Federal Issues
Regulatory

**Federal COVID-19 Policy Guidance and Other Developments**

HHS Delays Release of Provider Relief Fund Data Collection Instructions: The Department of Health and Human Services delayed the expected release of additional details regarding data elements for providers who accepted Provider Relief Fund program funds.

In July, HHS said the instructions and templates for those who received one or more payments for more than $10,000 would be available August 17. However, a notice from HHS said providers should still receive detailed instructions and a data template well before the reporting system’s October 1 availability.

Providers should continue checking the [Provider Relief Fund website](https://providerrelief.hhs.gov) for updates.

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FDA Authorizes ‘Groundbreaking’ Test; Lists PPE, Other Devices in Shortage: The Food and Drug Administration Saturday issued an emergency use authorization to Yale School of Public Health for a new test to detect SARS-CoV-2 in saliva, which does not require saliva collection tubes containing preservatives or specialized equipment for nucleic acid extraction.

“Providing this type of flexibility for processing saliva samples to test for COVID-19 infection is groundbreaking in terms of efficiency and avoiding shortages of crucial test components like reagents,” said FDA Commissioner Stephen Hahn, M.D.

The SalivaDirect test is authorized for use by Yale-designated laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 and meet requirements to perform high complexity tests.

Last Friday, the FDA listed personal protective equipment, testing supplies and other medical devices in shortage or discontinued. The Coronavirus Aid, Relief, and Economic Security requires manufacturers to notify FDA when a manufacturing discontinuance or interruption is likely to disrupt the U.S. supply of certain devices during a public health emergency. The agency plans to update the lists as the pandemic evolves.

CDC Releases Antigen Testing Guidance: The Centers for Disease Control and Prevention recently released guidance for clinicians and laboratory professionals on rapid antigen testing for SARS-CoV-2. Topics include regulatory requirements; collecting and handling clinical specimens; and test performance, evaluation and reporting.

HHS Awards McKesson Contract to Distribute COVID-19 Vaccine: McKesson Corporation will serve as a central distributor of future COVID-19 vaccines and related supplies, the departments of Health and Human Services and Defense announced Friday. The Centers for Disease Control and Prevention is executing an existing contract option with McKesson to support the vaccine distribution. The company also distributed the H1N1 vaccine during the H1N1 pandemic in 2009-2010.

FEMA Extends and Modifies Scarce PPE Allocation Order and Issues DPA Voluntary Agreement Text: The Federal Emergency Management Agency August 10 issued a temporary final rule allocating certain health and medical resources exclusively for domestic use to ensure front line healthcare workers’ needs are met during the COVID-19 pandemic. The policy, which will remain in effect through December 31, states that FEMA can review and hold for domestic use the following PPE items in the event of their attempted export: surgical N-95 respirators, surgical masks, nitrile surgical and exam gloves, and level 3 and 4 surgical gowns and surgical isolation gowns.

In other news, FEMA published the text of a voluntary agreement under the Defense Production Act that would permit private sector organizations to coordinate their efforts with other organizations to produce and distribute critical health care resources during the COVID-19 pandemic, including PPE, pharmaceuticals, respiratory devices, vaccines, raw materials, supplies and medical devices.

HHS to Distribute $1.4 Billion to Free-standing Children’s Hospitals: Almost 80 free-standing children’s hospitals will receive $1.4 billion in relief funds from the Coronavirus Aid, Relief, and Economic Security Act and the Paycheck Protection Program and Health Care Enhancement Act, the Department of Health and Human Services today said.
To receive funding, children's hospitals must be exempt under the Centers for Medicare & Medicaid Services inpatient prospective payment system or be a Health Resource and Services Administration-defined Children's Hospital Graduate Medical Education facility.

HHS said eligible hospitals will receive 2.5% of their net revenue from patient care.

**CDC Study Confirms More Adults Reporting Mental Health Challenges During Pandemic:** U.S. adults were more likely this June than a year ago to report adverse mental health conditions, substance use and suicidal ideation, according to a report released by the Centers for Disease Control and Prevention.

About 41% of adults completing the online survey on June 24-30 reported an adverse mental or behavioral health condition. This includes 31% who reported anxiety disorder or depressive disorder symptoms; 26% who reported trauma- and stressor-related disorder (TSRD) symptoms related to COVID-19; 13% who reported substance use to cope with stress or emotions related to COVID-19; and 11% who reported seriously considering suicide in the past 30 days.

