Issues for the week ending January 4, 2019

Federal and National Issues

Legislative Issues

116th Congress Convenes Amid Shutdown

The House and the Senate convened Thursday to begin the 116th session of the U.S. Congress (2019-2020). Newly elected and reelected lawmakers were sworn into office in both chambers. Democrats now hold a 235-199 majority in the House of Representatives and Republicans hold a 53-47 majority in the Senate. The freshman class includes 88 new House members (59 Democrats, 29 Republicans) and nine new senators (seven Republicans, two Democrats).

The House elected Rep. Nancy Pelosi (D-CA) to serve as Speaker of the House. She overcame the opposition of a number from within her own party, who had pushed for a change in leadership. Other top congressional leaders—Senate Majority Leader Mitch McConnell (R-KY), Senate Democratic Leader Charles Schumer (D-NY), House Majority Leader Steny Hoyer (D-MD), and House Republican Leader Kevin McCarthy (R-CA)—were elected to their leadership positions in November.

First Up: Significant portions of the federal government have been shut down since December 21 due to disagreements over immigration and border security.

- **Democrats in the House** wasted no time in passing two bills aimed at ending the partial government shutdown, one that would provide appropriations for the remainder of fiscal year 2019 for the remaining unfunded federal agencies except the Department of Homeland Security (DHS), and another that would provide temporary appropriations through February 8 for DHS without providing funds the President has requested for a border wall.
- **The bills face a veto threat** from the White House and Senate Majority Leader Mitch McConnell (R-KY) said they will not be considered by the Senate in their current form.

Texas ACA Litigation Moves Forward

As previously reported**,** the United States District Court for the Northern District of Texas on December 14 granted partial summary judgment to Texas and a number of other states and individuals in *Texas v. United States*. That decision declared the Affordable Care Act's individual mandate with the zeroed-out penalty unconstitutional and invalidated the remainder of the ACA on the basis it could not be severed from the individual mandate.

Updates: Last week, the court ruled on several pending issues related to the ruling.

- **The judge** finalized his December 14 decision invalidating the ACA and issued an order staying that decision pending an appeal. Together, these actions clarify that the ACA remains in effect (*i.e.* the court's earlier decision has no immediate effect) and clear the path for an appeal to be filed.
- **A separate order** was also issued staying any remaining district court proceedings until an eventual appeal is resolved.
- **California** and 16 other intervenor states filed a Notice of Appeal on Thursday challenging the December 14 decision.
- **The U.S. House of Representatives** also on Thursday filed a motion to intervene in *Texas v. United States* in the now-stayed district court proceedings in the Northern District of Texas. The House states in its motion that it plans to simultaneously seek to intervene in the recently noticed Fifth Circuit appeal as soon as a docket number exists that would permit it to do so.

What it means: These moves signal the beginning of a lengthy and potentially complicated appeals process, the timing of which is uncertain.

Regulatory Issues

Critical Guidance Delayed During Government Shutdown

The federal government is in the midst of a partial shutdown due to lack of funding. The Department of Health and Human Services (HHS), including the Centers for Medicare and Medicaid Services (CMS) is not impacted by the shutdown. However, the Office of Management and Budget (OMB) Office of Information and Regulatory Affairs (OIRA) is impacted by the shutdown. As a result, we have been advised that HHS will not be able to release any new proposed rules during the shutdown.

Background

Significant portions of the federal government have been shut down since December 21 due to disagreements over immigration and border security. Most agencies within the Department of Health and Human Services (HHS) have received appropriations for fiscal year 2019 and therefore are operating under normal status. However, the Office of Management and Budget (OMB), which

plays a key role in clearing all federal regulations, also is affected by the partial shutdown. As a result, critical guidance relevant to exchange participation and development of product offerings and rates for the 2020 plan year is in abeyance until further action. Critical guidance on hold, includes the 2020 Notice of Benefit and Payment Parameters proposed rule, Draft 2020 Letter to Issuers, modified Unified Rate Review Template (URRT), and QHP certification templates. The 2020 annual prosed payment notice is critically important because it sets policy for the ACA exchanges. Potential consequences of a continued delay have been communicated by AHIP and BCBSA to HHS and to CMS.

