



# Florida AHRMM Spring Conference: Washington Update

Jenna Stern  
May 4, 2022

**vizient.**<sup>®</sup>

# Who are we?

Together with our external consultants, we are a team of **bipartisan** professionals with more than 100 years of experience in Washington, D.C. politics and policy:

- Shoshana Krilow leads our team in D.C. She has worked as a health policy advisor in both the House of Representatives and the United States Senate, most notably during the debate and passage of the Affordable Care Act
- Steve Rixen has been with Vizient for more than 11 years and previously worked on Capitol Hill for two U.S. Senators, handling a variety of issues with a focus on health policy
- Jenna Stern became a part of Vizient's D.C. team in 2020. She previously worked on a variety of health policy issues for a large healthcare professional association and as a consultant
- Daniel Lubertazzi joined our team after several political and policy internships, including a governor's office, and assists with research, drafting correspondence and conducting day-to-day administrative support
- Mina Kato is the newest member of our team, leading advocacy communications initiatives. Previously, she managed policy communications for an education association and worked on Capitol Hill.

More importantly, we are NON-PARTISAN

# How do we communicate?

**Washington Update Newsletter** – Bi-weekly email newsletter covering developments from Capitol Hill and the regulatory agencies, and how they may impact hospitals.

**Public Policy Updates** – Deliver in-person or virtual updates to member hospitals.

**Connecting with Policymakers** – Connect members to officials on Capitol Hill or in the Executive Branch agencies.

**Legislative and Regulatory Summaries** – Provide summaries of emerging legislative and regulatory issues.

**Answering Questions** – We answer questions or conduct research into legislative or regulatory issues.



# What do we work on? In more “normal” times?

- Efficiency and value in health care delivery
- 340B Drug Pricing Program
- Hospital outpatient department site-neutral payment policies
- Graduate medical education
- Prescription drug shortages
- Prescription drug pricing
- Biosimilars
- Telehealth
- Tariffs/trade policy
- Non-profit health care tax exemption
- Quality measurement
- Cybersecurity
- SUPPLY CHAIN RESILIENCY!



# 2022 Elections

# 2022 Elections – At a Glance

- Democrat's control of House and Senate very much at risk in 2022 elections – with GOP favored to retake the House, and the Senate expected to be very close.
- Off-year elections traditionally favor the party out of power.
- Virginia and New Jersey elections highlighted GOP ascendance.
- Presidential popularity will have a significant impact on outlook.
- House Democrats retiring or leaving for another office (31 so far – including several competitive districts) – another canary in the coalmine.
- Redistricting likely to be a factor – though both parties will use to their advantage where they are able.

# Senate Balance of Power

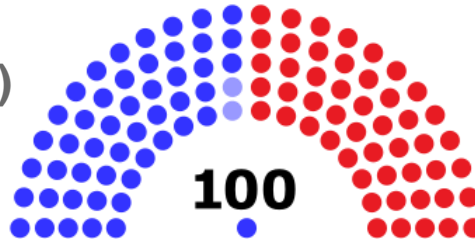
- Senate currently evenly divided 50-50, with Democrats in the majority due to the VP holding tie-breaking vote.
- Republicans defending more seats (20) than Democrats (14)

## GOP Targets:

- Sen. Mark Kelly (D-AZ)
- Sen. Raphael Warnock (D-GA)
- Sen. Catherine Cortez Masto (D-NV)
- Sen. Maggie Hassan (D-NH)

