Federal Issues
Regulatory

CMS Delays Releasing Rule on Physician Self-referral Law for One Year
On August 24, 2020, the Centers for Medicare & Medicaid Services (CMS) announced an “extension of the timeline” for publication of a final rule addressing changes to the Physician Self-Referral Law (or Stark Law) regulations. In its announcement, CMS set a new deadline of August 31, 2021 for publication of a final rule.

According to CMS, the delay – which was announced as the industry awaited publication of the final rule by the end of August 2020 – is due to “the complexity of the issues raised by comments received on the proposed rule.” The proposed rule had been published in October 2019.

The proposal would create new and permanent exceptions to the 30-year-old Stark Law for value-based arrangements, permitting physicians, and other providers to try innovating solutions without fear that their legitimate efforts to coordinate care might violate the law, according to an agency fact sheet. Those new exceptions would apply for Medicare and non-Medicare populations alike.
It remains to be seen whether the Department of Health and Human Services will similarly delay publication of new proposed safe harbor regulations under the Anti-Kickback Statute and federal Civil Monetary Penalties Law that were issued in October 2019 and had been expected any day.

**Why this matters:** The proposed rule was first unveiled in October 2019, as part of the Trump administration’s "Patients Over Paperwork” initiative.

The news was a disappointment for the American Hospital Association, which in August had urged the Office of Management and Budget for an "expeditious review and release of the Physician Self-Referral and Anti-Kickback Statute final regulations" that the Centers For Medicare & Medicaid Services had submitted in July.

The AHA has long complained that the Stark Law prohibiting physician self-referrals is a major hindrance in the transition to value-based care, and that the proposed reforms would “provide space for the types of innovative arrangements among hospitals and physicians that can enhance care coordination, improve quality and reduce costs.”

**Collaboration Brings New Approach to Evaluating Hospital Contributions**

The Bloomberg American Health Initiative and the Johns Hopkins Center for Health Equity are collaborating with IBM Watson Health to develop a proposed approach to evaluating hospital contributions to community health and equity and are seeking the hospital community’s feedback.

The proposal largely is based on practices occurring in hospitals across the nation and includes four components to measure community health and equity:

- **Component 1:** Population-level outcomes. This component assesses improvement in county-level metrics of community health and equity;
- **Component 2:** Hospital as a health care provider. This component assesses whether hospitals meet best practice standards for offering preventive services. Examples include offering tobacco cessation services, violence intervention, and substance use disorder treatment on site;
- **Component 3:** Hospital as a community partner. This component assesses whether hospitals meet best practice standards for contributing to community health initiatives. Examples include supporting community health workers, home visiting, and healthy housing programs; and
- **Component 4:** Hospital as an anchor institution. This component assesses whether hospitals meet best practice standards for employers. Examples include plans to diversify boards and management, paying a living wage, and offering childcare to all employees.

This measure is being developed for potential inclusion in the Fortune/IBM Watson Health 100 Top Hospitals Program. Public comments can be submitted online or via email until September 10, 2020.
**Why this matters:** As a result of COVID-19, health disparities and inequities have become glaringly evident and hospitals are working to determine the best approaches to take a lead role in combatting health disparities and inequities.

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**AHA to Seek Rehearing of U.S. Appeals Court Decision on Cuts to 340B Hospitals**

The American Hospital Association announced on August 28, 2020, that it will seek a rehearing related to the recent decision from the U.S. Court of Appeals for the District of Columbia Circuit *upholding* as a reasonable interpretation of the Medicare statute the U.S. Department of Health and Human Services’ decision to cut 2018 and 2019 Medicare payment rates by nearly 30% for certain hospitals in the 340B Drug Pricing Program.

The AHA plans to file the petition for a rehearing during mid-September.

The AHA, 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 during the calendar year 2018 and 2019 outpatient prospective payment system final rule violated the Administrative Procedure Act and exceeded the agency’s statutory authority.

