This Week in Health Policy, Congressional Lookback, Regulatory Lookback, Comment & Application Deadlines

Wynne Health Group Weekly



WYNNE HEALTH GROUP STATEMENT ON BLACK LIVES MATTER & ACTIONS WE ARE TAKING ON RACIAL JUSTICE

All of us at Wynne Health Group mourn the death of George Floyd and are outraged at the longstanding police brutality and systemic racism resulting in his murder. We stand in solidarity with the protesters pleading for justice for Mr. Floyd and the numerous other Black Americans whose lives have been cut short, including Breonna Taylor, Ahmaud Arbery, Tony McDade, Eric Garner, and countless others. We want to state unequivocally that Black Lives Matter and commit to actions that we are taking to combat racism and further racial justice.

As a mission-driven, public-service government relations firm, we believe in the power of policy to effect positive change. Yet we know that policies have long been used as a tools to devalue and oppress Black Americans from the times of slavery through Jim Crow to this very day, by insidious discriminatory processes such as redlining, voter suppression, and mass incarceration.

The inequities borne of generations of systemic racism constitute a public health crisis, both in access and outcomes for conditions such as heart disease and asthma, and across the lifespan. Black mothers are three to four times more likely to experience a pregnancy-related death than White mothers, and Black Americans are currently experiencing a mortality rate 2.4 times as high as White Americans for COVID-19.

Our Commitment

We want to be explicit about the actions we are taking at Wynne Health Group to support the Black community and to further anti-racism. Specifically, we are:

- Committing at least 2.5 percent of net profit in 2020 to health care and social justice causes affecting Black communities and other communities of color;
- Matching employee donations during the month of June up to a total of \$2,500 firmwide to support causes dedicated to racial justice;
- Standing up a firmwide diversity, equity, and inclusion (DEI) initiative a platform for us to continue this work beyond this moment that addresses recruiting and hiring; internal surveying on inclusion; and teamwide training;
- Supporting Wynne Health Group clients in their own efforts to further federal policies on racial and ethnic disparities in health and health care, including proactively producing resources on these topics and making them available to the public;
- Providing up to four hours/month for employee efforts to volunteer, participate in community-based organizing, volunteer for voter registration and political campaigns, etc., with an emphasis on addressing systemic inequities and barriers to participation; and
- Providing reimbursement up to \$50 per employee for anti-racist literature purchased from Blackowned bookstores such as <u>Mahogany Books</u> in Washington, D.C.

We know there is more work to do. We commit to learning from – and amplifying – the voices of Black leaders as we put these strategies into place and practice anti-racism throughout our work. We welcome your feedback and partnership in this process.

FRAMING THE WEEK

Today, House and Senate Democrats unveiled the **Justice in Policing Act of 2020**, following nearly two weeks of protests sparked by the murder of George Floyd. The comprehensive package that would make structural changes to the way police officers do their jobs. Holding police officers accountable, establishing a national database to increase transparency about police misconduct, and requiring training on racial bias and duty to intervene are among the reforms. The House is expected to vote on the measure this month. It is unclear if Republicans will support the legislation and if the Republican-controlled Senate will take up the bill, as Republicans were not involved in its development. President Trump is hosting a roundtable with law enforcement this afternoon.

Throughout the week, both chambers will convene hearings on the **COVID-19 pandemic** focused on a range of issues – including small businesses, unemployment insurance, housing – that may inform the next coronavirus relief package. Last Friday, President Trump and Senate Republicans signaled that an additional "targeted" stimulus bill is necessary. Senate Majority Leader Mitch McConnell (R-KY) reiterated "future efforts" would be "laser-focused" on reopening the economy.

Tomorrow, the Senate Homeland Security and Governmental Affairs Committee (HSGAC) will evaluate **federal procurement and distribution of medical supplies in response to the COVID-19 pandemic**. The witness panel features FEMA Administrator Peter Gaynor; Rear Admiral John Polowczyk who was appointed to run the White House supply chain task force; and Admiral Brett Giroir who will soon be leaving his position as the Trump administration's testing czar and returning to the Department of Health and Human Services (HHS).

Based on his <u>oversight plans</u> released following passage of the CARES Act (<u>Public Law No: 116-136</u>), HSGAC Chairman Ron Johnson's (R-WI) questions may focus on the readiness of the Strategic National Stockpile, supply chain issues, and the use and accuracy of infectious disease modeling to guide response efforts. On a related note, the Government Accountability Office (GAO) released a <u>report</u> (<u>requested</u> by House Energy and Commerce Committee leaders) recommending that HHS improve coordination of infectious disease modeling across federal agencies – which can help guide disease control policies and allocate resources.

