Federal Issues

Legislative

Senate Clears Stopgap Funding Legislation
By a vote of 82-15, the Senate on Wednesday passed stopgap spending legislation that prevents the government from shutting down and maintains federal funding through November 21st. The House had already passed the measure. The legislation includes a number of federal funding extensions including Medicaid funding for Puerto Rico and other U.S. territories.

- The bill also contains the Fair and Accurate Medicaid Pricing Act, legislation which would close a loophole that allows authorized generic prices to be used when calculating a brand drug’s rebate in the Medicaid program.
- This legislation is expected to save the government about $3.1 billion dollars over the next decade.
- By allowing authorized generics in the calculation of the AMP, drug manufacturer rebate liability will increase.

House Panels Examine Pelosi’s Drug Pricing Plan
Following the release of House Speaker Nancy Pelosi’s (D-Calif.) drug pricing plan, two House committees held separate hearings to discuss the proposal last week.

The House Energy & Commerce Subcommittee on Health held a hearing Wednesday that examined four prescription drug bills, including Pelosi’s bill.

- Members debated various policy issues throughout the hearing, including government negotiations for the 250 most expensive drugs, capping Part D out-of-pocket costs, and international reference pricing.
- Full Committee Chairman Frank Pallone (D-NJ) said it was “crucial” that the final drugs package includes a provision that overturns the non-interference clause. Republicans at the hearing stated that the process of developing a prescription drug package was partisan. A number of Republicans expressed support for out-of-pocket costs caps for Part D, but were skeptical of government negotiations.

On Thursday, the House Education and Labor Committee’s Subcommittee on Health, Employment, Labor and Pensions Subcommittee held its hearing, which also focused largely on Pelosi’s bill. The hearing was partisan, with Democrats on the panel touting the bill’s benefits and Republicans calling it a first step toward socialism that would hurt innovation and access.

Looking Ahead: Several House committees are expected to take up the legislation in October, with the goal of a House vote before the end of the month.

In the Senate, Finance Committee Chairman Chuck Grassley (R-IA) said he expects that there’s a “good chance” a major drug pricing package wouldn’t be considered in that Chamber before next year but said that he was working with House Democrats and the White House to reach a deal. Senate Finance Committee leaders released the statutory text for S. 2543, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019. During July, the Senate Finance Committee approved the bipartisan drug package negotiated between Chairman Grassley and ranking member Ron Wyden (D-OR). The Grassley-Wyden legislation makes policy changes to payment for drugs through Medicare Part B and Part D, and Medicaid.

The Senate Finance bill would:
- Eliminate the coverage gap and reduce beneficiary cost-sharing to $3,100 under Medicare Part D, and tie drug price increases to the rate of inflation;
- Make more information about pharmacy benefit manager (PBM) practices and manufacturer drug pricing publicly available;
- Increase health plan responsibility in the catastrophic phase resulting in 20% reinsurance and 60% liability in 2024;
- Sunset the existing manufacturer discount program and create a new manufacturer discount of 20% on brand drugs in the catastrophic phase; and
• Change how Medicare calculates Part B prescription drug payment amounts to lower spending and beneficiary out-of-pocket costs.

Two other Senate Committees—the Health, Education, Labor and Pensions (HELP) and Judiciary—have produced prescription drug legislation. All of the policy may be packaged in the HELP Committee’s Lower Health Care Costs Act, which includes surprise balance billing policy as well as provisions addressing transparency and promoting public health.

Arguments Heard in Risk Adjustment Lawsuit
The Tenth Circuit has heard oral arguments in the New Mexico Health Connections v. HHS appeal. The lawsuit involves a challenge to the Department of Health and Human Services’ (HHS) policy of using a statewide average premium in its 2014-2018 risk adjustment regulations and decision to operate the program in a budget neutral manner.

