Federal Issues
Legislative

U.S. Senate Fails to Clear Slimmed Down COVID-19 Relief Package
The U.S. Senate on Thursday fell short of the 60 votes necessary to pass the latest version of a COVID-19 relief package introduced by Senate Republicans. The 52-47 vote was largely along party lines with all Democrats and one Republican opposed.

The odds of an agreement between the Republican-controlled Senate and Democratic-controlled U.S. House—which voted for a $3 trillion HEROES Act package during May—are increasingly bleak. The package that failed in the Senate last week carried a $500 billion price tag. Action may be delayed until after the November election.

Major issues of disagreement include unemployment benefits, stimulus payments, and state and local aid.

Hospital industry perspective: The House proposal would have dedicated $100 billion in additional resources for health care provider relief to account for lost revenue and increased expenses; the Senate proposal would have allocated $25 billion.

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In addition to calling for further support through the provider relief fund, the hospital community continues to advocate for:

- Forgiveness from repaying Medicare accelerated payments;
- Appropriate federal liability protections to frontline medical providers and facilities;
- Additional federal support for health care workers; and
- Maintained health benefits for individuals and families, and increased coverage options for those who are uninsured.

**Why this matters:** Next steps on the federal package are not clear. The House and Senate are expected to vote for a continuing resolution to fund the government past the election. Action on COVID-19 relief could be delayed until after the election if negotiations do not produce a deal.

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**Senate Panel Examines Vaccine Development and Distribution**

On Wednesday, the Senate Health Education Labor Pensions (HELP) Committee held a hearing entitled “Vaccines: Saving Lives, Ensuring Confidence, and Protecting Public Health”. The witnesses -- Dr. Francis Collins, Director of the National Institutes of Health (NIH), and VADM Jerome Adams, U.S. Surgeon General -- discussed how vaccines work, the importance of routine immunizations, safety of the future COVID-19 vaccine, and vaccine distribution.

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**Majority of House Members Sign onto 340B ‘Dear Colleague’ Letter**

Two hundred forty-six members of the House of Representatives signed onto a Dear Colleague letter that asks the Department of Health and Human Services to use its authority to address recent actions taken by a number of drug companies to limit the distribution of certain 340B drugs to hospitals and health systems.

**Background:** In response to a series of unilateral actions by pharmaceutical manufacturers that violate the 340B statute and are intended to undermine the 340B program, a group of U.S. House members circulated a letter urging HHS Secretary Alex Azar to use his authority to require pharmaceutical companies to comply with the law. The action comes in response to recent announcements by several pharmaceutical companies that they will no longer charge the 340B discount price for some or all of their drugs when they are dispensed by community-based pharmacies, and letters to covered entities demanding claims data that go beyond the scope of the 340B statute.
**Why this matters:** Hospitals throughout the nation are under severe stress by the need to prepare for, and/or care for, COVID-19 patients, while coping with the financial damages inflicted by the virus. Hospitals need immediate action against any drug manufacturer employing these pernicious tactics to ensure that 340B drugs are available and accessible to vulnerable communities.

**Federal Issues**

**Regulatory**

**CMS Proposes New Medicare Coverage Pathway for Breakthrough Devices**

The Centers for Medicare & Medicaid Services (CMS) issued a proposed rule creating a new Medicare coverage pathway, Medicare Coverage of Innovative Technology (MCIT), for Food & Drug Administration (FDA)-designated breakthrough medical devices.

**Why this matters:** The MCIT proposal would provide national Medicare coverage on the same day as FDA market authorization for breakthrough devices and coverage would last for four years. The MCIT pathway would be available for devices that meet specific criteria included in the 21st Century Cures Act for breakthrough device designation. Breakthrough devices must also fit within a statutory Medicare benefit category to be covered.

In addition to creating the MCIT, the draft rule proposes to codify a definition of “reasonable and necessary” for all items and services that may be covered under Medicare Parts A and B. The proposed codification is similar to the definition currently published in Chapter 13 of the Medicare Program Integrity Manual and, according to CMS, will not have any effect on existing National Coverage Determinations, Local Coverage Determinations or other coverage decisions.

Public comments on the proposed rule are due November 2, 2020.

**White House Releases Additional Executive Order Aimed at Addressing High Drug Prices**

President Trump signed a new executive order aimed at lowering the price of prescription drugs. Three executive orders were signed in July seeking to do the same. The latest order directs the Secretary of Health and Human Services to test a “most-favored-nation” pricing model for Part B, and some Part D, drugs.

