Washington Update

October 19, 2023

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Vizient D.C. Team – Public Policy & Government Relations

Monitor → Educate → Advocate

Bi-Partisan/Non-Partisan

How Do We Help?

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 Your Questions – We are always available to answer questions or conduct research into specific legislative or regulatory issues.

Key Policy Themes

Transparency

Finding savings opportunities (e.g., site neutral payment policy)

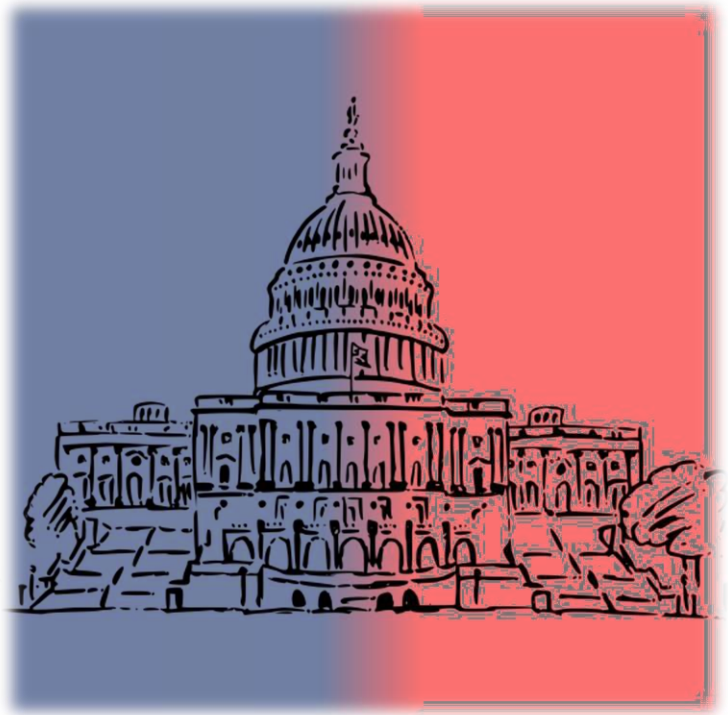
Oversight

Addressing supply chain challenges

Moving on from the COVID-19 pandemic

Current Dynamics in a Divided Congress

Recap: November 2022 midterms



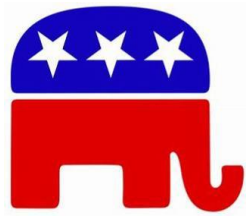
Democrats maintain a narrow majority in the Senate
(51*D : 49 R)

Republicans hold a slim majority in the House
(212 D : 222 R)

1. The “red wave” many pollsters predicted never materialized
2. State elections yielded policy referendums, federal election did not
3. The 118th marks a return to divided government & intraparty politics will impact policy focus
4. Significant action will need to be bipartisan…and could take a while

Health Policy: A Difficult Path to Action

GOP Priorities



Healthcare oversight and policy

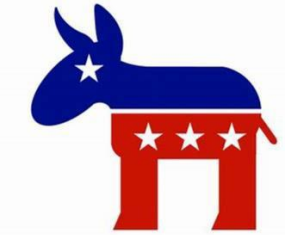
- COVID-19 Provider Relief Fund
- DSH Payments
- Workforce
- Pharmacy Benefit Managers
- MA regulatory requirements
- IRA oversight
- 340B program transparency
- Lifting the moratorium on physician-owned-hospitals
- Telehealth
- Mental and Behavioral Health
- Public Health Preparedness

Bipartisan Agreement

Where is there common Interest?

Hospital oversight – consolidation, cost, transparency

Democratic Priorities



Strengthening social programs and access to care

- Strengthen Inflation Reduction Act (IRA)
- Medicaid expansion
- Reproductive rights
- Health equity
- Mental and Behavioral Health
- Public Health Preparedness
- Pharmacy Benefit Managers
- 340B?
- Telehealth
- Workforce
- DSH Payments

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Government Funding Issues Highlight Congressional Dynamics

September was dominated by fights over government funding bills

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Key Takeaways…

Legislative change will be incremental and slow moving; dynamics matter!

Many discrete health policy issues have bipartisan interest

For leading health system partners, uncertainty in the political environment leads to uncertainty in business

Hospitals on the Agenda

Tax Exempt Status and Community Benefit

Nonprofit hospitals save more in tax exemptions than they provide in charity care: KFF

FORBES > MONEY > TAXES

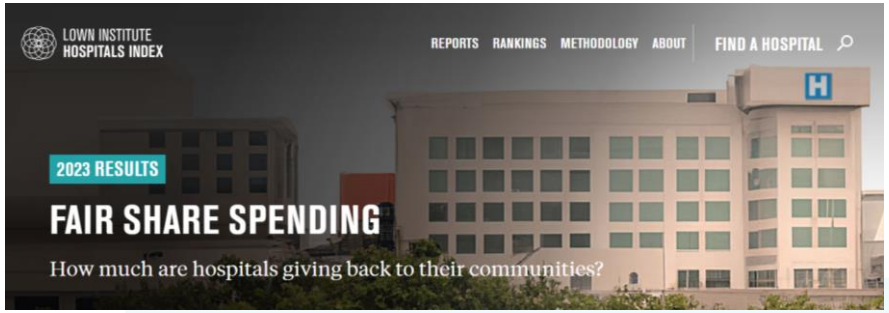
Putting The Charity Back In Charitable Hospitals — A Bipartisan Agreement?

