

Wynne Health Group Weekly



FRAMING THE WEEK

The political stakes are huge for the **upcoming elections** tomorrow. At the moment, former Vice President Joe Biden appears to be maintaining his lead in the popular vote and in the crucial swing states that will be necessary to garner a majority of the electoral votes. The margin of victory for either candidate is sure to be close and could be subject to protracted review or legal challenges.

President Donald Trump's unpopularity will likely influence the outcome of highly competitive Senate races, with Democrats favored to flip the Senate by a narrow margin. Democrats need a net gain of at least four seats to win a Senate majority, or a Biden presidency and three net wins. They appear very close to obtaining this goal with likely wins in Colorado and Arizona along with competitive races in Maine, North Carolina, Montana, South Carolina and Iowa. In the U.S. House of Representatives, Democrats are very likely to maintain and expand their comfortable margin.

While a record-breaking [94 million](#) people have already voted, the timing of the final election results is unclear. Key battleground states to watch are Pennsylvania, Florida, Wisconsin, and Michigan. While Biden has increased his lead in the critical state of Pennsylvania (4.8 percent), this state is still close enough that it could provide a narrow path for a Trump reelection.

The gap between Pennsylvania and Wisconsin and Michigan has actually grown in the waning days of the election. And no state has emerged out of the pack of Arizona, North Carolina, Florida and Georgia to be Biden's clear Plan B (Biden is forecasted to win each state by between 1 and 3 points). Arizona is probably Biden's best bet in this group, but winning it would also require him to win either Nebraska's 2nd Congressional District or Maine's 2nd Congressional District to break a 269-269 Electoral College tie; he's favored in both districts but they aren't sure things.

As for the **COVID-19 relief negotiations**, House Speaker Nancy Pelosi (D-CA) and Treasury Secretary Steven Mnuchin failed to reach a deal before Election Day. Whether both parties will have an appetite to work together after the election during the lame duck session remains to be seen. According to [Speaker Pelosi](#) and [Secretary Mnuchin](#), major points of disagreement include funding for COVID-19 testing and vaccines, funding for states and localities, aid for schools and child care providers, the Earned Income Tax Credit and Child Tax Credit, unemployment insurance, and worker protections. The expiration of the continuing resolution, December 11, is the likely new deadline for congressional action on both COVID-19 relief as well as fiscal year 2021 government funding.

In the meantime, the bulk of the policymaking is expected to happen through **rulemaking**. Last week, the Trump administration released an array of highly anticipated regulations, including – the fourth COVID-19 [interim final rule](#), Transparency in Coverage [final rule](#), [interim final rule](#) extending compliance dates for information blocking and the ONC Health IT Certification Program, and the Medicare Advantage and Part D [Advance Notice Part II](#). We expect the administration to soon issue the **calendar year 2021 Medicare**

payment final rules, such as the Physician Fee Schedule, which may include finalized **telehealth policies** in response to the COVID-19 pandemic. We may also soon see the final end-stage renal disease (ESRD) [payment rule](#), which cleared the Office of Management and Budget last week.

To support the COVID-19 response, the Wynne Health Group is making its coverage of related legislative and regulatory updates publicly available. We encourage you to share our COVID-19-related summaries available [here](#).

An overview of health policy events of interest in the coming week is posted to [Policy Hub](#) and included below for your convenience.

THIS WEEK IN HEALTH POLICY

Mon. (11/2)

- **9:00am-1:00pm – Maternal Health** – FDA hosts the virtual “Sentinel Initiative Public Training on Maternal Health and Pregnancy.” [Details](#).
- **9:00am-1:00pm – Pain Management** – FDA convenes a meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee to discuss new drug application (NDA) 209257, proposed tradename, HYDEXOR, a fixed-dose combination oral tablet, submitted by Õlas Pharma, Inc. for short-term management of acute post-operative pain [Details](#).

Tue. (11/3)

- **Election Day**

Wed. (11/4)

- **10:30am-4:00pm – CDC Meeting: Worker Health** – CDC convenes a meeting of the Subcommittee for Dose Reconstruction Reviews Subcommittee (SDRR) of the Advisory Board on Radiation and Worker Health to discuss dose reconstruction program quality management and assurance activities, among other topics. [Details](#).

Thurs. (11/5)

- **TBD – HRSA Meeting: Providers** – HRSA convenes a meeting of the National Advisory Council on the National Health Service Corps. [Details](#).
- **9:00am-3:00pm – CDC Meeting: Infection Control** – CDC convenes a meeting of the Healthcare Infection Control Practices Advisory Committee. [Details](#).