In its most recent effort to stop the devastating reductions in payments, the AHA engaged Don Verrilli of the law firm of Munger, Tolles & Olson. Verrilli is the former Solicitor General of the United States and one of the nation’s premier Supreme Court and appellate advocates. As Solicitor General, he argued dozens of cases before the U.S. Supreme Court and was responsible for representing the United States government in all appellate matters before the Supreme Court and in the Court of Appeals. Among Verrilli’s landmark victories is his successful advocacy in defense of the Affordable Care Act.

**Why this matters:** The AHA believes that the D.C. Circuit Court of Appeals ruling allowing the cuts to stand will have dire and lasting consequences for America’s 340B hospitals and the millions of patients they serve. The decision conflicts with Congress’ intent and defers to the government’s inaccurate interpretation of the law, a point that was clearly articulated by the judge who dissented from the opinion.

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**CMS Makes COVID-19 Data Reporting a Medicare Condition of Participation**

The Centers for Medicare & Medicaid Services unexpectedly issued an interim final rule (IFR) that, along with other changes, now makes collecting and reporting COVID-19 data a Medicare condition of participation (CoP) for hospitals.

The rule is effective upon publication and is scheduled to be included in the *Federal Register* by September 2, 2020. It will require hospitals to report daily data including, but not limited to, the numbers of confirmed or suspected COVID-19 positive patients, intensive care unit beds occupied, and availability of supplies and equipment, such as ventilators and personal protective equipment.

By making this data reporting a CoP, the penalty for a hospital’s noncompliance could be termination from the Medicare program if corrective action is not taken.

**CMS’s interim final rule:**
• Makes the daily collection and reporting of COVID-19-related data a condition of participation for hospitals in the Medicare program, potentially subjecting hospitals to termination from participation in the Medicare and Medicaid programs for noncompliance;
• Implements new laboratory reporting requirements in accordance with the CARES Act, subjecting noncompliance to potential civil monetary penalties;
• Instructs surveyors to inspect nursing homes for adherence to new COVID-19 testing requirements with the potential for civil monetary penalties in instances of violations;
• Proposes to update the performance period for the SNF VBP program in light of the extraordinary circumstance exception extended to the value programs; and
• Clarifies that CMS will not use any data from quarters 1 and 2 of 2020 in calculating performance in future years of certain Hospital Value Programs.

Failure to comply with these requirements could result in civil monetary penalties of $1,000 for the first day and $500 a day for each subsequent day.

Over the course of the COVID-19 response, Pennsylvania hospitals have been subject to many different data reporting requirements, with varying intervals and required data elements. On numerous occasions, changes to the process, reporting method, and data sets have occurred on short or no notice. Hospitals are currently working with the U.S. Department of Health and Human Services and the commonwealth about streamlining the hospital process for both federal and state COVID-19 reporting.

**Why this matters:** While hospitals and health systems remain focused on patient care, they're also committed to providing the government with the public health data it needs. However, this regulatory approach threatens to expel hospitals from the Medicare program. This move, announced in final form without consultation, or the opportunity to provide feedback through appropriate administrative procedures prior to it becoming effective, could jeopardize access to care and leave patients and communities without vital health services from their local hospital during a pandemic.

Hospitals and health systems consistently have put forward a good faith effort to report the data needed to battle COVID-19 under very trying circumstances, despite the ever-changing requests from the government on data reporting. Since February, the government has made at least six changes to how they want hospitals to report data. The vast majority of hospitals (94%) are reporting information, according to the federal government.

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

The Department of Health and Human Services’ (HHS) Office of Civil Rights (OCR) issued amended guidance on how the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule permits covered health care providers and health plans to contact their patients and beneficiaries who have recovered from COVID-19 to inform them about how they can donate their convalescent plasma to help treat others with COVID-19.

