



## Policy Brief

March 4, 2022



### A World in Crisis: How the War in Ukraine Could Impact U.S. Health Care

The invasion of Russian forces in Ukraine has shocked the world. In response, the U.S., like much of the free world, has levied a multitude of sanctions against President Putin, his inner circle, and Russian industry and financial institutes—ratcheting up the tension and creating instability in the global economy. The U.S. health care industry should take note of the potential strain this crisis could have on our ability to function. Soon, the health care industry could be dealing with cybersecurity concerns, a refugee and humanitarian crisis, and rising inflation and supply chain woes. Keep reading to learn more about the impact of this quickly-evolving situation.

#### **Agencies and associations have warned of potential cybersecurity threats to health systems.**

The Cybersecurity and Infrastructure Security Agency (CISA) recently issued a “[Shields Up](#)” advisory urging organizations across public and private sectors to employ enhanced security measures. Cybersecurity researchers have disclosed that malware known as HermeticWiper is being used against organizations in Ukraine. This type of malware targets Windows devices and presents a direct threat to an organization’s daily operations. The AHA has released two bulletins regarding cybersecurity threats with potential actions and resources for providers:

[Cybersecurity Advisory | Destructive Malware](#)

### **This may be the largest refugee and humanitarian crisis of the 21<sup>st</sup> century.**

Already, more than [one million](#) people have left Ukraine in the last seven days; the United Nations [speculates](#) that the war could lead to 5 million Ukrainians leaving their homeland. Poland and other European nations are receiving the vast majority of refugees, but the U.S. has expressed its preparedness to accept those in need. All Ukrainian men between the ages of 18 and 60 are [not permitted](#) to leave the country, creating an imbalance of women and children seeking shelter.

If the U.S. receives refugees, behavioral health care will be high on the list of needs from individuals dealing with the stress of leaving a warzone—a need that will be mirrored by Americans also impacted by the crisis. First Lady Jill Biden [expressed](#) concern for behavioral health as the Ukraine crisis unfolds and urged anyone whose mental health is suffering due to the conflict to reach out for help. White House Press Secretary Jen Psaki stated that the U.S. is [working](#) with European neighbors of Ukraine to identify where there is capacity and ability to handle refugees.

### **Inflation and supply chain woes from instabilities in the market impact everyone.**

The political fallout from the invasion of Ukraine will have financial ramifications for every American. [Oil prices](#), which hit an eight-year high last week, are likely to surge even further with the instability in the market. Additionally, [sanctions against](#) Russia could worsen current semiconductor shortages as the country is a leading supplier of nickel and lithium-ion. Semiconductors are an [essential component](#) of many medical devices used in hospitals. The usage of semiconductors in the healthcare market [allows](#) for digitization, automation and wireless technology. The price of food is also subject to [increase](#) as Russia and Ukraine [combined](#) account for approximately 20% of the world's corn supply and 80% of sunflower oil. Many individuals in the U.S. are already struggling to make ends meet; the global instability is poised to tighten the financial strains on everyone. The health care industry should stay abreast of how this will impact the patients in our care.



## Meet the New FDA Commissioner

Last month, the Senate voted 50-46 to [confirm](#) Dr. Robert Califf as Commissioner of the Food and Drug Administration (FDA), putting an end to the year-old vacancy at this health agency. President Biden's selection of Dr. Califf was rife with controversy from both Democratic and Republican senators, with five Democrats voting against and six Republicans voting for the nominee. Keep reading to learn more about the new commissioner, reasons for controversy around his nomination and his plan for the future of the FDA.

### Who is Robert Califf?

Dr. Califf, a cardiologist by trade, [previously](#) served as FDA Commissioner for less than a year at the end of President Obama's second term. During his previous stint as Commissioner, Califf sought to combat the opioid epidemic and make drugmakers advertise off-label uses for products approved by FDA. Previously, Califf was a senior adviser to Verily Life Sciences and served as vice chancellor for clinical and translational health at Duke University. At present, Califf is an adjunct professor for clinical and translational health at Duke and Stanford and serves on the corporate board of biopharmaceutical company Cytokinetics.