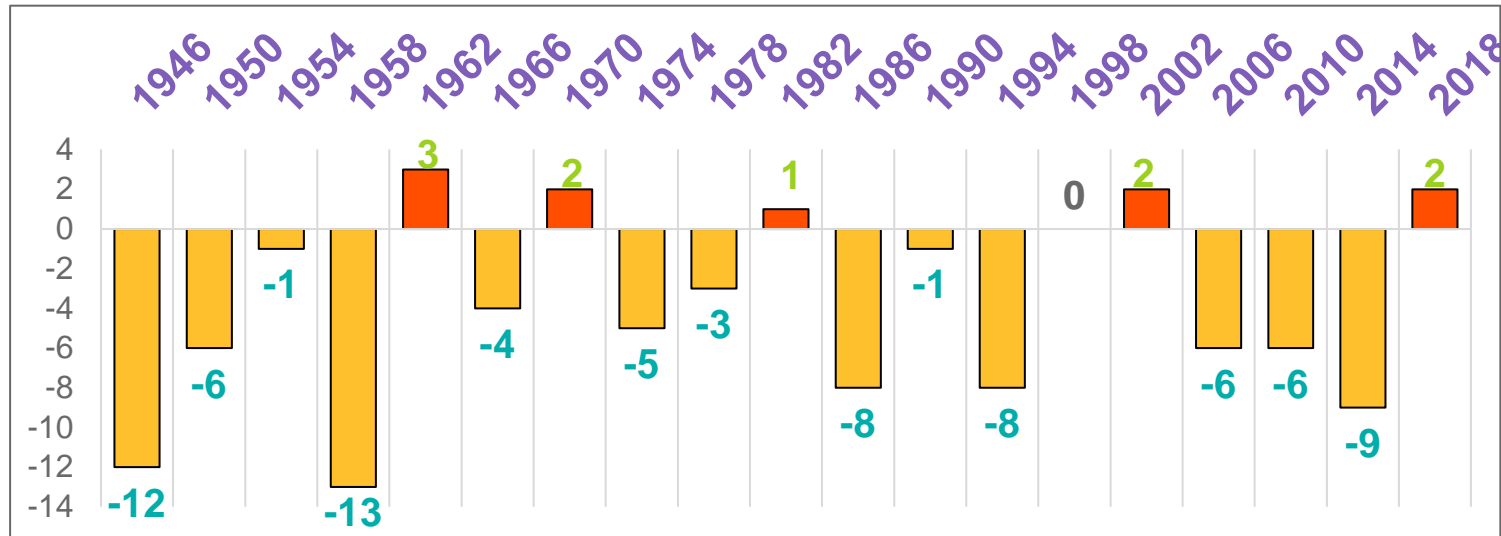
## Democratic Targets:

- Sen. Ron Johnson (R-WI)
- Pennsylvania Open Seat
- Ohio Open Seat
- North Carolina Open Seat
- Sen. Marco Rubio (R-FL)