Arkansas hospital sued thousands of patients over medical bills during the pandemic, including hundreds of its own employees

As Nonprofit Hospitals Reap Big Tax Breaks, States Scrutinize Their Required Charity Spending

How Nonprofit Hospitals Put Profits Over Patients

A Times investigation revealed that many of these institutions are abandoning patients and straying from their charitable missions.



KEY TAKEAWAYS

Out of 1,773 nonprofit hospitals evaluated, 77% spent less on charity care and community investment than the estimated value of their tax breaks – what we call a "fair share" deficit.

The total "fair share" deficit for these hospitals amounted to $14.2 billion in 2020. That's enough to erase the medical debts of 18 million Americans or rescue the finances of more than 600 rural hospitals at risk of closure.

Many of the hospitals with the largest "fair share" deficits also received millions in COVID-19 relief funding and ended the year with high net incomes.

In four states (MA, MN, RI, and Washington, DC), the total "fair share" deficit for all hospitals is enough to wipe out all medical debt on credit reports in the state.

In 41 states, the total "fair share" deficit for all hospitals is enough to cover the net losses of all rural hospitals in the state in 2020.

Sources: https://www.axios.com/2023/03/15/nonprofit-hospitals-tax-exemptions-charity-care; https://www.cnn.com/2023/09/08/us/arkansas-hospital-debt-collections-lawsuits-pandemic/index.html; https://kffhealthnews.org/news/article/nonprofit-hospitals-tax-breaks-community; https://www.nytimes.com/2023/01/25/podcasts/the-daily/nonprofit-hospitals-investigation.html -benefit/#:~:text=Policy%20analysts%20at%20KFF%20estimated,portion%20of%20their%20community%20benefits; https://www.forbes.com/sites/deanzerbe/2023/05/09/putting-the-charity-back-in-charitable-hospitals---a-bipartisan; https://lownhospitalsindex.org/2023-fair-share-spending/-agreement/?sh=180993a15c30

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Attention to Hospital Compliance, 340B and Relief Payments

July 18, 2023

FCA Lawsuit Alleges Three Hospitals Were Overpaid PRF 'High-Impact' Money and Kept It

Nina Youngstrom

Health Care Compliance Association (HCCA)

How one bad law drives hospital consolidation and high health care costs

Congress must reform 340B.

PROVIDERS

Pandemic relief funds saved some hospitals' finances but unnecessarily bolstered many more

By **Dave Muoio** · Jul 20, 2023 10:30am

HOSPITALS

Feds expected to scrutinize Covid-era payments to providers

Hospitals, clinics, nursing homes and other providers collected billions in government aid during the pandemic. Federal auditors may soon come knocking to ensure the money was spent correctly.

By JOEL BERG

Just more than a third of hospitals are complying with price transparency rules: report

BY JOSEPH CHOI - 07/20/23 12:27 PM ET

New analysis: CMS vastly overestimates hospital price transparency efforts

By Cynthia A. Fisher March 2, 2023

Sources: https://www.fiercehealthcare.com/providers/pandemic-relief-funds-saved-some-hospitals-finances-unnecessarily-bolstered-many-more; https://medcitynews.com/2023/03/feds-expected-to-scrutinize-covid-era-payments-to-providers/; https://thehill.com/policy/healthcare/4107837-just-over-a-third-of-hospitals-are-complying-with-price-transparency-rules-report/; https://arkansasadvocate.com/briefs/fulton-county-hospital-faces-63900-fine-for-lack-of-price-transparency/; https://www.statnews.com/2023/03/02/cms-vastly-overestimates-transparency-hospital-prices/; https://www.dallasnews.com/opinion/commentary/2023/01/28/how-one-bad-law-drives-hospital-consolidation-and-high-healthcare-costs/; https://www.jdsupra.com/legalnews/fca-lawsuit-alleges-three-hospitals-8146935/

Developments in California Gaining National Attention

- California broadens Medicaid to unauthorized immigrants
- California increases minimum wages for healthcare workers
  - Law signed by Gov. Newsom on October 13, 2023
  - Nation’s first law create a statewide healthcare worker minimum wage standard
  - June 1, 2024, effective date
- Oct 7, 2023, Gov. Newsom signs law (SB 770) to evaluate alternative health insurance coverage
  - Provides various deadlines in 2025 to build towards a federal waiver framework for a potential single-payer system