Why this matters
This creates the possibility of compressed timelines for finalizing products and rates for 2020 plan offerings which must be filed in the spring of 2019.

Court Rules Payment Cut for 340B Hospitals Was Unlawful

In a **December 27, 2018 ruling**, the U.S. District Court of the District of Columbia ruled in favor of hospitals participating in the 340B Drug Pricing Program and blocked a nearly 30 percent cut in reimbursement, described by the court as "unlawful." The judge granted the hospital plaintiffs' motion for a permanent injunction, and ordered both the hospital associations and the government to submit briefs about the proposed remedy within 30 days and responses to those briefs within 14 days after that.

Background
The Trump administration ordered the cuts in Medicare Part B payments under the Outpatient Prospective Payment System (OPPS) in late 2017, reducing payments from the average sales price (ASP) plus 6 percent that is paid to all hospitals to ASP minus 22.5 percent. In November, three hospital groups—the American Hospital Association (AHA), the Association of American Medical Colleges, and America's Essential Hospitals—and three plaintiff hospitals **sued** the U.S. Department of Health and Human Services (HHS) to stop the payment cuts which took effect January 1, 2018.

Key takeaways:

- **The ruling does not yet affect 2019 payment rates.** Although the unauthorized reductions are set to continue this year, the court states that the current lawsuit against the cuts "does not explicitly challenge the 2019 rule" and that no claims have been submitted under the 2019 rule at this point. For this reason, the court did not issue an injunction that would have immediately stopped the 2019 cuts. Additional legal action in this area is expected to occur quickly.
- **The court is asking for more information to determine a 2018 remedy.** The judge is asking for recommendations on the "proper remedy" for the $1.6 billion in unauthorized reductions that affected 340B hospitals in 2018, as well as how to handle drug claims for last year that haven't been paid yet. The question of the 2018 cuts is complicated by the fact that HHS was required to implement them in a "budget-neutral" manner. That means for every dollar they cut from 340B hospitals for outpatient drugs, Medicare increased payments to other providers for services and items other than drugs.
- **Hospitals should not yet make any changes to how they bill.** The ruling does not immediately affect how hospitals bill Medicare for their drugs nor the rates that they receive for them.
- **The administration has the option to appeal the ruling.** HHS has at least 90 days from the date of the ruling to appeal the judge's decision, if it decides to do so. The department has not yet announced how it will proceed.

Why this matters

- This ruling validates the hospital community's concerns with the regulatory policy, and prevents significant cuts that undermine a crucial program.

- The decision will allow 340B hospitals, including West Penn and Saint Vincent Hospitals within the Allegheny Health Network, to continue fulfilling the intent of the 340B program without being hampered by detrimental payment cuts.

Federal Task Force Draft Report on Pain Management Available for Public Comment

A federal task force charged with identifying, reviewing, and updating best practices surrounding pain management has released its long-awaited ***Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations***.

The draft report:

- Provides extensive insight into the different types of acute and chronic pain
- Recognizes special population groups, such as children, women, older adults, and others
- Warns of ongoing medication shortages and other details that are worsening the nation's quality of pain care

Background

The Pain Management Best Practices Inter-Agency Task Force was established under Section 101 of the **Comprehensive Addiction and Recovery Act of 2016** (CARA). Task force members include hospital officials; federal agency representatives; clinical experts in pain management, pain advocacy, addiction, recovery, and substance use disorders; patients; first responders; medical board members; and others.