**Highlights of the order:**

- The executive order directs the HHS Secretary to immediately take steps to conduct rulemaking on a model that would test limiting Medicare payments for Part B drugs to no more than a “most-favored-nation” price.
- This is similar to a model set forth by the Centers for Medicare & Medicaid Services in October 2018.
- At that time, the agency released an advanced notice of proposed rulemaking that solicited comments on a new payment model, known as the International Pricing Index (IPI) model, which would phase down Medicare payments for certain Part B drugs to more closely align with an index price made up of drug prices from a mix of different countries.
Hearing Stakeholders’ Concerns, CMS Withdrawing Medicaid Regulation

In a tweet on Monday, Seema Verma, administrator of the Centers for Medicare & Medicaid Services (CMS) announced the Administration would withdraw a proposed Medicaid regulation, which stakeholders cautioned would have significant consequences, putting economic pressure on states and negatively impacting Medicaid beneficiaries across the country.

The Medicaid Fiscal Accountability Regulation (MFAR), proposed by CMS during November 2019, would dramatically reshape state Medicaid program financing and supplemental payments for providers, ultimately affecting access to care for more than 2.8 million Pennsylvanians who rely on Medicaid for quality coverage.

On Monday afternoon, Verma, CMS Administrator tweeted, “We’ve listened closely to concerns that have been raised by our state and provider partners about potential unintended consequences of the proposed rule, which require further study. Therefore, CMS is withdrawing the rule from the regulatory agenda.”

During March, U.S. Congressmen Brendan Boyle (D, PA-02) and Mike Kelly (R, PA-16) spearheaded a letter—signed by all 18 members of the Pennsylvania U.S. House delegation—recognizing the Administration’s efforts to foster accountability within the Medicaid program, but cautioning that MFAR “puts into jeopardy the care and services the Commonwealth of Pennsylvania provides to the most vulnerable and sick in our communities.”

The delegation letter called for the Administration to “continue to engage and work with relevant stakeholders” and urges “fundamental rethinking of the MFAR proposal... recogniz[ing] the jeopardy it places on our rural and urban safety net hospital systems, providers, children, and low-income Medicaid beneficiaries.”

Urgency for the Administration to rethink MFAR has been heightened in light of COVID-19; stakeholders have called for federal policymakers to take steps to strengthen the Medicaid program, which will serve as an even more important safety net as the economic toll of the pandemic deepens.

Why this matters: Prior to COVID-19, estimates projected, under the proposed rule, the Medicaid program could face total funding reductions between $37 billion and $49 billion annually or 5.8% to 7.6% of total program spending nationally. If MFAR had been finalized, hospitals and health systems specifically, could have seen reductions in Medicaid payments of $23 billion to $31 billion annually, representing 12.8% to 16.9% of total hospital program payments. The implications of those reductions would be even more profound as state economies reel from the pandemic and more beneficiaries rely on Medicaid for coverage.

CMS still must formally withdraw the rule through a notice published in the Federal Register.

FEMA Extends Performance Period for Reimbursement; Issues an Interim Policy Effective September 15

The Pennsylvania Emergency Management Agency (PEMA) recently received notification from the Federal Emergency Management Agency (FEMA) that the Category B, Emergency Protective Measures performance period has been extended indefinitely and will not expire at the end of September, as previously stated. This means that eligible applicants who incurred these specific costs can continue to include them in grant submissions.
On September 9, 2020, FEMA released an Interim Policy—“COVID-19 Pandemic: Work Eligible for Public Assistance”—and fact sheet to clarify eligible work under the Public Assistance program as part of the response to the COVID-19 pandemic. The interim policy applies to eligible applicants only, is exclusive to emergency and major disaster declarations for the COVID-19 pandemic, and applies to work performed on or after September 15, 2020.

The interim policy defines the framework, details and requirements for eligibility of work and costs under the Public Assistance Program, to ensure consistent and appropriate implementation across all COVID-19 emergency and major disaster declarations. Only work associated with the performance of emergency protective measures specifically listed in this policy is eligible for Public Assistance in COVID-19-declared events.