Health Systems in the Congressional Hot Seat

Congressional Hearings Illuminate Bipartisan Distrust

- *Hearing on **Tax-Exempt Hospitals** and the Community Benefit Standard* | W&M April 26
- *Searing on Examining Policies that Inhibit Innovation and **Patient Access*** | W&M May 10
- *Hearing on Health Care **Price Transparency**: A Patient's Right to Know* | W&M May 16
- *Subcommittee Hearing on Why Health Care is Unaffordable: **Anticompetitive** & **Consolidated** Markets* | W&M May 17
- *Hearing on **Consolidation** and Corporate Ownership in Health Care: Trends and Impacts on Access, Quality and Costs* | Finance June 8

High Interest in Hospital Oversight

- **Provider Relief Funds (PRF):** W&M Oversight Cmte Chairman letter to HHS Secretary asking for clarity on the decision-making process for the disbursement of PRF
- **Facility Fees/Site-Neutral:** Growing interest in "facility fees"
- **Price Transparency:** Oversight of existing price transparency regulations remains a popular talking point; confusion around who is complying

Recent Deluge of Unfriendly Legislation

- 340B transparency, site-neutral payments, new price transparency requirements, consolidation reporting, and phase-out of inpatient-only list for certain procedures
- Other legislation introduced to lift the moratorium on physician-owned hospitals

House Committees Actively Engaged

House Energy and Commerce Committee: Advanced the Healthcare Price Transparency Act (H.R. 4822) along party lines

- Codifies **price transparency** regulations for hospitals and health plans and increases penalties for non-compliance
- **Site-neutral payment policy** for off-campus HOPDs for drug administration; $3.8 billion cut over 10 years
- Requirements for off-campus hospital outpatient departments (HOPDs) to obtain a **unique national provider ID** and submit an attestation of compliance for each HOPD as a Condition of Participation (CoP) in Medicare
- But the good news… delays Medicaid Disproportionate Share Hospital (DSH) payment cuts for two-years

House Ways and Means Committee: Advanced the Healthcare Price Transparency Act (H.R. 4822) along party lines

- Codifies and expands **price transparency** regulations for hospitals and health plans (e.g., requirements to ambulatory care centers clinical diagnostic lab tests, and imaging services)
- Adopts **site-neutral payment policy** for HOPDs for drug administration starting in 2025; there is a delay to 2026 for cancer centers, rural, and health professional shortage area hospitals
- Requires off-campus HOPDs to obtain **national provider ID** for claims and services
- Extends sequestration by two months at a rate of 1.5 percent

House Education & Workforce Committee: Transparency in Billing Act (H.R. 4509)

- Requires each off-campus HOPD to obtain **unique health identifier** and include it on all claims for services billed to commercial group health plans

Lower Costs, More Transparency Act

The combined bill (H.R. 5378) between House Ways and Means Committee's *Health Care Price Transparency Act* (H.R. 4822) and the Energy and Commerce Committee and Education and Labor Committee's PATIENT Act (H.R. 3561).

- Codifies price transparency regulations for hospitals and health plans, clinical diagnostic lab tests, imaging and in Ambulatory Surgery Centers, and increases noncompliance fines
- Adopts site-neutral payment policy for HOPDs for drug administration starting in 2025. There is a delay to 2026 for cancer centers, rural, and health professional shortage area hospitals.
- Prohibits PBMs from using spread pricing with Medicaid Managed Care
- Requires off-campus HOPDs to obtain national provider ID for claims and services.
- Includes MA prior authorization reform.
- Delays Medicaid DSH cuts for two-years
- Reauthorizes CHCs, National Health Service Corps and Teaching Health Centers GME

Bipartisan Primary Care and Health Workforce Act

Senate HELP Committee Chairman Bernie Sanders (I-VT) released legislation with Sen. Roger Marshall, M.D. (R-KS) to support workforce investment and make other healthcare reforms	More than $500 million in funding to support rural residency programs, increasing number of primary care doctors, and invests in primary care training and enhancement
	Additional investments in nursing workforce, including loan repayment and scholarship programs
	Reauthorizes and invests in community health centers, the National Health Services Corps, Teaching Health Center GME.
	Requires HOPD provider identifier, restricts facility fees for telehealth and certain E/M visits and prohibits anti-competitive clauses in hospital contracts with health plans

PAHPA Reauthorization – Supply Chain Focus

Congress needed to reauthorize the Pandemic and All Hazards Preparedness Act before Sept. 30…

- It had been considered a priority item for Congress to address this year – especially in the aftermath of COVID-19 pandemic
- PAHPA includes programs under HHS that are responsible for national preparedness, including the National Health Preparedness Strategy, Strategic National Stockpile, Hospital Preparedness Program (HPP) and Health Care Coalitions (HCC).

What happened?