**HHS Updates Resources for Hospitals Via Workforce Virtual Toolkit:** The Department of Health and Human Services released its [COVID-19 Workforce Virtual Toolkit](#), which includes updated resources for hospitals. The toolkit provides a curated set of resources and tools for decision-makers managing health care workforce challenges in response to the COVID-19 emergency.
HHS Procures 150 Million COVID-19 Rapid Tests From Abbott: The Department of Health and Human Services announced a contract award to Abbott for the delivery of 150 million rapid Abbott BinaxNOW COVID-19 Ag Card Point of Care SARS-CoV-2 diagnostic tests. HHS said the $760 million deal will expand strategic, evidence-based testing in the U.S., with the tests potentially deployed to schools and to assist with serving other special needs populations.

“By strategically distributing 150 million of these tests to where they’re needed most, we can track the virus like never before and protect millions of Americans at risk in especially vulnerable situations,” said HHS Secretary Alex Azar.

NIH Funds Establish Early-warning Network for Emerging Infectious Diseases: The National Institutes of Health’s National Institute of Allergy and Infectious Diseases announced $17 million in grants to establish the Centers for Research in Emerging Infectious Diseases, which will support multidisciplinary investigations into how and where viruses and other pathogens emerge from wildlife and spillover to cause disease in people.

NIH intends to provide approximately $82 million over five years to support the network.

“The CREID network will enable early warnings of emerging diseases wherever they occur, which will be critical to rapid responses,” said NIH Director Anthony Fauci, M.D. “The knowledge gained through this research will increase our preparedness for future outbreaks.”

CDC Reports on Universal COVID-19 Testing in W.Va. Nursing Homes: The Centers for Disease Control and Prevention credited universal testing of residents and staff of all 123 West Virginia nursing homes for SARS-CoV-2, irrespective of symptoms, as a key factor for limiting COVID-19 transmissions and reducing the pandemic's impact on the state’s vulnerable populations.

West Virginia conducted universal testing from April 21 to May 8, during which the state identified eight outbreaks with 17 staff members and five residents, some who were asymptotic. “The testing likely prevented the occurrence of ongoing transmission and larger outbreaks, had the asymptomatic infections gone undetected,” reported the CDC.

HHS Awards $1.5 Billion in Opioid Response Grants to States and Tribes: State Opioid Response and Tribal Opioid Response grant programs are receiving the first of two rounds of funds totaling $1.5 billion, the Department of Health and Human Services’ Substance Abuse and Mental Health Services Administration announced. In total, the two programs, meant to provide community-level opioid prevention, treatment, and recovery resources, will receive nearly $3 billion over two years. HHS said the programs are intended to provide access to medication to treat opioid use disorders, in addition to psychosocial services.

CDC Study Shows Increase of Nonfatal Drug and Polydrug Overdoses Treated in EDs: A Centers for Disease Control and Prevention study released recently shows an increase between 2018 and 2019 in rates of suspected nonfatal drug overdoses involving opioids, cocaine, amphetamines, and of polydrug overdoses co-involving opioids and amphetamines that were treated in the emergency department.

The study, using data from EDs in 29 states, indicates that overdose rates increased 9.7% for opioids, 11% for cocaine and 18.3% for amphetamines, while the rate of benzodiazepine-involved overdoses decreased 3%. The authors note the importance of expanding syndromic surveillance, increasing naloxone provisions, and identifying specific risk factors for those using these drugs.
NIH Report Says People with Intellectual and Developmental Disabilities Disproportionately Affected by COVID-19: Those with intellectual and developmental disabilities who require in-person care, including in-classroom settings, are disproportionately affected by the COVID-19 pandemic, the directors of the National Institutes of Health-funded Intellectual and Developmental Disabilities Research Centers Network said in an American Journal of Psychiatry article.

Researchers said care staff must use techniques and procedures to protect these individuals from COVID-19 infection, with caregivers employing virtual care when possible. However, the authors note that in-person care must be prioritized for those who cannot benefit from virtual care.