Key highlights from the draft report include:

- Focusing on individualized patient care vital to addressing the national public health pain crisis
- Considering a multidisciplinary approach to chronic pain that includes medication, physical therapies, minimally invasive interventional procedures, and complementary approaches (such as yoga and tai chi)
- Addressing drug shortages that may affect acute and chronic pain treatments
- Addressing the existing stigma and providing empathetic and non-judgmental treatment for better outcomes
- Incorporating innovative solutions such as telemedicine, mobile apps, and newer medications and medical devices
- Highlighting special populations for specialized treatment

The draft report also describes the impact of the 2016 opioid prescribing guideline issued by the Center for Disease Control and Prevention, noting that "an unintended consequence of the guideline is the forced tapering or patient abandonment that many patients with chronic pain on stable long-term doses of opioids have experienced."

Comments about the draft report will be accepted during the 90-day public comment period. Following the 90-day comment period, the report will be finalized and presented to Congress.

Why this matters

- In Pennsylvania, hospitals and health systems, including the Allegheny Health Network, continue to assist individuals with opioid use disorders. Key programs include warm hand-off protocols, prescription guidelines, and drug takeback boxes.
- Additionally, hospitals are:
  - ✓ Working to develop research-based best practices for medication-assisted treatment
  - ✓ Providing patients with pain management alternatives
  - ✓ Advocating for additional funding for inpatient and outpatient behavioral health treatment
  - ✓ Addressing workforce shortages in physician and non-physician providers that address chronic pain, to include expanding opportunities in health care educational programs

Final Rule Issued for 2018 Risk Adjustment Program

On December 10, CMS issued the final rule, "Patient Protection and Affordable Care Act; Methodology for the HHS-operated Permanent Risk Adjustment Program for 2018," which reissues, with additional explanation, the HHS-operated risk adjustment methodology previously established for the 2018 benefit year.

Why this matters

A federal judge vacated the use of statewide average premium under the HHS methodology earlier this year. Issuing this rule allows CMS to continue normal operations of the Risk Adjustment program for the 2018 benefit year.

RADV Comment Deadline Extended

CMS announced that it is extending the comment deadline from Dec. 31 until April 30, 2019 for feedback on proposed changes to the methodology for recouping "overpayments" under Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) audits. The notice was published on the December 27 in the Federal Register.

Why this matters

AHIP, BCBSA and other industry stakeholders remain concerned these changes will significantly disrupt the MA coverage and care plans provide for beneficiaries. AHIP has urged CMS to withdraw the RADV proposal and begin a meaningful dialogue with stakeholders to develop a fair and appropriate oversight process.

CMS estimates the proposed **new methodology would result in MA plans returning up to $4.5 billion in overpayments** to the Trust Fund over 10 years.

CMS stated "to maximize the opportunity for the public to provide meaningful input to CMS, we believe it is important to allow additional time for the public to prepare comments on the RADV provisions of the proposed rule." CMS also plans to release data underlying the FFS adjuster study it included as part of the proposed rule.

The December 31 comment deadline on the remainder of the proposed rule did not change.

State Issues

Pennsylvania

Legislative

Pennsylvania General Assembly Convenes for 2019-2020 Legislative Session

Tuesday, January 1 marked the official beginning of the 2019-2020 legislative session of the Pennsylvania General Assembly. Members of the Senate and House of Representatives took the oath of office and proceeded to elect their respective leaders. Senator Joe Scarnati (R-Jefferson) was re-elected President Pro Tempore of the Senate and Representative Mike Turzai (R-Allegheny) was re-elected Speaker of the House.

Also taking place on Tuesday was the acceptance of the resignation of former state senator Guy Reschenthaler (R-Allegheny), who was elected to the U.S. House of Representatives in November. A special election for the 37th district seat has been set for April 2. The House will have two special elections of its own on March 12 to fill the vacancies of the 190th district seat formerly held by Rep.

Vanessa Lowery Brown (D-Philadelphia), who resigned from her position in late December 2018 due to her probation sentencing, and the 114th district seat formerly held by the late Rep. Sid Michaels Kavulich (D-Lackawanna), who passed away late last year from complications related to heart surgery.

The General Assembly reconvenes on January 15 for the swearing-in ceremonies of Gov. Tom Wolf and Lt. Gov. John Fetterman.