The authors recommend that community-level prevention efforts prioritize young adults, racial/ethnic minorities, essential workers and unpaid adult caregivers, who were more likely to report mental health challenges.

**FDA Finds Certain Hand Sanitizers Contaminated with 1-propanol:** The Food and Drug Administration warned health care providers and consumers that certain hand sanitizers have tested positive for 1-propanol, including products made by Harmonic Nature S de RL de MI in Mexico.

“1-propanol, not to be confused with 2-propanol/isopropanol/isopropyl alcohol, is not an acceptable ingredient for hand sanitizer products marketed in the United States and can be toxic and life-threatening when ingested,” FDA said.

The agency has expanded its list of do-not-use hand sanitizers to include products that contain or may contain this ingredient, and encourages providers and others to report adverse events or quality problems associated with hand sanitizers to its MedWatch program.

In other news, FDA recently approved for marketing in the U.S. a surgical gown (K200977) and three polymer patient examination gloves (K201530, K201531, K193666), including for use during the COVID-19 pandemic. In addition, the agency authorized for emergency use molecular tests made by LumiraDx UK Ltd. and Biomeme Inc. to detect SARS-CoV-2. Laboratories certified to perform high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 may use the tests.

**HHS Invests in Labs to Expand COVID-19 Testing Capacity:** The Department of Health and Human Services said it will invest $6.5 million in two laboratories, Aegis Sciences Corporation and Sonic Healthcare USA, to add capacity for up to 4 million additional SARS-CoV-2 tests each month.

HHS said the two laboratories will use the funds to increase staffing, infrastructure, and critical supplies to meet a goal of performing one million more weekly tests by October.

**AHA and Others Release Joint Update to COVID-19 Essential Surgery Roadmap:** The American Hospital Association, along with the American College of Surgeons, American Society of Anesthesiologists,

The joint statement provides a list of principles and considerations to guide physicians, nurses, and hospitals and health systems as they provide essential care to their patients and communities and seek to ensure ongoing preparation to meet patients’ needs for recommended essential procedures.

FDA Issues FAQs on Importing and Donating Personal Protective Equipment: The Food and Drug Administration released FAQs describing the procedures for importing respirators, face masks, and other personal protective equipment or medical devices for which the agency has issued an emergency use authorization or enforcement discretion policy during the COVID-19 pandemic.

It also includes information on donating masks or other equipment, monitoring import status and FDA contacts for import questions.

Moderna to Produce 100M Doses of its Vaccine Candidate for U.S.: The departments of Health and Human Services and Defense will pay Moderna Inc. about $1.5 billion to produce and deliver 100 million doses of its COVID-19 vaccine candidate to vaccinate Americans if authorized by the Food and Drug Administration, the agencies announced yesterday. Under the agreement, the government also may acquire up to 400 million additional doses, the agencies said. The National Institutes of Health recently announced a phase three trial to test the vaccine’s safety and efficacy in about 30,000 adults who do not have COVID-19.

The agencies have recently announced similar agreements with other companies to produce and deliver their vaccine candidates for potential U.S. use.

“In creating a vaccine portfolio for Operation Warp Speed, the Trump Administration is increasing the likelihood that the United States will have at least one safe, effective vaccine by 2021,” said HHS Secretary Alex Azar. “Today’s investment represents the next step in supporting this vaccine candidate all the way from early development by Moderna and the National Institutes of Health, through clinical trials, and now large-scale manufacturing, with the potential to bring hundreds of millions of safe and effective doses to the American people.”

HHS Announces Expanded Eligibility for General Distribution Funds: The Department of Health and Human Services announced yesterday, it has expanded the providers eligible for its Public Health and Social Services Emergency Fund “General Distribution.”

HHS clarified that those who bill Medicare, Medicaid, Medicaid Managed Care or CHIP, or are a dental provider, are eligible to apply as long as they have not already received 2% of their patient revenue from the fund.

This includes Medicare Part A providers who experienced a change in ownership and billed Medicare fee-for-service in 2019 or 2020 and had previously been ineligible to apply. The deadline for applying for this funding is August 28.