The article also said individuals with intellectual and development disabilities cannot always verbalize their symptoms; thus, providers should use their best judgement when considering COVID-19 infection.

HHS Distributes $2.5 Billion in Nursing Home Relief Funds: The Health Resources and Services Administration has distributed the first half of a planned $5 billion Coronavirus Aid, Relief, and Economic Security Act’s Provider Relief Fund allocation to nursing homes, the agency announced. The previously announced funding will support increased testing, staffing, and personal protective equipment needs.

Agencies Update COVID-19 Testing Guidance: People who have been within six feet of someone with COVID-19 for at least 15 minutes but do not have symptoms, do not need to get a COVID-19 diagnostic test unless they are “a vulnerable individual” or their health care provider or public health officials recommend it, the Centers for Disease Control and Prevention said August 24 in the updated guidance.

People in a high COVID-19 transmission area who attend a gathering of more than 10 people without widespread mask wearing or physical distancing also do not need a test unless they are vulnerable or their provider or public health officials recommend one, but they should monitor for symptoms and adhere to mitigation protocols, CDC said.

FDA Approves New Rapid Antigen Test: The Food and Drug Administration authorized the first COVID-19 antigen test that allows health care providers to read the results in minutes directly from the testing card, similar to some pregnancy tests. Under the emergency use authorization, laboratories certified under the Clinical Laboratory Improvement Amendment to perform moderate, high or waived complexity tests and health care providers with a CLIA certificate of waiver, compliance or accreditation may use the test, made by Abbott Diagnostics Scarborough Inc. The company plans to make up to 50 million tests available monthly in the U.S. beginning in early October. Antigen tests are less sensitive than molecular tests, meaning negative results may need to be confirmed with a molecular test, FDA said.

Nursing Homes to Receive N95 Respirators From Stockpile: The Defense Logistics Agency Friday will begin distributing 1.5 million N95 respirators from the Strategic National Stockpile to about 3,330 nursing homes in the Medicare and Medicaid programs that have less than a three-day supply, the Department of Health and Human Services announced.

The agency will distribute the respirators based on the number of medical staff at each facility, as reported to the Centers for Medicare & Medicaid Services database.

CMS Releases COVID-19 Training for Nursing Homes: The Centers for Medicare & Medicaid Services released its national training program to prevent and control COVID-19 in Medicare- and Medicaid-certified
nursing homes. The training incorporates best practices and lessons learned from COVID-19 outbreaks in nursing homes and CMS inspections, with input from Centers for Disease Control and Prevention experts. Topics range from basic infection control to telehealth, emergency preparedness, and vaccine delivery.

CMS offers an online self-assessment tool at its Quality Improvement Organization website to help nursing home staff identify their prevention training needs. To access the CMS Targeted COVID-19 Training for Frontline Nursing Home Staff & Management, visit the agency’s Quality, Safety & Education Portal.

According to the Department of Health and Human Services, nursing homes must participate in the training to qualify for funding from the Coronavirus Aid, Relief, and Economic Security Act’s Provider Relief Fund.

CMS and CDC also will offer bi-weekly Q&A webinars on COVID-19 prevention for nursing home managers’ through January 7. Register for the webinars here.

FEMA Urged Not to Change COVID-19 Reimbursable Expenses: The National Governors Association and other organizations representing cities and states expressed concern that the Federal Emergency Management Agency may eliminate personal protective equipment and disinfectants as eligible reimbursable expenses under public assistance for COVID-19, citing recent communications from the agency.

AHA Urges Flexible Approach to New CMS Documentation Requirement: The American Hospital Association urged the Centers for Medicare & Medicaid Services to provide flexibility regarding the agency’s new COVID-19 test documentation requirement for the diagnostic-related group add-on payment.

“This new requirement will put substantial administrative burden on hospitals at a time when they are focusing their efforts and resources on critical patient care,” the association wrote. “Thus, we urge CMS to allow provider documentation to suffice if the test result is unavailable.”