### Why all the fuss over his appointment?

Reactions to Califf's appointment were split, with his nomination drawing praise from many health experts and lawmakers. However, skeptics [criticized](#) his ties to the pharmaceutical industry given the current opioid epidemic. Pro-life groups [urged](#) congressional members to vote against Califf's nomination due to concerns about how he might handle abortion drug rules.

### What does this mean for the direction of the FDA?

During the confirmation hearing, Califf discussed key priorities that the FDA will address, which included:

- Focusing on digital health technology, applying a risk-based approach for medical devices.
- Harnessing data to innovate trial designs for rare diseases.

- Addressing the opioid crisis, with Dr. Califf highlighting that current efforts to tackle the problem had come up short.
- Tackling [scientific misinformation](#), which is increasingly prevalent and poses a significant public health threat. Dr. Califf stated, "The kinds of distortions and half-truths that find their way into the public domain do enormous harm, both by leading people to behavior that is detrimental to their health and by causing them to eschew interventions that would improve their health."



### 340B Drug Pricing Program: 2022 Update

The 340B Drug Pricing Program, which provides drug discounts to eligible health providers, continues to face several threats. Although the program was originally created in 1992 to help health providers stretch “federal scarce resources,” critics argue that the program lacks transparency and doesn’t help patients. This has resulted in several media articles targeting 340B hospitals. Additionally, the COVID-19 pandemic has inadvertently jeopardized the eligibility of 340B hospitals, with many already being terminated from the program. Keep reading for the latest updates on 340B.

- **Critics of 340B** [continue to claim](#) that the program has grown too big, with patients seeing little benefit from the discounts provided. A [recent study](#) funded by the Community Oncology Alliance names the 340B program as a contributor to rising costs, claiming some hospitals price drugs at 3.8 times higher than their 340B acquisition costs and pocket the savings. Other [media articles](#) also single out hospitals and note how they are “putting profits over patients.”
- **Payer-mix changes caused by the COVID-19 pandemic have** [cost some hospitals](#) their **340B program-eligibility**. Eligibility is determined using a [complex calculation](#) based on, among other things, Medicaid patients’ length of an inpatient stay, as well as the number of overall Medicaid patients. Many patients delayed their care during the pandemic, impacting hospitals’ eligibility for 340B discounts during the public health emergency.

- **A federal judge [ruled against HHS](#) in the Administration's latest defense of 340B-entities, instead ruling in favor of AstraZeneca.** The ruling hinges on whether HHS has the authority to issue warnings against drugmakers who cut off contract pharmacies' access to 340B discounts.
- **By the summer, the Supreme Court is expected to release its opinion on the 28.5% payment reduction to 340B drugs originally instituted during the Trump Administration.** [Here's more](#) on *American Hospital Association v. Becerra* and its potential long-term ramifications.

## Federal Court Rules on Surprise Billing Arbitration

Last week, a federal court [ruled](#) on the mediation process created to settle out-of-network payment disputes. The ruling fell in favor of the Texas Medical Association and took issue with select portions of surprise billing regulations related to the arbitration process. Specifically, the independent dispute resolution process will no longer give [increased weight](#) to rates from insurers and providers contracted with in the past. The ruling does not strike down any of the patient protections included in the No Surprises Act.

## CMS Redesigns ACO Model to Advance Health Equity

Last week, CMS announced a [redesigned](#) Accountable Care Organization (ACO) model to better reflect the Biden Administration's goal of advancing health equity. CMS will replace the current Global and Professional Direct Contracting model with the new Realizing Equity, Access, and Community Health (REACH) model, which will launch in January 2023. The new model will require that all participating organizations develop a health equity plan to identify underserved communities and implement initiatives to reduce health disparities within their beneficiary populations. This model gives an indication of how CMS will incorporate health equity into value-based care, making hospitals more accountable for addressing health disparities.