FDA Authorizes SARS-CoV-2 Molecular Test and Updates Guidance for Hand Sanitizer Makers: The Food and Drug Administration authorized the emergency use of George Washington University Public
Health Laboratory’s **GWU SARS-CoV-2 RT-PCR Test**. The molecular test uses respiratory specimens to detect the virus in suspected COVID-19 cases.

The FDA also recently updated its [hand sanitizer guidance](https://www.fda.gov/about-fda/medical-products-and-medical-devices/sanitizers-and-hand-rubs) to make sure products do not contain unsafe levels of methanol by suggesting manufacturers test every lot of active ingredient for the substance. Additional guidance includes another denaturant formula to deter children from unintentional ingestion.

**NIH-supported Trials to Test Synthetic Antibody Treatments:** Researchers have launched two clinical trials to test whether monoclonal (laboratory-made) antibodies can safely prevent SARS-CoV-2 infection or symptoms in healthy adults, the National Institutes of Health [announced yesterday](https://www.nih.gov/press-news/abraham-s-Methods-Trials-Test-Synthetic-Antibody-Treatments-COVID-19).

One trial will evaluate a Regeneron Pharmaceuticals investigational treatment in about 2,000 asymptomatic adults who are household contacts of people infected with SARS-CoV-2. The other will assess an Eli Lilly and Company investigational treatment in up to 2,400 people who reside or work in skilled nursing or assisted living facilities.

**HHS FAQ Provides More Information on CARES Act Provider Relief Fund Eligibility:** The Department of Health and Human Services continues to update its [CARES Act FAQ](https://www.hhs.gov/coronavirus/policy-providers-provider-relief-fund/index.html) to aid hospitals and health systems in understanding the nuances of the provider relief fund.

Among the new answers, HHS discusses hospitals’ eligibility for future funding via targeted distributions, stating that “Future General Distributions will take into account previous allocations, including General Distributions and Targeted Distributions. HHS may consider providers that have only received a Provider Relief Fund General Distribution for priority under future General Distributions.”

Other topics include general distribution, including the payment portal and data sharing; distributions for rural, skilled nursing and safety net hospitals; general information, such as rejecting payments, auditing and reporting, and balance billing; and distribution for Medicaid and CHIP providers.

**AMA Releases Additional CPT Codes for SARS-CoV-2 Testing:** The American Medical Association released new Current Procedural Terminology codes for reporting SARS-CoV-2 laboratory testing on medical claims.

They are code 86408 for SARS-CoV-2 neutralizing antibody screen; code 86409 for SARS-CoV-2 neutralizing antibody titer; and codes 0225U and 0226U for proprietary laboratory analyses to detect SARS-CoV-2. The codes are effective immediately. For details, see the [latest CPT coding guidance](https://www.ama-assn.org/practice-management/codes/detailed-codes).


This means the AUC program will not impact claims for diagnostic imaging services until January 1, 2022, at the earliest.

**HHS Releases COVID-19 Testing Plans From States and Other Jurisdictions:** Health and Human Services posted [COVID-19 testing plans](https://www.hhs.gov/coronavirus/policy-providers/testing/index.html) for state, local and territorial jurisdictions through the rest of calendar year 2020.
The Centers for Disease Control and Prevention in May distributed $10.25 billion from the Paycheck Protection Program and Health Care Enhancement Act to state, territorial and local jurisdictions for COVID-19 testing, surveillance, contact tracing and related activities. The recipients were required to submit a plan for using the funds, including their strategy and goals for diagnostic and serology tests for the rest of this year.

"Testing is not just about overall numbers — it is about making sure we’re testing the right people at the right time, and incorporating testing into a comprehensive plan for addressing COVID-19," said Assistant Secretary for Health ADM Brett Giroir, M.D.

**Federal Circuit Holds Government Responsible for CSRs, But Allows Premium Credit Offset**

In a pair of decisions, a three-judge Federal Circuit panel affirmed the government’s “unambiguous obligation” to make cost-sharing reduction (CSR) payments to qualified health plans, but held that a plan’s payments should be reduced by “the amount of additional premium tax credits” a plan received as a result of the government’s termination of CSR payments. While these offsets are not applicable to 2017 CSRs because premiums (and therefore premium tax credits) were not adjusted during the portion of the year following the cut-off of CSRs, the decision sets up fact-intensive liability determinations in the Court of Federal Claims. Those determinations may be delayed, or made unnecessary, if the parties seek review by the full Federal Circuit or the Supreme Court.