**Under the policy, FEMA provides assistance for emergency protective measures in response to COVID-19 declared events, to include the following:**

- Purchase and distribution of personal protective equipment (PPE) that is directly related to the performance of otherwise eligible emergency work, or is provided to health care workers, patients with confirmed or suspected COVID-19 infection, and first responders;
  - Funding for stockpiling a supply of eligible PPE is limited to a 60-day supply from the date of purchase;
  - Funding for storing eligible PPE is limited to what is necessary to store a 60-day PPE supply;
- Medical care, in accordance with COVID-19 specific policy—“COVID-19 Pandemic: Medical Care Costs Eligible for Public Assistance, Version 2 (Interim)”—being concurrently released or subsequent updates;
- Purchase and distribution of food, in accordance with COVID-19-specific policy or subsequent updates;
- Non-congregate medical sheltering, in accordance with COVID-19-specific policy or subsequent updates;
- Operation of Emergency Operations Centers to direct and coordinate resources and response activities for COVID-19 declarations;
- Communications to disseminate public information regarding health and safety measures and provide warnings about risks and hazards;
- Mass casualty management, including the storage of human remains and mass mortuary services needed to manage mass fatalities caused by COVID-19; and
- Assistance for other activities may be eligible when necessary to perform otherwise eligible emergency work listed in the policy; for example, the purchase and distribution of face masks, temperature screening, disinfecting in accordance with Centers for Disease Control and Prevention guidance, and temporary physical barriers.

The interim policy is not retroactive; costs captured after January 20, 2020, and before September 14, 2020, will continue to be handled under the previous FEMA policy.

Hospitals should know that FEMA may provide funding for eligible work under the COVID-19 declarations that also may be eligible for funding under another federal agency’s authorities. Applicants have the flexibility to determine which source of funding to use for their costs, subject to the purpose and eligibility requirements of each of the federal programs and funding sources. They are responsible for ensuring that each cost is submitted to only one source of reimbursement.
The COVID-19 Disaster Recovery Resources by Topic contains a list of resources provided by the federal government since the start of the response to COVID-19 and is designed to assist with recovery efforts. Applicants should review each agency’s program information to verify the applicability of a resource as a reimbursement vehicle.

Why this matters: FEMA released this interim policy as part of President Trump’s March 13 nationwide emergency declaration and subsequent major disaster declarations for COVID-19. Because of these declarations, state, local, tribal, and territorial government entities and certain private non-profit organizations, including hospitals, are eligible to apply for assistance under the FEMA Public Assistance Program.

The Centers for Medicare & Medicaid Services recently issued new surveyor guidance regulations for COVID-19 laboratory test results reporting for Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories, with the expectation that laboratories will be in compliance by September 23, 2020. This new guidance complements the September 2, 2020, interim final rule (IFR) that, among other changes, made collecting and reporting COVID-19 data a Medicare condition of participation (CoP) for hospitals.

Background: All laboratories that perform or analyze any COVID-19 test (molecular, antigen, antibody, etc.) must report data, regardless of the type of CLIA certificate the laboratory holds. In addition, all negative and positive test results, irrespective of method, must be reported. Any facility using point-of-care COVID-19 testing devices under a CLIA waiver also is required to report.

- Laboratories operating under a certificate of waiver (CoW) and certificate for provider-performed microscopy (PPM) are generally not routinely surveyed; however, for the duration of the public health emergency, 5% of CLIA, CoW and PPM laboratories will be surveyed for compliance with COVID-19 reporting requirements, assuring the appropriate CLIA certificate is held, and compliance for CLIA requirements for PPM procedures.
- Laboratories operating under a certificate of compliance and certificate of registration will be assessed for compliance at the time of an initial, recertification or complaint survey.

Why this matters: Failure to comply with the reporting requirements will result in a mandatory citation. All laboratories must have documentation demonstrating compliance. After September 23, 2020, a laboratory’s failure to report COVID-19 test results will result in a condition-level violation of the CLIA regulations and CMS will impose a $1,000 civil monetary penalty (CMP) for the first day of noncompliance and a $500 CMP for each subsequent day of noncompliance.

In those instances where exempt states (ES) conduct their own oversight of programs, CMS expects those ESs to report laboratories that fail to report and impose CMPs based on their own updated CMS-approved standards.

NASEM Releases Draft Framework for Allocating a COVID-19 Vaccine
The National Academies of Sciences, Engineering, and Medicine released for public comment a discussion draft of a preliminary framework to assist policymakers in planning for equitable allocation of a vaccine against COVID-19. The committee that developed the draft framework was formed in July in response to a request from the National Institutes of Health and Centers for Disease Control and Prevention.
The public comment period will be open from noon September 1 until September 4. Commenters will be able to download and review the discussion draft before submitting a comment through a form on the NASEM website. The committee’s final report is expected early this fall.