HSGAC Ranking Member Gary Peter (D-MI) is expected to push for the <u>COVID-19 Testing Inventory Act</u>. His bill would require HHS, in consultation with FEMA, the Food and Drug Administration (FDA), and the Indian Health Service (IHS), to publish key information on the nation's COVID-19 testing capacity, including the distribution of tests, authorized laboratories, authorized tests, and testing sites.

Also, on Tuesday, House Energy and Commerce Subcommittee on Environment and Climate Change will examine the relationship between **environmental pollution and demographic disparities in COVID-19**. Of note, the updated Report to Congress, required by the Paycheck Protection Program and Health Care Enhancement Act (<u>Public Law No: 116-139</u>), on COVID-19 testing and demographic characteristics is due next Monday (June 15). It is unclear how impactful HHS' new <u>guidance</u>, as directed by the CARES ACT, requiring laboratories report demographic data (including race, ethnicity, age, and sex), beginning August 1, will be on producing a more comprehensive report.

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 <u>Policy Hub</u> and included below for your convenience.

THIS WEEK IN HEALTH POLICY

Mon. (6/8)

No events scheduled.

Tue. (6/9)

- **Presidential Primaries** Georgia and West Virginia hold primary elections.
- **9:00am-5:00pm HHS Meeting: Vaccines** HHS convenes a meeting of the National Vaccine Advisory Committee. <u>Details</u>.
- 10:00am Hearing: COVID-19 & Medical Supplies The Senate Homeland Security and Governmental Affairs Committee convenes a hearing titled, "Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic," featuring FEMA Administrator Peter Gaynor, Vice Director of Logistics at DOD Rear Admiral John Polowczyk, and Assistant Secretary for Health Admiral Brett Giroir. Details.
- 10:00am Hearing: COVID-19 & Law Enforcement The Senate Judiciary Committee convenes a hearing titled, "COVID-19 Fraud: Law Enforcement's Response to Those Exploiting the Pandemic." Details.
- **10:00am-1:00pm NIH Meeting: Musculoskeletal Diseases** NIH convenes a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council. Details.
- 11:00am Briefing: COVID-19 & Antibody Testing The House Oversight and Reform Subcommittee on Economic and Consumer Policy convenes a briefing titled, "COVID-19 Antibody Testing: Uses, Abuses, Limitations, and the Federal Response." Details.
- 12:00pm Hearing: COVID-19 & Environmental Justice The House Energy and Commerce Subcommittee on Environment and Climate Change convenes a hearing titled, "Pollution and Pandemics: COVID-19's Disproportionate Impact on Environmental Justice Communities."

 Details.
- 12:00pm-1:00pm FDA Webcast: COVID-19 & Respirators FDA hosts a webcast titled, "Respirators for Health Care Personnel Use during COVID-19 Pandemic," featuring FDA Commissioner Stephen Hahn and other senior FDA officials. Details.
- 12:15pm-1:15pm FDA Town Hall: COVID-19 & Diagnostic Tests FDA hosts a virtual town hall titled, "Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests." Details.
- **2:30pm Hearing: COVID-19 & Unemployment** The Senate Finance Committee convenes a hearing titled, "Unemployment Insurance During COVID-19: The CARES Act and the Role of Unemployment Insurance During the Pandemic." <u>Details</u>.
- **3:00pm Hearing: VA Supply Chain** The Senate Veterans' Affairs Committee convenes a hearing titled, "Building a More Resilient VA Supply Chain." Details.

Wed. (6/10)

• 10:00am – Hearing: COVID-19 & Schools – The Senate Health, Education, Labor and Pensions Committee convenes a hearing titled, "COVID-19: Going Back to School Safely." Details.

- **10:00am Hearing: Law Enforcement** The House Judiciary Committee convenes a hearing titled, "Oversight Hearing on Policing Practices and Law Enforcement Accountability." <u>Details</u>.
- 10:00am Hearing: COVID-19 & Small Businesses The Senate Small Businesses and Entrepreneurship Committee convenes a hearing titled, "Implementation of Title I of the CARES Act," featuring SBA Administrator Jovita Carranza and Treasury Secretary Steven Mnuchin.

 Details.
- **12:00pm Hearing: COVID-19 & Housing** The House Financial Services Subcommittee on Housing, Community Development, and Insurance convenes a legislative hearing titled, "The Rent Is Still Due: America's Renters, COVID-19 and an Unprecedented Eviction Crisis." <u>Details</u>.
- 1:00pm Hearing: COVID-19 & Small Businesses The House Small Business Committee convenes a hearing titled, "The Economic Injury Disaster Loan Program: A View from Main Street." Details.
- **2:00pm-3:00pm Brookings Webinar: COVID-19 & Rural Areas** The Brookings Institute hosts a webinar titled, "Mitigating the economic impacts of COVID-19 in rural areas." <u>Details</u>.