Fri. (11/6)

- **10:00am-4:00pm – FDA Meeting: Alzheimer’s Disease** – FDA convenes a meeting of the Peripheral and Central Nervous System Drugs Advisory Committee to discuss biologics license application (BLA) 761178, for aducanumab solution for intravenous infusion, submitted by Biogen Inc., for the treatment of Alzheimer’s disease. [Details](#).
- **1:00pm-3:00pm – FDA Webcast: New Drugs** – FDA hosts a webcast titled, “Office of New Drug (OND) Research: Seeking Collaborators, Funding Opportunities Available.” [Details](#).

Additional Multi-Day Events

- **November 5-November 6 – CDC/HRSA Meeting: STDs** – CDC and HRSA convene a meeting of the Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment to discuss the “President’s initiative on “Ending the HIV Epidemic: A Plan for America” and the COVID-19 pandemic.” [Details](#).

FEATURED WHG ANALYSIS

- **WHG 2020 Election Preview** – In the Policy Hub Insight Bank [here](#).
- **WHG Issue Brief: COVID-19 Vaccine State of Play** – In the Policy Hub Insight Bank [here](#).
- **WHG Catalogue of COVID-19 Government Response** – October Edition – In the Policy Hub Insight Bank [here](#).

CONGRESSIONAL LOOKBACK

Fri. (10/30)

- **MACPAC** convened virtually for Day Two of its October public [meeting](#), hosting sessions on mental health services for adults, access to mental health treatment for adults, considerations for extending postpartum coverage, DSH allotments, and addressing high-cost drugs. All WHG session summaries are available on Policy Hub [here](#).

Thurs. (10/29)

- **MACPAC** convened virtually for Day One of its October public [meeting](#), hosting sessions on Medicaid eligibility redeterminations after the public health emergency (PHE), a new program for dual eligibles, the Non-Emergency Medical transportation (NEMT) benefit, and nursing facility acuity adjustments. All WHG session summaries are available on Policy Hub [here](#).

Mon. (10/26)

- **The Senate** confirmed the nomination of Judge Amy Coney Barrett to the Supreme Court by a [52-48 vote](#). Sen. Susan Collins (R-ME) was the only Republican that sided with Democrats and voted against the nominee. [Details](#).

REGULATORY LOOKBACK

Fri. (10/30)

- **NIH** [issued](#) a request for information (RFI) to gather public input on the NIH-Wide Strategic Plan for COVID-19 Research. The agency notes that this will be a “living document,” which will be continually updated to reflect new challenges presented by COVID-19. Comments can be made [here](#) and are due December 7. [Details](#).
- **FDA** published a [list](#) of essential medicines, medical countermeasures, and critical inputs that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms. The list was pursuant to an August 6 executive order. Comments can be made [here](#). [Details](#).
- **CMS** has released the third annual update to its Medicaid and Children’s Health Insurance Program (CHIP) Scorecard. [Details](#).

Thurs. (10/29)

- **HHS, DOL, and the Treasury** issued the Transparency in Coverage [final rule](#). This insurer-focused final rule, along with previously finalized hospital transparency requirements, aim to enhance transparency for consumers and increase competition among hospitals and insurers by requiring that such entities make all health care pricing information publicly available. [Details](#).
- **ONC** [announced](#) the release of an Interim Final Rule with Comment Period (IFC) extending compliance dates and timeframes for Information Blocking and the ONC Health IT Certification Program that were outlined in the ONC 21st Century Cures Act Final Rule that was released in March 2020. Comments will be due 60 days after publication. [Details](#).

- **CMS** released its fourth COVID-19 interim final rule (IFC), which includes several provisions to prepare for coverage of forthcoming vaccines and treatments for the disease. [Details.](#)

Wed. (10/28)

- **ONC** released a report that discusses the state of interoperability among major U.S. cities. While prior research has examined interoperability among hospitals nationally, ONC notes that little is known about the rates of interoperability of hospitals within cities. [Details.](#)

Tue. (10/27)

- **CMS** recently released its CY 2021 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Policy Issues and Healthcare Common Procedure Coding System (HCPCS) Level II proposed rule, containing provisions pertaining to the DMEPOS Competitive Bidding Program (CBP) and the DMEPOS fee schedule. Comments are due on or around January 3, 2021 (i.e., 60 days after scheduled publication in the Federal Register). [Details.](#)
- **CDC** [announced](#) that it is seeking nominations of qualified candidates for appointment to the Lead Exposure and Prevention Advisory Committee (LEPAC). Nominations are due December 15, 2021. [Details.](#)
- **USPSTF** [issued](#) a draft recommendation and evidence review that recommends screening for colorectal cancer in all adults ages 45 to 75. The draft recommendation statement for adults ages 50 to 75 years was issued an “A” grade, while the draft recommendation statement for adults ages 45 to 49 years was issued a “B” grade. Comments are due November 23. [Details.](#)
- **HHS** released updated COVID-19 hospital [data](#) indicating only 62 percent of hospitals are reporting all mandated coronavirus data and about three-fourths of hospitals are 90 percent compliant. [Details.](#)