**Sanford Health Plan v. United States**: the Federal Circuit panel held the federal government had breached its statutory obligation when it failed to reimburse plans for CSRs they made during the last months of 2017. Guided by the Supreme Court’s decision in *Maine Community Health Plans v. United States*, involving risk corridor obligations, the Federal Circuit held the provision of the Affordable Care Act (ACA) commanding CSR payments is a “money-mandating” provision, the violation of which allows plans to obtain reimbursement under the Tucker Act. The Court also noted the mere “[e]xistence of the premium tax credit mechanism” in the ACA (without plans actually obtaining additional premium tax credits as a result of the government’s termination of CSR payments), is insufficient to infer Congress intended to make the Tucker Act remedy unavailable.

**Community Health Choice v. United States**: the Federal Circuit panel considered the situation in which additional premium tax credits were received as a result of the government’s termination of CSR payments. The court noted, because of the federal government’s refusal to make CSR payments, many states allowed plans to increase premiums with the result the plans received additional premium tax credits. Relying on an analogy to contract law, the court held that plan’s recovery must be reduced by the amount they were able to mitigate their losses (i.e., through the receipt of additional premium tax credits in 2018 because of higher premiums resulting from the termination of CSR payments).

The court indicated determination of the amount of relevant premium tax credits to be recovered when the cases return to the Court of Federal Claims should be guided by three principles:
Recoveries should not be reduced by increased premium tax credits attributable to factors other than the loss of CSR payments (e.g., market forces or increased medical costs);

- When regulators allowed plans to increase premiums for non-silver, as well, as silver plans, the increased premium tax credits for all of those plans should reduce the government's liability. The court explicitly did not reach the issue of whether the government's liability should be reduced for increased premium credits associated with non-silver plans when CSR-related increases were limited to silver plans.

- Plans have the burden of persuasion with respect to the amount of the tax credit increase attributable to the termination of CSR payments.

State Issues

Pennsylvania
Regulatory

Pennsylvania Insurance Department Publishes Section 1332 Reinsurance Waiver Application Approval and First Year Parameters
On July 24, 2020, the Centers for Medicare & Medicaid Services approved the Insurance Department's 1332 Waiver Application. This approval is effective for a waiver period of January 1, 2021, through December 31, 2025, with a provision for a possible extension at the end of the initial term.

The reinsurance program will be a claims-based, attachment point reinsurance program that will reimburse health insurers for claims costs of qualifying Affordable Care Act-compliant individual enrollees, where a percentage of the claims costs exceeding a specified threshold (attachment point) and up to a specified ceiling (reinsurance cap) will be reimbursed. For the first year of the program, beginning January 1, 2021, the adopted parameters are an attachment point of $60,000, a cap of $100,000 and a coinsurance rate of 60%.

Industry Trends
Policy / Market Trends

Partnership for America’s Health Care Future Releases New Report on Downsides of Public Option
The Partnership for America’s Health Care Future released a new report examining how the current health care system would have responded if a public option was implemented before the COVID-19 crisis.

The report found the public option could increase the projected hospital revenue loss by 60% to $79.2 billion, reducing access to quality care for tens of millions of Americans. Hospitals serving rural and vulnerable patients could see their revenue loss increased by more than 40% to $20 billion. These
findings on the public option underline its ability to exacerbate stresses on the health system, increase risk of hospital closures, and threaten access to quality care, hampering the response to the current crisis.

The U.S. Chamber of Commerce released a similar report on the negative economic effects of Medicare Buy-In and a Public Option.

Interested in reviewing a copy of a bill(s)? Access the following web sites:

- Pennsylvania Legislation: [www.legis.state.pa.us](http://www.legis.state.pa.us)
- West Virginia Legislation: [http://www.legis.state.wv.us/](http://www.legis.state.wv.us/)

For copies of congressional bills, access the Thomas website – [http://thomas.loc.gov/](http://thomas.loc.gov/).

If you have any questions about a DE, PA, WV or congressional bill, contact the Government Affairs Department at (717).302.3978.

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