# Midterms Ahead: Senate Too Close to Call

## Presidential Party Performance in Senate Midterms Since WWII

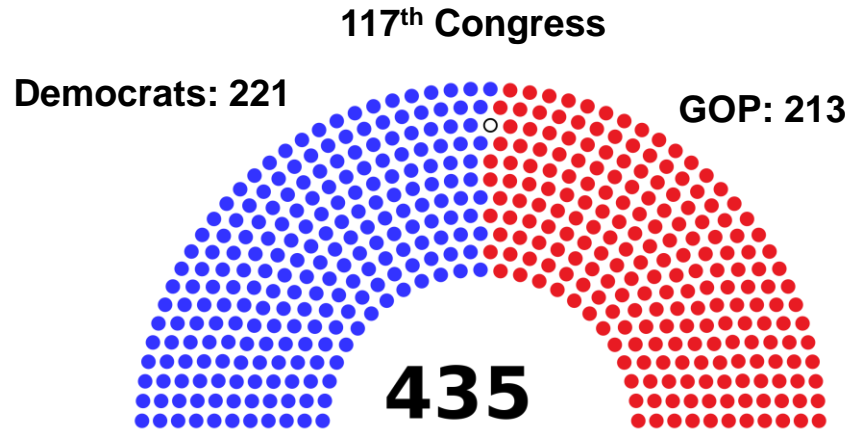


Source: Cook Political Report



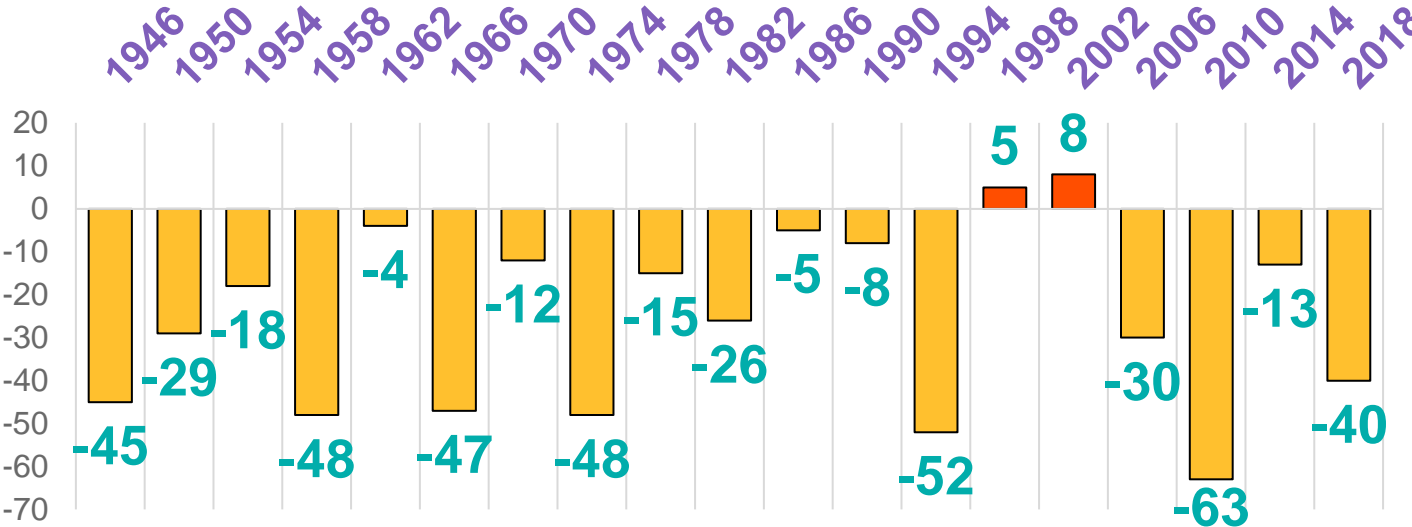
# House Balance of Power

- Democrats narrow majority leaves little room for error in 2022
- 19 House Democrats are either retiring, or seeking another office, including several in very competitive seats
- Only 11 Republicans are retiring or seeking other office – but nearly all are from safe GOP seats



# Midterms Ahead: GOP Favored To Win Back House

## Presidential Party Performance in Midterm Elections Since WWII



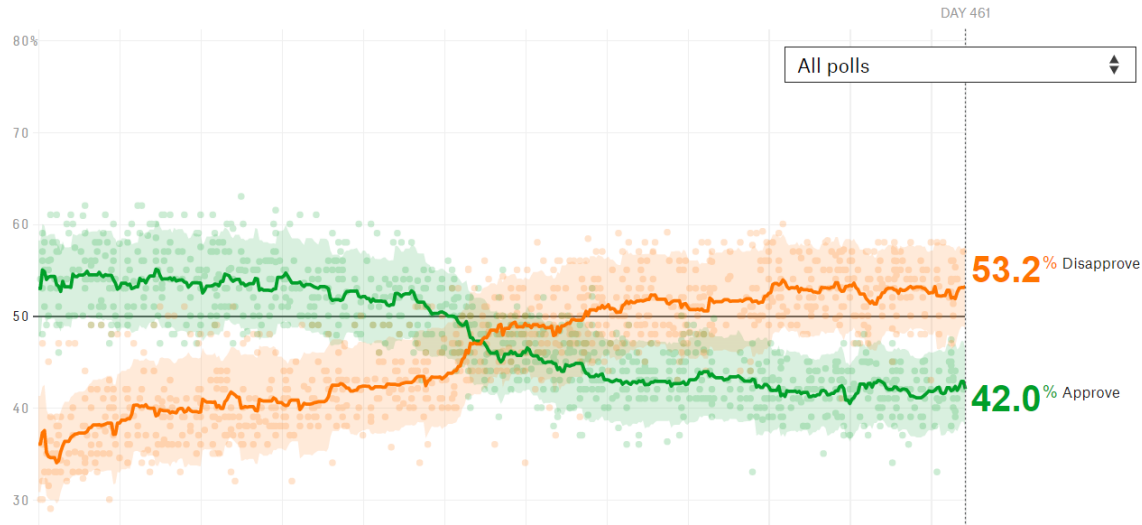
*5 seats need to flip to in 2022 for GOP to claim majority; Already 31 Dems retiring, resigning or running for another office*

Source: [UCSB](#)

# Will the President's popularity be a dominant factor?

## How popular is Joe Biden?

An updating calculation of the president's approval rating, accounting for each poll's quality, recency, sample size and partisan lean. [How this works »](#)

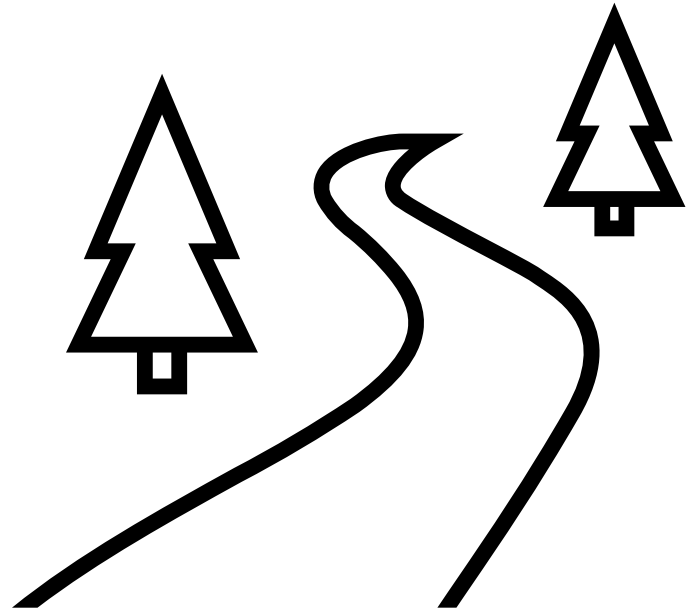


\*As of April 25, 2022

Source: <https://projects.fivethirtyeight.com/biden-approval-rating/>

# And of course... a lot can change before November!

- Primaries
- Ads, ads, and more ads...
- Economy and inflation
- Voter enthusiasm
- War in Ukraine
- COVID-19