• The government’s appeal seeks to overturn an earlier district court decision that set aside and vacated the HHS policy of using a statewide average premium in its 2014-2018 risk adjustment regulations and remanded the case to the agency for further proceedings.
• While finding that the HHS risk adjustment regulations are not contrary to law, the district court’s decision held that the regulations were “arbitrary and capricious” because they were based on the agency’s assumption that the ACA required risk adjustment payments to be budget neutral.
• The New Mexico district court’s decision conflicted with a separate federal court’s decision in Massachusetts that upheld the risk adjustment methodology.

During the hearing, the government emphasized the importance of operating the risk adjustment program in a predictable manner and how that need for predictability informed HHS’s decision to operate the program in budget neutral manner. The government also noted the significant uncertainty that would result if the district court’s decision to vacate earlier risk adjustment rules was upheld.

• Insurer viewpoint: America’s Health Insurance Plans and the Blue Cross Blue Shield Association filed a joint amicus brief emphasizing that same issue, which the government relied upon to help bolster its arguments.

The court gave no indication on when it would issue a decision.

Federal Issues
Regulatory

CMS Issues State Medicaid DSH Allotment Reductions Final Rule
On September 23, 2019, the Centers for Medicare & Medicaid Services (CMS) published a final rule for calculating $4 billion in state Medicaid disproportionate share hospital (DSH) allotment reductions for federal fiscal year (FFY) 2020 and $8 billion for each subsequent year through 2025.

Background: During 2013, CMS issued a final rule to implement the Affordable Care Act’s (ACA) reductions to state Medicaid DSH allotments, including the methodology it planned to use. As the health care environment evolved differently than the ACA anticipated, subsequent legislative actions delayed the
implementation of the cuts until FFY 2020. **This final rule modifies the methodology developed during 2013 by incorporating new and updated data sources.**

**Why this matters:** Delaying the implementation of the impending cuts has been a top advocacy priority for hospitals. The U.S. House of Representatives last week passed a continuing resolution to fund the government, and within that was a provision to delay the DSH cuts until November 21. The U.S. Senate passed the bill last Thursday and President Trump is expected to sign the measure into law.

**Next steps:** Provider groups continue advocating for longer-term relief from the DSH cuts leading up to the new November 21 deadline.

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**CMS Finalizes Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies**

Last week, the Centers for Medicare & Medicaid Services (CMS) released its discharge planning final rule revising the discharge planning requirements that hospitals (including short-term acute care hospitals, long-term care hospitals, rehabilitation hospitals, psychiatric hospitals, children’s hospitals, and cancer hospitals), critical access hospitals (CAH), and home health agencies (HHA) must meet in order to participate in the Medicare and Medicaid programs.

**Summary of rule:** The rule implements provisions requiring hospitals and CAHs to create discharge planning evaluations for patients who are likely to suffer adverse health consequences in the absence of adequate discharge planning, as well as when patients, their representatives, or physicians requests such a plan. The rule also requires hospitals, CAHs, and HHAs to provide certain medical information to the receiving facility when transferring patients. Additionally, under the rule, hospitals, CAHs, and HHAs will be required to assist patients in selecting post-acute care services by using and sharing data related to quality measures and resource use measures.

The rule is effective November 29, 2019.

**Why this matters:** The final rule revises many of the proposals CMS put forward in its November 2015 discharge planning proposed rule. Addressing many of the concerns that hospitals flagged in its public comments—including concerns related to administratively burdensome and overly prescriptive documentation requirements—CMS either streamlined or eliminated most of the proposed discharge planning requirements, such as the design, applicability, and timeframe requirements for hospitals and CAHs. Additionally, CMS chose not to finalize its proposal to require hospitals and CAHs to establish a post-discharge follow-up process for some patients discharged to their homes.

More details regarding the changes in the final rule are provided in CMS' press release and fact sheet.

**Next steps:** As noted in the final rule, CMS intends to publish interpretative guidance to provide further clarification for implementing the final discharge planning requirements.

