

Federal Issues

Legislative

House Postpones Recess as COVID-19 Relief Talks Stall

U.S. House Majority Leader Steny Hoyer (D-MD) announced Friday that the chamber would remain in session and **forgo its traditional August recess until Congress finishes its next coronavirus bill**. The announcement came after Senate Republicans released a series of bills collectively known as the [HEALS Act](#) to address the crisis last week, sparking negotiations with Democrats who ushered the [HEROES Act](#) through the House in May.

Despite talks between both parties and the White House, **the sides remain \$2 trillion apart** and negotiators reportedly made little ground last week despite the fact that millions remain unemployed and enhanced unemployment benefits expire July 31.

What's next: It seems unlikely a resolution will be reached soon, although President Trump has expressed a willingness to cede ground to the Democrats to get a deal. Key points of contention are levels of funding for state and local governments, liability protections for reopening facilities, the amount of additional unemployment benefits, and additional COVID-19 testing dollars.

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Coalition Urges Congressional Leaders to End Surprise Billing

The Coalition Against Surprise Medical Billing (CASMB), of which AHIP is a founding member, sent a [letter](#) to Congressional Leaders urging Congress to take immediate and comprehensive action to end surprise medical billing as millions of Americans face the looming threat of these bankrupting charges during the COVID-19 crisis.

Why this matters: The letter recommends establishing fair, market-based payments for out-of-network reimbursement to ensure protection against egregious pricing for essential medical care, and to extend protections against surprise medical bills during unexpected emergencies and for care provided at an in-network hospital.

Federal Issues

Regulatory

CMS Releases Part D National Average Monthly Bid Amount and Other Bid/Payment-Related Information

The Centers for Medicare & Medicaid Services (CMS) [announced](#) the average basic premium for Medicare Part D prescription drug plans will be \$30.50 in 2021, the second lowest average basic premium in Part D since 2013. CMS also issued three [memorandums](#) announcing the Medicare Part D national average monthly bid amount for CY 2021 will be \$43.07; the CY 2021 Part D base beneficiary premium amount will be \$33.06; and the de minimis amount is \$2.

The agency's second memorandum provides other bid/premium-related information, including information about the Part D regional low-income premium subsidy amounts, MA regional PPO benchmarks, and the MA regional Employer Group Waiver Plan (EGWP) payment rates. The third memorandum includes additional information related to release of the de minimis amount, including the timeline and process for notifying CMS of decisions to waive the de minimis amount. Plans will have from Thursday, August 6, until 11:59 PM PDT on Thursday, August 13 to inform CMS of their intent to participate in the de minimis program. This memorandum also includes operational guidance on rebate reallocation, which must be completed by Wednesday, August 5.

Appeals Court Upholds Payment Cut for 340B Hospitals

The U.S. Court of Appeals for the District of Columbia Circuit last week overturned a 2018 district court decision that found the Department of Health and Human Services exceeded its statutory authority when it reduced 2018 and 2019 Medicare payment rates for many hospitals in the 340B Drug Pricing Program by nearly 30%.

"We hold that HHS's decision to lower drug reimbursement rates for 340B hospitals rests on a reasonable interpretation of the Medicare statute," Chief Justice Sri Srinivasan said in the [opinion](#) for the court.

The American Hospital Association, Association of American Medical Colleges, America's Essential Hospitals, and three hospital plaintiffs challenged the \$1.6 billion per year payment cut for outpatient drugs purchased under the 340B program, arguing that the 340B provisions in the calendar year 2018 and 2019 outpatient prospective payment system final rule violated the Administrative Procedure Act and exceeded the agency's statutory authority.

Why this matters: 340B hospitals will suffer lasting consequences from the D.C. Circuit Court of Appeals ruling allowing Medicare Part B cuts to stand. Hospitals believe the decision conflicts with Congress' clear intent and defers to the government's inaccurate interpretation of the law, a point that was articulated by the judge who dissented from the opinion.

For more than 25 years, the 340B program has helped hospitals stretch scarce federal resources to reach more patients and provide more comprehensive services.

CMS Seeks Input for Rule to Mandate E-prescribing of Controlled Substances

The Centers for Medicare & Medicaid Services seeks input on a rulemaking to require electronic prescribing for controlled substances covered by Medicare Part D and Medicare Advantage prescription drug plans beginning January 1, in accordance with the Substance Use-Disorder Prevention that Promotes Opioid Recover and Treatment for Patients and Communities Act of 2018.

The [request for information](#) asks whether there should be exceptions to the requirement and under what circumstances, and whether CMS should impose penalties for noncompliance.