# Legislative Update

# Infrastructure Investment and Jobs Act (H.R. 3684)

On November 13, President Biden signed the \$1.2 trillion, Infrastructure Investment and Jobs Act into law. **\$550 billion in NEW SPENDING over 5 years**

## Key Provisions:

- **\$65B** for broadband (e.g., grants to states for broadband deployment, increase broadband accessibility)
- **\$16.6B** for ports and waterways (e.g., port infrastructure, inland waterway improvements)
- **\$55B** for water and wastewater projects
- Other funding for public transit and rail, public schools, energy infrastructure

## Key Pay-fors:

- **\$21B** from extending, by two years, the 2% Medicare sequester
- **\$22B** in repurposing unused COVID-19 relief funds (e.g., Economic Injury Disaster Loan program, Payment Protection Program and more)
- **\$51B** from delaying the Medicare Part D drug rebate rule

# 2022 Congressional Calendar

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- House in Session Only
- Senate in Session Only
- House & Senate in Session
- Federal Holiday

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- Important Phone Numbers**
- [White House Switchboard](#)  
(202) 456-1414
  - [U.S. Capitol Switchboard](#)  
(202) 224-3121
  - [Senate Republican Cloakroom](#)  
(202) 224-6191
  - [Senate Democratic Cloakroom](#)  
(202) 224-4691
  - [House Republican Cloakroom](#)  
(202) 225-7350
  - [House Democratic Cloakroom](#)  
(202) 225-7330

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Current as of December 14, 2021

Campaign season is underway and mid-term elections take place in November!



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# FY2022 Omnibus Bill

**At \$1.5 trillion the FY 2022 Omnibus Appropriations bill contains significant several health policy provisions, and more**

## Increased Agency Funding

- \$8.45 billion for CDC (+\$582 million over FY 2021), including \$200 million in new flexible funding for public health infrastructure and capacity.
- \$2.8 billion for ASPR, including \$845 million for the SNS

**Telehealth:** Extends pandemic telehealth flexibilities for 5 months after the end of declared PHE, including:

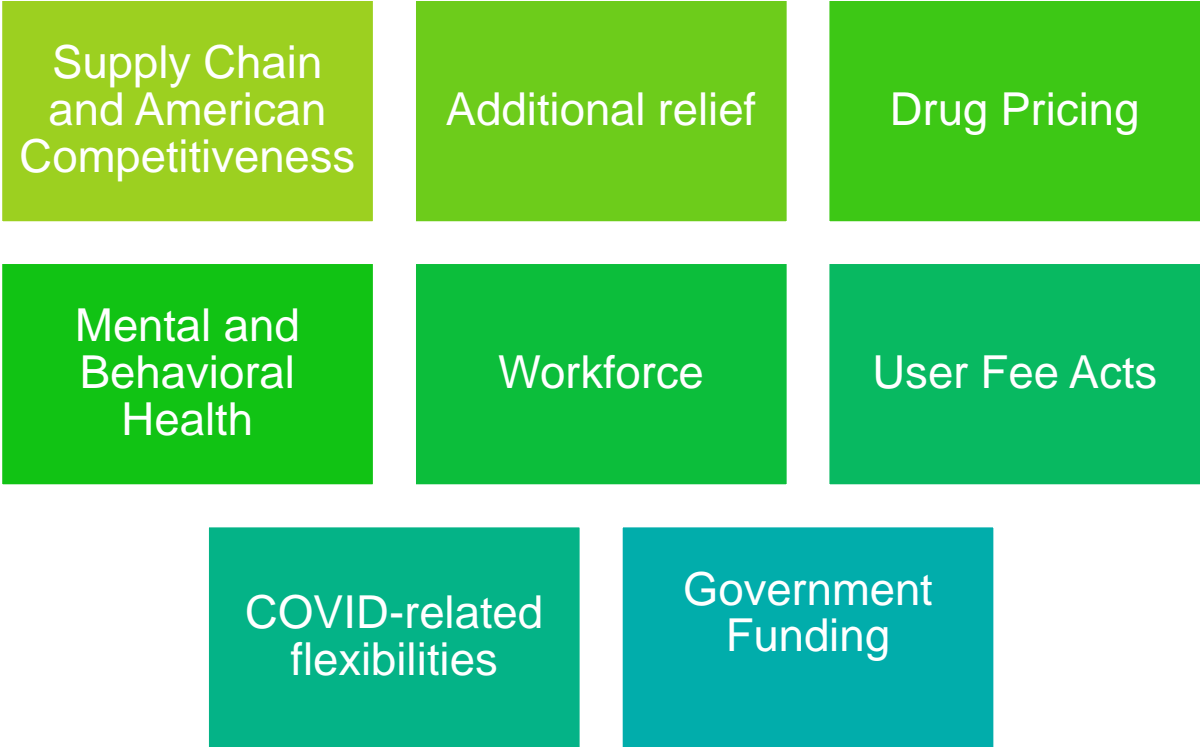
- The removal of geographic requirements and expansion of originating sites for service
- The furnishing of audio-only telehealth services
- Delays face-to-face requirements for eligibility for certain telehealth services