**Why this matters:** While major efforts are being made to have a significant supply of COVID-19 vaccine as soon as possible, the committee has been tasked with considering the tough choices that will need to be made for allocating the tightly constrained initial supplies.

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**CMS Finalizes Medicare Inpatient Final Rule**

The Centers for Medicare & Medicaid Services (CMS) finalized various proposals in the final Medicare inpatient prospective payment system (IPPS) rule for fiscal year (FY) 2021, including policies related to payment rates, uncompensated care payments, quality incentive programs, and disclosure of certain payor-specific rates.

Overall, the rule will increase IPPS rates by a net 2.9% during FY 2021, compared to FY 2020, for hospitals that are meaningful users of electronic health records and submit quality measure data.

Despite ongoing legal battles, CMS has finalized a policy that will require hospitals to report the median payor-specific negotiated rates for inpatient services by Medicare severity-diagnosis related group for Medicare Advantage organizations on the Medicare cost report effective January 1, 2021.

The final rule indicates that CMS will distribute approximately $8.3 billion in uncompensated care payments for FY 2021, a decrease of $60 million from FY 2020. This estimate reflects the Office of the Actuary’s projections that incorporate the estimated impact of the COVID-19 pandemic.

For FY 2021, CMS also will use a single year of data from Worksheet S-10 of hospitals’ FY 2017 cost reports. Additionally, CMS finalized a policy to use the most recent available single year of audited Worksheet S-10 data to distribute uncompensated care payments for all subsequent years.

The rule also creates a new Medicare Severity Diagnostic Related Group (MS-DRG) for Chimeric Antigen Receptor (CAR) T-cell therapies.

CMS also finalized several policies governing what can be reported as Medicare bad debt.

In other key policy changes finalized in the rule, CMS will:

- Begin increasing the number of quarters of electronic clinical quality measure data until it reaches a full year for the calendar year 2023 performance period;
- Begin publicly reporting eCQM measure results during late 2022; and
- Make changes to the Hospital IQR Program validation process.

**Why this matters:** This final rule is issued on an annual basis to reflect payment system updates and other policy changes for the following fiscal year. Of particular importance is the requirement for hospitals to report the median payor-specific negotiated rates for inpatient services. Hospitals oppose this requirement—along with the broader rate disclosure policy set to take effect during January—and legal challenges are ongoing.
CMS Issues LTCH PPS Final Rule for FY 2021

The Centers for Medicare & Medicaid Services issued a final rule for the long-term care hospital prospective payment system for fiscal year 2021.

Under the rule, net payments for LTCHs will decrease by 1.1% (-$40 million) relative to FY 2020 payments. This net decrease is largely due to a reduction in payment for site-neutral cases, which account for 25% of all cases. Specifically, in FY 2021 and beyond, site-neutral cases will be paid the full site-neutral rate, rather than the higher, blended rate that was previously in effect for a transition period.

CMS did not make any changes or updates to the LTCH quality reporting program.

Why this matters: As with other final rules, this rule is issued on an annual basis to reflect payment system updates and other policy changes for the following fiscal year.

Federal COVID-19 Policy Guidance and Other Developments

The Centers of Medicare & Medicaid Services (CMS) released their monthly Medicare COVID-19 Data Snapshot that reports COVID-19 cases and hospitalizations for Medicare beneficiaries and includes Medicare Fee-for-Service claims data, Medicare Advantage encounter data, and Medicare enrollment information.

The Equal Employment Opportunity Commission (EEOC) updated several of its FAQs addressing employers administration of COVID-19 tests (FAQ A6), the ability for employers to exclude employees that are COVID-19 positive or have symptoms from the workplace (A8), and prohibiting employers from asking questions about family members that may have symptoms or have recently tested positive (A10), and several questions regarding confidentiality.

The Department of Health and Human Services (HHS) issued guidance under the Public Readiness and Emergency Preparedness Act (PREP Act) to expand access to safe and effective COVID-19 vaccines when they are made available. This guidance authorizes state-licensed pharmacists to order and administer, and state-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist, to administer COVID-19 vaccinations to persons ages 3 or older, subject to certain requirements.