Comments are due October 3.

Why this matters: There has been significant support, to date, for the electronic prescribing of controlled substances (EPCS) due to its ability to further streamline care coordination, oversee overprescribing, and reduce the potential for prescription fraud or diversion. Stakeholders have the opportunity to provide input

regarding the types of exceptions and under what circumstances providers can avoid penalty for EPCS noncompliance.

State Medicaid Directors Urge CMS to Suspend Medicaid Fiscal Accountability Rule

On July 27, the National Association of Medicaid Directors (NAMD) asked the Centers for Medicare & Medicaid Services (CMS) to suspend finalizing the [Medicaid Fiscal Accountability Rule](#) (MFAR) while states respond to the COVID-19 pandemic and its impact on state budgets.

NAMD [said](#), “Significant reductions to state general revenues are forcing difficult budgetary decisions across state governments, including within Medicaid.” The directors go on to say that MFAR was proposed in a pre-COVID environment. The circumstances states are facing now are dramatically different. “In this environment, states need assurances that all existing financial tools will be available to weather what is expected to be a significant and years-long economic downturn. MFAR would remove these assurances and exacerbate these already substantial fiscal challenges.”

Key changes: Some of the [proposed changes](#) in the rule include: more and more detailed, state reporting on supplemental payments; new regulatory definitions for base payments and supplemental payments; and stricter rules regarding state financing mechanisms.

Why this matters: Even before the pandemic, many stakeholders [urged](#) CMS to withdraw the proposed rule, saying it would severely curtail the availability of health care services to millions of individuals and many of its provisions are not legally permissible.

Federal COVID-19 Policy Guidance and Other Developments

The Centers for Medicare & Medicaid Services (CMS) [released](#) its first monthly update of [data](#) that provides a snapshot of the impact of COVID-19 on the Medicare population ([FAQs](#)). For the first time, the snapshot includes data for American Indian/Alaskan Native Medicare beneficiaries. The new data indicate that American Indian/Alaskan Native beneficiaries have the second highest rate of hospitalization for COVID-19 among racial/ethnic groups after African American beneficiaries.

The Federal Communications Commission (FCC) issued a [Public Notice](#) stating that phone calls and texts made on behalf of commercial labs, health insurers, physicians, and pharmacies (health care entities) that communicate with individuals who have tested positive for COVID-19 to provide them with information regarding donating their plasma after recovering are considered to fall under “emergency purposes” and are lawful.

The Centers for Disease Control and Prevention (CDC) updated the [list](#) of underlying medical conditions that put individuals at increased risk for severe illness upon contracting COVID-19. The list is based on published reports, articles in press, unreviewed pre-prints, and internal data available between December 1, 2019 and July 10, 2020.

HHS and Defense Department Invest in Manufacturing Demonstration to Produce 100 Million COVID-19 Investigational Vaccine Doses: The Department of Health and Human Services [announced](#) that it will partner with the Department of Defense to fund the advanced development — including clinical trials and large-scale manufacturing — of a COVID-19 investigational vaccine from Sanofi and GlaxoSmithKline.

The investment is expected to yield 100 million fill-finished doses, meaning vaccine doses are packaged and ready to ship immediately if clinical trials are successful and the Food and Drug Administration authorizes its use.

Campaign Encourages Convalescent Plasma Donation: President Trump [announced](#) a national call to action and campaign to encourage individuals who recover from COVID-19 to donate their plasma, which may contain antibodies that could help other patients fight the virus. As part of the effort, the Department of Health and Human Services released several [public service announcements](#) featuring public health experts. The [Fight Is In Us](#) campaign seeks to dramatically increase convalescent plasma donations by the end of August. The American Hospital Association is a partner in the campaign.

“This important campaign is making it easier to find FDA licensed donor centers and hospitals across the country where you can donate plasma safely,” [said](#) FDA Commissioner Stephen Hahn.

FDA Releases FAQs on Remdesivir EUA, Antibody Tests: The Food and Drug Administration [updated its FAQs](#) on the emergency use authorization of remdesivir for use on certain hospitalized COVID-19 patients. The document includes information on the changes to Gilead’s fact sheets for health care providers and patient caregivers. The FDA last week also posted a patient-and-consumer-focused [FAQ](#) about SARS-CoV-2 antibody or serology testing, including a guide to understanding test results and where to obtain them.