## 340B Eligibility Fix

- Preserves 340B eligibility for certain covered entities who lost 340B status due to a reduction in their DSH adjustment percentage during the COVID-19 PHE as long as all other requirements are met.



# Congress and the rest of 2022...



# Supply Chain is all the Rage!

Multiple bills in Congress to promote greater supply chain resilience, with a focus on:

- Pandemic preparedness
- Global competitiveness

Administration action steps include:

- Executive orders on supply chain
- President's Call to Action on expansion of port operating hours on the U.S. west coast
- Launched "Freight Logistics Optimization Works" (FLOW) to pilot key freight information exchange
- Established "Li-Bridge" a public-private partnership for lithium-based batteries
- Biden-Harris Supply Chain Disruptions Task Force

# PREVENT Pandemics Act – S.3799

Establishes bipartisan Task Force to examine emergence of SARS-CoV-2 and assess the United States' preparedness and response

Strengthens domestic supply chain through grants to support warm base manufacturing and surge capacity

Enhances transparency in Strategic National Stockpile, and creates state stockpiles of critical medical products;

Requires medical device manufacturers to establish redundancy risk management plans and provide notices of expected shortages

Strengthens FDA enforcement authority against selling counterfeit medical devices;

Requires FDA to issue or revise guidance to regarding longest feasible expiration dates for certain drugs

# Global Competitiveness Bills – Supply Chain Impact



## America Creating Opportunities for Manufacturing, Pre-Eminence in Technology, and Economic Strength (COMPETES) Act of 2022 (H.R. 4521):

- Sets aside \$50 billion for incentives to produce semiconductors in the US
- Authorizes broad future investments to improve America's supply chain
- Establishing a new office at the Department of Commerce to monitor, analyze, and support the resiliency of our supply chains and domestic manufacturing.
- Requires collection, verification, and disclosure of information from third party sellers on online marketplaces

## U.S. Innovation and Competition Act (S. 1261):

- Sets aside \$50 billion for incentives to purchase and produce semiconductors in the US
- Supports for critical supply chain resilience
- Updates Buy-American sourcing requirements
- Funding for STEM education and new protections for sensitive research
- Prohibits importation of products made with forced labor and stolen IP

# What ever happened to the Build Back Better Act?

**The Build Back Better Act was President Biden's priority legislation to invest in the social safety net.**

- Democrats aimed to use the budget reconciliation process to advance this package
- Exhaustive negotiations between the White House, Moderate Senate Democrats and progressive House Democrats for much of 2021.
- The bill includes provisions related to health care coverage, workforce, drug pricing and other significant policy changes.
- House narrowly approved the BBBA 220-213 in Nov. 2021, but has since stalled

# Drug Pricing Reforms Possible?

- \$35 per month cap on insulin costs
- Part D redesign (e.g., changing annual caps on out-of-pocket costs, reducing the amount of spending beneficiaries are responsible for during the initial phase of the benefit)
- Limit annual drug pricing increases in Medicare and private insurance
- Negotiation for limited drugs in Part D and then Part B
- Removing vaccine cost sharing for Part D



# 340B Drug Pricing Program Under Attack

## Federal Policy Challenges:

- CMS has been implementing payment cuts of ASP-22.5% since Jan. 1, 2018, for drugs purchased through 340B Drug Pricing Program.
- Legal challenges have been argued to the Supreme Court – with a decision expected soon.

## Manufacturer Challenges:

- Several drug makers are restricting access to 340B drug discounts through contract pharmacies.
- HHS has issued warning letters and enforcement actions targeting drug makers.
- Litigation is underway in multiple lawsuits, including seven drug makers, seeking to clarify HHS's authority to enforce 340B guidance



**Good news:** FY 2022 Omnibus legislation included protection for certain 340B hospitals who lost eligibility during cost reporting periods of 2020, 2021, and ending Dec. 31, 2022.