Main Street Lending Program Now Fully Operational: On September 4 the Federal Reserve said that its Main Street Lending Program is now fully operational and accepting submissions of eligible loans to nonprofit organizations.

The program is designed to help small- and medium-sized for-profit businesses’ and nonprofit organizations’ credit flow, particularly those that were in sound financial condition prior to the COVID-19 public health emergency.

Under the program, the Federal Reserve purchases 95% of each loan’s debt issued by eligible lenders, with the lender retaining the remaining 5%. Borrowers pay no interest until the loan’s second year and no principal until year three. The program requires lenders to evaluate borrowers’ financial condition and
creditworthiness based on the terms of the Main Street program and the lenders’ own underwriting standards.

Applications should be submitted through the Main Street lender portal by registered eligible lenders.

**FDA Greenlights Injection to Aid Tracheal Intubation:** The Food and Drug Administration approved a new drug for facilitating tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

FDA said that approving cisatracurium besylate USP 20 mg/10mL injections via an abbreviated new drug application addresses a shortage for a medical product that is in increased demand. The agency noted the drug’s side effects include bradycardia, hypotension, flushing, bronchospasm, and rash.

**NIH Awards Contracts for COVID-19 Rapid Point-of-care Tests:** The National Institutes of Health announced as part of its Rapid Acceleration of Diagnostics initiative $129.3 million in contracts to nine companies for technologies that include portable point-of-care tests for immediate results and high-throughput laboratories that can return results within 24 hours.

Among the tests are some that use RT-PCR and a device that can give results in 15 minutes and strips that can be read without specialized equipment, similar to pregnancy tests.

In addition, NIH said it is adding five additional laboratories to expand the network of coverage and potentially manage tens of thousands of additional tests daily.

**FDA Loosens Restrictions on Remdesivir:** The Food and Drug Administration further expanded the authorized use of remdesivir for treating COVID-19 patients, the agency announced. Now, remdesivir can be used for all admitted COVID-19 patients, confirmed or suspected, whether on oxygen, off oxygen or intubated. This is a departure from the previous policy that restricted such treatment to those who required oxygen.

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

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 author’s note the importance of expanding syndromic surveillance, increasing naloxone provisions and identifying specific risk factors for those using these drugs.

**NIH Launches Clinical Trials of COVID-19 Blood-clotting Treatments:** The National Institutes of Health announced the launch of two of three planned, worldwide three phase clinical trials of varying types of blood thinners to treat adults with COVID-19.

Trials will include hospitalized and non-hospitalized patients; the expected third trial will later focus on those discharged after hospitalization for moderate-to-severe disease.
NIH said research shows many COVID-19 patients who died suffered from blood clots throughout their bodies; these blood thinners, known as ACTIV-4 antithrombotics, could provide insights for care.

**Study Shows 4 in 10 U.S. Adults Deferred Medical Care Due to COVID-19 Worries:** A new Centers for Disease Control and Prevention study is revealing the extent to which adults are bypassing medical care because of their COVID-19-related concerns. According the authors, 41% of U.S. adults delayed or avoided medical care as of June 30. This includes urgent or emergency care (12%) and routine care (32%).

The trend was more prevalent among unpaid caregivers for adults, individuals with underlying medical conditions, Black adults, Hispanic adults, young adults, and individual with disabilities.

Hospitals have warned that such deferrals are putting lives at risk unnecessarily during the COVID-19 public health emergency and urge patients to seek necessary care, noting that many facilities have posted information on their websites about how patients are protected from COVID-19 when they seek care.

**IRS Issues Initial Guidance on Deferral of Employee Portion of Social Security Tax:** The Department of Treasury’s Internal Revenue Service recently issued guidance for implementing the White House’s August 8 executive order on payroll taxes, which applies to wages paid September 1 through December 31, 2020. Under the memorandum, non-federal employers may defer withholding and payment of an employee’s portion of the Social Security tax if the employee earns less than $4,000 biweekly.

The IRS says these taxes must be repaid between January 1 and April 30, 2021, or interest, penalties and additions to tax will begin to accrue on May 1, 2021. This differs from the Coronavirus Aid, Relief, and Economic Security Act payroll tax delay of the employer share, which began March 27 and allows repayment over a two-year period.