HHS Reports on Medicare Primary Care Telehealth Use During Pandemic: Nearly 44% of primary care visits for Medicare fee-for-service beneficiaries were telehealth visits in April, up from 0.1% in February, [according to a report](#) released last week by the Department of Health and Human Services. Medicare fee-for-service telehealth visits for primary care climbed from about 14,000 per week before the COVID-19 pandemic to 1.3 million per week in April, HHS said. The Centers for Medicare & Medicaid Services has waived Medicare geographic and originating site restrictions on telehealth and expanded the list of telehealth-eligible services and practitioners during the emergency.

HHS Secretary Alex Azar [said](#) the report “shows that Medicare providers and beneficiaries rapidly embraced these new opportunities. The meteoric rise of telehealth during the pandemic has not only helped us combat the virus, but also prompted a new conversation around the future of patient-centered care.”

CMS Releases ICD-10 Codes for New COVID-19 Therapies: The Centers for Medicare & Medicaid Services added 12 new [ICD-10 procedure codes](#) to identify new therapies for COVID-19. These include remdesivir and convalescent plasma, as well as any future COVID-19 therapeutic that does not have a unique name.

CMS also released a new ICD-10 Medicare Severity-Diagnosis Related Group Grouper software package ([Version 37.2](#)) to accommodate the new codes, effective for discharges on or after August 1.

The new codes will not affect the MS-DRG assignment.

ASPR Releases COVID-19 Resources: The Department of Health and Human Services’ Office of the Assistant Secretary for Preparedness and Response recently posted these new and updated COVID-19 resources at its [Technical Resources, Assistance Center, and Information Exchange](#):

- A [recorded webinar](#) on using telemedicine at alternate care sites;

- A [compilation of reports and findings](#) on the clinical presentation of COVID-19 patients;
- An [updated resource](#) compiling key COVID-19 guidance for hospitals in areas such as hospital surge, crisis standards of care, workforce protection and resumption of services; and
- COVID-19 lessons from [urgent care centers](#).

FDA Seeks Non-laboratory Diagnostic Tests and Updates List of Bad Hand Sanitizers: The Food and Drug Administration released a [new template](#) to help commercial developers submit emergency use authorization requests for COVID-19 diagnostic tests that can be performed in non-laboratory settings and available by prescription or over-the-counter.

“We hope that with the innovation we’ve seen in test development, we could see tests that you could buy at a drug store, swab your nose or collect saliva, run the test, and receive results within minutes at home, once these tests become available,” said FDA Commissioner Stephen Hahn, M.D. “These types of tests will be a game changer in our fight against COVID-19 and will be crucial as the nation looks toward reopening.”

In other news, the FDA yesterday issued emergency use authorizations to [Eli Lilly](#) and [Sandia National Laboratories](#) for molecular diagnostic tests for SARS-CoV-2.

The agency also [continues to warn](#) health care providers and the public not to use hand sanitizers containing methanol. The FDA has updated its [do-not-use list](#) of hand sanitizer products; in most cases, methanol does not appear on the product label.

CMS Answers Questions on Medicare Fee-for-service Billing During COVID-19: The Centers for Medicare & Medicaid Services updated its [COVID-19 FAQs](#) to address emerging questions regarding Medicare fee-for-service billing. Among the additions are updates to the questions and answers on hospital billing for remote services and outpatient therapy services.

There are also new sections on whether hospitals can bill for and receive separate payment for COVID-19 testing services that are provided in the outpatient department prior to an inpatient admission, as well as the application of cost-sharing modifiers to pre-survey testing services that include COVID-19 testing.

Report Examines Clinical Staffing Considerations When Implementing Crisis Standards of Care: A new rapid expert consultation [report](#) from the National Academies of Sciences, Engineering, and Medicine outlines clinical staffing considerations when implementing crisis standards of care. Building on prior NASEM reports on crisis standards of care, the report focuses on staffing needs and strategies for the care of COVID-19 patients.

FDA Authorizes New Antibody Tests: The Food and Drug Administration issued emergency use authorizations to [Xiamen Biotime Biotechnology Co.](#) and [Access Bio Inc.](#) for serology-based tests to detect SARS-CoV-2 antibodies indicating recent or prior infection.

The tests are approved for use by laboratories certified under the Clinical Laboratory Improvement Amendments that meet requirements to perform moderate or high complexity tests.

Kodak to Produce Active Ingredients in Shortage for Generic Drugs: The U.S. International Development Finance Corporation today signed a [letter of interest](#) to provide a \$765 million loan to Eastman Kodak Company to repurpose and expand its facilities in Rochester, NY, and St. Paul, MN, to produce active pharmaceutical ingredients in short supply.