Thurs. (6/11)

- 9:30am Hearing: COVID-19 & Seniors The Senate Special Committee on Aging convenes a hearing titled, "Combating Social Isolation and Loneliness During the COVID-19 Pandemic." Details.
- 11:00am-5:00pm PCORI Meeting: Health Disparities PCORI convenes a meeting of the Advisory Panel on Healthcare Delivery and Disparities Research. <u>Details</u>.
- 1:00pm Hearing: COVID-19 & IHS The House Appropriations Subcommittee on Interior, Environment, and Related Agencies convenes a hearing titled, "Indian Health Service Covid-19 Response." Details.
- **2:00pm Hearing: COVID-19 & Veterans** The House Veterans' Affairs Committee convenes a hearing titled, "Assessing VA's Response to the COVID-19 Pandemic: 90 Days Later." Details.
- **2:00pm-3:00pm NQF Meeting: Quality Measures** The National Quality Forum hosts a webinar titled, "Moving Beyond Individual Measures: The Evolution of Measure Sets & Measurement Systems." Details.
- **2:00pm-3:00pm AHIP Briefing: COVID-19 & Billing** America's Health Insurance Plans (AHIP) hosts a briefing titled, "Healthcare Billing: COVID-19 Impacts, Industry Consolidation, and Modernization Agenda." <u>Details</u>.

Fri. (6/12)

- **10:00am-12:30pm NIH Meeting: Eye Health** NIH convenes a meeting of the National Advisory Eye Council. <u>Details</u>.
- **2:00pm-3:00pm Brookings Webinar: COVID-19 & Equity** Brookings Institute hosts a webinar titled, "Reopening America Equitable solutions for workers and their families in the COVID-19 era." Details.

Additional Multi-Day Events

• June 9-June 10 – FDA Webcast: Regulatory Education – FDA hosts a webcast titled, "Regulatory Education for Industry (REdI): Pharmacovigilance and Risk Management Conference – New Approaches, Tools, and Technologies." Details.

FEATURED WHG ANALYSIS

• Chart: Key Federal COVID-19 Funding Opportunities for Providers & Hospitals – Updated 5/29/20 – In the Policy Hub Insight Bank here.

- Chart: Compilation of Federal COVID-19 Telehealth Flexibilities In the Policy Hub Insight Bank here.
- WHG COVID-19 Government Response Catalogue Updated 5/22/20 In the Policy Hub Insight Bank here.
- Chart: Key Federal COVID-19 Funding Opportunities for Employers Last Updated 4/24/20 In the Policy Hub Insight Bank here.
- Chart: Key Federal COVID-19 Funding Opportunities for State and Local Government Last Updated 4/24/20 In the Policy Hub Insight Bank here.

CONGRESSIONAL LOOKBACK

Fri. (6/5)

• **President Trump** signed into law the Paycheck Protection Program Flexibility Act of 2020 (<u>H.R. 7010</u>), which makes several reforms to the Small Business Administration's (SBA) Paycheck Protection Program (PPP). <u>Details</u>.

Thurs. (6/4)

• The House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies <u>convened</u> a hearing to discuss the CDC response to the COVID-19 pandemic. <u>Details</u>.

Wed. (6/3)

 House Energy and Commerce Committee Chairman Pallone and Ranking Member Walden and Senate Finance Committee Chairman Grassley and Ranking Member Wyden released a bipartisan letter sent to HHS Secretary Azar, requesting information on the distribution of the Provider Relief Fund to providers that heavily rely on Medicaid funding. <u>Details</u>.

Mon. (6/1)

• **Sen. Maggie Hassan (D-NH)**, along with 16 Senate Democrats, <u>sent</u> a <u>letter</u> to the CDC urging the agency develop and implement a plan to address the decline in routine childhood immunization rates amid the COVID-19 pandemic. <u>Details</u>.

REGULATORY LOOKBACK

Thurs. (6/4)

- The Bipartisan Policy Center (BPC) convened a virtual discussion to explore the effect of pandemic-related expansions to telehealth on rural health in the United States. <u>Details</u>.
- HHS OIG posted its Semiannual Report to Congress for the six month period ending March 31, 2020, which includes data on HHS OIG reports issued, expected recoveries, criminal and civil actions, and other statistics. Details.
- The Office of the Assistant Secretary for Health (OASH) issued a request for information (RFI) to better understand how stakeholders across the healthcare system have defined "resilience," including in the use of data, analytic methods, and proven indicators. Details.
- **CMS** has announced its first set of COVID-19 nursing home data is now available online. An accompanying FAQ document answers questions such as how the information is being displayed; how often the information will be updated; why there is not a specific tag for COVID-19 findings, and more. Details.
- **HHS** released new guidance, as directed by the CARES Act, that specifies the additional data laboratories must report to HHS with COVID-19 test results. <u>Details</u>.