Shortages Continue to be Focal Point

Interest in Congress and administration to take steps to address ongoing drug shortages:

- Senate Homeland Security and Government Reform released report and held a hearing; House E&C also focused on shortages
- White House convenes roundtable on recent cancer drug shortages

Multifactorial causes of drug shortages:

- Manufacturing quality challenges
- Lack of supply chain visibility
- Interruption in supply, including active pharmaceutical ingredient

Key Takeaways…

No rest for the weary

Hospitals have a lot at stake

Advocacy and communications are critical

End of the COVID-19 PHE

End of COVID-19 Public Health Emergency (PHE)

On May 11, 2023, the COVID-19 PHE Ended

FOR IMMEDIATE RELEASE
May 9, 2023

Contact: HHS Press Offic
202-690-634
media@hhs.go

Fact Sheet: End of the COVID-19 Public Health Emergency

Based on current COVID-19 trends, the Department of Health and Human Services (HHS) is planning for the federal Public Health Emergency (PHE) for COVID-19, declared under Section 319 of the Public Health Service (PHS) Act, to expire at the end of the day on May 11, 2023.

Since HHS Secretary Xavier Becerra's February 9, 2023, letter to Governors announcing the planned end of the COVID-19 PHE, the Department has been working closely with partners—including Governors; state, local, Tribal, and territorial agencies; industry; and advocates—to ensure an orderly transition out of the COVID-19 PHE.

Today, HHS is releasing a Fact Sheet with an update on current flexibilities enabled by the COVID-19 emergency declaration and how

Source: https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html

Many CMS flexibilities expired on May 11, 2023

Topic	Status
Increased Medicare Reimbursement	Hospitals no longer receive the 20% payment increase for discharges of patients diagnosed with COVID-19 when the PHE expires.
Out-of-network (OON) reimbursement for COVID-19 vaccines and testing	Plans are no longer required to reimburse OON providers for COVID-19 vaccines and testing
Hospital Without Walls (i.e., temporary expansion sites)	Hospitals no longer able to provide care (e.g., nursing or other hospital services) at remote locations; need to meet Conditions of Participation (CoPs) (e.g., physical environment requirements for lighting, gas and water for emergencies)
Life Safety Code (LSC) CoPs	Hospitals will need to adhere to more specific LSC requirements, such as the storage requirements for alcohol-based hand-rub dispensers, quarterly fire drills, and removing temporary walls and barriers between patients
FDA's ability to detect shortages of certain devices	FDA asking Congress for authority to extend device manufacturers' requirement to notify FDA of interruptions/discontinuances of critical devices outside of a PHE
COVID-19 data reporting and surveillance	Lab test reporting for COVID-19 is no longer required (hospital data reporting will continue through April 30, 2024, but reduced from daily to weekly reporting)

Source: https://www.cms.gov/files/document/hospitals-and-cahs-ascs-and-cmhcs-cms-flexibilities-fight-covid-19.pdf

Device Shortages Notifications – End of the PHE

Recent law required manufacturers of certain devices to notify FDA of a permanent discontinuance or an interruption in the manufacturing of a device that is likely to lead to a meaningful disruption in domestic supply of the device during, or in advance of, a public health emergency declared by the Secretary under section 319 of the Public Health Service Act.

- Known as “506J” notifications
- Since 506J notifications are required only during or in advance of a declared public health emergency, and the COVID-19 PHE expired May 11, 2023, FDA no longer expects manufacturer to submit such notifications for critical devices

FDA may still receive voluntary notifications outside of a public health emergency (per Consolidated Appropriations Act, 2023)

- FDA aims to issue draft guidance on voluntary 506J notifications in the near future

Sources: https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/notify-fda-about-medical-device-supply-issue; https://www.fda.gov/medical-devices/medical-device-safety/medical-device-supply-chain-and-shortages#:~:text=May%2012%2C%202023%2C%20Update%3A,advance%20of%2C%20a%20public%20health

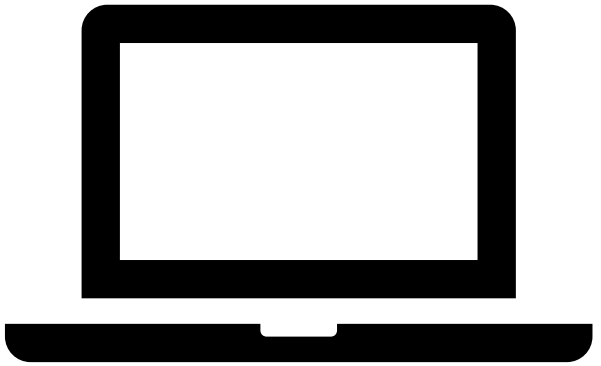
Telehealth Prescribing Policy from the Drug Enforcement Administration (DEA)

On Feb. 24, DEA announced proposed rules for prescribing controlled substances via telehealth after the COVID-19 PHE which were more stringent than PHE-era flexibilities

BUT…

In May and October 2023, DEA issued rulemaking to temporarily extend COVID-19 telehealth controlled substance prescribing flexibilities:

- Extends full set of telemedicine flexibilities until November 11, 2023
- For patient-provider relationships established up to December 31, 2024, full set of telemedicine prescribing flexibilities remain



Sources: https://www.dea.gov/press-releases/2023/05/09/dea-samhsa-extend-covid-19-telemedicine-flexibilities-prescribing ; https://public-inspection.federalregister.gov/2023-22406.pdf

COVID-19 Vaccination Mandate for Healthcare Workers Lifted

The Centers for Medicare and Medicaid Services (CMS), withdrew the requirement that healthcare workers be fully vaccinated for COVID-19.