# FDA User Fee Acts (UFA) – Reauthorization Efforts Underway!

**5-year sunset (e.g., PDUFA VI expires Sept. 30 2022; PDUFA VII negotiations underway)**

- Reauthorization process takes place over several years
- Includes FDA and industry negotiations, and several public meetings before bill text is developed

**Fees must be used only for human drug and device approval activities (e.g., increase staffing, other resources)**

- How funds are used depends, in part, on discussion with industry
- Performance goals negotiation by industry and FDA related to drug and device review times

**User fees supplement congressional appropriations**



# FDA User Fee Acts Cont'd

**PDUFA VII; GDUFA III;  
BsUFA III; and MDUFA V**

- **“Must pass” legislation by Sept. 30, 2021**
- Potential vehicle for other legislation
- **FDA has submitted all “UFA” commitment letters to Congress**
- Congressional hearings have already begun

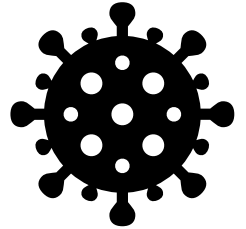
**Topics included in  
commitment letters  
include:**

- Real-world evidence advancement (e.g., to support new labeling claims, post-approval requirements) (PDUFA)
- Efforts to speed drug development for rare diseases (PDUFA)
- More opportunities for generic drug sponsors to meet with FDA (e.g., FDA consultation on the proposed labeling of a generic drug) (GDUFA)
- Enhancing development of complex generic products (GDUFA)
- Demonstration project focused on evaluating data and information needed to meet standards for determining interchangeability (BsUFA)
- Total product lifecycle advisory program (MDUFA)

# Calls for more funding and COVID-19 Relief

Bipartisan measure in the Senate reached but did not advance

- Funding for vaccines, therapeutics and testing capacity (\$9.25B)
- Funding for research, clinical trials and development of vaccines (including to potentially support manufacturing capacity)
- Offset by unspent COVID-related relief funds
- Did not include additional funding related to hospital calls for relief e.g., Medicare sequestration; Provider Relief Fund)



# Workforce Challenges

COVID-19 pandemic has stretched health care workforce to the brink:

- Hospitals across the country are struggling with high-turnover and staffing shortages.
- COVID exposure health impact on workforce
- Health care workforce stress/burnout/trauma, and mental and behavioral health challenges
- Increased patient counts for extended duration, driving need for more care staff – particularly where firm minimum staffing requirements exist
- National labor shortage
- Growth in demand and competition from travel/contract nursing agencies
- Existing regulatory limitations for foreign nurses and physicians



# Health Care Work Force Legislation Examples

TREAT Act (H.R. 708) – Would grant flexibility to allow health care workers to practice across state lines, and through telemedicine during the declared Public Health Emergency + 6 months.

Resident Physician Shortage Reduction Act (S. 834) – Would build on recent addition of 1,000 Medicare supported Graduate Medical Education spots by adding 14,000 additional slots over 7 years.

Children's Hospital GME Funding – Urging Congress to continue increasing funding for CHGME by \$485 million in 2022 – Omnibus provided \$375 million

S. 610 - Dr. Lorna Breen Health Care Provider Protection Act – Would provide grants and training to support health care workforce mental health, resilience and suicide prevention – Just signed into law!

Healthcare Workforce Resilience Act (S. 1024/H.R. 2255) - Expedites and expands visa process to allow up to 40,000 unused employment-based immigrant visas to be used for foreign physicians and nurses.

Bipartisan House and Senate Letters: Bipartisan members of Congress have been pressing the administration to investigate activities from health care staffing agencies.

# Acute Hospital Care at Home Program

In November 2020, CMS announced the Acute Hospital Care at Home (AHCA) program which provides certain hospitals with flexibilities to treat eligible patients at home.



- CMS accepts requests to waive requirements (i.e., nursing services be provided on premises 24/7 and the immediate availability of a registered nurse for care of any patient); waivers are granted on an individual basis
  - The waiver is only in effect for the duration of the COVID-19 PHE
  - AHCA relies both on previously issued blanket waivers and an individually requested/granted waiver
- Hospitals must submit monitoring data to participate (e.g., patient volume, unanticipated mortality during an acute episode of care, escalation rate, safety committee, patient list)

**Vizient endorsed the Hospital Inpatient Services Modernization Act (H.R. 7053/S. 3792) to extend by two years the AHCA waiver flexibilities**

# President's Budget Request Released

**On March 28, the President released his FY 2023 budget. Highlights include:**

- \$846B on Medicare spending and \$536B on the Medicaid program in FY 2023
  - Medicare spending would increase by approx. \$93 million and Medicaid spending would decrease by \$26B
- \$81.7B over 5 years for pandemic preparedness
- \$45 million for HRSA to promote telehealth among providers and others (25% increase over the FY 2022 actual)
- Add \$324 million in new workforce spending (more than \$2 billion in FY 2023)
- \$17 million in spending for FY 2023 to improve operations and oversight of the 340B Program (Note this is a \$6 million increase over FY 2022 enacted levels)
- \$127 billion in discretionary funding for the Department of Health and Human Services