**CDC September 17 Webinar for Clinicians on Flu Testing and Treatment During the COVID-19 Pandemic:** On September 17 at 2 p.m. ET, the Centers for Disease Control and Prevention will host a Clinician Outreach and Communication Activity webinar on using antivirals to treat influenza and whether the U.S. could see fewer cases, as indicated by data from the Southern Hemisphere’s 2020 flu season. Presenters will give an overview of CDC’s recommendations for health care providers regarding influenza diagnostics and the use of antiviral medications for the upcoming flu season, including considerations to account for the ongoing COVID-19 pandemic.

Join the webinar here using ID 160 498 4692. A recording will be available for viewing on the COCA Call webpage a few hours after the live event concludes.

**New CPT Codes Address Advancing Understanding of COVID-19:** An updated set of Current Procedural Terminology (CPT) codes includes two for reporting medical services necessitated during the COVID-19 pandemic public health response. The American Medical Association recently announced the update, which include:

- CPT code 99072, which describes additional supplies and clinical staff time to perform safety protocols for the provision of evaluation, treatment or procedural services during a public health emergency in a setting where extra precautions are taken to ensure the safety of patients as well as health care professionals; and
• CPT code 86413, which accounts for laboratory tests that can measure antibodies to investigate a person’s adaptive immune response to the virus and help access the effectiveness of treatments used against the infection.

Long, short and medium descriptors for both codes can be accessed on the AMA website, along with several other recent modifications to the CPT code set that have helped streamline the public health response to the SAR-CoV-2 virus and the COVID-19 disease.

State Issues

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Senate Judicial Committee Holds Hearing on the Impact of the Return to Venue Shopping

Last week, the Pennsylvania Senate Judiciary Committee held a public hearing to review the February 2020 report of the Legislative Budget & Finance Committee entitled “A Study of the Impact of Venue for Medical Professional Liability Actions.”

Background: The Civil Procedural Rules Committee of the Supreme Court of Pennsylvania is planning to propose changes to the procedural rules regarding venue in medical malpractice actions. The proposed change, detailed in a notice published in the December 22, 2019, Pennsylvania Bulletin, would revive the venue rules that largely created PA’s severe medical malpractice insurance crisis.

In its proposed rule, the Civil Procedural Rules Committee is proposing an amendment of Rule 1006 to rescind subdivision (a.1), which limits venue in medical professional liability actions to the county in which the cause of action arose.

The Hospital & Healthsystem Association of Pennsylvania offered expert testimony about the potentially harmful impacts of a return to medical liability venue shopping. Their testimony emphasized that:

• The LBFC report lacked references to an important actuarial analysis, which demonstrates that medical liability insurance rates will increase if the proposed rule change takes effect;
• The LBFC report found no link between venue and fairness of payouts to plaintiffs, so the trial bar’s premise for making a rule change has no support from the data the LBFC examined;
• The plaintiff’s bar is motivated by potentially higher payouts, and not patients and families;
• Many hospitals have a hard time recruiting practitioners, and this proposed rule change will make it even more difficult to bring health care providers to the commonwealth. This could seriously impact patient access to care.
• Physician fright and flight: Pennsylvania ranks fourth in training medical students, but 34th in retaining them. Struggles with recruiting and retention are related to the lawsuit climate in the commonwealth; and
• Roadblocks in implementing strategies to bring high-quality care to every place in the commonwealth. Decisions to establish new joint ventures or partnerships between facilities and health systems will be put at risk by this proposal. As a result, access to care will suffer.
Hospitals Advocate in Support of Interstate Licensure Compacts

Recently, the Hospital & Healthsystem Association of Pennsylvania shared with members of the state House Professional Licensure Committee a memo in support of three pieces of legislation that address some of the issues identified by HAP’s Health Care Talent Task Force.

The bills would allow Pennsylvania to participate in interstate compacts that enable health care practitioners to use their license in other participating compact states. They include:

- **Senate Bill 655**, sponsored by Senator Lisa Boscola (D–Northampton), would authorize Pennsylvania to join the Nurse Licensure Compact.
- **House Bill 2584**, sponsored by Representative Jesse Topper (R–Bedford), would provide for clarification of the sharing of information raised by the Federal Bureau of Investigation so that Pennsylvania can fully participate in the Interstate Medical Licensure Compact.
- **House Bill 862**, sponsored by Representative Steve Barrar (R–Delaware), would authorize Pennsylvania to join the Physical Therapy Licensure Compact.

The committee is expected to take up the three bills during the fall legislative session.