Source: https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/revised-guidance-staff-vaccination-requirements

Other Flexibilities to Watch

Acute Care Hospital at Home Program and Several Telehealth Changes
(flexibilities remain until Dec. 31, 2024)

FDA **Emergency Use Authorizations** for drugs and devices

Sources: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-supply-chain-and-shortages#:~:text=May%2012%2C%202023%2C%20Update%3A,advance%20of%2C%20a%20public%20health; https://www.cms.gov/newsroom/fact-sheets/cms-waivers-flexibilities-and-transition-forward-covid-19-public-health-emergency; https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Information About COVID-19 EUAs for Medical Devices

Information about COVID-19 EUAs for medical devices can be found below and at: Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices.

Transition guidances update

March 24, 2023 - The FDA finalized two guidances: Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency and Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19). The guidances outline the FDA's general recommendations to transition from certain policies adopted and operations implemented during the COVID-19 pandemic to normal operations, including the FDA's recommendations for:

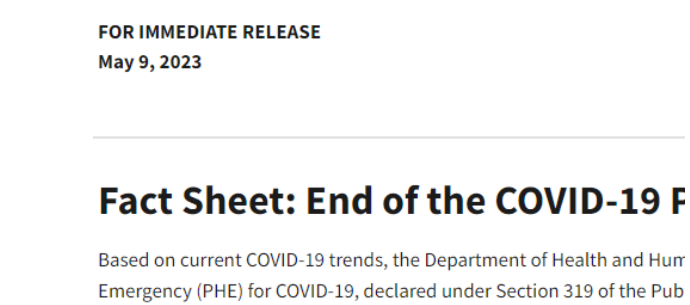
- Developing a transition implementation plan,
- Submitting a marketing submission, and
- Taking other actions with respect to these devices.

The FDA encourages stakeholders to review the two final guidances, attend the webinar noted below, and reach out to the FDA if they have questions. In particular, for manufacturers that are planning to seek marketing authorization for their devices, the FDA recommends beginning work on a marketing submission, including a transition implementation plan, as described in the guidances.

Additional resources:

- Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Resources…



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May 9, 2023

Fact Sheet: End of the COVID-19 P

Based on current COVID-19 trends, the Department of Health and Hum
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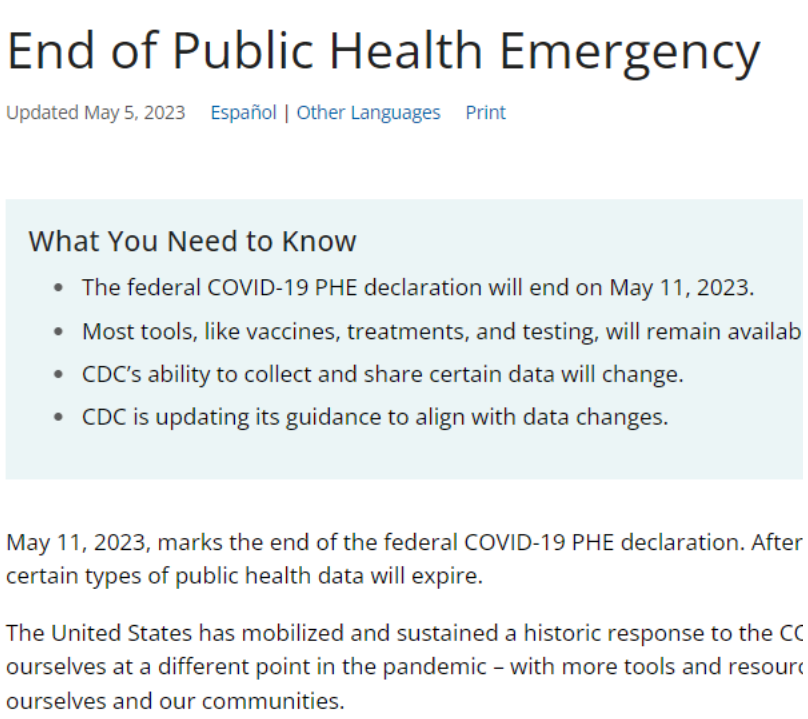
May 11, 2023.

Since HHS Secretary Xavier Becerra's February 9, 2023, letter to Goverr
Department has been working closely with partners—including Goverr
advocates—to ensure an orderly transition out of the COVID-19 PHE.

Today, HHS is releasing a Fact Sheet with an update on current flexibili
they will be impacted by the end of the COVID-19 PHE on May 11.

What has been accomplished:



End of Public Health Emergency

Updated May 5, 2023 Español | Other Languages Print

What You Need to Know

- The federal COVID-19 PHE declaration will end on May 11, 2023.
- Most tools, like vaccines, treatments, and testing, will remain availab
- CDC's ability to collect and share certain data will change.
- CDC is updating its guidance to align with data changes.