Once the facilities are fully operational, the company expects to produce up to 25% of the active pharmaceutical ingredients used in non-biologic, non-antibacterial generic pharmaceuticals.

The agency recently requested private-sector proposals for financing to support domestic production or distribution of pharmaceuticals, vaccines, personal protective equipment and medical testing supplies under the Defense Production Act, as authorized by a May executive order in response to the COVID-19 emergency.

HHS Reserves More Vaccine Manufacturing Capacity; Vaccine Candidate Enters Late-stage

Trial: The Department of Health and Human Services' Biomedical Advanced Research and Development Authority issued a \$265 million task order reserving vaccine manufacturing capacity through December 2021 at an advanced manufacturing center in Texas. The Center for Innovation in Advanced Development and Manufacturing, a public-private partnership between BARDA and the Texas A&M University System, manufactures medical countermeasures to respond to public health emergencies.

The order also will allow FUJIFILM Diosynth Biotechnologies to expand its manufacturing capacity at the center, the second in the nation to receive BARDA funding to reserve and expand COVID-19 vaccine manufacturing capacity as part of HHS' Operation Warp Speed.

"To ensure we have the needed capacity, we are engaging domestic centers for advanced manufacturing that HHS has helped build in recent years," [said](#) HHS Secretary Alex Azar. "Securing more manufacturing capacity here in America will help get a vaccine to Americans without a day wasted and prepare our nation for future emergencies." In other news, Pfizer and BioNTech launched a global [Phase 2/3 study](#) to evaluate the safety and efficacy of a COVID-19 vaccine candidate in up to 30,000 people.

CMS Further Delays Submission of Occupational Mix Survey Until September 3: Due to continued COVID-19 pandemic concerns, the Centers for Medicare & Medicaid Services (CMS) is further extending its deadline to submit 2019 occupational mix survey for the wage index beginning federal fiscal year 2022 to September 3, 2020. The revised deadline had been August 3.

CMS collects data every three years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. **Hospitals must submit their occupational mix survey and supporting documentation to National Government Services by September 3**, using the Excel hospital reporting form available on [CMS' website](#).

Federal Court Issues Temporary Nationwide Stay of "Public Charge" Rule

The U.S. District Court for the Southern District of New York issued a [decision and order](#) temporarily staying the Department of Homeland Security's (DHS) final rule, ["Inadmissibility on Public Charge Grounds"](#) or "Public Charge" rule. The district court's stay, which applies nationwide, prevents the federal government from "enforcing, applying, implementing, or treating as effective the [Public Charge] Rule for any period during which there is a declared national health emergency in response to the COVID-19 outbreak."

Why this matters: Under the public charge rule, those immigrating to United States who are classified as Likely or Liable to become a Public Charge may be denied visas or permission to enter the country due to their being "primarily dependent on the government for subsistence." Through regulatory action, the Administration sought to expand the definition of "public charge" to "more likely than not" to use certain public benefits at any point in the future.

The new policy expanded the definition of government benefits to be considered in the public charge determination, which included nonemergency Medicaid benefits with exceptions for children under age 21, those with disabilities, pregnant women, and mothers within 60 days after giving birth.

Fifth Circuit Decision in Favor of Health Plans Medicaid MCO Health Insurance Tax Lawsuit

The U.S. Court of Appeals for the Fifth Circuit issued a unanimous 3-0 [decision](#) rejecting claims brought by attorneys general from six states challenging the inclusion of the ACA health insurance tax (HIT) in Medicaid managed care organizations' (MCOs) capitation rates for years prior to 2018. The decision, which reverses an earlier district court ruling, represents a significant win for the government and aligns with a [joint amicus brief](#) filed by AHIP and the Blue Cross Blue Shield Association supporting the government's effort on appeal.

State Issues

Delaware

Regulatory

Delaware Department of Insurance Finalizes Regulation Requiring the Registration of Pharmacy Benefit Managers (PBM)

The regulation requires PBMS to register with the Commissioner before providing pharmacy benefits management services in Delaware to a "purchaser" (a "purchaser" is defined as an insurance company, health service corporation, health maintenance organization, managed care organization, and any other entity that: (1) provides prescription drug coverage or benefits in Delaware, and (2) enters into agreement with a pharmacy benefits manager for the provision of pharmacy benefits management services); and to annually renew their registration on the May 1 after the initial date of registration and every May 1 thereafter. This [regulation](#) goes into effect on August 11, 2020

State Issues

Pennsylvania

Regulatory

Governor Extends Certain License Renewal Deadlines

On July 29, Governor Wolf approved a request by the Department of State to extend several license renewal deadlines to August 28, 2020. It was made clear, however, that **this will be the final extension and there will be no additional extensions for this cohort.**

The action includes the following State Board of Nursing license types:

- Registered Nurse;
- Clinical Nurse Specialist;
- Certified Registered Nurse Practitioner; and

- Prescriptive Authority.