# Regulatory Update

# Key HHS Leaders

- HHS Secretary: **California AG Xavier Becerra**
- Surgeon General: **Dr. Vivek Murthy**
- Centers for Disease Control & Prevention (CDC) Director: **Dr. Rochelle Walensky**
- COVID-19 Equity Task Force Chair: **Dr. Marcella Nunez-Smith**
- COVID-19 Response Coordinator and Counselor to the President: **Jeff Zients**
- Chief Medical Adviser to the President on COVID-19: **Dr. Anthony Fauci**
- Centers for Medicare & Medicaid Services (CMS) Administrator: **Chiquita Brooks-LaSure**
- Center for Medicare and Medicaid Innovation Director: **Liz Fowler**
- Food and Drug Administration (FDA) Commissioner: **Dr. Robert Califf (Confirmed February 15, 2022)**



# Public Health Emergency (PHE)

- The PHE declaration is critical to ensuring COVID-related flexibilities remain in place
- HHS Secretary Becerra extended the COVID-19 Public Health Emergency (PHE) for an additional 90 days in April
- PHE remains in effect until July 16, 2022
- Sec. Becerra committed to 60-days notice to states before ending PHE
- Growing pressure from lawmakers in Congress and state governors to bring PHE to a close.



ASPR Homepage > Public Health Emergency Declarations

## Renewal of Determination That A Public Health Emergency Exists

As a result of the continued consequences of the Coronavirus Disease 2019 (COVID-19) pandemic, on this date and after consultation with public health officials as necessary, I, Xavier Becerra, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby renew, effective January 16, 2022, the January 31, 2020, determination by former Secretary Alex M. Azar II, that he previously renewed on April 21, 2020, July 23, 2020, October 2, 2020, and January 7, 2021, and that I renewed on April 15, 2021, July 20, 2021, and October 18, 2021 that a public health emergency exists and has existed since January 27, 2020, nationwide.

January 14, 2022

/s/

\_\_\_\_\_

Date

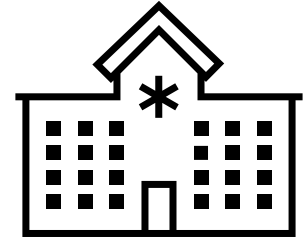
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Xavier Becerra

# Emergency Temporary Standard

March 23, 2022, the Occupational Health and Safety Administration (OSHA) provided notice of a limited re-opening of the comment prior regarding the OSHA standard for healthcare and healthcare support service workers as related to occupational exposure to COVID-19.

- Comments accepted until April 22, 2022, and a virtual informal hearing to be held April 27, 2022 → [OSHA is preparing to publish a final standard](#)
- Provides changes to certain portions of the June 2021 ETS



# Provider Relief Fund

**Nov. and Dec. 2021:** HRSA began distributing ARP Rural payments and Phase 4 General Distribution payments

- **May 2, 2022:** Phase 4 / ARP Rural reconsideration applications due.

**March 31, 2022:** Reporting Period 2 ends for funds received July 1, 2020 – Dec. 31, 2020

**Sept. 30, 2022:** Reporting Period 3 ends for funds received Jan 1, 2021 – June 30, 2021

**March 31, 2023:** Reporting Period 4 ends for funds received July 2, 2021 – Dec. 31, 2021

## Recent WIN:

- HRSA clarified that funds can be used for “a variety of direct and indirect costs of recruiting and retaining personnel during the pandemic”

## Ongoing CONCERN:

- Need to distribute remaining PRF dollars – not much left
- Due to a lack of funds, providers are no longer able to submit claims for testing, treating and vaccinating the uninsured (as of March 22 and April 5)

# FDA Center for Devices and Radiological Health – Strategic Priorities 2022 - 2025

## Three Key Goals

Promote a modern and diverse workforce

Enhance organizational agility and resilience

Advance health equity

## 2022-2025 Measures of Success:

1. By Dec. 31, 2025, more than 50% of manufacturers of newly authorized novel technologies for the U.S. market brought their devices to the U.S. first or in parallel with other major markets
2. By Dec. 31, 2025, more than 75% of the time, FDA identifies and acts on significant safety signals related to medical devices marketed in the US and other major markets first or in coordination with regulatory agencies of other major markets

# Transition Plan for Certain Medical Devices

On December 23, FDA issued draft guidances regarding its transition plan for medical devices issued emergency use authorizations (EUAs) during the COVID-19 PHE. Key issues for comment include:

1. Whether the 180-day period proposed for advance notice of termination of each EUA declaration pertaining to devices would sufficiently allow for an appropriate transition period that avoids exacerbating product shortages and supply chain disruptions.
2. Whether FDA's issuance of this guidance with a proposed transition policy and requesting public comment may help the Agency to satisfy ... the requirement ... to consult with a manufacturer that was issued an EUA for an unapproved product on the appropriate disposition of the product.