Wed. (6/3)

- **FDA** issued 25 new draft PSGs and 24 revised draft product-specific guidances (PSGs). Comments are due August 3. <u>Details</u>.
- **CDC** announced a funding opportunity to provide Pediatric Environmental Health Specialty Units (PEHSUs) with supplemental funding to support their COVID-19 response efforts. Applications are due June 17. Details.
- **CMS Administrator Seema Verma** published a blog post outlining new model flexibilities for the CMS Innovation Center's value-based models in response to the COVID-19 pandemic. <u>Details</u>.
- **CMS** announced new <u>enforcement actions</u> it will take against nursing homes in an effort to address the spread of COVID-19. <u>Details</u>.

Tue. (6/2)

- **USPSTF** <u>issued</u> a draft recommendation and evidence review that recommends interventions for tobacco smoking cessation in adults. Comments are due by June 29. <u>Details</u>.
- **CMS** released <u>guidance</u> yesterday on implementation of the new, optional Medicaid eligibility group for uninsured individuals created under the Families First Coronavirus Response Act (FFCRA). Details.
- **HRSA** <u>awarded</u> \$20.3 million to 44 recipients to increase the number of fellows at accredited addiction medicine and addiction psychiatry fellowship programs. The awardees will train addiction specialists at facilities in underserved communities. <u>Details</u>.

Mon. (6/1)

• **FDA** <u>announced</u> the process for publishing Emergency Use Authorizations (EUAs) for medical devices related to the COVID-19 public health emergency (PHE). <u>Details</u>.

COMMENT & APPLICATION DEADLINES

- **June 9:** CMS is accepting comments on proposed rules for fiscal year (FY) 2021 Medicare payment across three different payment streams: Skilled nursing facilities (SNF); the Hospice wage index and payment rate update; and Inpatient psychiatric facilities (IPF). <u>Details</u>.
- **June 15:** CMS requests comment on the fiscal year (FY) 2021 inpatient rehabilitation facility (IRF) prospective payment system (PPS) proposed rule (<u>fact sheet</u>). <u>Details</u>.
- **June 16:** CDC issued a <u>request for comment</u> soliciting input on and experiences with pain and pain management to inform the agency's assessment of the need for updating or expanding the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain. Details.
- **June 17:** USDA extended the comment period on the proposed rule titled, "Employment and Training Opportunities in the Supplemental Nutrition Assistance Program (SNAP)." <u>Details</u>.
- **June 21:** OASH within HHS seeks public comment regarding Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act, addressing recommendations for maintaining an adequate national blood supply. <u>Details</u>.
- **June 21:** FDA seeks comments on draft guidance on technical considerations for demonstrating reliability of emergency-use injectors. <u>Details</u>.
- **June 27:** ASPR <u>announced</u> the establishment of the National Advisory Committee on Children and Disasters (NACCD) and a request for nominations for members. <u>Details</u>.
- **June 30:** NIH issued two requests for letters of interest (LOIs): 1) LOIs for National Cancer Institute (NCI) Molecular Analysis for Therapy Choice (MATCH); and 2) LOIs for pediatric-focused NCI-MATCH. LOIs are due June 30. <u>Details</u>.

- **June 30:** CDC re-opened the public comment period for the proposed update of the 2006 "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings." Details.
- June 30: The White House Office of National Drug Control Policy (ONDCP) issued an <u>Advance Notice of Proposed Rulemaking</u>, soliciting comments on proposed criteria for designating emerging drug threats. Details.
- **July 2:** CMS issued a <u>proposed rule</u> to amend the Department of Health and Human Services' ACA risk adjustment data validation (HHS-RADV) program. <u>Details</u>.
- **July 3:** AHRQ <u>announced</u> a request for nominations for members. AHRQ advises the Secretary of HHS and produces evidence to make health care safer, higher quality, more accessible, equitable, and affordable. <u>Details</u>.
- **July 7:** CMS is accepting comments on an interim final rule with comment period (IFC) containing a second set of wide-reaching regulatory changes and flexibilities for providers in response to the COVID-19 pandemic. **Details**.
- **July 10:** CMS is accepting comments on the FY 2021 inpatient prospective payment system (IPPS) and long-term care hospital prospective payment system (LTCH PPS) proposed rule. Details.
- **July 14:** CDC <u>issued</u> a request for information regarding personnel and the retention of next generation sequencing (NGS) data in clinical and public health laboratories. <u>Details</u>.
- July 31: FDA issued a request for information (RFI) on rare disease clinical trials. Details.
- Aug. 3: CDC <u>announced</u> it is seeking nominations for individuals to serve as members of the Healthcare Infection Control Practices Advisory Committee (HICPAC). <u>Details</u>.
- **Aug. 20:** FTC is requesting public comment on its Health Breach Notification Rule, which is now subject to the agency's 10-year rule review cycle. <u>Details</u>.