Mon. (10/26)

- **EBSA** released the finalized 2020 Mental Health Parity and Addiction Equity Act (MHPAEA) Self-Compliance Tool – a guide aimed at helping group health plans and issuers in the group and individual markets comply with parity requirements. [Details.](#)

Fri. (10/23)

- **HHS** [revised](#) Provider Relief Fund (PRF) eligibility and reporting requirements for its forthcoming “Phase 3” general distribution. The changes expand eligibility to a broader array of provider types including those who do not serve Medicare and Medicaid beneficiaries, such as: allopathic and osteopathic physicians; nursing service and related providers; hospice providers; respiratory, developmental, rehabilitative and restorative service providers; residential treatment facilities; laboratories; and ambulatory health care facilities, among others. [Details.](#)

COMMENT & APPLICATION DEADLINES

- **Nov. 5:** HHS is [soliciting nominations](#) for appointment to the tick-borne disease working group. [Details.](#)
- **Nov. 6:** HHS is accepting applications for Phase 3 General Distribution of \$20 billion from the Provider Relief Fund (PRF). The funds will be open to previously ineligible providers (e.g., those who began practicing in 2020) and will permit those who have already received funds through previous distributions to apply for additional funding that reflects financial losses and changes in operating expenses due to the pandemic. [Details.](#)
- **Nov. 7:** FDA [issued](#) draft guidance on drug-drug interaction assessments for therapeutic proteins. [Details.](#)

- **Nov. 13:** CMS is accepting comments on [Part I of its Advance Notice](#) of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part D Payment Policies for Calendar Year (CY) 2022. [Details.](#)
- **Nov. 16:** HHS [announced](#) two challenges focused on improving maternal health: the Hypertension Innovator Award Competition and the Reducing Disparities in Breastfeeding Innovation Challenge. [Details.](#)
- **Nov. 16:** HRSA is accepting applications for a funding opportunity titled, “Rural Health Network Development Planning Program.” The grant supports one year of planning to develop and assist integrated health care networks in becoming operational. [Details.](#)
- **Nov. 16:** HRSA announced a funding opportunity titled, “Rural Health Care Services Outreach Program” to support the expansion of health care service delivery in rural areas. [Details.](#)
- **Nov. 18:** CMS announced that it extended the public comment period for the request for information (RFI) titled, “Recommended Measure Set for Medicaid-Funded Home and Community-Based Services.” [Details.](#)
- **Nov. 30:** FDA announced two quality management maturity (QMM) pilot programs: one for domestic drug product manufacturers of prescription and over-the-counter OTC drug products; and one for foreign facilities manufacturing APIs that are used in FDA-regulated prescription and OTC drugs. [Details.](#)
- **Dec. 1:** FDA seeks comment on draft guidance for developing drugs and biologics for adjuvant treatment of renal cell carcinoma and bladder cancer. [Details.](#)
- **Dec. 14:** NIOSH [announced](#) a request for information regarding the use of “elastomeric half-mask respirators” healthcare settings during the COVID-19 pandemic. [Details.](#)
- **Dec. 14:** HHS issued a [proposed rule](#) that would add a Smallpox Countermeasures Injury Table for designated covered smallpox countermeasures. [Details.](#)
- **Dec. 14:** FDA requests nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee (DGMPAC) and the Medical Devices Advisory Committee (MDAC) device panels in the Center for Devices and Radiological Health. [Details.](#)
- **Dec. 18:** HHS [announced](#) a request for information (RFI) regarding research integrity and the responsible conduct of research. [Details.](#)
- **Jan. 5:** CDC announced a funding opportunity for “PrEP Choice: Increasing the Use of HIV Pre-exposure Prophylaxis in an Era of Choices.” The application deadline is January 5, 2021. [Details.](#)
- **Jan. 18:** CMS announced that the Community Health Access and Rural Transformation (CHART) [model](#) is open for applications. Letters of intent are due by January 18, 2021. [Details.](#)
- **Jan. 21:** HRSA announced a Notice of Funding Opportunity for the Behavioral Health Workforce Education and Training (BHWET) Program for Professionals for FY 2021. [Details.](#)

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