*Comments were due March 23, 2022, and a final guidance has yet to be released*

# Notice Related to Permanent Discontinuance or Interruption of Device Manufacturing

FDA issued a draft guidance to help prevent device shortages after the COVID-19 PHE.

GUIDANCE DOCUMENT

## Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act

*Draft Guidance for Industry and Food and Drug Administration Staff*

JANUARY 2022

[Download the Draft Guidance Document](#)

[Read the Federal Register Notice](#)

Draft

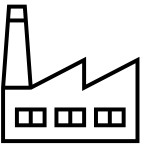
Not for implementation. Contains non-binding recommendations.

This guidance is being distributed for comment purposes only.

# FDA Quality Metrics Reporting Program

On March 9, FDA issues a notice and request for comments regarding changes to FDA's previously proposed quality metrics reporting program. Comments are due June 7, 2022.

- Current regulations require manufacturer compliance with current good manufacturing practice (CGMP) requirements BUT this does not indicate whether a manufacturer has an effective “Pharmaceutical Quality System” (PQS) which ensures both sustainable CGMP compliance and supply chain robustness
- FDA is proposing a direction for an FDA Quality Metrics Reporting Program with four general practice areas:
  - Manufacturing Process Performance (e.g., right-first-time rate measure)
  - PQS Effectiveness (e.g., unplanned maintenance measure)
  - Laboratory Performance (e.g., calibration timeliness measure)
  - Supply Chain Robustness (e.g., fill rate)



# Executive Order 14017 on America's Supply Chains - One Year Later

On Feb 24, HHS released the “Public Health Supply Chain and Industrial Base One-Year Report”, which details what the agency has done to help make our public health supply chains and biological preparedness industrial base more resilient, diverse, and secure.

- Growing the nation's stockpiles
- Coordinating efforts to foster the use of domestic sourcing and promoting domestic raw material manufacturing
- Working to address silicone shortages
- Establishing an Essential Medical Device list
- Increasing Visibility to Prevent Disruptions and Shortages



# Inpatient Prospective Payment System (IPPS) Proposed Rule

On April 18, CMS released the IPPS Proposed Rule which contains key payment policies and several requests for information:

Estimate payment rate update for FY 2023 (before applying budget neutrality factors): 3.2%

Condition of participation to report data element for future pandemics and epidemics

Medicare Disproportionate Share Hospital (DSH) payments anticipated to decrease by \$834 million

CMS seeking feedback on various social determinants of health (SDoH) and health equity topics

Permanent cap on wage index decreases

Updates to quality programs, including COVID-related policies

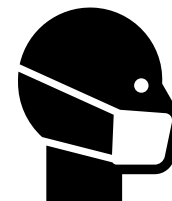
# IPPS Request for Comment – Potential N95 supplemental payment

To support a wholly domestic supply chain for NIOSH-approved surgical N95 respirators, CMS is considering making a payment adjustment (in a budget neutral manner). Such payment adjustments could potentially apply to 2023 and potentially subsequent years.

CMS seeks comment on the following two possible frameworks:

1. *Biweekly interim lump sum payments that would be reconciled as cost report settlement*
2. *MS-DRG add-on payment that could be applied to each applicable Medicare IPPS discharge*

***CMS welcomes feedback on these potential payment adjustments!***



# CY22 Physician Fee Schedule FINAL Rule

## Key Takeaways Include:

- **Updates Payment Amounts for 2022:** \$33.58 conversion factor which is a - 3.75% change from 2021 (not including potential cuts due to sequestration and statutory Pay-As-You-Go Act of 2010)
- **Permanent expansion of telehealth for mental health services per Consolidated Appropriations Act, 2021 – beginning in 2023**
  - Permits the patients home to be an originating site and eases geographic restrictions for mental health care services
  - Permits audio-only mental health telehealth services
- **Permits temporary, additional telehealth services on the Category 3 list to remain covered until the **end of CY 2023****

# CY 2022 Outpatient Prospective Payment System (OPPS) FINAL Rule

Increase payment rates by 2.0% when quality reporting requirements are met

Due to COVID-19, use CY 2019 data to set CY 2022 OPPS/ASC payment system rates

Increase range of financial penalties for hospital price transparency penalties; \$300/day - \$5,500/day depending on bed count

Halt the CY 2021 policy to eliminate the inpatient only (IPO) list; 291 services added back to IPO list, and 255 procedures removed from the ASC covered procedures list

Continuation of 340B cuts (ASP-22.5%) and site neutral payment reductions

# Thank you!

# Questions?

# Let's work together

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**Senior Regulatory Affairs and Public Policy Director**

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