Regulatory

Proposed Venue Rule Change in Medical Malpractice Actions

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 *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.

Background

As a result of the passage of the Medical Care Availability and Reduction of Error (MCARE) Act, Act 13 of 2002, both the legislature and the Supreme Court adopted reforms that reduced the number of malpractice claims brought in Pennsylvania, especially in Philadelphia and Allegheny Counties. This was accomplished by limiting venue in medical liability actions to the county "in which the cause of action arose." Previously, expansive venue rules allowed medical liability plaintiffs to sue defendants almost anywhere they did business, even if the alleged malpractice occurred elsewhere.

The MCARE Act established an Interbranch Commission on Venue, which was required to study venue issues that were driving unreasonable medical liability insurance rates, and issue a report to the General Assembly. Based on the report of this commission, on October 17, 2002, the legislature enacted Act 27 of 2002, which provided that medical liability cases shall be filed only in the county where the cause of action arose. Later, in early 2003, the Supreme Court, by per curiam order, promulgated amendments to the Rules of Civil Procedure (Rule 1006) adopting the language of Act 27.

These reform efforts are widely seen as the most important step in Pennsylvania's efforts to address the medical liability insurance crisis, substantially reducing medical malpractice filings statewide.

Now, the Civil Procedural Rules Committee is proposing to ask the Supreme Court to consider a proposal to rescind the venue reform and restore the prior venue rules. This change is being proposed on the theory that the insurance crisis is over and medical malpractice defendants are no longer entitled to special treatment.

Why this matters

- The venue reform is primarily responsible for easing (although not eliminating) the malpractice insurance crisis that existed before 2003.
- Pennsylvania physicians and hospitals would be adversely affected by this venue rule change. By allowing venue in counties with little to no relation to the underlying cause of action, claimants could shop for verdict-friendly venues in which to file their suits.

- This would again lead to higher premiums for medical liability insurance and make Pennsylvania less attractive to physicians considering practicing in the state, and to those graduating from Pennsylvania medical schools.

Comments on the proposed changes must be received no later than February 22, 2019. The Hospital & Healthsystem Association of Pennsylvania (HAP) plans to implement a comprehensive advocacy effort to prevent this action. Specifically, HAP will:

- Prepare a comment letter to the Civil Procedural Rules Committee, which will explain why changes to the venue rules will lead to the return of skyrocketing medical liability rates and threaten access to care.
- Work with other leading advocacy groups, including but not limited to, the Pennsylvania Coalition for Civil Justice Reform, the Insurance Federation, the Pennsylvania Medical Society, and the Chamber of Commerce, to coordinate advocacy before the Pennsylvania Supreme Court and General Assembly.

The Allegheny Health Network will also submit individual comments to the Court opposing the changes.

Industry Trends

Policy / Market Trends

Litigation Update Regarding Contraception Rules

A U.S. appeals court blocked the administration's final rules permitting businesses to claim moral and religious exemptions to the contraception mandate. However, the ruling only applies to the five states that filed a joint lawsuit against the rules: California, Delaware, Maryland, New York and Virginia. The states argued the administration made changes to the contraception mandate without the required notice and public comment period.

A three-judge panel of the 9th U.S. Circuit Court of Appeals upheld a preliminary injunction on the rules by a district court.

Why this matters

The contraceptive mandate within the Affordable Care Act has been divisive since its inception. While some argued the Obama Administration's exemptions did not go far enough, the Trump Administration proposed rules would allow most businesses to claim moral or religious exemptions to covering birth control for their employees. The administration finalized these rules last fall. A nationwide injunction is still in effect following a ruling from a separate case, but it is under appeal in the 3rd Circuit.

State

The Pennsylvania General Assembly is in recess until January 15.

The Delaware General Assembly is in session January 8-10.

The West Virginia Legislature is in session January 9 - March 10.

Congress

The U.S. Congress is in session January 8-11.

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/.