May 11, 2023, marks the end of the federal COVID-19 PHE declaration. After certain types of public health data will expire.

The United States has mobilized and sustained a historic response to the CC ourselves at a different point in the pandemic – with more tools and resourc ourselves and our communities.

CDC has been working for many months to fold the agency's COVID-19 emergency response activities into its exi structure and programs, as part of an ongoing transition to sustainable public health practice. The agency has al

Frequently Asked Questions:

CMS Waivers, Flexibilities, and the End of the COVID-19 Public Health Emergency

While some FAQs are relevant for all programs, including Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and private insurance, other questions are program specific as indicated below.

1. **When is the COVID-19 Public Health Emergency expected to end?**

   Based on current COVID-19 trends, the Department of Health and Human Services (HHS) is planning for the federal Public Health Emergency for COVID-19 (PHE) declared by the Secretary of the Department of Health and Human Services (Secretary) under Section 319 of the Public Health Service (PHS) Act to expire at the end of the day on May 11, 2023.

2. **On April 10, 2023, the President signed H.J.Res.7. into law, which terminated the national COVID-19 emergency immediately. Did this end the COVID-19 PHE declared by the Secretary?**

   The PHE for COVID-19 declared by the Secretary under section 319 of the PHS Act is not the same as the COVID-19 National Emergency declared by President Trump in 2020, which ended when President Biden signed H.J.Res.7. Therefore, the end of the COVID-19 National Emergency generally does not impact current operations at HHS, and it does not impact the expected May 11, 2023, expiration of the federal PHE for COVID-19 or any associated unwinding plans. Further, any existing waivers currently in effect and authorized under section 1135 of the Social Security Act will remain in place until the end of the PHE for COVID-19 declared by the Secretary under section 319 of the PHS Act.

Sources: HHS: https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html; CDC: https://www.cdc.gov/coronavirus/2019-ncov/your-health/end-of-phe.html; CMS: https://www.cms.gov/files/document/frequently-asked-questions-cms-waivers-flexibilities-and-end-covid-19-public-health-emergency.pdf

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Regulatory Season is Winding Down…

What did we read this season?

Inpatient Prospective Payment System Proposed Rule (652 Federal Register pages)

Outpatient Prospective Payment System (OPPS) Proposed Rule (370 Federal Register pages)

340B Remedy Proposed Rule (OPPS) (19 Federal Register pages)

Physician Fee Schedule Proposed Rule (936 Federal Register pages)

FY 2024 IPPS Final Rule

Overall payment rate update to 3.1% for FY 2024 compared to FY 2023

- 3.3% market basket
- -0.2% productivity cut

Overall hospital payments increase by $2.2 billon compared to FY 2023

- DSH payments down by $957 million & $364 decrease in new medical technology payments

Increased fix-loss threshold for FY 2024 to $42,750; hospitals to incur more losses before qualifying for outlier payment

Affirmed New COVID-19 Add-on Payments not available for FY 2024

Changes NTAP policies for FY 2024 (e.g., require complete and active FDA market authorization at time of submission and move FDA approval deadline from July 1 to May 1)

Finalized a rule related to Medicare DSH calculations

Source: https://www.federalregister.gov/documents/2023/08/28/2023-16252/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the

Recap: Buffer Inventory / Stockpiling

Show of hands, who had challenges implementing Assembly Bill (AB) 2537?

- California Labor Code Section 6403.3 implements the law requiring public and private employers in hospital settings to have a three-month stockpile of personal protective equipment (PPE) and ensure PPE supplied is used
- Normal consumption defined in regulation
- Regulations for Aerosol Transmissible Disease Exposure Control Plans include requirement that procedures address how PPE will be stockpiled, accessed or procured

Recap: Additional Payment Available for Wholly Domestically Made N95s

Show of hands: Is your hospital receiving payment adjustments for domestic NIOSH-approved surgical N95 respirators?

- CMS provides payment adjustments to hospital for NIOSH-approved surgical N95 respirators that a are “wholly domestically made” (Berry Amendment compliant)
- Payment adjustments based on the estimated difference in the reasonable cost incurred by the hospital for these respirators compared to other NIOSH-approved surgical N95 respirators purchased through the cost reporting period
  - Cost differential is included on a N95 supplemental cost reporting form
- Payment adjustments apply to cost reporting periods beginning on or after January 1, 2023
- Note: There are additional requirements (e.g., written statement from a manufacturer; completion of supplemental cost reporting form)

Source: https://www.cms.gov/files/document/mm13052-new-payment-adjustments-domestic-n95-respirators.pdf

Outpatient Prospective Payment System (OPPS) Proposed Rule

2.8% payment update for hospitals that meet applicable quality reporting requirements (3% market basket update)

Request for comment on IPPS and OPPS payment adjustments for the additional costs of establishing and maintaining a buffer stock of essential medicines

