA-07 Wild | IA-02 Hinson |
| NJ-05 Gottheimer | MD-06 Trone | NV-01 Titus | OH-01 Chabot | TX-15 Open | MT-01 New Seat |
| NM-03 Leger Fernandez | NC-01 Open | NV-03 Lee | | WI-03 Open | NE-02 Bacon |
| NY-04 Open | NY-17 Maloney | NV-04 Horsford | | | NY-02 Garbarino |
| OR-04 Open | RI-02 Open | NY-03 Open | | | |
| OR-06 New Seat | TX-34 Merged Seat | NY-18 Open | | | |
| | | NY-19 Vacant | | | |
| | | OH-09 Kaptur | | | |
| | | OH-13 Open | | | |
| | | OR-05 Open | | | |
| | | PA-08 Cartwright | | | |
| | | PA-17 Open | | | |
| | | TX-28 Cuellar | | | |
| | | VA-02 Luria | | | |
| | | VA-07 Spanberger | | | |
| | | WA-08 Schrier | | | |

CIVITAS
Networks for Health

# Political Outlook 2022 - Senate

**A total of 34 Senate seats are up for election in 2022, including 7 open seats due to retirements. 15 Republican and 13 Democratic incumbents are running.**

- Democratic advantage: not defending any competitive open seats or seats in states Trump won in 2020

- Republican advantage: need a net gain of only 1 seat to win the majority

- Most competitive races:
  - AZ – Mark Kelly (D)
  - FL – Marco Rubio (R)
  - GA – Raphael Warnock (D)
  - NC – Open (R)
  - NH – Maggie Hassan (D)
  - NV – Catherine Cortez Masto (D)
  - OH – Open (R)
  - PA – Open (R)
  - WI – Ron Johnson (R)



Legend:
- Solid Republican
- Likely Republican
- Lean Republican
- Toss Up
- Solid Democratic
- Likely Democratic
- Lean Democratic

CIVITAS
Networks for Health

16

# Civitas 2022 Priorities and Activities

**1** Educate and advise policymakers and regulators about Civitas members and their significance to the nation's public health systems and health care infrastructure.

**2** Support legislative proposals that revitalize public health and advance opportunities to address SDOH with an emphasis on long-term infrastructure funding.

**3** Support legislative proposals and models identified by the Centers for Medicare & Medicaid Services' Innovation Center that drive accountable care, advance health equity and address health care affordability.

**4** Encourage the creation of and funding for Health Data Utilities (HDU), which would empower nonprofit or state agency-run health information networks across the country. Our goal is to support and facilitate information flow between public health and clinical/claims health IT systems while protecting privacy and ensuring security.

**5** Build industry partnerships by engaging other community stakeholders and industry leaders to build support for various policy positions and regulatory actions.

**CIVITAS**
Networks for Health

# Civitas Outreach as of 6/28

## Senate

| | Member Name | Party / State |
|---|---|---|
| 1 | Sen. Ben Cardin | D-MD |
| 2 | Sen. Ben Ray Lujan | D-NM |
| 3 | Sen. Bernie Sanders | I-VT |
| 4 | Sen. Bill Cassidy | R-LA |
| 5 | Sen. Bob Casey | D-PA |
| 6 | Sen. Chris Murphy | D-CT |
| 7 | Sen. Chris Van Hollen | D-MD |
| 8 | Sen. Jackie Rosen | D-NV |
| 9 | Sen. Jerry Moran | R-KS |
| 10 | Sen. Joe Manchin | D-WV |
| 11 | Sen. John Hickenlooper | D-CO |
| 12 | Sen. Lisa Murkowski | R-AK |
| 13 | Sen. Maggie Hassan | D-NH |
| 14 | Sen. Mark Warner | D-VA |
| 15 | Sen. Martin Heinrich | D-NM |
| 16 | Sen. Mike Braun | R-ID |
| 17 | Sen. Mike Crapo | R-ID |
| 18 | Sen. Mitt Romney | R-UT |
| 19 | Sen. Patty Murray | D-WA |
| 20 | Sen. Rand Paul | R-KY |
| 21 | Sen. Richard Burr | R-NC |
| 22 | Sen. Roger Marshall | R-KS |
| 23 | Sen. Ron Wyden | D-OR |
| 24 | Sen. Roy Blunt | R-MI |
| 25 | Sen. Shelley Moore Capito | R-WV |
| 26 | Sen. Susan Collins | R-ME |
| 27 | Sen. Tammy Baldwin | D-WI |
| 28 | Sen. Tim Kaine | D-VA |
| 29 | Sen. Tim Scott | R-SC |
| 30 | Sen. Tina Smith | D-MN |
| 31 | Sen. Tommy Tuberville | R-AL |

## House of Representatives

| | Member Name | Party / State |
|---|---|---|
| 1 | Rep. Ami Bera | D-CA |
| 2 | Rep. Andy Harris | R-MD |
| 3 | Rep. Anna Eshoo | D-CA |
| 4 | Rep. Ben Cline | D-VA |
| 5 | Rep. Brenda Lawrence | D-MI |
| 6 | Rep. Brett Guthrie | R-KY |
| 7 | Rep. Cathy McMorris Rogers | R-WA |
| 8 | Rep. Cheri Bustos | D-IL |
| 9 | Rep. David Trone | D-MD |
| 10 | Rep. David Trone | D-MD |
| 11 | Rep. Debbie Dingell | D-MI |
| 12 | Rep. Diana DeGette | D-CO |
| 13 | Rep. Doris Matsui | D-CA |
| 14 | Rep. Dutch Ruppersberger | D-MD |
| 15 | Rep. Frank Pallone | D-NJ |
| 16 | Rep. Fred Upton | R-MI |
| 17 | Rep. John Moolenaar | R-MI |
| 18 | Rep. John Sarbanes | D-MD |
| 19 | Rep. Kay Granger | R-TX |
| 20 | Rep. Kevin Brady | R-TX |
| 21 | Rep. Lloyd Doggett | D-TX |
| 22 | Rep. Melanie Stansbury | D-NM |
| 23 | Rep. Michael Burgess | R-TX |
| 24 | Rep. Mike Kelly | R-PA |
| 25 | Rep. Richard Neal | D-MA |
| 26 | Rep. Ron Kind | D-WI |
| 27 | Rep. Rosa DeLauro | D-CT |
| 28 | Rep. Suzan Kay DelBene | D-WA |



CIVITAS
Networks for Health

**Questions?**