Why this matters: Due to the COVID-19 emergency, on March 27, the Department of State requested and Governor Wolf granted, the extension for 90 days of certain license renewal deadlines for licensees under the State Board of Nursing from April 30 to July 29, 2020. Despite the extension, a large number of registered nurses (and others) had not met the July 29, 2020, deadline. As the deadline approached, provider groups advocated that patient care could be disrupted absent an additional extension, which was ultimately granted.

PA Secretary of Health Issues Order on Hospital Emergency Department Specimen Collection for SARS-CoV-2 Viral Testing On July 29, 2020, Pennsylvania Secretary of the Department of Health, Dr. Rachel Levine, issued an [order](#) requiring hospitals to implement specimen collection procedures for viral testing for any COVID-19 symptomatic person coming to the hospital's emergency department for treatment. **Hospitals must comply with this order beginning at 12:01 a.m. on July 30, 2020 and continue until further notice.**

Pursuant to authority granted to the Secretary of Health by Pennsylvania law and regulations (35 P.S. § 521.5; 71 P.S. § 532(a), and 1403(a); 28 Pa. Code § 27.60), the Secretary of Health may order general control measures, including, but not limited to, closure, isolation, and quarantine in order to mitigate public health threats. To protect the public from the spread of COVID-19, Secretary Levine orders the following:

- All hospitals licensed by DOH with emergency services organized as a department shall offer to collect specimens for SARS-CoV-2 viral testing from all COVID-19 *symptomatic* persons that have sought treatment or testing at its emergency department, when such testing is clinically indicated.
- Each hospital shall develop and implement policies and procedures for offering and providing the required specimen collection for SARS-CoV-2 viral testing in accordance with the U.S. Centers for Disease Control and Prevention (CDC) guidance and DOH's Health Alerts found at its [website](#).
- SARS-CoV-2 viral testing of the specimens collected by the hospitals pursuant to this order shall be either performed by the hospital, if available, or any laboratory approved by the DOH's Bureau of Laboratories for SARS-CoV-2 viral testing. Specimens shall be handled and submitted in accordance with CDC guidance and the DOH's Health Alerts.

Why this matters: In her [letter](#) accompanying the signed order, Secretary Levine clarifies that this order does not mean that hospital emergency departments should be the new universal COVID-19 testing hub for Pennsylvanians. Secretary Levine further assures the hospital community that DOH will continue to encourage individuals who are experiencing symptoms of COVID-19 to contact their health care provider or visit a local public testing site.

Industry Trends

Policy / Market Trends

HHS Releases Report on Addressing Surprise Medical Billing

HHS' Assistant Secretary for Planning and Evaluation (ASPE) released an expected [report](#) required under the June 24, 2019 [Executive Order 13877](#) on health care price transparency. The Executive Order called for a [report](#) to the President on additional steps the Administration could take to implement its

principles on ending the practice of surprise medical billing The report details the origin of surprise medical bills, discusses pending federal legislation to address the problem, and calls on Congress to act in accordance with the Administration's principles.

Why this matters: The report highlights many of the key points that the [Coalition Against Surprise Medical Billing](#) (CASMB) has made on the issue including the argument for a market-based benchmark solution that protects consumers while lowering costs. It also highlights the role that ancillary providers play in driving the majority of surprise bills, as well as a discussion of private equity-owned staffing firms that use surprise bills as a market strategy. The report also includes mention of Doctor Patient Unity, a private-equity backed group that has aired millions of dollars in advertising to counter messaging from CASMB.

In response to the report and its call on Congress to pass legislation, Reps. Pallone (D-NJ), Walden (R-OR), Scott (D-VA), Foxx (R-NC), and Sens. Alexander (R-TN) and Murray (D-WA) released a [statement](#) calling on Congress to take action, noting that they have agreed on "a transparent, market-based solution that will lower patients' premiums and will not interfere with strong protections states already have in place."

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

Delaware State Legislation: <http://legis.delaware.gov/>.

Pennsylvania Legislation: www.legis.state.pa.us.

West Virginia Legislation: <http://www.legis.state.wv.us/>

For copies of congressional bills, access the Thomas website – <http://thomas.loc.gov/>.

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