Modifies the hospital price transparency regulations, including changes to the standard charge display requirements and enforcement process

Request for comment on five alternative diagnostic radiopharmaceutical payment approaches

CMS proposes to except biosimilars from the OPPS threshold packaging policy when their reference biologicals are separately paid

CMS proposes that all 340B covered entity hospitals report the “TB” modifier effective January 1, 2025 (“JG” modifier to phase out)

Hospital Price Transparency

- April 26, CMS announced changes to its enforcement process for the hospital price transparency rule
- CMS to automatically impose a civil monetary penalty if hospitals fail to submit a corrective action plan within 45 days or fails to complete the plan within 90 days.
- CMS to no longer issue warning notice to hospitals that have not posted any machine-readable file or shoppable services list/price estimator tools
- These changes did not need to go through rulemaking…signaling more changes were coming

Source: https://www.cms.gov/newsroom/fact-sheets/hospital-price-transparency-enforcement-updates

OPPS – 340B Remedy Proposed Rule

Lump sum payments to affected providers for 340B-acquired drugs; payments as early as late 2023 to early 2024

Total CMS payments to providers as part of remedy is approx. $9 billion

-0.5% payment adjustment to future OPPS payments, starting 2025 and extending approx. 16 years; “New Providers” (enrolled after Jan. 1 2018) would be excepted from the negative payment adjustment

Addendums AAA and BBB list the proposed amount of lump sum payment and which “new providers” are exempted from repayment, respectively

No comment regarding what MA plans may/must do

Physician Fee Schedule (PFS) Proposed Rule

Conversion factor of $32.75 which is a $1.14 decrease from CY 2023 ($33.89)

Extending telehealth flexibilities to align with extensions from the CAA, 2023

Another one year delay to implement of the agency's definition of the "substantive portion" of a split/shared visit (through at least Dec. 31, 2024)

Changes to the Medicare Shared Saving Program (e.g., financial benchmarking and assignment methodology)

Continued postponement of updated Medicare Economic Index weights

Permanently sunset the Appropriate Use Criteria Program

… and the Environmental Protection Agency

Show of hands…

Who has heard about ethylene oxide regulations and the impact on the medical device supply chain?

EPA: Ethylene Oxide Regulation

On April 11, 2023, the Environmental Protection Agency (EPA) issued a proposal to reduce ethylene oxide (EtO) emissions from commercial sterilization facilities

- Proposed Air Toxics Rule for EtO sterilization facilities
- Regulatory Impact Analysis for the Proposed National Emission Standards for Hazardous Air Pollutants (NESHAP) for EtO Commercial Sterilization and Fumigation Operations

Why it matters?

Per the Food and Drug Administration, **more than 20 billion devices sold in the U.S. every year are sterilized with EtO** which is approximately half of all devices that require sterilization

Source: https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities#rule-history; https://earthjustice.org/wp-content/uploads/2023/08/2023.08.24-ccat-v.-epa-consent-decree-signed.pdf ; https://www.fda.gov/news-events/press-announcements/fda-continues-efforts-support-innovation-medical-device-sterilization

What Other Stakeholders are Saying?

AdvaMed: EPA Proposals Create Significant Risk of a Healthcare Crisis

Ethylene Oxide / June 27, 2023

Association Calls for Working Together to Ensure Patient Access

WASHINGTON, D.C. – In comments filed with the Environment Protection Agency (EPA) today, AdvaMed, the Medtech Association, called for continued cooperation between the industry and the agency as the regulations covering medical device sterilization using ethylene oxide (EtO) move forward. AdvaMed said if the proposals are finalized as written, the United States will see a massive interruption in patient care and access

"we urge the agency to advance efforts to mitigate environmental impact without buckling the supply chain for care delivery. Specifically, we are concerned that moving too quickly to implement and enforce new standards will result in the unexpected consequence of reducing EtO sterilization capacity, ultimately leading to delays in patient care." *American Hospital Association*

"The 114 undersigned business, community, environmental, faith, health, and labor organizations urge the EPA to include in its final commercial sterilizer rule: the regulation of offsite storage warehouses, fenceline monitoring, and a quicker compliance deadline. We further urge the agency to use its authority under FIFRA to better protect workers and communities from ethylene oxide." *Signatories included: Sierra Club, Earthjustice, Respiratory Health Association and many more*

Sources: https://www.advamed.org/industry-updates/news/advamed-epa-proposals-create-significant-risk-of-a-healthcare-crisis/; https://www.aha.org/lettercomment/2023-06-27-aha-letter-epas-proposed-standards-use-ethylene-oxide ; https://www.regulations.gov/comment/EPA-HQ-OAR-2019-0178-0638

EtO Regulation… a long road

Rule History

06/01/2023- Extension of Comment Period

04/11/2023 - Proposed Air Toxics Rule for EtO Sterilization Facilities - Federal R