The Coronavirus Aid, Relief, and Economic Security Act provided a 20% add-on to the inpatient prospective payment system DRG rate for patients diagnosed with COVID-19 during the public health emergency. CMS recently added a requirement to have a positive COVID-19 laboratory test documented in the patient’s medical record in order for the claim to be eligible. The new requirement would be applied to admissions on or after September 1, 2020.

“We have heard from our hospital members that acquiring test results from other health care providers, local testing centers and other third party entities can be a burdensome process, sometimes resulting in long delays or unobtainable results,” the letter notes. “In order to receive the add-on payment, hospitals would have to dedicate considerable time and effort to obtain a patient’s third party result to manually add into the medical record, and in some cases would ultimately have to re-test the patient.”

SBA Issues Rule on Paycheck Protection Program Appeals Process: The Small Business Administration released an interim final rule, effective immediately, on the process for Paycheck Protection Program borrowers to appeal certain SBA loan review decisions to the SBA Office of Hearings and Appeals. The rule was published in the August 27 Federal Register with comments accepted for 30 days.

HHS Extends Deadline to Apply for Emergency Funds to September 13: The Department of Health and Human Services has extended the deadline for applying for its Public Health and Social Services Emergency Fund “Phase 2 General Distribution” to September 13, the previous deadline was August
28. Earlier this month, HHS clarified that those who bill Medicare, Medicaid, Medicaid Managed Care or the Children’s Health Insurance Program, or are dental providers, are eligible to apply as long as they have not already received 2% of their patient revenue from the fund.

HHS also stated that first-time or previous applicants may apply as long as they haven’t already received 2% of their patient revenue. 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.

**New CDC Data Shows COVID-19 Impacted Access to Care for Nearly 4 in 10 Americans:** A recently released [analysis](#) from the Centers for Disease Control and Prevention revealed additional insight into the impact of COVID-19 on patients across the country. The data—compiled through the Research and Development Survey (RANDS) platform—found that nearly 40% of patients saw reductions in their access to one or more types of care as a direct result of the pandemic.

The RANDS data was collected between June 9 and July 6 and measured the impact on access to care during the previous two months. The survey included access to several types of services, including:

- Dental care;
- Diagnostic or medical screening tests;
- Hearing care;
- Prescription drugs or medications;
- Regular checkups;
- Surgical procedures;
- Treatment for ongoing conditions;
- Urgent care; and
- Vision care.

During the early phases of the pandemic, Pennsylvania’s health care providers and facilities—including hospitals and health systems—complied with the order to cancel scheduled, routine, and non-emergency services and procedures as a way to preserve resources and capacity for COVID-19 patients. The order was lifted during the spring, and hospitals gradually began to safely [resume](#) these important services.

### State Issues

**Pennsylvania**

**Legislative**

**House Returns to Harrisburg for Abbreviated Legislative Session**

The Pennsylvania House of Representatives will return to Capitol Hill Tuesday, September 1 for two days. Proposals scheduled to receive consideration impact public schools and COVID-19, teacher professional development, election efficiency, municipalities’ financial recovery, and information from licensing boards.

**Regulatory**
Allegheny County Increases Number for Outdoor Event Attendance

Allegheny County Health Department Director Dr. Deborah Bogen announced Friday, August 28 that the department will amend its July COVID-19 order that capped attendance at outdoor events at 50. The new cap is 100 persons. All other requirements of the order — which went into effect July 17 — will remain in place.

The change was made to reflect the decrease in the county’s virus positivity rate and rolling daily average case counts over the past month. The updated order will take effect at 12:01 a.m. August 29.