## President Biden Nominates First Black Woman to SCOTUS

President Biden has [announced](#) his nomination of Judge Ketanji Brown Jackson to serve on the Supreme Court of the United States. After a rigorous consideration process and the counsel of both Republican and Democratic Senators, the President chose [Judge Jackson](#) for her unique legal perspective, her experience as a public defender, and her robust legal and service background. Prior to her nomination, President Biden repeatedly expressed his desire that the Supreme Court reflect "the full talents and greatness of our nation." If confirmed, Judge Jackson

will become the sixth woman to ever serve on the Supreme Court—and the first Black woman to do so.

## President Biden Addresses the Nation

President Biden's State of the Union address this week laid out his vision for tackling many health care related issues. Here's a breakdown of the key areas he highlighted:

- **Behavioral Health and the Opioid Crisis**
  - Biden plans to [increase access](#) to behavioral health providers and require full parity between behavioral and physical health care. The administration seeks to remove barriers to opioid treatment by expanding treatment options and [rescinding](#) the X waiver.
- **Strengthening Nursing Home Oversight**
  - The President signaled that CMS will set higher standards for [nursing homes](#) and increase inspections of facilities.
- **Medicare Drug Pricing Negotiations**
  - Biden urged Congress to let Medicare [negotiate drug prices](#), and that the price of insulin should be capped at \$35 a month. Both of those proposals cleared the House in November as part of the Build Back Better Act, which ended up falling apart in the Senate.
- **Combating Cancer**
  - Biden called for Congress to fund his proposed [biomedical research](#) agency, the Advanced Research Projects Agency for Health (ARPA-H) to cut cancer death rates in half over the next 25 years.

## Updates to COVID-19 Regulations

AHPA continues to follow new COVID-19 regulations, guidance, and other government actions. The updates below are the latest developments to help mitigate the impacts of COVID-19.

### **CDC Recommends Men Wait Longer Between First and Second Dose of mRNA Vaccines**

The CDC recommends males ages 12-to-39 consider waiting eight weeks between the first and second doses of Pfizer and Moderna vaccines to reduce a rare risk of heart inflammation. The CDC still recommends that other eligible individuals wait three weeks between Pfizer shots and four weeks between Moderna doses, particularly the elderly and those with compromised immune systems.

## **New Test-to-Treat Initiative to Provide Free Antiviral Pills at Pharmacies**

President Biden unveiled a new initiative that will provide free access to antiviral COVID-19 treatments for patients who test positive at designated pharmacies and community centers.

## **New CDC Framework for Masking Policy**

The CDC has released a new framework for determining masking requirements in a given region. Americans living in areas deemed to have “low” levels of COVID-19 no longer need to wear masks indoors.

## **President Biden Unveils New COVID-19 Strategy**

The White House has released the new National COVID-19 Preparedness Plan. The initiative lays out a roadmap to help fight COVID-19 as the country transitions back to more normal routines. The plan focuses on four key goals: protecting against and treating COVID-19, preparing for new variants, preventing economic and educational shutdowns, and continuing to vaccinate the world.



## AHPA Resources

### **Missed a recent AHPA Webinar?**

Visit AHPA's [YouTube channel](#), where members can stream webinars on demand at their convenience.

### **Below is a directory of the recent regulatory work that AHPA has conducted:**

	Initial Summary	AHPA Comment	AHPA Summary
Cures 2.0 Act	<a href="#">X</a>		
Medicaid and CHIP RFI	<a href="#">X</a>		

## WHAT WE'RE READING...

[How to Make Sense of the Case and Hospitalization Data as Omicron Take Off](#) – Vox

[Two Years After World's Biggest Lockdown, India Surges Back to Normal Life](#) – Reuters

[How to Donate to Ukraine Relief Efforts](#) – Forbes

[Sacklers and Purdue Pharma Reach New Deal with States Over Opioids](#) – New York Times