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**CMS Seeks Comment on 340B Drug Acquisition Cost Data Collection**

The Centers for Medicare & Medicaid Services proposed surveying hospitals about their acquisition costs for specified covered outpatient drugs under the 340B drug savings program.
**Background:** In the outpatient prospective payment system final rule for calendar year 2018, CMS finalized a policy to adjust payment for separately payable outpatient drugs acquired by 340B-eligible hospitals from Average Sales Price plus 6% to ASP minus 22.5%. In a lawsuit brought by the American Hospital Association (AHA), and joined by The Association of American Medical Colleges, America’s Essential Hospitals and three hospital plaintiffs, a federal judge last year ruled that the cut was unlawful, in part because the Department of Health and Human Services had not collected the necessary data to set payment rates based on acquisition costs.

**Why this matters:** CMS has appealed the ruling. “In the event that the ruling is affirmed, CMS believes that it is important to begin obtaining acquisition costs for specified covered outpatient drugs to set payment rates based on cost for 340B-acquired drugs when they are furnished by certain covered entity hospitals,” the CMS notice states.

The notice will be published in Monday’s Federal Register with comments accepted for 60 days.

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**State Issues**

**Pennsylvania**

**Legislative**

**Rural Health Initiative Clears House Committee**

On September 23, the House Health Committee considered Senate Bill 314, the Pennsylvania Rural Health Redesign Center Authority Act and the Pennsylvania Rural Health Redesign Center Fund. The measure was reported by a vote of 24–1.

**Background:**

Senate Bill 314 will create a new voluntary payment pilot program for rural hospitals, providing $25 million in federal support from the Centers for Medicaid and Medicare Services (CMS) to establish a rural redesign center to offer technical and other assistance to hospitals. The cost estimated to administer the act is $2.2 million.

Six hospitals are currently participating in the program. DOH Executive Deputy Secretary Sarah Boateng shared that up to 30 hospitals are in line to be recruited. While supportive of the program’s concept, several committee members expressed concern over program funding and future sustainability.

**Why this matters:**

With Pennsylvania laying the groundwork for this national approach, rural hospitals will be able to stay in their communities providing access to medically necessary services.

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**House Committee Adjusts Requirements for Breast and Cervical Cancer Screening Program**

The House Health Committee voted unanimously to approve legislation, House Bill 419, which amends the age eligibility requirements under the Pennsylvania Breast and Cervical Cancer Early Detection Program
(PA-BCCEDP). Women age 30 to 65 would now be eligible for program benefits versus women age 40 to 49.

**Background:** The PA-BCCEDP is a free breast and cervical cancer early detection program of the Pennsylvania Department of Health (DOH). Funding is provided by the DOH and via a grant from the Centers for Disease Control and Prevention. According to committee staff, the DOH is paying for cervical screening for women from age 21 and up and other changes have been incorporated into the program based on screening recommendations.

**Why this matters:** The PA-BCCEDP provides access to screening services for women who are uninsured and cannot afford to pay for prescribed screening tests out-of-pocket. The earlier women are screened and potential problems are identified, they have a better opportunity to seek life-saving treatment.

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**State Issues**

**West Virginia**

**Legislative**

**Candidates Express Interest in WV Gubernatorial Race**

Now that West Virginia Senator Joe Manchin (D) has made his decision to not seek the state’s highest office, several elected officials are close to announcing their intentions to enter the contest. State Sen. Ron Stollings (D) is likely to announce saying he’s 95 percent in. Kanawha County Commissioner Ben Salango (D) is also nearing an announcement along with state House Minority Leader Tim Miley and television personality Mark Bowe.

Meanwhile, West Virginia Attorney General Patrick Morrisey (R) is seeking financial assistance from donors. More specifically, he posted a Facebook video requesting small-dollar donations for his next political venture, which he’s still exploring. Part of the fundraising will help to retire debt from previous campaigns. Morrisey first won election in 2012 and reelection to a four-year term in 2016.

The Pennsylvania General Assembly is in recess until October 21.

The Delaware Legislature has adjourned for the year.

The West Virginia Legislature has adjourned for the year.

**Congress**

The U.S. Congress is in recess until October 15.
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/).

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