The following provisions will remain in effect in Allegheny County:

- Indoor and outdoor seating areas for sit-down, dine-in service at bars, restaurants, and private catered events shall be closed to patrons by 11:00 p.m. Takeout sales continue to be permitted after 11:00 p.m., consistent with applicable Pennsylvania law.
- The use of tobacco products, including e-cigarettes, is prohibited at all indoor and outdoor dining facilities and indoors at casinos.
- Events and gatherings other than those in businesses in the retail food services industry are limited to 25 people at indoor gatherings and 100 people at outdoor gatherings.

State Issues

West Virginia
Legislative

COVID-19 Impacting Cost of Care in West Virginia

West Virginia’s health care system is taking a financial hit due to the cost of treating COVID-19 patients. A number of health care executives have reported on the negative impact, particularly in light of lost revenues from voluntary elective surgeries and the reduction in emergency room visits. COVID-19 patients tend to have longer hospital stays, with much of the time spent in intensive care.

The West Virginia Hospital Association (WVHA) has been tracking COVID-19 hospital stays across the state. While the latest numbers are from April, the data show that charges for the average COVID patient are $21,000 higher than other in-patients and COVID patients stay in the hospital more than four days longer.

Data from the WVHA for April also covers the average charges by primary insurance providers:

- **Medicare**: 48 patients with average charges of $59,000
- **Commercial Insurance**: 25 patients with average charges of $64,000
- **Medicaid**: 10 patients with average charges of $53,000
- **Government**: 6 patients with average charges of $71,000
- **PEIA**: 3 patients with average charges of $98,000
- **Self-Pay**: 2 patients with average charges of $180,000

Not included in this list are the additional, out-of-hospital care of more than $6 million in healthcare costs, such as physical therapy.
News reports show that men are more likely to have severe outcomes from COVID-19. In April, 48 women were hospitalized in West Virginia versus 46 men. However, the average charges for men were $73,700 compared to $54,800 for women, for a difference of just under $19,000 per patient. For the 17 patients who died from COVID-19 in West Virginia hospitals in April, the average charges for each was $129,000.

Regulatory

West Virginia Mandates Mask Requirements for Students Riding School Buses
West Virginia public school students must now wear face coverings on buses, regardless of their county’s color designation under the four-color school reopening plan. Face coverings will be required in schools in yellow counties for grades six and up, and in orange counties for grades three and up. The original green, yellow, orange, and red reopening plan released August 14 didn’t require students to wear face masks at all times until a county hit orange — and even then, only for grades six and up.

According to the West Virginia Department of Education, many counties are implementing stricter mask requirements. However, the face covering requirement doesn’t apply to students exempt for health reasons and, the state’s rules still include other face covering requirements that may be left up to counties’ and schools’ interpretation.

Update from Gov. Jim Justice
On a related note, Gov. Jim Justice announced changes that may reduce the number of counties that turn yellow, orange or red, which is impacted by the average new COVID-19 cases per day per 100,000 residents, excluding infected prisoners and nursing home residents.

Using the average over the previous seven days was the original plan for all counties, but now the state will use 14 days for the counties with fewer than 16,000 residents. That’s 20 of the state’s 55 counties.

Dr. Clay Marsh, the state’s COVID-19 czar and vice president and executive dean for health sciences at West Virginia University, supports the change because it is a fairer assessment of smaller counties that do not meet population numbers.

Industry Trends
Policy / Market Trends

AHIP Highlights Price Gouging During the Public Health Crisis
AHIP published new data showing out-of-network claims for COVID-19 testing significantly exceed average in-network charges.

Why this matters: The findings come from a July 2020 survey of health insurance providers in the commercial market, which gathered information on prices charged by out-of-network providers for diagnostic and antibody tests for COVID-19.

Findings from the data include:
• On average, a COVID-19 test in the commercial market costs $130. In contrast, out-of-network test providers charged significantly higher (more than $185) prices for nearly 40% of diagnostic tests and 25% of antibody tests;
• One in ten out-of-network test claims charged more than $390 (three times the average cost); and
• Nearly a tenth (9.4%) of all claims for COVID-19 tests were from out-of-network test providers.

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

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/.
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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