State Issues

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**Governor Amends Proclamation of Disaster Emergency**

On March 6, 2020, Governor Tom Wolf declared a disaster emergency due to the coronavirus disease 2019 (COVID-19) pandemic, which would have expired on June 4, 2020. The proclamation, however, was renewed on June 3, 2020 for an additional 90 days with an expiration date of September 1, 2020. To avoid expiration of the proclamation and in light of the continued presence of COVID-19 in the Commonwealth, the Governor amended the proclamation again on August 31, 2020.

A notice of this action by the Governor can be found here.

Department of Health Issues Temporary Scheduling of Isotonitazene as Schedule I Controlled Substance

The Department of Health issued a notice in the September 5 Pennsylvania Bulletin of its intent to temporarily schedule Isotonitazene as a Schedule I drug. Isotonitazene is not currently listed in any schedule of The Controlled Substance, Drug, Device and Cosmetic Act. The Secretary is taking this action because the scheduling of Isotonitazene in this Commonwealth on a temporary basis is necessary to avoid an imminent hazard to public safety.

This DOH order will be effective once notice has been provided to the Pennsylvania Attorney General.
Background: The United States Drug Enforcement Administration temporarily scheduled Isotonitazene as a Schedule I narcotic under the Federal Controlled Substance Act on August 20, 2020. Under the CSA, every controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause.

Substances in Schedule I are those that have a high potential for abuse, not currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The final order temporarily scheduling Isotonitazene will be in effect for a period of 2 years, with a possible extension of 1 additional year, pending completion of the regular (permanent) scheduling process.

Isotonitazene is not currently a scheduled substance in this Commonwealth. In the United States, Isotonitazene is considered one of the most persistent and prevalent new opioids. Isotonitazene has been identified in at least 18 deaths in the United States that occurred between August 2019 and January 2020. Pharmacological data suggest that the group of synthetic opioids that includes Isotonitazene (along with Etonitazene, Metonitazene and Clonitazene) has potency similar to or greater than fentanyl based on their structural modifications.

Why this matters: Because Isotonitazene poses a substantial risk, DOH has determined to schedule it as a Schedule I controlled substance on a temporary basis. In doing so, the Secretary is acting to protect the citizens of this Commonwealth and bring the Commonwealth into conformity with Federal law.

State Board of Medicine Reviews Prescribing Guidelines; Biennial Renewal Fees Waived
The State Board of Medicine (SBM) met on September 2 where copies of the following opioid prescribing guidelines developed by the Safe and Effective Prescribing Practices Task Force were shared:

- Safe Administration of Subanesthetic Ketamine
- Treating Pain in Patients with OUD
- Treatment of Acute and Chronic Pain in Patients with Sickle Cell Disease

Board members raised concerns with some of the language in the guidelines and questioned whether the guidelines had a statutory basis that could be used for punitive consequences for medical professionals. The executive assistant for the Department of Health's Deputy Secretary for Health Innovation indicated that the guidelines were voluntary recommendations and, therefore, would not have any statutory effect.

Board members did not vote to affirm the proposed guidelines, but rather, determined it would be best to conduct a conference call with the task force to discuss their concerns. The board chair instructed the board administrator to schedule that call.

In further business, the board discussed the action taken by the United States Medical Licensing Examination (USMLE) regarding policy changes related to the number of times applicants can take the examination for medical licensure. The USMLE changed the requirement indicating that applicants would now be only able to retake the exam four times, rather than the six times granted in their former policy. The board approved the adoption of USMLE’s changes and will update its regulations.

Lastly, the board approved the waiver of the biennial renewal fees for the 2021–2022 licensure cycle for all practitioners under the purview of the medical board.
The next board meeting is scheduled for October 27, 2020.

**Industry Trends**

**Policy / Market Trends**

**HHS Releases Rural Action Plan**

The Department of Health and Human Services (HHS) released the Rural Action Plan, the first HHS-wide assessment of rural health care efforts in more than 18 years. The report is a product of HHS’ Rural Task Force, convened to analyze existing and upcoming efforts to improve rural health.

The Action Plan outlines four points of strategy:

- Building a sustainable health and human services model for rural communities;
- Leveraging technology and innovation, which includes funding for the Telehealth Network Grant Program;
- Focusing on preventing disease and mortality; and
- Increasing rural access to care, through strategies like funding for rural residency programs.

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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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