05/10/2021 - Proposed Information Collection Request, 2nd Notice

06/05/2020 - Proposed Information Collection Request

12/12/2019 - Advanced Notice of Proposed Rulemaking

04/07/2006 - Final Decision

03/25/2005 - Proposed Rulemaking

12/19/2005 - Final Rule (Title V Operating Permit Deferrals for Area Sources)

10/24/2005 - Proposed Decision; request for comment

11/02/2001 - Final Rule; amendments

12/14/1999 - Final Rule; amendments (Title V Operating Permit Deferrals for Area Sources)

08/18/1999 - Proposed Amendments (Title V Operating Permit Deferrals for Area Sources)

10/23/1997 - Notice

06/03/1996 - Final Rule

12/13/1995 - Proposed Rule

12/06/1994 - Final Rule

03/07/1994 - Proposed Rule & Notice of Public Hearing

EPA has stated that it would issue a final rule by March 1, 2024 on "Commercial Sterilization Standards"

(Note: the rule may take 15 business days to be published in the Federal Register)

EPA: Standards Development?

November 2022: EPA launched a process to expand the Environmentally Preferable Purchasing (EPP) program's *Recommendations of Specifications, Standards and Ecolabels for Federal Purchasing (Recommendations)*

- Invited standards development organizations and ecolabel programs to apply for potential inclusion in the *Recommendations*
- EPP program's *Recommendations* help the government use private sector standards and ecolabels to meet sustainable acquisitions goals
- EPA particularly interested in assessing standards and ecolabels in the healthcare sector (among others)

And the FDA is also active!

Show of hands…

Do you find the FDA's device shortage list helpful?

Device Shortages and Discontinued Devices

Device shortage reporting requirements lapsed after the end of the COVID-19 PHE

Reports indicate few suppliers are voluntarily reporting shortages

Device Shortage List

Categories of devices that are currently c

- Anesthesiology
- Cardiovascular - Circulatory Support, Stı
- Cardiac Diagnostic and Monitoring Prod
- Dialysis-Related Products
- General Hospital and Plastic Surgery Dev
- Radiological Devices
- Certain Ventilation-Related Products

Search:

Category	Product Code (Description)	Availability and Estimated Shortage Duration[2]	Addition
Cardiovascular - Circulatory Support, Structural and Vascular Devices	**DSP** (Intra-aortic Balloon and Control System)	• Data not available to estimate duration at	To provic to health facilities devices.

Medical Device Shortages List

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Discontinuance List

As part of the list required to be established and maintained pursuant to section 506J(g) of the FD&C Act, the FDA is providing a separate, publicly available, up-to-date list of the devices that the FDA has been informed by the manufacturer have been permanently discontinued. The FDA will update this list when it receives additional information regarding device discontinuances.

Categories of devices in the discontinuance list are:

- Clinical Chemistry Products
- General ICU/Hospital Products
- Infusion Pumps and Related Accessories
- Orthopedic
- Personal Protective Equipment
- Peritoneal Dialysis System and Accessories
- Sterilization Products
- Testing Supplies & Equipment
- Ventilation-Related Products
- Vital Sign Monitoring

earch:

Category	Product Code	Manufacturer Name	Device Trade Name	Reason for Discontinuance	Date Posted (YYYY/MM/DD)
Anesthesiology - Ventilation-	**BSZ** (Anesthesia system- Ventilation-	GE Healthcare	• Aestiva MRI	Discontinuance of the manufacture of the	2022/10/31

Sources: https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/medical-device-shortages-list https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/medical-device-shortages-list#discontinuance; https://subscriber.politicopro.com/article/2023/08/medical-device-shortage-reporting-falls-off-a-cliff-00110153

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Drug Supply Chain Security Act – Enforcement Discretion

In August, FDA issued three guidance documents related to DSCSA implementation.

Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act

- Describes the process authorized trading partners should use to request a waiver, exception, or exemption
- Describes FDA's process to review and potentially renew waivers, exceptions or exemptions, where applicable
- Finalized May 9, 2018 draft guidance

Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act – Compliance Policies

- Provides one year of enforcement discretion for requirements for the interoperable, electronic, package level product tracing that go into effect on November 27, 2023

Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product — Compliance Policies

- Revised final compliance policy guidance
- Clarifies enforcement policies noted in the guidance related to saleable returns and dispenser verification requirement; specifically, enforcement will be delayed until November 27, 2024

Drug Supply Chain Security Act – Enforcement Discretion Considerations

This guidance is not intended to provide, and should not be viewed as providing, a justification for delaying efforts by trading partners to implement the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act. FDA strongly urges trading partners to continue their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements.

Excerpt from: Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act — Compliance Policies

Source: https://www.fda.gov/media/171592/download

What does it all mean?

Key Takeaways

- Congress will again need to act to avoid a government shutdown and continue key programs
- The COVID-19 PHE has ended
- Annual payment regulations suggest reimbursement will continue to be inadequate
- Supply chain continues to receive significant attention from policymakers
- Ethylene oxide regulations should be out by March 2024… but what will a final rule look like?

Questions?

Thank you!

Let’s work together

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